UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2025

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _to_

Commission File Number 001-36352

AKEBIA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**20-8756903**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
245 First Street, Cambridge, MA	**02142**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (617) 871-2098

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	**AKBA**	**The Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the registrant's Common Stock on The Nasdaq Capital Market on June 30, 2025, was $946,381,036.

The number of shares of registrant's Common Stock outstanding as of February 23, 2026 was 267,879,239.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A in connection with its 2026 Annual Meeting of Stockholders within 120 days after the end of the registrant's fiscal year ended December 31, 2025. Portions of the proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

Akebia Therapeutics, Inc.
Form 10-K
For the Year Ended December 31, 2025

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In this Annual Report on Form 10-K, or Form 10-K, unless otherwise stated or the context otherwise requires, references to "Akebia," "we," "us," "our," "the Company," "our Company" and similar references refer to Akebia Therapeutics, Inc. and, where appropriate, its consolidated subsidiaries. On December 12, 2018, in connection with the consummation of the merger, or Merger, with Keryx Biopharmaceuticals, Inc., or Keryx, Keryx became a wholly owned subsidiary of the Company.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, or Form 10-K, contains forward-looking statements that are being made pursuant to the provisions of the U.S. Private Securities Litigation Reform Act of 1995 with the intention of obtaining the benefits of the "safe harbor" provisions of that Act. All statements contained in this Form 10-K other than statements of historical fact are forward-looking statements. These forward-looking statements may be accompanied by words such as "anticipate," "believe," "build," "can," "contemplate," "continue," "could," "should," "designed," "estimate," "project," "expect," "forecast," "future," "goal," "intend," "likely," "may," "plan," "possible," "potential," "predict," "strategy," "seek," "target," "will," "would," and other words and terms of similar meaning, but the absence of these words does not necessarily mean that a statement is not forward-looking. These forward-looking statements include, but are not limited to, statements about:

- our plans with respect to commercializing Vafseo® (vadadustat) and any potential label expansion opportunities for Vafseo or any current or future product candidate;
- our ability to maintain contracts with dialysis organizations for the sale of Auryxia® (ferric citrate) and Vafseo in the U.S.;
- the potential therapeutic benefits, safety profile, and effectiveness of Vafseo and our product candidates;
- our pipeline and portfolio, including its potential, and our related research and development activities, including with respect to AKB-097 and praliciguat;
- the timing, investment and associated activities involved in continued commercialization of Auryxia, its growth opportunities and our ability to execute thereon;
- the timing and number of additional generic versions of Auryxia that enter the market following the loss of exclusivity for Auryxia which occurred in March 2025, the pricing of generic versions of Auryxia, and the impact of the loss of exclusivity on the product revenue from Auryxia, including the impact on the price of Auryxia;
- the potential indications, demand and market opportunity, potential and acceptance of Auryxia, Vafseo and our product candidates, including the size of eligible patient populations;
- the potential therapeutic applications of the hypoxia inducible factor pathway;
- the entry into therapeutic modalities, such as biologics, that differ significantly from our existing small-molecule expertise, potentially requiring the recruitment of personnel with new technical, regulatory, manufacturing, and commercialization capabilities;
- our competitive position, including estimates, developments and projections relating to our competitors and their products and product candidates, and our industry;
- our expectations, projections and estimates regarding our capital requirements, need for additional capital, financing our future cash needs, costs, expenses, revenues, capital resources, cash flows, financial performance, profitability, tax obligations, liquidity, growth, contractual obligations and the period of time our cash resources will fund our current operating plan, estimates with respect to our ability to operate as a going concern, our internal control over financial reporting and disclosure controls and procedures, and any future deficiencies or material weaknesses in our internal controls and procedures;
- delivering value broadly to the kidney community, as well as others who may benefit from our medicines, will result in delivering value for stockholders;
- our manufacturing, supply and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences;
- estimates, beliefs and judgments related to the valuation of goodwill, debt and other assets and liabilities, including classification of expenses, assets and liabilities, our impairment analyses and our methodology and assumptions regarding fair value measurements;
- the timing of the availability and disclosure of clinical trial data and results;
- the designs of our studies, and the type of information and data expected from our studies and the expected benefits thereof;
- our and our collaborators' strategy, plans and expectations with respect to the development, manufacturing, supply, commercialization, launch, marketing and sale of Auryxia and Vafseo and the associated timing thereof;
- our ability to maintain any marketing authorizations we currently hold or will obtain, including our marketing authorizations for Auryxia and our ability to complete post-marketing requirements with respect thereto;

- our ability to negotiate, secure and maintain adequate pricing, coverage and reimbursement terms and processes on a timely basis, or at all, with third-party payors for Auryxia and Vafseo;
- the timing of initiation and progress of our clinical trials and plans to conduct preclinical studies and clinical trials in the future;
- the timing and amounts of payments from or to our collaborators and licensees, and the anticipated arrangements and benefits under our collaboration and license agreements, including with respect to milestones and royalties;
- our intellectual property position, including obtaining and maintaining patents, and the timing, outcome and impact of administrative, regulatory, legal and other proceedings relating to our patents and other proprietary and intellectual property rights, patent infringement suits that we have filed or may file, or other actions that we may take against companies, and the timing and resolution thereof;
- expected ongoing reliance on third parties, including with respect to the development, manufacturing, supply and commercialization of Auryxia and Vafseo;
- our ability to maintain adequate inventory levels of Auryxia, Vafseo and any other products or product candidates;
- accounting standards and estimates, their impact, and their expected timing of completion;
- estimated periods of performance of key contracts;
- our facilities, lease commitments, and future availability of facilities;
- cybersecurity;
- insurance coverage;
- management of personnel, including our management team, and our employees, including employee compensation, employee relations, and our ability to attract, train and retain high quality employees;
- the implementation of our business model, current operating plan, and strategic plans for our business, product candidates and technology, and business development opportunities, including potential collaborations, alliances, mergers, acquisitions or licensing of assets;
- additional costs we may incur as we expand our development activities or other operating expenses, including additional costs related to Vafseo, AKB-097 and praliciguat, and selling, general and administrative expenses;
- the potential impact of global economic developments and geopolitical events on our business, operations, strategies and goals; and
- the timing, outcome and impact of current and any future legal proceedings.

Any or all of these forward-looking statements in this Form 10-K may turn out to be inaccurate. These forward-looking statements involve risks and uncertainties, including those that are discussed below under the heading "Risk Factors Summary", and the risk factors identified further in Part I, Item 1A. "Risk Factors" included in this Form 10-K and elsewhere in this Form 10-K and in our Securities and Exchange Commission reports filed after this report, that could cause our actual results, financial condition, performance or achievements to be materially different from those indicated in these forward-looking statements. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements speak only as of the date of this Form 10-K. Except as required by law, we assume no obligation to publicly update or revise these forward-looking statements for any reason. Unless otherwise stated, our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

This Form 10-K also contains estimates and other information concerning our industry and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Unless otherwise expressly stated, we obtained this industry, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

RISK FACTORS SUMMARY

Investing in our common stock involves numerous risks, including the risks summarized below and described in further detail in "Part I, Item 1A. Risk Factors" of this Form 10-K, any one of which could materially adversely affect our business, financial condition, results of operations, and prospects. These risks include, but are not limited to, the following.

- We have incurred significant losses since our inception, and anticipate that we will continue to incur losses and cannot guarantee when, if ever, we will become and remain profitable.
- We may require substantial additional financing to fund our business. A failure to obtain this necessary capital when needed, or on acceptable terms, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our products and product candidates on unfavorable terms to us.
- We may not be successful in our efforts to identify, acquire, in-license, discover, develop and commercialize additional products or product candidates or our decisions to prioritize the development of certain product candidates over others may not be successful, which could impair our ability to grow.
- We may engage in strategic transactions to acquire assets, businesses, or rights to products, product candidates or technologies or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense.
- Our obligations, requirements and restrictions in connection with the BlackRock Credit Agreement could adversely affect our financial condition and restrict our operations.
- Our Royalty Interest Acquisition Agreement contains various covenants and other provisions, which, if violated, could materially adversely affect our financial condition.
- Our business is substantially dependent on the commercial success of Auryxia and Vafseo. If we are unable to continue to successfully commercialize Auryxia and Vafseo, our results of operations and financial condition will be materially harmed.
- If we are unable to maintain sales and marketing capabilities or enter into or maintain agreements with third parties, we may not be successful in commercializing Auryxia, Vafseo or any other product candidates that may be approved.
- Our, or our partners', failure to obtain or maintain adequate coverage, pricing and reimbursement for Auryxia, Vafseo or any other future approved products, could have a material adverse effect on our or our collaboration partners' ability to sell such approved products profitably and otherwise have a material adverse impact on our business.
- We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.
- The commercialization of ferric citrate, and our current and potential future efforts with respect to the development and commercialization of our products and product candidates outside of the United States, or U.S., subject us to a variety of risks associated with international operations, which could materially adversely affect our business.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and we will incur additional costs in connection with, and may experience delays in completing, or ultimately be unable to complete, the development of any of our product candidates.
- Auryxia, Vafseo or any other product or product candidate, including those that may be in-licensed or acquired, may cause undesirable side effects or have other properties that may delay or prevent marketing approval or limit their commercial potential.
- We may not be able to obtain marketing approval for any potential label expansion for Vafseo or any current or future product candidate, or we may experience significant delays in doing so, any of which would materially harm our business.
- We may not be able to obtain orphan drug exclusivity for praliciguat or any potential future product candidates that we may develop, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.
- If we are unable to obtain or maintain marketing approval in jurisdictions outside the United States, we and our partners will not be able to market any of our products or product candidates outside of the United States.

- Products approved for marketing are subject to extensive post-marketing regulatory requirements, including post-approval pediatric studies for Auryxia and Vafseo, and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties, including withdrawal of marketing approval, if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, or product candidates, when and if approved.
- We are subject to complex regulatory schemes that require significant resources to ensure compliance and our failure to comply with applicable laws could subject us to government scrutiny or enforcement, potentially resulting in costly investigations, fines, penalties or sanctions, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.
- We will incur significant liability if it is determined that we are promoting any “off-label” use of Auryxia, Vafseo or any other product we may develop, in-license or acquire or we are found to have improperly promoted such products through direct-to-consumer advertising, or if it is determined that any of our activities violates the federal Anti-Kickback Statute.
- Disruptions at the FDA and other government agencies from funding cuts, personnel losses, regulatory reform, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development program and develop and secure approval of our product candidates in a timely manner, which would negatively impact our business.
- Legislative and regulatory healthcare reform may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain for any products that are approved in the U.S. or foreign jurisdictions.
- We depend on collaborations with third parties for the development and commercialization of Auryxia, an authorized generic version of Auryxia, Riona and Vafseo. If these collaborations are not successful or if our collaborators terminate their agreements with us, we may not be able to capitalize on the market potential of Auryxia, Riona and Vafseo, and our business could be materially harmed.
- We rely upon third parties to conduct our clinical trials and certain of our preclinical studies. If they do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain or maintain marketing approval for Auryxia, Vafseo or any of our product candidates, and our business could be substantially harmed.
- If the licensor of certain intellectual property relating to Auryxia terminates, modifies or threatens to terminate existing contracts or relationships with us, our business may be materially harmed.
- Manufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our AKB-097 development program or other product candidates.
- Changes in the geopolitical environment, including U.S. and international trade policies, particularly with respect to China, Europe or Canada, may adversely impact our business and operating results.
- If we are unable to adequately protect our intellectual property, third parties may be able to use our intellectual property, which could adversely affect our ability to compete in the market.
- We may not be able to protect our intellectual property rights throughout the world.
- The intellectual property that we own or have licensed and related non-patent exclusivity relating to our current and future products is, and may be, limited, which could adversely affect our ability to compete in the market and adversely affect the value of Auryxia, Vafseo or other future products.
- The market entry of one or more generic competitors or any third party’s attempt to challenge our intellectual property rights will likely limit Auryxia and Vafseo sales and have an adverse impact on our business and results of operation.
- Litigation and administrative proceedings, including third party claims of intellectual property infringement and opposition/invalidation proceedings against third party patents, may be costly and time consuming and may delay or harm our drug discovery, development and commercialization efforts.
- Our stock price has been and may continue to be volatile, which could result in substantial losses for holders or future purchasers of our common stock and lawsuits against us and our officers and directors and could result in substantial costs and divert management's attention.

PART I

Item 1. Business

Overview

We are a fully integrated biopharmaceutical company with two commercial products for patients impacted by kidney disease. We have built a business focused on developing and commercializing innovative therapeutics that we believe serve as a foundation for future growth, including by contributing net product revenue to support the development and advancement of our robust pipeline of mid-stage programs targeting rare kidney diseases and early-stage programs targeting kidney disease and non-kidney focused indications.

We have established the Company as a leader in the kidney community and believe our cross-organizational expertise in kidney disease positions us for success. Chronic kidney disease, or CKD, is a condition in which the kidneys are progressively damaged to the point that they cannot properly filter the blood circulating in the body. This damage causes waste products to build up in the patient's blood, leading to other health problems, including anemia, cardiovascular disease and bone disease. CKD significantly impacts the United States, or U.S., healthcare system, potentially affecting approximately 35.5 million patients. In 2022, in the U.S. treating Medicare beneficiaries with CKD cost an estimated $95.7 billion, and treating people on dialysis cost an estimated $45.3 billion. Our two commercial products address certain complications of kidney disease.

Our current product portfolio includes:

Vafseo® (vadadustat) is an orally administered medicine that was approved by the U.S. Food and Drug Administration, or the FDA, in March 2024 for the treatment of anemia due to CKD in adult patients on dialysis for at least three months. The current U.S. market opportunity for the treatment of anemia due to CKD in patients with dialysis is approximately $1 billion based on current erythropoiesis stimulating agent, or ESA, pricing. Vafseo is the only oral hypoxia inducible factor, or HIF, based treatment available in the U.S. Vafseo entered the market in January 2025, at which time we had commercial supply agreements for the purchase of Vafseo in place with dialysis organizations caring for nearly 100% of dialysis patients in the U.S. Throughout 2025, we worked closely with dialysis organizations as their medical teams developed, implemented and operationalized protocols to enable prescribers to write Vafseo prescriptions for clinically appropriate patients. Currently, approximately 290,000 dialysis patients in the U.S. have prescribing access to Vafseo.

Vafseo is approved for use in adults in 37 countries and is marketed in certain countries outside the U.S. by our partners. See the section titled, "License and Collaboration Agreements" for details.

Auryxia® (ferric citrate) is an orally administered medicine approved and marketed in the U.S. for two indications: (1) the control of serum phosphorus levels in adult patients with dialysis dependent chronic kidney disease, or DD-CKD, and (2) the treatment of iron deficiency anemia, or IDA, in adult patients with non-dialysis-dependent chronic kidney disease, or NDD-CKD.

Today, we market Auryxia in the U.S. Auryxia became part of our portfolio in 2018 and has historically contributed meaningful revenue to the business. In March 2025, Auryxia reached loss of exclusivity, or LoE. On January 22, 2026, Teva Pharmaceuticals Ltd., or Teva, received tentative approval for its Abbreviated New Drug Application for Auryxia. Currently, there is only one authorized generic for Auryxia sold by our distributor, but we expect additional generic competition in 2026. If additional generics are approved and enter the market, we expect it will adversely impact our revenue.

Ferric citrate is approved for use and marketed in certain countries outside the U.S. by our partners. See the section titled "License and Collaboration Agreements" for details.

Our development pipeline includes:

Our mid-stage rare kidney disease pipeline assets, praliciguat and AKB-097, are being evaluated to target areas of unmet need. In June 2021, we licensed praliciguat from Cyclerion Therapeutics, Inc., or Cyclerion, via an exclusive global license, which includes certain intellectual property rights to research, develop and commercialize the asset. Praliciguat is an oral, once-daily soluble guanylate cyclase, or sGC, stimulator. We are evaluating praliciguat for the treatment of biopsy-confirmed focal segmental glomerulosclerosis, or FSGS, a rare kidney disease, in a Phase 2 clinical trial. The first patient was dosed in this trial in December 2025. We also plan to assess the use of praliciguat in other rare podocytopathies in the future.

In November 2025, we entered into an asset purchase agreement with Q32 Bio Inc. and Q32 Bio Operations Inc., together Q32, pursuant to which we purchased and assumed substantially all assets and liabilities of Q32 and its

affiliates related to the research, development, manufacture and commercialization of Q32's clinical-stage development candidate known as ADX-097, now referred to as AKB-097, an anti-C3d-Factor H fusion protein complement inhibitor. AKB-097 is a potential next-generation complement inhibitor, and we believe AKB-097 has applicability across a wide range of complement-mediated rare kidney diseases. AKB-097 is intended to provide targeted regulation of complement activation at sites of tissue injury while limiting systemic complement inhibition. We expect to initiate a Phase 2 basket study in the second half of 2026 to evaluate AKB-097 for the following indications: IgA Nephropathy, or IgAN; C3 Glomerulopathy, or C3G; and Lupus Nephritis, or LN.

Our early-stage pipeline assets include AKB-9090 and AKB-10108, which are HIF molecules. We plan to initially evaluate AKB-9090 for the treatment of cardiac surgery-related acute kidney injury, or CS-AKI, and we expect to initiate a Phase 1 study in healthy volunteers in the first half of 2026. We may also study AKB-9090 in acute respiratory distress syndrome, or ARDS, as well as other acute treatment indications. AKB-10108 will potentially be evaluated for retinopathy of prematurity, or ROP, in neonates, and other indications, and is currently in preclinical development.

We continue to explore additional commercial and development opportunities to expand our pipeline and portfolio of novel therapeutics through both internal research and external innovation to leverage our fully integrated team.

Strategy

Our deep understanding of kidney disease helps us serve the unmet needs of kidney patients and others impacted by chronic and debilitating illness. Our commitment to patients informs our business decisions and short and long-term planning. There is a clear need to improve quality of life and clinical outcomes of people living with kidney disease. The progression of CKD towards renal failure is complicated by multiple conditions which further deteriorate kidney function and the general health of patients if left untreated.

With two revenue-generating products and the research and development capabilities to discover, advance and commercialize new therapies, we continue to work toward our purpose to better the lives of those impacted by kidney disease.

Our strategic imperatives are threefold:

1. **Drive Vafseo to be standard of care for the treatment of anemia due to CKD for patients on dialysis in the U.S.** In January 2025, Vafseo became available in the U.S. for adult patients with anemia due to CKD on dialysis for at least three months. As of December 31, 2025, nearly 1,000 total prescribers from 24 different dialysis organizations have written a Vafseo prescription for a patient. To accomplish our goal to make Vafseo standard of care, we continue to work towards increasing prescribing access to Vafseo, as well as the breadth and depth of prescribing among dialysis organizations with prescribing access. We also continue to generate data that we believe could identify additional clinical benefits of Vafseo compared to the current standard of care, ESAs.
2. **Build on our commitment to those impacted by kidney disease.** We plan to continue to support the commercial availability of Auryxia and advance our rare kidney disease pipeline. We currently have two mid-stage programs that we plan to evaluate for multiple rare kidney diseases. We expect to continue to enroll patients in a Phase 2 clinical trial of praliciguat for the treatment of FSGS. We also plan to initiate a Phase 2 basket study in the second half of 2026 to evaluate AKB-097 in IgAN, C3G and LN. We expect to report initial data from this study in 2027. We also expect to initiate a Phase 1 study of AKB-9090 in healthy volunteers in the first half of 2026. AKB-9090, the first product candidate from our internal discovery efforts, is targeted initially for development in CS-AKI.
3. **Create a future for Akebia beyond kidney disease.** We intend to leverage our robust discovery, research and development expertise in HIF biology gained through the development of Vafseo, to advance our early pipeline assets.

We also plan to continue to explore strategic growth opportunities that further our strategic imperatives and continue our approach of financial discipline, cross-organizational efficiency and operational effectiveness.

Drive Vafseo to be Standard of Care in the Treatment of Anemia due to CKD for Patients on Dialysis in the U.S.

Anemia is common in patients with CKD, and its prevalence increases with disease progression. Anemia due to CKD results from inadequate erythropoietin, or EPO, levels, negatively affecting red blood cell production. Left untreated, anemia accelerates the overall deterioration of patient health with increased morbidity and mortality. According to the U.S. Renal Data System 2025 Annual Data Report, there were more than 558,000 patients in the U.S. on dialysis by the end of 2023, of which approximately 85% were on in-center hemodialysis and the remainder on home dialysis, which includes both peritoneal dialysis and home hemodialysis.

The current standard of care for anemia due to CKD is treatment by injectable recombinant human ESAs such as Epogen® (epoetin alfa), Aranesp® (darbepoetin alfa) or Mircera® (methoxy polyethylene glycol-epoetin beta). Patients could also receive a blood transfusion. When administered to a patient, injectable ESAs provide supraphysiological levels of exogenous EPO to stimulate production of red blood cells, or RBCs. While injectable ESAs can be effective in raising hemoglobin levels, they have the potential to cause significant side effects and need to be injected subcutaneously or intravenously.

The current market opportunity for the treatment of anemia due to CKD in adult patients on dialysis is approximately $1 billion in the U.S. based on current ESA pricing. We believe there is a significant opportunity for Vafseo to become standard of care for the treatment of anemia due to CKD for adult patients on dialysis.

Vafseo is an oral HIF, prolyl hydroxylase, or HIF-PH inhibitor, that stimulates the body's natural response to hypoxia. Through activation of the HIF pathway, Vafseo stimulates the body's natural production of EPO and improves mobilization of stored iron to help dialysis patients with CKD manage their anemia. Our data from the INNO$_2$VATE trials show Vafseo corrected and maintained hemoglobin within target range through a gradual increase over time with evidence of fewer hemoglobin overshoots. Our clinical data showed that Vafseo has a safety profile similar to the ESA standard of care. These findings contribute to why we believe Vafseo offers a compelling choice for physicians for anemia management. Upon Vafseo approval, we implemented a launch plan to commercialize Vafseo for the treatment of anemia due to CKD in adult patients on dialysis to make Vafseo available in the U.S. beginning in January 2025. Prior to availability in the U.S., we completed critical commercialization initiatives, including securing reimbursement for Vafseo under the Transitional Drug Add-on Payment Adjustment, or TDAPA, and securing access to Vafseo for patients through commercial supply agreements with dialysis organizations.

Medications covered under the end-stage renal disease, or ESRD, Prospective Payment System, or PPS, in Medicare are known as the ESRD Bundle, a payment structure with a flat base rate per dialysis session adjusted for individual patient and facility characteristics. Dialysis-related drugs are included in the ESRD Bundle if they fall into functional categories such as anemia management. The TDAPA provides separate payment for new drugs for two years based on the drug’s average sales price that is in addition to the base rate in the bundle to facilitate the adoption of innovative therapies. Vafseo met the criteria for TDAPA in the anemia management ESRD PPS functional category beginning on January 1, 2025. The TDAPA program provides two years of reimbursement for Vafseo in addition to the ESRD bundled rate to dialysis organizations.

Most dialysis clinics operate within dialysis organization networks, the largest of which are DaVita, Inc., or DaVita, Fresenius KidneyCare Group LLC, or Fresenius, and U.S. Renal Care, or USRC. Together with Dialysis Clinic, Inc. or DCI, and Innovative Renal Care, or IRC, these top five U.S. dialysis organizations treat 82% of the total dialysis patient population. Following Vafseo's U.S. approval, we engaged with dialysis organizations and group purchasing organizations to secure commercial supply agreements for Vafseo. Prior to the availability of Vafseo in the U.S. in January 2025, we had contracts in place with dialysis organizations caring for nearly 100% of dialysis patients.

Treatment is usually driven by medical protocols that dialysis organizations implement across their entire network of clinics. With commercial supply contracts in place, our medical team worked closely with dialysis organization medical professionals, and the dialysis organizations developed protocols for the use of Vafseo in appropriate patient populations. When implemented, protocols can facilitate uptake in prescriptions for the patient population covered by the protocol. In 2025, several dialysis organizations developed, implemented and operationalized protocols, enabling prescribing access. Currently, approximately 290,000 patients on dialysis in the U.S. have prescribing access to Vafseo through protocols operationalized at dialysis organizations.

We are aware that some of these dialysis organizations continue to add or refine their protocols. For instance, both USRC and IRC added a protocol for the use of Vafseo with observed dosing for in-center patients as a result of the recommendations of each dialysis organization’s medical professionals, based in part on efficacy and safety data for vadadustat when dosed three times weekly. The process of refining or adding protocols at dialysis organizations that already have a protocol in place continues, while other dialysis organizations are working to implement an initial protocol for Vafseo.

Today, we have an established and embedded commercial team with approximately 35 key account managers, or KAMs, supported by our commercial operations and national accounts teams. In 2025, in parallel with protocol development, our KAMs continued to detail Vafseo to prescribers. In 2026, the KAMs will continue to engage providers at dialysis organizations with Vafseo prescribing access with the goal of increasing the breadth and depth of prescriptions. Nephrologists have identified home dialysis patients as a particularly underserved patient group given that injectable ESAs, which are typically used by this patient segment, are cumbersome. We anticipate Vafseo near-term adoption in this patient population, particularly among dialysis organizations that do not have an observed dosing protocol in place.

Effective commercialization provides the foundation for a new treatment to potentially become the standard of care. We also rely on our medical affairs team to share data and engage in scientific exchange with prescribers, key medical experts and other medical professionals within dialysis organizations. In addition to currently available data related to Vafseo, we believe

it is also important to generate additional data to educate physicians on potential clinical benefits and differentiation as they make care decisions.

In November 2025, Glenn M. Chertow, M.D., M.P.H., Professor of Medicine, Stanford University School of Medicine, presented a post-hoc win-odds analysis of all-cause mortality and hospitalization from the Phase 3 INNO$_2$VATE trials of vadadustat at the American Society of Nephrology Kidney Week 2025. The analysis demonstrated favorable and statistically significant effects of Vafseo relative to the ESA darbepoetin alfa on the composite endpoint of death and hospitalization. A win-odds analysis is a statistical method used to analyze clinical trial data to evaluate the effectiveness of treatments. It provides a novel way to measure treatment effect by comparing the number of wins and losses for the treatment and control group in studies that prioritized multiple outcomes. In June 2025, enrollment was completed in the Vafseo Outcomes In-Center Experience, or VOICE, collaborative clinical trial being conducted with USRC. Approximately 2,100 patients were randomized to oral Vafseo 300 mg tablets administered three times per week or epoeitin alpha, an ESA. The primary endpoint is the win-odds hierarchical analysis of all-cause mortality and all-cause hospitalization, the same endpoint that was analyzed in the win-odds analysis of the Phase 3 INNO$_2$VATE trials. The VOICE trial was powered to demonstrate non-inferiority for the primary endpoint. We expect to report top-line data from the VOICE trial in early 2027.

We also initiated the VOCAL trial, a post-marketing study conducted within DaVita clinics, to generate data to evaluate the efficacy and safety of three times per week dosing of vadadustat compared to standard of care ESA in patients with anemia of CKD receiving in-center hemodialysis. 353 patients have been enrolled, and top-line data from the VOCAL trial is expected in late 2026. The VOCAL trial includes a sub-study of 27 patients from three clinics who will have blood samples collected and analyzed over the course of a 6-month treatment period. One major factor contributing to the anemia of CKD patients is reduced RBC quality. The intent of the sub-study is to better understand the impact of Vafseo on RBC characteristics compared to ESA treatment.

We previously completed the FO$_2$CUS study and the MO$_2$DIFY study which both evaluated alternative dosing. See Part I, Item 1, Clinical Development Programs, for additional information on the FO$_2$CUS study and the MO$_2$DIFY study.

We believe there is an unmet need for an oral treatment for patients with anemia due to CKD who are not on dialysis. We planned to conduct the VALOR clinical trial for the use of vadadustat to treat anemia in patients with late-stage CKD not on dialysis. However, following a Type C meeting with the FDA in October 2025, we believe that, based on the FDA feedback, regulatory alignment on a path forward for the design of the VALOR trial would require a significantly larger number of patients than proposed, and accordingly would require meaningfully more time and cost to complete than we anticipated. As a result, we announced in October 2025 that we do not plan to initiate the VALOR trial and, therefore, will not pursue a broad label for Vafseo for CKD non-dialysis dependent patients. We continue to engage with the FDA regarding smaller subpopulations of CKD non-dialysis dependent patients where we believe we may be able to align on a potential path forward. Based on our communications to date, however, we remain cautious about a path forward.

Build on our Commitment to People Impacted by Kidney Disease

We believe our leadership in the kidney community and deep understanding of the CKD market creates a competitive advantage to develop and commercialize therapeutics for kidney disease, including rare kidney diseases. We market Auryxia in the U.S., which launched in December 2014.

Auryxia – An oral treatment for hyperphosphatemia and iron deficiency anemia

Hyperphosphatemia is a metabolic disorder characterized by elevated serum phosphorus levels. Phosphorus is a vital element required for most cellular processes and, in individuals with normal kidney function, excess dietary phosphorus is removed by the kidneys and excreted in urine. In adults on dialysis, elevated phosphorus levels, or hyperphosphatemia, can be associated with adverse effects, including increased risk for cardiovascular disease, bone disease and death. According to the U.S. Renal Data System 2023 Annual Data Report, in 2021 there were approximately 541,000 patients in the U.S. on dialysis, of which approximately 81% were treated with a phosphate binder. Phosphate binders and phosphate inhibitors are the only interventions marketed for the treatment of hyperphosphatemia.

IDA is a common form of anemia that is caused by patients not having enough iron to manufacture healthy RBCs. Although anyone can develop IDA, it is particularly common in patients with CKD not on dialysis. IDA is associated with fatigue, lethargy, decreased quality of life, cardiovascular complications, hospitalizations and increased mortality. We estimate there are more than 500,000 adult patients in the U.S. with CKD not on dialysis diagnosed with IDA and managed by a nephrologist. Currently, there are two forms of iron therapy used to treat IDA: oral iron supplements and iron delivered via intravenous infusion, or IV.

Auryxia, an oral-only phosphate binder, was included in the ESRD PPS bundle payment beginning in January 2025, representing a shift, as Auryxia was previously covered by Medicare under Part D and commercial channels. In addition, dialysis organizations will receive a TDAPA payment for claims that include phosphate binders through

2026. After two years, CMS will adjust the bundle price based on the amount spent on phosphate binders during that time and no longer include an extra TDAPA payment in claims. We enabled broad access to Auryxia by executing contracts with dialysis organizations that care for nearly 100% of patients on dialysis in the U.S. and deliver Auryxia directly to dialysis organizations or to their distribution partners. In March 2025 Auryxia reached LoE. On January 22, 2026, Teva received tentative approval for its Abbreviated New Drug Application for Auryxia. Currently, there is only one authorized generic for Auryxia sold by our distributor, but we expect additional generic competition in 2026. If additional generics are approved and enter the market, we expect it will adversely impact our revenue.

We also leverage our research and development competency to address areas of unmet medical need and have invested resources to build our mid-stage rare kidney disease pipeline.

Praliciguat – An oral soluble sGC stimulator being studied in a Phase 2 trial for FSGS

FSGS is a condition characterized by focal and segmental scarring in the kidney's filtering units known as glomeruli. At least 40,000 people in the U.S. are diagnosed with FSGS, which can cause various symptoms including high blood pressure and the presence of too much protein in urine (known as proteinuria), and approximately 50% of FSGS patients will progress to kidney failure. Currently, there are no FDA-approved drugs indicated for FSGS, although an endothelin receptor blocker is in development and under review by the FDA. Treatments such as steroids, other immunosuppressives and antihypertensives may slow kidney failure progression caused by FSGS. Since FSGS is heterogenous in nature, we expect more than one therapy may be needed to fully address the needs of FSGS patients, and a combination of therapies may have a beneficial impact for FSGS patients.

Praliciguat is a sGC stimulator licensed from Cyclerion Therapeutics, Inc. since June 2021. sGC is an enzyme that catalyzes the synthesis of cyclic guanosine 3',5'-monophosphate in response to nitric oxide, or NO, binding. In the kidney, this pathway influences the structure and function of podocytes, highly specialized cells in the kidney's glomerulus, protecting podocytes from injury, foot process effacement, and cell loss. Praliciguat amplifies endogenous NO signaling to stimulate this pathway.

Data from nonclinical studies of praliciguat in kidney disease models showed praliciguat protected glomerular structure, inhibited fibrosis, inhibited inflammation, preserved kidney function and lowered blood pressure. In a Phase 2 trial of praliciguat in patients with diabetic kidney disease, or DKD, data demonstrated a reduction in the urinary albumin creatinine ratio, or UACR, in the modified intent-to-treat population. We evaluated praliciguat in two animal models of FSGS either as a monotherapy or in combination with renin-angiotensin system, or RAS, inhibitors. Data demonstrated that praliciguat synergized with the RAS inhibitor, which is standard of care, to preserve podocyte health, reducing glomerulosclerosis. Data also demonstrated that praliciguat administered in addition to the standard of care showed improvement in renal function and lessened proteinuria. No significant safety issues were observed with praliciguat in Phase 1 studies in healthy volunteers and Phase 2 studies in patients with heart failure with preserved ejection fraction and DKD. Praliciguat adverse events were infrequent and consistent with its known blood pressure lowering effect.

Importantly, through efforts of the PARASOL (Proteinuria and GFR as Clinical Trial Endpoints in FSGS) Project, an initiative co-sponsored by NephCure, the International Society of Glomerular Disease, the FDA, the Kidney Health Initiative, and the National Kidney Foundation, the FDA accepted proteinuria as an approvable endpoint for FSGS clinical trials.

In December 2025, we initiated a Phase 2, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of praliciguat in adults with biopsy-confirmed FSGS. Approximately 60 patients who are currently receiving maximally tolerated doses of an angiotensin-converting enzyme inhibitor, or ACEi, or an angiotensin receptor blocker, or ARB, will be randomized 1:1 to receive either praliciguat or a placebo for an initial 24-week treatment period. Following this double-blind period, all patients will receive praliciguat in the open-label portion of the study for an additional 24 week treatment period. The primary endpoint is defined as change from baseline in urine protein-to-creatinine ratio, or UPCR, measured at week 24. The secondary endpoint is defined as the percentage of patients with partial remission at week 24 (measured as a 40% reduction in UPCR and UPCR<1.5 gram/gram). The first patient in the study was dosed in December 2025.

AKB-097 – Anti-C3d-Factor H fusion protein complement inhibitor

AKB-097 is an investigational recombinant fusion protein designed to modulate activation of the alternative pathway of the complement system. The complement system is a component of innate immunity that, when dysregulated, has been implicated in certain inflammatory and autoimmune diseases, including multiple kidney disorders.

AKB-097 consists of a monoclonal antibody directed against C3d, a degradation fragment of complement component C3 that remains deposited at sites of complement activation, genetically fused to regulatory domains derived from human Factor H. Factor H is a naturally occurring negative regulator of the alternative complement pathway. By

binding to deposited C3d, AKB-097 is designed to localize Factor H regulatory activity to sites of tissue complement activation. Factor H promotes dissociation of alternative pathway C3 and C5 convertases and, together with Factor I, mediates inactivation of C3b, thereby limiting further complement amplification.

AKB-097 is intended to provide targeted regulation of complement activation at sites of tissue injury while limiting systemic complement inhibition. However, this tissue-targeting hypothesis has not been clinically validated, and there can be no assurance that AKB-097 will demonstrate safety or efficacy in clinical trials.

In preclinical studies conducted by Q32, AKB-097 demonstrated tissue distribution consistent with its mechanism of action and pharmacodynamic effects on markers of complement activation. In a completed Phase 1 clinical trial in healthy volunteers, AKB-097 was generally well tolerated, and anti-drug antibodies were observed at low incidence. These early-stage data are limited, and results in healthy volunteers may not be predictive of outcomes in patients with complement-mediated diseases.

We plan to initiate a Phase 2 open label basket study in the second half of 2026 that is expected to enroll multiple cohorts. In the basket study, we plan to evaluate AKB-097 for:

- C3G, an ultra-rare complement-mediated kidney disease with an estimated incidence of 1-3 cases per million people in the U.S.
- IgAN, chronic immune-mediated kidney disease characterized by proteinuria and risk of progressive kidney function decline, with a U.S. prevalence range of 198,887 - 208,184 persons.
- LN, a kidney manifestation of systemic lupus erythematosus, or SLE, clinically evident in 50-60% of the approximately 200,000 people with SLE in the U.S.

The primary objectives of the planned study are expected to include evaluation of safety, tolerability, pharmacokinetics, pharmacodynamics, and effects on disease-relevant biomarkers, including proteinuria and measures of kidney function. We expect to report initial data from this study in 2027, subject to enrollment rates, regulatory interactions, and other development factors.

Our commitment to people impacted by kidney disease motivates our team to explore the potential to treat additional kidney-related diseases and injury. Our early-stage pipeline includes AKB-9090, a HIF-based product candidate that we believe could be appropriate as a potential acute care treatment for use in CS-AKI.

Cardiac Surgery-related Acute Kidney Injury

AKI is a sudden decline in the ability of the kidneys to perform their normal functions. AKI occurs in many settings including 20-30% of the approximately two million patients worldwide who undergo cardiac surgery with the use of cardio-pulmonary bypass each year. There are no current treatments available for CS-AKI. Stabilization of HIF by prolyl hydroxylase inhibition leads to the release of erythropoietin, a shift to anaerobic metabolism (glycolysis) and decreased inflammatory responses that collectively lessen kidney ischemia-reperfusion injury and ameliorate the decline in kidney function seen in many clinical settings including CS-AKI. Data from our preclinical studies showed AKB-9090 to be highly active in lessening the severity of AKI in an animal model of ischemia-reperfusion injury. We expect to initiate a Phase 1 trial of AKB-9090 in the first half of 2026.

Create a Future for Akebia in Kidney Disease and Beyond

Our expertise in HIF science enables our research and development team to further examine the central role of oxygen sensing in many diseases. As we have seen through the development of Vafseo as a treatment for anemia due to CKD, when stabilized, HIF triggers wide-ranging adaptive, protective responses during hypoxic or ischemic conditions. In addition to studying AKB-9090 in CS-AKI, we expect to explore its potential use in ARDS. AKB-10108 is a second early-stage HIF-based product candidate in our pipeline. We are exploring AKB-10108 for potential use in ROP.

Acute Respiratory Distress Syndrome (ARDS)

ARDS is a life-threatening acute form of lung disease characterized by acute bilateral pulmonary edema and severe hypoxemia (low blood oxygen). Despite improvement in supportive care, a third-party study indicated high hospital mortality rates for patients with ARDS admitted to participating intensive care units. The mortality rate among patients with ARDS in the study was: 34.9% with mild ARDS; 40.3% with moderate ARDS and 46.1% with severe ARDS. There are currently no treatments available for ARDS except for supportive care. Stabilization of HIF by prolyl hydroxylase inhibition leads to the release of erythropoietin, increased extracellular adenosine signaling, increased glycolytic activity and decreased inflammation in lung epithelial cells that promote resolution of the lung injury. In earlier studies, vadadustat lessened the severity of COVID-19 pneumonia in a clinical trial (NCT04478071) and improved outcomes in animal models of acute lung injury. In addition, the University of Texas Health Science Center, Houston initiated a Phase 2 study (NCT07086755) to assess the efficacy and safety of vadadustat for treating

hospitalized patients with non-intubated ARDS secondary to pathogen-associated lung injury. We intend to leverage existing data and potential data from the current Phase 2 study to potentially support clinical development of AKB 9090 for ARDS.

Retinopathy of Prematurity (ROP)

ROP is the leading cause of blindness in preterm infants globally and occurs due to incomplete retinal development and abnormal blood vessel growth in the retina. ROP is caused by the high-oxygen therapy used to treat preterm babies, which prevents retina growth. Annually, there are approximately 100,000 new cases of infant blindness worldwide due to ROP and currently no preventative therapy. HIF-PH inhibitors can protect the retina by stabilizing HIF, which degrades during hyperoxia, allowing normal retinal development and preventing abnormal blood vessel growth that can lead to scarring, bleeding, retinal detachment and blindness. Data from our preclinical studies of AKB-10108 in mouse and rat models of ROP showed significant improvements in retinal development under hyperoxic conditions, as well as significant reductions in abnormal blood vessel growth after returning to normal oxygen levels.

Clinical Development Programs

Below is a summary of the clinical development work completed for vadadustat.

Vadadustat Global Phase 3 Clinical Program in Anemia Due To CKD

We conducted a global Phase 3 clinical development program for vadadustat, which included two programs, INNO$_2$VATE and PRO$_2$TECT. INNO$_2$VATE evaluated vadadustat in adult DD-CKD patients with anemia due to CKD in two studies, and PRO$_2$TECT evaluated vadadustat in adult NDD-CKD patients with anemia due to CKD in two studies. Combined, we enrolled approximately 7,500 patients in these studies and evaluated a once daily oral dosing of vadadustat against an injectable ESA active comparator, darbepoetin alfa.

Both the INNO$_2$VATE and PRO$_2$TECT Phase 3 programs were global, multicenter, open-label, sponsor-blind, active-controlled non-inferiority programs. In both programs, patients were randomized 1:1 to receive either oral vadadustat or injectable darbepoetin alfa. The primary efficacy endpoint for each study in the INNO$_2$VATE and PRO$_2$TECT programs was the mean change in hemoglobin between baseline and the primary evaluation period. Non-inferiority, or NI, for the primary efficacy endpoint was achieved if the lower bound of the 95% confidence interval for the between-group difference of the mean hemoglobin change did not fall below the pre-specified NI margin. Both the INNO$_2$VATE and PRO$_2$TECT programs included the primary safety endpoint of the assessment of MACE, with a comparison of vadadustat to darbepoetin alfa. MACE is defined as the composite endpoint of all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke. The primary safety analysis for each program was based on the combined MACE events from the two studies in each of INNO$_2$VATE and PRO$_2$TECT. NI for the primary safety analysis was achieved if the upper bound of the 95% confidence interval for the hazard ratio, or HR, of vadadustat to darbepoetin alfa did not exceed the pre-specified NI margin. We prospectively defined and agreed to non-inferiority margins with the U.S. and European regulatory authorities and agreed with the U.S. regulatory authorities on the key components of our statistical analysis plan.

Top-line Results from Global Phase 3 INNO$_2$VATE Program within DD-CKD Adult Patients

The two INNO$_2$VATE studies (Correction/Conversion and Conversion), which collectively enrolled 3,923 patients, evaluated the efficacy and safety of vadadustat versus darbepoetin alfa for the treatment of anemia due to CKD in DD-CKD adult patients.

Vadadustat achieved the primary and key secondary efficacy endpoint in each of the two INNO$_2$VATE studies, demonstrating non-inferiority to darbepoetin alfa as measured by a mean change in hemoglobin, or Hb, between baseline and the primary evaluation period (weeks 24 to 36) and secondary evaluation period (weeks 40 to 52). Vadadustat also achieved the primary safety endpoint of the INNO$_2$VATE program, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of MACE across both INNO$_2$VATE studies.

Vadadustat achieved the INNO$_2$VATE program's primary safety endpoint of non-inferiority for MACE. In the primary analysis of time to first MACE event, vadadustat demonstrated non-inferiority to darbepoetin alfa using a non-inferiority margin of 1.25 based on discussion with the FDA and a non-inferiority margin of 1.3 based on discussion with the EMA. INNO$_2$VATE results on key secondary safety endpoints showed that vadadustat also demonstrated non-inferiority to darbepoetin alfa in analyses of expanded MACE, cardiovascular MACE, cardiovascular mortality, and all-cause mortality.

Top-line Results from Global Phase 3 PRO$_2$TECT Program within NDD-CKD Adult Patients

The two PRO$_2$TECT studies (Correction and Conversion), which collectively enrolled 3,476 patients, evaluated the efficacy and safety of vadadustat for the treatment of anemia due to CKD in NDD-CKD adult patients.

Vadadustat achieved the primary and key secondary efficacy endpoint in each of the two PRO$_2$TECT studies, demonstrating non-inferiority to darbepoetin alfa as measured by a mean change in Hb between baseline and the primary evaluation period

(weeks 24 to 36) and secondary evaluation period (weeks 40 to 52). Vadadustat did not meet the primary safety endpoint of the PRO_2TECT program, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of MACE, across both PRO_2TECT studies.

Primary and Key Secondary Efficacy Endpoint Results

Vadadustat achieved each of the PRO_2TECT studies' primary efficacy endpoints of mean change in Hb between baseline and the primary evaluation period compared to darbepoetin alfa, in adult patients on dialysis, demonstrating non-inferiority to darbepoetin alfa using an NI margin of -0.75 g/dL.

In PRO_2TECT's Correction study (n=1,751):

- ***Primary Efficacy Endpoint Result***: Vadadustat was non-inferior to darbepoetin alfa. The least square mean difference in Hb was 0.05 g/dL (95% CI: -0.04, 0.15), achieving the pre-specified NI criterion of -0.75 g/dL. The mean (SD) Hb level at week 24 to week 36 was 10.39 (0.99) g/dL for vadadustat-treated patients compared to 10.35 (1.03) g/dL for darbepoetin alfa-treated patients.
- ***Key Secondary Efficacy Endpoint Result***: Vadadustat sustained the target Hb efficacy response at weeks 40 to 52 achieving non-inferiority compared to darbepoetin alfa. The least square mean difference in Hb was 0.04 g/dL (95% CI: -0.06, 0.14). The mean (SD) Hb level at week 40 to week 52 was 10.48 (1.05) g/dL for vadadustat-treated patients compared to 10.45 (1.01) g/dL for darbepoetin alfa-treated patients.

In PRO_2TECT's Conversion study (n=1,725):

- ***Primary Efficacy Endpoint Result***: Vadadustat was non-inferior to darbepoetin alfa. The least square mean difference in Hb was -0.01 g/dL (95% CI: -0.09, 0.07), achieving the pre-specified NI criterion of -0.75 g/dL. The mean (SD) Hb level at week 24 to week 36 was 10.77 (0.98) g/dL for vadadustat-treated patients compared to 10.77 (0.99) g/dL for darbepoetin alfa-treated patients.
- ***Key Secondary Efficacy Endpoint Result***: Vadadustat sustained efficacy in the Conversion study demonstrating non-inferiority to darbepoetin with a least square mean difference in Hb of 0.00 g/dL (95% CI: -0.10, 0.09). The mean (SD) Hb level at week 40 to week 52 was 10.80 (1.04) g/dL in the vadadustat-treated patients compared to 10.79 (1.05) g/dL for darbepoetin alpha-treated patients.

Primary Safety Major Adverse Cardiovascular Events (MACE) Endpoint Result

The PRO_2TECT program (Correction and Conversion studies) (n=3,471):

- ***Primary Safety MACE Endpoint Result***: Vadadustat did not meet the PRO2TECT program's primary safety endpoint of non-inferiority for MACE. The upper bound of the 95% confidence interval of the HR was above the pre-specified NI margin of 1.25 for primary MACE analysis (HR 1.17, 95% CI: 1.01, 1.36).

Analysis of MACE events conducted by the Company in the PRO_2TECT program revealed that the greater number of MACE events observed among vadadustat patients as compared to the active comparator was primarily related to an excess of non-cardiovascular death and death-of-unknown-cause in regions outside of the U.S. where significant differences in treatment patterns for NDD-CKD patients were observed.

The PRO_2TECT analysis plan was prospectively designed to analyze the effect of regional differences, most notably, well-known differences in Hb treatment targets. Within PRO_2TECT, U.S. patients were treated to a target Hb range of 10 to 11 g/dL and non-U.S. patients were treated to a target Hb range of 10 to 12 g/dL. In October of 2020, we presented a pre-specified regional analysis that showed vadadustat was not associated with a clinically meaningful increase in cardiovascular risk compared to darbepoetin alfa in U.S. patients treated to a target Hb range of 10 to 11 g/dL, in an analysis of MACE (HR 1.06, 95% CI: 0.87, 1.29).

The incidence of treatment emergent adverse events, or TEAEs, during the Correction study in the vadadustat-treated patients was 90.9%, and 91.6% in darbepoetin alfa-treated patients. During the study, the most common TEAEs reported in vadadustat/darbepoetin alfa-treated patients were end-stage renal disease (34.7%/ 35.2%), hypertension (17.7%/ 22.1.%), hyperkalemia (12.3.%/ 15.6%), urinary tract infection (12.9%/ 12.0%), diarrhea (13.9%/ 10.0%), peripheral oedema (12.5%/ 10.5%), fall (9.6%/ 10%) and nausea (10%/ 8.2%). Serious TEAEs were 65.3% for vadadustat-treated patients and 64.5% for darbepoetin alfa-treated patients. The incidence of TEAEs during the Conversion study in vadadustat treated patients was 89.1% and 87.7% in darbepoetin alfa-treated patients. During the study, the most common TEAEs reported in vadadustat/darbepoetin alfa-treated patients were end-stage renal disease (27.5%/ 28.4%), hypertension (14.4%/ 14.8%), urinary tract infection (12.2%/ 14.5%), diarrhea (13.8.%/ 8.8.%), peripheral oedema (9.9%/ 10.1%) and pneumonia (10.0%/ 9.7%). Serious TEAEs were 58.5% for vadadustat-treated patients and 56.6% for darbepoetin alfa-treated patients.

Hepatic Safety Profile of Vadadustat in Clinical Studies

During the conduct of our Phase 3 program our team and hepatic experts analyzed hepatic cases (unblinded to treatment). Further, following the completion of our global Phase 3 clinical program for vadadustat, there was a review of hepatic safety across the vadadustat clinical program, which included eight completed Phase 2 and 3 studies in NDD-CKD patients, 10 completed Phase 1, 2, and 3 studies, and two then-ongoing Phase 3b studies in DD-CKD patients, and 18 completed studies in healthy subjects (17 Phase 1 and one Phase 3). This review consisted of a blinded re-assessment of hepatic events conducted by a separate panel of hepatic experts. While hepatocellular injury attributed to vadadustat was reported in less than 1% of patients, there was one case of severe hepatocellular injury with jaundice, and we cannot guarantee that similar events will not happen in the future. In the clinical review of our NDA in March 2024, the FDA concluded that there is a hepatocellular injury risk with the use of vadadustat in patients with CKD, although the risk of serious liver injury appears rare.

Modified Dosing Studies

From May 2020 to January 2023, we also conducted additional studies of vadadustat evaluating a modified approach to a once-daily and three-times weekly dosing, including assessment of a vadadustat starting dose based on an individual's pre-conversion ESA dose prior to study entry and higher titration doses of vadadustat (up to 1200 mg).

The FO_2CUS study evaluated the efficacy and safety of vadadustat in hemodialysis patients who were converted from a long-acting ESA to three-times weekly oral vadadustat dosing for the maintenance treatment of anemia. FO_2CUS was an open-label, active-controlled, sponsor-blinded study that evaluated 456 hemodialysis patients who were randomized (1:1:1) into a vadadustat 600mg starting dose, vadadustat 900mg starting dose, or a long-acting ESA (Mircera®) treatment arms.

The MO_2DIFY study evaluated the efficacy and safety of vadadustat in hemodialysis patients using a modified once-daily dosing regimen different from the $INNO_2$VATE program dosing and a three-times-weekly dosing regimen of oral vadadustat compared to darbepoetin alfa.

FO_2CUS Study

Primary and Secondary Efficacy Endpoint Results

In the FO_2CUS study, each vadadustat starting dose regimen (600 mg, 900 mg) and the combined vadadustat-treated group achieved the primary efficacy endpoint of the mean change in Hb between baseline and the primary evaluation period (weeks 20-26) compared to Mircera in adult patients on hemodialysis, demonstrating non-inferiority to Mircera based on a non-inferiority margin of -0.75 g/dL. Similarly, each starting dose regimen of vadadustat and the combined vadadustat-treated group achieved the secondary efficacy endpoint of the mean change in Hb between baseline and the secondary evaluation period (weeks 46-52).

In the FO_2CUS study in hemodialysis patients (n=456):

- ***Primary Efficacy Endpoint Results***: Vadadustat demonstrated non-inferiority to Mircera. The least square mean difference in Hb was -0.43 g/dL (-0.67, -0.20) for the vadadustat 600 mg starting dose group, -0.23 g/dL (-0.46, 0.01) for the vadadustat 900 mg starting dose group, and -0.33 g/dL (-0.53, -0.13) for the combined vadadustat-treated group, achieving the pre-specified non-inferiority margin of -0.75 g/dL. The mean Hb level during the primary evaluation period was 10.11 (0.061) g/dL for the combined vadadustat-treated group compared to 10.41 (0.068) g/dL for Mircera-treated group.
- ***Secondary Efficacy Endpoint Results:*** Vadadustat demonstrated non-inferiority to Mircera. The least square mean difference in Hb was -0.27 g/dL (-0.54, -0.00) for the vadadustat 600 mg starting dose group, -0.38 g/dL (-0.67, -0.10) for the vadadustat 900 mg starting dose group, and -0.33 g/dL (-0.56, -0.09) for the combined vadadustat-treated group. The mean Hb level during the secondary evaluation period was 10.03 (0.066) g/dL for the combined vadadustat-treated group compared to 10.28 (0.076) g/dL for the Mircera-treated group.

Safety Results

In the FO_2CUS study, a total of 78.7% of patients experienced any TEAEs in the combined vadadustat-treated group, and 75.3% experienced any TEAEs in the Mircera-treated group. The data demonstrated that 44.5% of patients experienced any serious TEAEs in the combined vadadustat-treated group, and 44.7% of patients experienced any serious TEAEs in the Mircera-treated group. During the study, the most common TEAEs reported in vadadustat-/Mircera- treated patients were COVID-19 (14.6%/16.0%), diarrhea (12.3%/8.0%) and hyperkalaemia (9.0%/10.7%).

MO_2DIFY Study

Primary and Secondary Efficacy Endpoint Results

In the MO_2DIFY study, the vadadustat once-daily, or QD, treatment (starting dose: 300 or 450 mg) achieved the primary efficacy endpoint of the mean change in Hb from baseline to the primary evaluation period (weeks 20-26) compared to darbepoetin alfa in adult patients on hemodialysis, demonstrating non-inferiority to darbepoetin alfa based on a non-inferiority margin of -0.75 g/dL. Vadadustat three-times-weekly, or TIW, treatment (starting dose: 600 or 750) did not

demonstrate noninferiority to darbepoetin alfa. Based on a sensitivity analysis using the per protocol population, both vadadustat dosing regimens demonstrated noninferiority to darbepoetin alfa of the mean change in Hb between baseline and the primary evaluation period.

Neither dosing regimen of vadadustat achieved the secondary efficacy endpoint of the mean change in Hb between baseline and the secondary evaluation period (weeks 46-52).

In the MO_2DIFY study in hemodialysis patients (n=319):

- ***Primary Efficacy Endpoint Results***: Vadadustat QD treatment was non-inferior to darbepoetin alfa. The least square mean difference in Hb was -0.27 g/dL (-0.55, 0.01) for the vadadustat QD-treated group, meeting the pre-specified non-inferiority margin of -0.75 g/dL. The least square mean difference in Hb was -0.53 g/dL (-0.80, -0.25) for the vadadustat TIW-treated group. The mean Hb level during the primary evaluation period was 10.23 (1.07) g/dL and 10.02 (0.87) g/dL for the vadadustat QD and vadadustat TIW groups respectively, compared to 10.45 (0.83) g/dL for the darbepoetin alfa group.
- ***Secondary Efficacy Endpoint Results***: The secondary efficacy endpoint was the change in average Hb between baseline and the secondary evaluation period (Weeks 46 to 52). The least square mean difference in Hb was -0.40 g/dL (-0.79, -0.02) for the vadadustat QD-treated group and -0.42 g/dL (-0.81, -0.02) for the vadadustat TIW-treated group. Since noninferiority for the secondary efficacy endpoint of vadadustat TIW to darbepoetin alfa was not established, no claims of noninferiority were made for the secondary efficacy endpoint.
- ***Other efficacy Endpoint:*** The proportion of subjects with an average Hb value within the target range (US [10.0 to 11.0 g/dL] and Europe [10.0 to 12.0 g/dL]) was similar in the vadadustat QD, vadadustat TIW and darbepoetin alfa treatment groups during the primary evaluation period (weeks 20 to 26) (51.0%, 50.7%, and 54.5%, respectively) and secondary evaluation period (weeks 46 to 52) (50.4%, 48.3%, and 51.3%, respectively).

Safety Results

Among all randomized patients who received at least one dose of the study medication (n=317), 84.8% and 84.6% of patients in the vadadustat QD and TIW groups, respectively, experienced any TEAEs, compared to 80.6% in the darbepoetin alfa group. The data showed that 44.8% of patients in the vadadustat QD group and 45.2% in the vadadustat TIW group experienced any treatment-emergent serious adverse events, compared to 43.5% of patients in the darbepoetin alfa group. The most commonly reported TEAEs in patients treated with vadadustat QD, vadadustat TIW, and darbepoetin alfa were COVID-19 (13.3%, 12.5%, and 13.0% respectively), diarrhea (13.3%, 14.4%, and 5.6% respectively), and anemia (7.6%, 10.6%, and 9.3% respectively).

Manufacturing and Supply

Overview

We neither own nor operate, and currently have no plans to own or operate, any manufacturing or distribution facilities. We rely on third-party contract manufacturing organizations, or CMOs, to produce all of our preclinical, clinical and commercial supply, and third-party distributors to distribute Auryxia and Vafseo. We have established relationships with several CMOs and expect to continue to rely on either existing or alternative CMOs and distributors to manufacture or distribute our products to support ongoing and planned preclinical, clinical and commercial distribution activities. Our CMOs have other clients and may have other priorities that could affect manufacturing line capacity and/or delivery schedules. Both of these occurrences would be beyond our control. All clinical and commercial supplies are manufactured under current Good Manufacturing Practices, or cGMPs, which is a regulatory requirement for the production of pharmaceuticals that will be used in humans.

We utilize third parties for the commercial distribution of Auryxia and Vafseo, including wholesale distributors and certain specialty pharmacy providers. We have also engaged Cardinal Health, Inc., as the exclusive third-party logistics distribution agent for commercial sales of Auryxia and Vafseo. The third-party logistics distribution agent provides services to us that include storage, distribution, processing product returns, customer service support, logistics support, electronic data interface and system access support.

Vafseo

We currently rely on suppliers for the direct manufacture of our drug substance and drug product for clinical and commercial supply of Vafseo. We have entered into supply agreements with STA Pharmaceutical Hong Kong Limited, or STA, for the manufacture of Vafseo drug substance and drug product for commercial use and Patheon Inc. for the manufacture of Vafseo drug product for commercial use. We plan to mitigate potential commercial supply risks for Vafseo, if any, through inventory management and we may enter into additional manufacturing arrangements for both drug substance and drug product. For more information about our manufacturing agreements for Vafseo, see Part II, Item 7. Management's Discussion and Analysis

and Note 10, *Commitments and Contingencies*, to our consolidated financial statements in Part II, Item 8. Financial Statements and Supplementary Data.

Vadadustat is a small molecule. The synthesis of vadadustat is reliable and reproducible from starting materials available from multiple sources at commercially relevant scale using no unusual manufacturing equipment. Vadadustat is formulated into compressed tablets using proprietary processes. As with any supply program, obtaining raw materials and finished drug product of the required quality and quantity cannot be guaranteed, and we cannot ensure that we will be successful in this endeavor.

Auryxia

The active pharmaceutical ingredient of Auryxia, ferric citrate, is a small molecule. The synthesis of ferric citrate is reliable and reproducible from starting materials available from multiple sources at a commercial scale. Ferric citrate is formulated into compressed tablets using proprietary manufacturing processes. As with any supply program, obtaining raw materials and finished drug product of the required quality and quantity cannot be guaranteed, and we cannot ensure that we will be successful in this endeavor.

We have established CMO relationships for the supply of Auryxia to help ensure that we will have sufficient material for ongoing commercial sales and clinical trials. We currently rely on single-source suppliers for the manufacture of our drug substance and drug product for clinical and commercial supply of Auryxia, including to supply our authorized generic. The drug substance for Auryxia is supplied by Siegfried Evionnaz SA, or Siegfried, pursuant to a supply agreement, as amended, with pricing structured on a per-kilogram basis. Auryxia drug product is supplied by Patheon Manufacturing Services LLC (Thermo Fisher) pursuant to a Master Manufacturing Service Agreement with per-bottle pricing structured on a tiered basis, with the price reduced as the product volume increases. The supply agreement with Siegfried requires that we satisfy certain minimum purchase requirements, but we are not obligated to use Siegfried as our exclusive supplier. For more information about our manufacturing agreements for Auryxia, see Part II, Item 7. Management's Discussion and Analysis and Note 10, *Commitments and Contingencies*, to our consolidated financial statements in Part II, Item 8. Financial Statements and Supplementary Data.

License and Collaboration Agreements

Vafseo License and Collaboration Agreements

Medice License Agreement

On May 24, 2023, or the Medice Effective Date, we entered into a License Agreement, or the Medice License Agreement, with Medice, under which we granted to Medice an exclusive license to develop and commercialize Vafseo for the treatment of anemia in adult patients with chronic kidney disease in the European Economic Area, or EEA, UK, Switzerland and Australia, or the Medice Territory.

Under the Medice License Agreement, we received an up-front payment of $10.0 million and are eligible to receive the following payments:

(i) commercial milestone payments up to an aggregate of $100.0 million, and

(ii) tiered royalties ranging from 10% to 30% of Medice's annual net sales of Vafseo in the Medice Territory, subject to reduction in certain circumstances.

The royalties will expire on a country-by-country basis upon the latest to occur of (i) the date of expiration of the last-to-expire valid claim of ours, Medice or joint patent that covers Vafseo in such country in the Medice Territory, (ii) the date of expiration of data or regulatory exclusivity for Vafseo in such country in the Medice Territory and (iii) the date that is 12 years from first commercial sale of Vafseo in such country in the Medice Territory.

Under the Medice License Agreement, we retain the right to develop Vafseo for non-dialysis patients with anemia due to CKD in the Medice Territory. If we develop Vafseo for non-dialysis patients and Vafseo receives marketing approval for non-dialysis patients in the Medice Territory, Medice will commercialize Vafseo for both indications in the Medice Territory. In this instance, we would receive 70% of the net product margin of any sales of Vafseo in the non-dialysis patient population, unless Medice requests to share the cost of the development necessary to gain approval to market Vafseo for non-dialysis patients in the Medice Territory and the parties agree on alternative financial terms.

We and Medice established a joint steering committee to oversee the development and commercialization of Vafseo in the Medice Territory.

The Medice License Agreement expires on the date of expiration of all payment obligations due thereunder with respect to Vafseo in the last country in the Medice Territory, unless earlier terminated in accordance with the terms of the Medice License Agreement. Either party may, subject to a cure period, terminate the Medice License Agreement in the event of the

other party's uncured material breach. Medice has the right to terminate the Medice License Agreement in its entirety for convenience upon twelve months' prior written notice delivered on or after the date that is twelve months after the Medice Effective Date.

The Medice License Agreement includes customary terms relating to, among others, indemnification, confidentiality, remedies, and representations and warranties.

On September 13, 2024, we entered into a supply agreement, or the Medice Supply Agreement, with Medice under which we supply Vafseo drug product to Medice for commercial and developmental use in the Medice Territory.

On November 12, 2025, we entered into Amendment #1 to the Medice License Agreement, or the Medice Amendment, with Medice. Pursuant to the Medice Amendment, we agreed to supply vadadustat drug substance, or the Drug Substance, to Medice pursuant to the terms of a supply agreement dated concurrently with the Medice Amendment and granted Medice the right to manufacture Vafseo tablets using the Drug Substance to be supplied by us. In addition, the Amendment provides that any know-how or patent rights arising out of Medice's manufacture of Vafseo tablets will be owned by us.

TPC Collaboration Agreement

In December 2015, we entered into a collaboration agreement with Tanabe Pharma Corporation, or TPC, formerly known as Mitsubishi Tanabe Pharma Corporation, as amended, or the TPC Agreement, providing TPC with exclusive development and commercialization rights to Vafseo in Japan and certain other Asian countries, or the TPC Territory. In addition, we supply Vafseo to TPC for both clinical and commercial use in the TPC Territory, and TPC has the option to manufacture commercial drug product in the TPC Territory. On July 15, 2020, we entered into a supply agreement with TPC for the commercial supply of Vafseo for use in Japan and certain other Asian countries, as contemplated by the TPC Agreement, which was amended effective as of December 5, 2022.

Unless earlier terminated, the TPC Agreement will continue in effect on a country-by-country basis until the later of the following: (i) expiration of the last-to-expire patent covering Vafseo in such country in the TPC Territory; (ii) expiration of marketing or regulatory exclusivity in such country in the TPC Territory; or (iii) ten years after the first commercial sale of Vafseo in such country in the TPC Territory. TPC may terminate the TPC Agreement upon twelve months' notice. Either party may terminate the TPC Agreement upon the material breach of the other party that is not cured within a specified time period or upon the insolvency of the other party.

Under the terms of the TPC Agreement, we are eligible to receive payments from TPC of up to approximately $225.0 million in the aggregate based on the achievement of certain development, regulatory and sales milestones, as well as tiered royalty payments ranging from 13% to 20% on annual net sales of Vafseo in the TPC Territory, subject to reduction upon launch of a generic product on a country-by-country basis.

In February 2021, we entered into a royalty interest acquisition agreement with HealthCare Royalty Partners IV, L.P., or HCR, whereby we sold our right to receive royalties and sales milestones for Vafseo in Japan and certain other Asian countries in the TPC territory under the TPC Agreement, subject to certain caps and other terms and conditions. For more information on our royalty interest acquisition agreement with HCR, see Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, to our consolidated financial statements in Part II, Item 8. Financial Statements and Supplementary Data of this Form 10-K.

CSL Vifor Agreements

On February 18, 2022, we entered into a Second Amended and Restated License Agreement, or the Vifor License Agreement, with Vifor (International) Ltd. (now a part of CSL Limited), or CSL Vifor, which amended and restated the License Agreement dated as of May 12, 2017. The Vifor License Agreement granted CSL Vifor an exclusive license to sell Vafseo to Fresenius Medical Care North America and its affiliates, including Fresenius Kidney Care Group LLC, to certain third-party dialysis organizations approved by us, to independent dialysis organizations that are members of certain group purchasing organizations and certain non-retail specialty pharmacies, collectively, the Supply Group, in the U.S.

The Vifor License Agreement was structured as a profit share arrangement between us and CSL Vifor in which we would receive approximately 66% of the profits, net of certain pre-specified costs. CSL Vifor made an upfront payment to us of $25.0 million in February 2022 in connection with the amendment and restatement of the Vifor License Agreement. In addition, we entered into certain investment agreements with CSL Vifor, pursuant to which we sold CSL Vifor an aggregate of 7,571,429 shares of our common stock for a total of $70.0 million. The shares have not been registered pursuant to the Securities Act of 1933, as amended, or the Securities Act, and were issued and sold in reliance upon the exemption from registration contained in Section 4(a)(2) of the Securities Act and Rule 506 promulgated thereunder as the transaction did not involve any public offering within the meaning of Section 4(a)(2) of the Securities Act.

On July 10, 2024, we and CSL Vifor entered into the Vifor Termination and Settlement Agreement, or the Vifor Termination Agreement, pursuant to which we and CSL Vifor agreed, among other things, to terminate, effective immediately, the Vifor License Agreement.

Pursuant to the terms of the Vifor Termination Agreement, we will pay CSL Vifor decreasing quarterly tiered royalty payments ranging from a high single-digit percentage of our net sales of Vafseo up to $450.0 million to mid-single digit percentage of our net sales of Vafseo above $450.0 million, in each case, in the U.S. during a calendar year, or the Settlement Royalty Payments. The Settlement Royalty Payments commenced upon the first sale of Vafseo by us to a third party for use in the U.S., and will continue until the later of the (i) expiration of the last-to-expire valid claim listed in the FDA Orange Book that would be infringed by the making, using, selling or importing of Vafseo in the U.S. or (ii) the expiration of marketing or regulatory exclusivity for Vafseo in the U.S., or the Settlement Royalty Term. Beginning on July 1, 2027 and throughout the Settlement Royalty Term, we have the option to make a one-time payment to CSL Vifor, or the Royalty Buy-Down Option, upon which the Settlement Royalty Payments will be adjusted as of the date of exercise of the Royalty Buy-Down Option such that we will then only pay CSL Vifor quarterly royalty payments based on a mid-single digit percentage of our net sales of Vafseo up to $450.0 million in the U.S. during a calendar year in lieu of the above Settlement Royalty Payments. If we exercise the Royalty Buy-Down Option, the WCF Royalty Payments, as described below, will continue.

The WCF Royalty Payments, as described below, the Settlement Royalty Payments and the Royalty Buy-Down Option are in consideration for the termination of the Vifor License Agreement and all obligations thereunder, and the covenants and agreements set forth in the Vifor Termination Agreement, including the settlement and release of all disputes and claims which could arise from the Vifor License Agreement.

Pursuant to the Vifor License Agreement, CSL Vifor contributed $40.0 million to a working capital facility, or Working Capital Fund, established to partially fund our costs of purchasing Vafseo from our contract manufacturers. On May 3, 2024, we and CSL Vifor entered into Amendment #1 to the Vifor License Agreement, or the Vifor Amendment. Pursuant to the Vifor Amendment, and as modified by the Vifor Termination Agreement, we and CSL Vifor agreed to modify the method of repayment of the Working Capital Fund such that the Working Capital Fund will be repaid through quarterly tiered royalty payments ranging from 8% to 14% of our net sales of Vafseo in the U.S., or the WCF Royalty Payments. The WCF Royalty Payments commenced on July 1, 2025, and will continue until the earlier of (i) the cumulative total of the WCF Royalty Payments equals $40.0 million, or (ii) May 31, 2028, or the WCF Royalty Term. The WCF Royalty Payments are subject to minimum true-up milestones of $10.0 million, $20.0 million and $40.0 million, or the WCF Royalty True-Up Payments, on each of May 31, 2026, May 31, 2027 and May 31, 2028, respectively, or the WCF Royalty True-Up Dates. If the cumulative total of the WCF Royalty Payments paid to CSL Vifor on any given WCF Royalty True-Up Date is less than the respective WCF Royalty True-Up Payment, we will pay CSL Vifor a one-time payment equal to the difference between the WCF Royalty True-Up Payment and the cumulative total of the WCF Royalty Payments paid by us through such WCF Royalty True-Up Date.

Auryxia License and Collaboration Agreements

Averoa License Agreement

On December 22, 2022, we and Averoa entered into a license agreement, or Averoa License Agreement, pursuant to which we granted to Averoa an exclusive license to develop and commercialize ferric citrate, or Averoa Licensed Product, in the EEA, Turkey, Switzerland and the United Kingdom, and in August 2024, we also granted Averoa an exclusive license to develop and commercialize ferric citrate in the Balkans and certain countries in Eastern Europe and the Middle East, or collectively, the Averoa Territory. We and Averoa have established a joint steering committee to oversee the development, manufacturing and commercialization of the Averoa Licensed Product in the Averoa Territory. In April 2024, Averoa submitted its marketing authorization application for ferric citrate in Europe. In March 2025, the Committee for Medicinal Products for Human Use of the European Medicines Agency adopted a positive opinion recommending the European Commission, or EC, approve Averoa’s marketing authorization, which the EC granted in June 2025. In November 2025, the Medicines and Healthcare Products Regulatory Agency, or MHRA, granted Averoa's UK marketing authorization. However, Averoa has not yet obtained pricing authorization nor commenced sales of ferric citrate in Europe or the UK.

Under the Averoa License Agreement, we are entitled to receive tiered, escalating royalties ranging from a mid-single digit percentage to a low double-digit percentage of Averoa's annual net sales of the Averoa Licensed Product in the Averoa Territory, including certain minimum royalty amounts in certain years, and subject to reduction in certain circumstances. The royalties will expire on a country-by-country basis upon the last to occur of (a) ten years following the date of first commercial sale of the Licensed Product in such country; (b) expiration of the last valid claim of our patent rights and joint patent rights in such country; and (c) the date of expiration of the data, regulatory, or marketing exclusivity period conferred by the applicable regulatory authority in such country with respect to the Licensed Product. As of December 31, 2025, we have not received any royalties under this agreement.

The Averoa License Agreement expires on the date of expiration of all royalty obligations due thereunder with respect to the Averoa Licensed Product on a country-by-country basis in the Averoa Territory, unless earlier terminated in accordance with the Averoa License Agreement.

The Averoa License Agreement provides that we and Averoa will enter into a supply agreement pursuant to which we will supply the Averoa Licensed Product to Averoa for commercial use in the Averoa Territory. We have not yet entered into a supply agreement with Averoa.

Sublicense Agreement with Japan Tobacco Inc. and Torii Pharmaceutical Co., Ltd.

In September 2007, we entered into a Sublicense Agreement with JT and Torii, under which JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate in Japan. Effective June 8, 2009, we entered into an Amended and Restated Sublicense Agreement, which was amended in June 2013, or the Revised Agreement, with JT and Torii.

In January 2014, JT and Torii received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate hydrate, which launched in May 2014 and is being marketed in Japan by Torii under the brand name Riona, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including NDD-CKD and DD-CKD. In July 2019, JT and Torii, reported positive top-line results from a pivotal Phase 3 comparative study evaluating Riona for the treatment of IDA in adult patients in Japan, which was approved in March 2021. In May 2020, JT and Torii filed an application for approval of IDA as an additional indication for Riona in Japan. Under the terms of the Revised Agreement with JT and Torii, we are eligible to receive royalty payments based on a tiered low double-digit percentage of net sales of Riona in Japan inclusive of amounts that we must pay to Panion & BF Biotech, Inc., or Panion, on JT and Torii's net sales of Riona under the Panion Amended License Agreement, subject to certain reductions upon expiration or termination of the Panion Amended License Agreement, and may also receive up to an additional $55.0 million upon the achievement of certain annual net sales milestones. We recorded $5.7 million in license revenue related to royalties earned on net sales of Riona in Japan during the year ended December 31, 2025.

The sublicense under the Revised Agreement terminates upon the expiration of all underlying patent rights. Also, JT and Torii may terminate the Revised Agreement with or without cause upon at least six months prior written notice to us. Additionally, either party may terminate the Revised Agreement for cause upon 60 days' prior written notice after the breach of any uncured material provision of the Revised Agreement, or after certain insolvency events.

License Agreement with Panion & BF Biotech, Inc.

On April 17, 2019, we and Panion entered into a second amended and restated license agreement, or the Panion Amended License Agreement, which amended and restated in full the license agreement between us and Panion. The Panion Amended License Agreement provides us with an exclusive license under Panion-owned know-how and patents covering the rights to sublicense, develop, make, use, sell, offer for sale, import and export ferric citrate worldwide, excluding certain Asian Pacific countries, or the Licensor Territory. The Panion Amended License Agreement also provides Panion with an exclusive license under our patents covering the rights to sublicense (with our written consent), develop, make, use, sell, offer for sale, import and export ferric citrate in certain countries in the Licensor Territory. Consistent with the Panion License Agreement, under the Panion Amended License Agreement, Panion is eligible to receive from us or any sublicensee royalty payments based on a mid-single digit percentage of net sales of ferric citrate in our licensed territories. We are eligible to receive from Panion or any sublicensee royalty payments based on a mid-single digit percentage of net sales of ferric citrate in Panion's licensed territories.

The Panion Amended License Agreement terminates upon the expiration of each of our and Panion's obligations to pay royalties thereunder. In addition, we may terminate the Panion Amended License Agreement (i) in its entirety or (ii) with respect to one or more countries in our licensed territory, in either case upon 90 days' notice. We and Panion also each have the right to terminate the Panion Amended License Agreement upon the occurrence of a material breach of the Panion Amended License Agreement by the other party, subject to certain cure provisions, or certain insolvency events. The Panion Amended License Agreement also provides that, on a country-by-country basis, during the term and until the second anniversary of the expiration of our or Panion's obligation, as applicable, to pay royalties in a country in which such party has ferric citrate for sale on the date of such expiration, neither the other party nor its affiliates will, directly or indirectly, sell, distribute or otherwise commercialize or supply or cause to supply ferric citrate to a third party for sale or distribution in such country. In addition, the Panion Amended License Agreement provides that each of us and Panion has the right, but not the obligation, to conduct litigation against any infringer of certain patent rights under the Panion Amended License Agreement in certain territories.

During the year ended December 31, 2025, we recorded $11.3 million in royalties due to Panion relating to the sales of Auryxia in the U.S. and JT and Torii net sales of Riona in Japan.

Cyclerion Therapeutics License Agreement

In June 2021, we entered into a license agreement, or the Cyclerion Agreement, with Cyclerion under which Cyclerion granted us an exclusive global license under certain intellectual property rights to research, develop and commercialize praliciguat, an investigational oral sGC stimulator.

Under the terms of the Cyclerion Agreement, we paid $3.0 million in cash upfront to Cyclerion and expensed the amount to research and development, or R&D, expense in June 2021. In December 2024, we amended the terms of the Cyclerion Agreement, or the Cyclerion Amendment, pursuant to which we paid an additional $1.25 million in cash upfront to Cyclerion and we paid an additional $0.5 million to Cyclerion in September 2025. In addition, we and Cyclerion agreed to the reduction of certain development milestones and the increase of certain royalty rates on net sales and sublicense income. We now control all clinical and commercial manufacturing of praliciguat, which will be conducted by a third party manufacturer. As of April 2025, we also control patent prosecution and pay intellectual property costs. In February 2026, pursuant to the terms of the Cyclerion Amendment, upon the first patient dosed in a Phase 2 clinical trial in the U.S. for a product, we paid a $1.0 million regulatory milestone payment to Cyclerion.

In addition, Cyclerion is eligible to receive up to an aggregate of $197.5 million from us in additional specified development and regulatory milestone payments on a product-by-product basis. Cyclerion will also be eligible to receive specified commercial milestones as well as tiered royalties ranging from a mid-single-digit percentage to twenty percent of net sales, on a product-by-product basis, and subject to reduction upon expiration of patent rights or the launch of a generic product in the territory.

Unless earlier terminated, the Cyclerion Agreement will expire on a product-by-product and country-by-country basis upon the expiration of the last royalty term, which ends upon the longest of (i) the expiration of the patents licensed under the Cyclerion Agreement, (ii) the expiration of regulatory exclusivity for such product and (iii) 10 years from first commercial sale of such product. We may terminate the Cyclerion Agreement in its entirety or only with respect to a particular licensed compound or product upon 180 days' prior written notice to Cyclerion. We and Cyclerion also have customary termination rights, subject to a cure period, in the event of the other party’s material breach of the Cyclerion Agreement or in the event of certain additional circumstances.

Q32 Asset Purchase Agreement

On November 28, 2025, or the APA Closing Date, we entered into an Asset Purchase Agreement, or the Q32 Purchase Agreement, with Q32, pursuant to which we purchased and assumed from Q32 substantially all assets and liabilities of Q32 and its affiliates related to the research, development, manufacture and commercialization of Q32’s clinical-stage development candidate known as ADX-097, now referred to as AKB-097, worldwide for the treatment, prevention or diagnosis of any disease or condition in humans. AKB-097, which has been evaluated in a Phase 1 clinical trial in healthy volunteers, is a tissue-targeted C3d-Factor H fusion protein complement inhibitor with the potential to treat rare kidney diseases.

Under the terms of the Q32 Purchase Agreement, we (i) made an upfront payment in an amount equal to $7.0 million on the APA Closing Date, (ii) will make an additional upfront payment in an amount equal to $3.0 million on the sixth-month anniversary of the APA Closing Date, (iii) will make certain milestone payments upon the achievement of specified development and regulatory milestone events related to AKB-097 up to an aggregate amount equal to $94.5 million, including a $2.0 million development milestone payment upon the earlier of initiation of a Phase 2 clinical trial and December 31, 2026, (iv) will make certain milestone payments upon the achievement of specified commercial milestone events with respect to the net sales of AKB-097 up to an aggregate amount equal to $487.5 million, and (v) will make certain royalty payments based on the net sales of AKB-097 with royalty percentage tiers ranging from the low single digits to mid-teen percentages. The royalties will expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

Intellectual Property

The proprietary nature of, and protection for, our products, product candidates and our discovery programs, processes and know-how are important to our business. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. Additionally, we may benefit from a variety of statutory frameworks in the U.S., Europe and other countries that provide periods of non-patent-based exclusivity for qualifying molecules.

Our commercial success will depend in part on obtaining and maintaining patent protection of our current products as well as current and future product candidates, methods of their use and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using,

selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes. Even once patents successfully issue, third parties may challenge the validity, enforceability, inventorship, or scope thereof, which may result in such patents being narrowed, invalidated or held not infringed or unenforceable. For this and more comprehensive risks related to our intellectual property, please see "Risk Factors—Risks Related to our Intellectual Property" in Part I, Item 1A. Risk Factors.

Individual patents extend for varying periods of time depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued from applications filed in the U.S. are effective for 20 years from the earliest filing date of a U.S. non-provisional application or an international application filed under the Patent Cooperation Treaty. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period, however, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest international filing date. Patent term recapture for loss of term as a result of the regulatory review period is available in some foreign jurisdictions. In the U.S., a patent's term may also be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office, or USPTO, in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

Changes in either the patent laws or interpretations of patent laws in the U.S. and other countries can diminish our ability to protect our inventions and enforce our intellectual property rights. Accordingly, we cannot predict the breadth or enforceability of claims that may be granted in our patents or in third-party patents. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Our ability to maintain and solidify our proprietary position for our drugs and technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of the patent applications that we may file or license from third parties will result in the issuance of any patents. The issued patents that we own or license or may receive or acquire in the future may be challenged, invalidated or circumvented, and the rights granted under any issued patents may not provide us with sufficient protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may be able to independently develop and commercialize similar drugs or duplicate our technology, business model or strategy without infringing our patents. Because of the extensive time required for clinical development and regulatory review of a drug we may develop, it is possible that, before any of our drugs can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of any such patent. The patent positions for vadadustat and Auryxia are summarized below.

Vadadustat Patent Portfolio

We hold 19 issued patents covering the composition of matter, polymorph, method of treating anemia, pharmaceutical compositions of vadadustat, and processes for manufacturing vadadustat in the U.S. and additional patents issued or pending in many other major jurisdictions worldwide, including Europe, Japan, China, South Korea, Brazil, Mexico, Russia, Israel and India. The expected expiration dates for these patents are between 2027 and 2039 plus any extensions or adjustments of term available under national law.

We also hold patents and patent applications directed to starting materials and intermediates in the processes for manufacturing vadadustat, dosing regimens, formulations and various other aspects relating to the treatment of anemia using vadadustat that are expected to expire between 2032 and 2042 exclusive of possible patent term extensions or adjustments.

We have an ongoing opposition proceeding relating to vadadustat. See Part I, Item 3. Legal Proceedings for further information relating to this matter.

Auryxia Patent Portfolio

Pursuant to the Panion Amended License Agreement, we have the exclusive rights under a series of patents and patent applications to commercialize Auryxia worldwide, excluding certain Asian-Pacific countries. These patents and patent applications include claims directed to compositions of matter, pharmaceutical compositions, methods of treatment, as well as methods for the manufacture of Auryxia.

Our patent rights currently include 3 issued patents that are listed in the Orange Book covering the composition of matter, method of treating hyperphosphatemia, and pharmaceutical compositions of Auryxia. The expected expiration dates for these patents are between 2026 and 2030.

Pursuant to the sublicense with our Japanese partner, Japan Tobacco Inc., or JT, and its subsidiary, Torii Pharmaceutical Co. Ltd., or Torii, we have exclusively sublicensed certain Japanese patent rights to JT and Torii. These sublicensed rights include several Japanese patents and pending patent applications with composition of matter claims, methods of synthesizing claims, and methods of use claims covering Riona, the trade name under which JT and Torii market ferric citrate in Japan. The expected expiration dates for these patents and pending patent applications are between 2026 and 2028. To date, to our knowledge, no contested proceedings or third-party claims have been lodged against any of these Japanese patents.

Pursuant to the sublicense with our European partner, Averoa, we have exclusively sublicensed certain European patent rights to Averoa. These sublicensed rights include several European patents and pending patent applications with composition of matter claims and methods of use claims covering ferric citrate. The expected expiration dates for these patents and pending patent applications are between 2026 and 2042. To date, to our knowledge, no contested proceedings or third-party claims have been lodged against any of these European patents.

We received Paragraph IV certification notice letters regarding abbreviated new drug applications, or ANDAs, submitted to the FDA by third parties requesting approval for generic versions of Auryxia tablets (210 mg ferric iron per tablet). In response we filed certain complaints for patent infringement against six third parties, and have entered into settlement and license agreements with each of the six ANDA filers. Each settlement agreement granted the defendants a license to market a generic version of Auryxia in the U.S. beginning on March 20, 2025 (subject to FDA approval). On January 22, 2026, Teva received tentative approval for its ANDA for Auryxia. Currently, there is only one authorized generic for Auryxia sold by our distributor, but we expect additional generic competition in 2026. If additional generics are approved and enter the market, we expect it will adversely impact our revenue. However, the impact on future Auryxia revenues will depend on many factors, including our ability to maintain contracts with dialysis organizations, the timing and number of additional generics and the pricing of generics and other products on the market that compete with Auryxia.

Other Intellectual Property Rights

We depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

In addition to patent protection, we may utilize orphan drug regulations, pediatric exclusivity or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, such as new chemical entity exclusivity or new formulation exclusivity, to provide market exclusivity for a product candidate. In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this pediatric exclusivity may provide an additional six months which are added to the term of data protection as well as to the term of a relevant patent, to the extent these protections have not already expired. We may also seek to utilize market exclusivities in other territories. We cannot assure you that our products or any product candidates we may acquire or in-license, will obtain such orphan drug designation, pediatric exclusivity, new chemical entity exclusivity or any other market exclusivity in the U.S., EU, or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection.

Know-How

In addition to patents, we rely upon unpatented know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our collaborators, employees and consultants and invention assignment provisions in the confidentiality agreements with our employees. These agreements are designed to protect our proprietary information and, in the case of the invention assignment provisions, to grant us ownership of technologies that are developed by our employees. These agreements may be breached, and we may not have adequate remedies for any breach.

To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

The Hatch-Waxman Act

Orange Book Listing

In seeking approval for a drug through an NDA, sponsors are required to list with the FDA each patent whose claims cover the sponsor's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA

provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA sponsors are usually not required to conduct, or submit results of, nonclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as “generic equivalents” to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA sponsor is required to make certain certifications to the FDA concerning any patents listed for the approved product in the FDA’s Orange Book. Specifically, the sponsor must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA sponsor may also elect to submit a Section viii statement, certifying that its proposed ANDA label does not contain or carve out any language regarding the patented method-of-use, rather than certify to a listed method-of-use patent.

If the sponsor does not challenge the listed patents, the ANDA will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product’s listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA sponsor has provided a Paragraph IV certification to the FDA, the sponsor must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months from receiving the Paragraph IV certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA sponsor. Also, the ANDA will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the FDA cannot accept any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approve an ANDA for a generic drug that includes such changes.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

Patent Term Extension

After NDA approval, owners of relevant drug patents or their agents may apply for up to a five-year patent extension for delays caused by FDA regulatory review. The allowable patent term extension is calculated as half of the drug’s testing phase which is the time between Investigational New Drug application, or IND submission, and NDA submission, and all of the review phase, which is the time between NDA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the sponsor did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years from the date of approval by virtue of the patent term extension.

We have filed patent term extension applications for U.S. Patent Nos. 7,811,595, 8,343,952, 8,323,671, 8,598,210, and 8,940,773 each of which covers Vafseo for delays caused by FDA regulatory review. If granted, we can utilize the patent term extension on one of the Vafseo patents, however, we cannot assure you that we can obtain any extension of the term of these patents. Upon expiration of these patents, competitors who obtain the requisite regulatory approval may potentially offer products with the same composition and/or method of use as our product, so long as the competitors do not infringe any other patents that we may own or license.

For patents that might expire before a determination regarding patent term extension, the patent owner or its agent may request an interim patent term extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely.

In addition, certain jurisdictions outside of the U.S., including Japan, have provisions that provide for patent term extension. In October 2014, following the regulatory approval of Riona in Japan, the Japan Patent office granted the patent term extensions filed by our sublicensee, JT, for Japanese Patents Nos. 4964585 and 4173553. As a result of the extension of patent term, Japanese Patent No. 4173553 expired in November 2022 and Japanese Patent No. 4964585 expired in November 2025 for hyperphosphatemia and will expire in December 2028 for iron deficiency anemia. We also sought and obtained patent term

extension for Japanese Patent Nos. 5113838, 6290781 and 6612479 following regulatory approval of Vafseo in Japan. As a result of the extension of patent term, Japanese Patent No. 5113838 will expire in June 2032, Japanese Patent No. 6290781 will expire in October 2034, and Japanese Patent No. 6612479 will expire in January 2035.

In the future, if and when our product candidates receive approval by the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents covering those drugs, depending upon the length of the clinical trials for each product candidate and other factors. There can be no assurance that any of our pending patent applications will issue or that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents.

Competition

The pharmaceutical and biotechnology industries are highly competitive. The growing prevalence of CKD and the increasing demand for better anemia management solutions continue to drive increased competition in this market. A number of large pharmaceutical companies and small to mid-sized and specialty biotechnology companies have marketed and are developing treatments for rare kidney diseases including indications we are pursuing with our mid-stage rare-kidney disease pipeline.

Our competitors include public and private pharmaceutical and biotechnology companies, academic institutions, and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in a larger concentration of resources among a smaller number of our competitors. These organizations, as well as others in the broader industries, compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations and license technologies competitive to ours.

While major pharmaceutical companies are continuously investing in R&D and have significantly greater capital resources, larger R&D teams and facilities and more experience in drug development, regulation, manufacturing and marketing than we do; we believe our novel HIF-PH inhibitors have the potential to revolutionize the treatment landscape in multiple areas, including anemia due to CKD in dialysis patients. To compete successfully in these industries, we must continue to identify novel and differentiated drugs or treatment methods and complete the development of those drugs as treatments before our competitors.

Vafseo Competition

Drugs that compete with Vafseo include Epogen® (epoetin alfa) and Aranesp® (darbepoetin alfa), both commercialized by Amgen, Procrit® (epoetin alfa) and Eprex® (epoetin alfa), commercialized by Johnson & Johnson in the U.S. and Europe, respectively, and Mircera® (methoxy PEG-epoetin beta), commercialized by CSL Vifor in the U.S. and Roche Holding Ltd. outside of the U.S. and Evrenzo® (roxadustat) in Europe commercialized by Astellas Pharma Inc., or Astellas, Eporatio® (epoetin theta) in Europe commercialized by Teva Pharmaceuticals Ltd., Silapo® (epoetin zeta) in Europe commercialized by Stada Arzneimittel AG, Epoetin Alfa Hexal® (epoetin alfa) in Europe commercialized by Hexal AG, Binocrit® (epoetin alfa-biosimilar) in Europe commercialized by Sandoz, and NeoRecormon® (epoetin beta) in Europe commercialized by Roche.

We and our partners may also face competition from potential new anemia therapies. There are several other HIF-PH inhibitor product candidates in various stages of development for anemia indications in territories outside of the U.S. that may be in direct competition with Vafseo. These candidates are being developed by companies such as JT and Bayer HealthCare AG, or Bayer. In Europe, roxadustat is approved for the treatment of anemia in patients with CKD.

Furthermore, certain companies are developing new therapies for renal-related diseases that potentially could reduce injectable ESA utilization and thus limit the market potential for Vafseo. Other new therapies are in development for treating conditions, including renal anemia, that may impact the market for anemia-targeted treatment.

In Japan, vadadustat is sold under the name Vafseo, which is approved for patients with CKD, including both DD-CKD and NDD-CKD, and competes with roxadustat, daprodustat and enarodustat. Roxadustat is approved for the treatment of DD-CKD patients and NDD-CKD patients. In addition, daprodustat and enarodustat are approved in Japan for the treatment of anemia due to CKD, and molidustat, Bayer HealthCare AG's product, is approved in Japan for the treatment of renal anemia. In China, roxadustat is commercialized for the treatment of anemia due to CKD in DD-CKD patients and for the treatment of anemia due to CKD in NDD-CKD patients.

A biosimilar is a biologic product that is licensed based on demonstrating that it is highly similar to an existing, FDA-approved branded biologic product (i.e., a reference biologic product). The patents for the existing, branded biologic product must expire in a given market before biosimilars may enter that market without the risk of being sued for patent infringement. In addition, an application for a biosimilar product can only be approved by the FDA 12 years after the existing, branded product was licensed under a Biologics License Application, or BLA. The patents for epoetin alfa, an injectable ESA, expired in 2004 in the EU, and expired between 2012 and 2016 in the U.S. Injectable ESAs are biologic products, and introducing biosimilars into the injectable ESA market in the U.S. will constitute additional competition for Vafseo. In the U.S., Pfizer’s biosimilar version of

injectable ESAs, Retacrit® (epoetin alfa-epbx), was approved by the FDA in May 2018 and launched in November 2018 and several biosimilar versions of injectable ESAs are available for sale in the EU.

Furthermore, Vafseo's commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective, safer or offer greater patient convenience than Vafseo.

Auryxia Competition

Hyperphosphatemia Competition

Auryxia is competing in the hyperphosphatemia market in the U.S. with other FDA-approved phosphate binders such as Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate), both marketed by Sanofi, PhosLo® and Phoslyra® (calcium acetate), marketed by Fresenius Medical Care North America, Fosrenol® (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, and Velphoro® (sucroferric oxyhydroxide), marketed by Fresenius Medical Care North America, as well as over-the-counter calcium carbonate products such as TUMS® and metal-based options such as aluminum, lanthanum and magnesium. Most of the phosphate binders listed above are now also available in generic forms. In addition, other agents are in development, including OPKO Health Inc.'s Alpharen™ Tablets (fermagate tablets) and Unicycive's RENAZORB™ (lanthanum dioxycarbonate) or could otherwise enter the market that may impact the market for Auryxia. XPHOZAH® (tenapanor), a phosphate absorption inhibitor that is marketed by Ardelyx, Inc., or Ardelyx, is indicated to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy, which may adversely impact the market for Auryxia.

Iron Deficiency Anemia Competition

Auryxia is competing in the IDA market in the U.S. with over-the-counter oral iron, ferrous sulfate, other prescription oral iron formulations, including ferrous gluconate, ferrous fumerate, and polysaccharide iron complex, and intravenous iron formulations, including Feraheme® (ferumoxytol injection), Venofer® (iron sucrose injection), Ferrlicit® (sodium ferric gluconate complex in sucrose injection), Injectafer® (ferric carboxymaltose injection), and Triferic® (ferric pyrophosphate citrate). In addition, other new therapies for the treatment of IDA may impact the market for Auryxia, such as Shield Therapeutic' plc's Feraccru® (ferric maltol), which is available in Europe for the treatment of IDA, and Accrufer® (ferric maltol), which was launched in the U.S. for the treatment of IDA in July 2021.

In Japan, our Japanese sublicensees, JT and Torii, commercialize Riona (ferric citrate hydrate). In the hyperphosphatemia market, Riona competes with Fosrenol® (lanthanum carbonate hydrate) marketed by Bayer Yakuhin Ltd., generic lanthanum carbonate hydrate products, and Phozevel® (tenapor hydrochloride) marketed by Kyowa Kirin Co., Ltd. In the IDA market in Japan, Riona competes with Ferromia® (sodium ferrous citrate) marketed by Alfresa Pharma Corporation and Fero-Gradumet® (dried ferrous sulfate) marketed by Viatris Inc.

Furthermore, Auryxia's commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective, safer or offer greater patient convenience than Auryxia. Other companies have product candidates in various stages of preclinical or clinical development to treat diseases and complications of the diseases for which we are marketing Auryxia.

We and our licensors entered into settlement agreements with all of the third parties who submitted Paragraph IV certification notice letters regarding ANDAs submitted to the FDA, pursuant to which we granted licenses to market a generic version of Auryxia in the U.S. beginning on March 20, 2025 (subject to FDA approval). On February 5, 2025, we entered into an Authorized Generic Distribution and Supply Agreement with Mylan Pharmaceuticals, Inc., as amended in September 2025, pursuant to which, they are currently selling an authorized generic version of Auryxia.

Praliciguat Competition

FSGS Competition

Currently, there are no FDA-approved drugs indicated for FSGS, although an endothelin receptor blocker is in development and under review by the FDA. Current treatment includes glucocorticoid steroids, calcineurin inhibitors, other immunosuppressives such as rituximab, and antihypertensives such as angiotensin-converting enzymes, such as enalapril, and angiotensin II receptor blockers, such as losartan. In some patients, these treatments may slow kidney failure progression caused by FSGS.

There are a number of treatments to address FSGS in development. Travere® Therapeutics developed FILSPARI® (sparsentan), a dual endothelin and angiotensin II receptor antagonist, which is under review by the FDA with a Prescription Drug User Fee Act target action date of April 13, 2026. There are additional therapies to address FSGS in development including DMX-200 (repagermanium), in Phase 3 development by Dimerix Limited, and other investigational treatments in Phase 3 or Phase 2 development by companies including Apellis Pharmaceuticals, Inc., or Apellis, Boehringer Ingelheim, Sanofi, Vera Therapeutics, or Vera, and Vertex Pharmaceuticals, or Vertex.

Since FSGS is heterogenous in nature, we expect a number of therapies will be needed to fully address the needs of the FSGS patient population. Additionally, a combination of therapies may also provide a beneficial impact for some patients.

AKB-097 Competition

We are developing AKB-097 for potential treatment of IgAN, LN and C3G. There are other complement inhibitors and medications in development or approved for treatment of these rare kidney diseases.

IgAN Competition

FABHALTA® (iptacopan) is FDA-approved and marketed by Novartis for reduction of proteinuria in adults with primary IgAN. FILSPARI® (sparsentan) is FDA-approved, indicated to slow kidney function decline in adults with primary IgAN. Both FABHALTA and FILSPARI labeling includes a Risk Evaluation and Mitigation Strategy, or REMS. TARPEYO® (budesonide), an FDA-approved medicine used to reduce the loss of kidney function in adults with primary IgAN, is marketed in the U.S. by Calliditas Therapeutics AB, or Calliditas (acquired by Asahi Kasei Corporation). VANRAFIA™ (atrasentan), marketed by Novartis, is an endothelin receptor antagonist indicated to reduce proteinuria in adults with primary IgAN. In November 2025, the FDA approved VOYXACT® (sibeprenlimab-szsi) to reduce proteinuria in adults with primary IgAN. VOYXACT is a humanized monoclonal antibody that binds to and blocks A PRoliferation-Inducing Ligand, or APRIL.

In November 2025, Vera was granted FDA Priority Review for their BLA for atacicept for the treatment of IgAN. Atacicept is an investigational recombinant fusion protein that binds to B-cell Activating Factor, BAFF, and APRIL cytokines. Vertex is investigating povetacicept, a dual antagonist of the BAFF and APRIL cytokines, for the treatment of IgAN, and initiated a rolling BLA filing for U.S. accelerated approval.

A number of complement inhibitors are in development for the treatment of IgAN by companies including Alexion Pharmaceuticals, (ULTOMIRIS, ravulizumab, C5 inhibitor, Phase 3), Apellis (EMPAVELI, pegcetacoplan, C3 inhibitor, Phase 2), and Arrowhead Pharmaceuticals, or Arrowhead (ARO-C3, C3 inhibitor, in Phase 1/2)

C3G Competition

There are two FDA-approved complement-inhibitor therapies to reduce proteinuria in C3G patients: FABHALTA® (Novartis, iptacopan, Factor B inhibitor) and EMPAVELI® (Apellis, pegcetacoplan, C3 inhibitor). Both FABHALTA and EMPAVELI labeling includes a REMS. Other complement inhibitors are in development by Kira Pharmaceuticals, with KP104 (dual C5 and Factor H inhibitor) in Phase 2 and Arrowhead with ARO-C3 (C3 inhibitor) in Phase 1/2.

LN Competition

There are three FDA-approved therapies for LN: BENLYSTA (belimumab, GSK), LUPKYNIS® (voclosporin, Aurinia Pharmaceuticals) and GAZYVA (obinutuzumab, Genentech/Biogen). Novartis is developing ianalumab in Phase 3 and complement inhibitor FABHALTA (iptacopan, Factor B inhibitor) in Phase 2.

Government Regulation and Product Approvals

Government authorities in the U.S., at the federal, state and local level, and in other countries and jurisdictions, including the EU, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sales, pricing, reimbursement, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the U.S. and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory requirements, require the expenditure of substantial time and financial resources.

Review and Approval of Drug Products in the U.S.

In the U.S., the FDA approves and regulates drugs under the FDCA and applicable implementing regulations and guidance.

Our product candidates must be approved by the FDA for therapeutic indications before we or our partners are able to market them in the U.S. A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products is referred to as a sponsor. A sponsor seeking approval to market and distribute a new drug product in the U.S. must typically undertake the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA's good laboratory practice, or GLP, regulations and consistent with International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, or ICH, requirements;
- design of a clinical protocol and submission to the FDA of an IND for human clinical testing, which must be reviewed and allowed by the FDA before human clinical trials may begin;

- approval by an independent local or central institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCP, to establish the safety and efficacy of the proposed product candidate for each indication;
- preparation and submission to the FDA of an NDA requesting marketing for one or more proposed indications;
- review of the product candidate by an FDA advisory committee, where appropriate or if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the product candidate, or components thereof, are produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the product candidate's identity, strength, quality and purity;
- satisfactory completion of FDA audits of clinical trial sites and records to assure compliance with GCPs and good practices, or GxPs, the integrity of the clinical data and that adequate controls and oversight are in place regarding manufacturing, clinical trials, pharmacovigilance, safety, data management, vendor oversight, collection and reporting of serious adverse events and other activities;
- payment of user fees pursuant to the Prescription Drug User Fee Act, or PDUFA;
- approval of an NDA for the new drug product authorizing marketing for particular indications in the U.S.; and
- compliance with any post-approval requirements and/or commitments, including the potential requirement to implement a risk evaluation and mitigation strategy, or REMS, and potentially post-market requirement, or PMR, and post-market commitment, or PMC, studies.

Preclinical Tests

Before a sponsor begins testing a product candidate with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as other studies to evaluate, among other things, the toxicity of the product candidate. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements, including GLP regulations and standards and the U.S. Department of Agriculture's Animal Welfare Act, if applicable. With the passage of the FDA's Modernization Act 2.0 in December 2022, Congress eliminated provisions in the FDCA that required animal testing in support of an NDA. In April 2025, the FDA released a roadmap to replace animal testing in preclinical safety studies with scientifically validated new approach methodologies, such as organ-on-a-chip systems, computational modeling, and advanced in vitro assays. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND and are generally referred to as IND-enabling studies. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

The IND and IRB Processes

Clinical trials involve the administration of the investigational product to human patients under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research patients provide their voluntary informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. In support of a request for an IND, sponsors must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

An IND is an exemption from the FDCA that allows an unapproved drug to be shipped through interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational drug to humans. Such authorization must be obtained prior to interstate shipment and administration of any new drug that is not the subject of an approved NDA. In addition to reviewing an IND to assure the safety and rights of patients, the FDA also focuses on the quality of the investigation and whether it will be adequate to permit an evaluation of the drug's safety and efficacy. The results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND.

The FDA requires a 30-day waiting period after the submission of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research patients will be exposed to unreasonable health risks. At any time during this 30-day period, or thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold or require that the

sponsor amend the clinical protocol to include additional safety measurements. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical trial or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a partial clinical hold might state that a specific protocol or part of a protocol may not proceed, while other parts of a protocol or other protocols may do so. No more than 30 days after the imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor with a written explanation of the basis for the hold. Following the issuance of a clinical hold or partial clinical hold, a clinical trial may only resume once the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed or recommence. Occasionally, clinical holds are imposed due to manufacturing issues that may present safety issues for the clinical trial subjects.

In addition to the foregoing requirements related to the IND submission and ongoing review, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct a continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to study patients. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by a Data Monitoring Committee, which is an independent group of qualified experts organized by the trial sponsor. This group provides authorization for whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the trial. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made by a sponsor based on evolving business objectives and/or competitive climate.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived by the FDA. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

Reporting Clinical Trial Results

Under the Public Health Service Act, or PHSA, sponsors of certain clinical trials of certain FDA-regulated products, including prescription drugs and biologics, are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the U.S. National Institutes of Health, or NIH. In particular, information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Although sponsors are also obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial.

The PHSA grants the Secretary of the U.S. Department of Health and Human Services, or HHS, the authority to issue a notice of noncompliance to a responsible party for failure to submit clinical trial information as required. The responsible party, however, is allowed 30 days to correct the noncompliance and submit the required information. As of December 31, 2025, the FDA has issued eight notices of non-compliance, thereby signaling the government's willingness to begin enforcing these requirements against non-compliant clinical trial sponsors. While these notices of non-compliance did not result in civil monetary penalties, the failure to submit clinical trial information to clinical trials.gov is a prohibited act under the FDCA with violations subject to potential civil monetary penalties of up to $10,000 for each day the violation continues. Violations may also result in injunctions and/or criminal prosecution or disqualification from federal grants.

Expanded Access to an Investigational Drug for Treatment Use

Expanded access, sometimes called "compassionate use," is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. FDA regulations allow access to

investigational drugs under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the drug under a treatment protocol or Treatment IND Application.

There is no obligation for a sponsor to make its investigational products available for expanded access; however, as required by amendments to the FDCA included in the 21st Century Cures Act passed in 2016, if a sponsor has a policy regarding how it responds to expanded access requests with respect to product candidates in development to treat serious diseases or conditions, it must make that policy publicly available. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 trial for a covered investigational product; or 15 days after the investigational product receives designation from the FDA as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy. In October 2025, the FDA issued final guidance further clarifying the statutory and regulatory requirements governing expanded access.

On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its product candidates available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Human Clinical Trials in Support of an NDA

Clinical trials involve the administration of the investigational product to human patients under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research patients provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written study protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

Human clinical trials are typically conducted in four sequential phases, which may overlap or be combined:

- **Phase 1.** The product candidate is initially introduced into a small number of healthy human patients or, in certain indications such as cancer, patients with the target disease or condition (e.g., cancer) and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early indication of its effectiveness and to determine optimal dosage.
- **Phase 2.** The product candidate is administered to a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product candidate for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- **Phase 3.** These clinical trials are commonly referred to as “pivotal” studies, which denote a study that presents the data that the FDA or other relevant regulatory agency will use to determine whether or not to approve a product candidate. The product candidate is administered to an expanded patient population, generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product candidate for approval, identify adverse effects, establish the overall risk-benefit profile of the product candidate and to provide adequate information for the labeling of the product candidate.
- **Phase 4.** Post-approval studies may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. Moreover, as noted above, a pivotal trial is a clinical trial that is believed to satisfy FDA requirements for the evaluation of a product candidate’s safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal trials, to support regulatory approval. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need. A company’s designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA.

In December 2022, with the passage of the Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan, or DAP, for each phase 3 clinical trial or any other “pivotal study” of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor’s goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In June 2024, as mandated

by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

On January 27, 2025, in response to an Executive Order issued by President Trump on January 21, 2025, relating to Diversity, Equity and Inclusion programs, the FDA removed the draft DAP guidance from its website. That action, along with similar actions by the Trump Administration to remove many other healthcare webpages, is currently the subject of ongoing litigation. On July 3, 2025, the U.S. District Court for the District of Columbia ruled that the Trump Administration's actions to remove these webpages, including the draft DAP guidance, is unlawful under the Administrative Procedure Act. The court ordered the restoration of many of these webpages. In late July 2025, the FDA restored the draft DAP guidance to its website with a statement that "information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law." Accordingly, in light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider diversity action plans in connection with its review of NDAs.

In September 2025, the FDA issued final guidance with updated recommendations for GCPs aimed at modernizing the design and conduct of clinical trials. The updates are intended to help pave the way for more efficient clinical trials to facilitate the development of medical products. The final guidance is adopted from the ICH's updated E6(R3) draft guideline that was developed to enable the incorporation of rapidly developing technological and methodological innovations into the clinical trial enterprise.

In October 2025, the FDA issued final guidance that focuses on patient-focused drug development. The guidance outlines how stakeholders, such as patients, caregivers, researchers and medical product developers, can submit patient experience data in support of the development and approval of drug products. To that end, the guidance provides an overview of clinical outcome assessments, or COAs, in clinical trials, and the role that COAs may play in evaluating the clinical benefit of a medical product.

Interactions with the FDA During the Clinical Development Program

Following the clearance of an IND and the commencement of clinical trials, the sponsor will continue to have interactions with the FDA. Progress reports detailing the results of clinical trials must be submitted annually within 60 days of the anniversary dates that the IND went into effect and more frequently if serious adverse events occur. These reports must include a development safety update report. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the product; and any clinically important increase in the occurrence of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, or at all. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted. In December 2025, the FDA released final guidance outlining its processes and practices applicable to bioresearch monitoring inspections.

In addition, a sponsor will continue to have interactions with the FDA and the sponsor may meet with the FDA at certain points in the clinical development program. Specifically, sponsors may meet with the FDA prior to the submission of an IND, or a pre-IND meeting, at the end of Phase 2 clinical trials and before an NDA is submitted, or a pre-NDA meeting. Meetings at other times may also be requested. These meetings provide an opportunity for the sponsor to share information about the data gathered to date with the FDA and for the FDA to provide advice on the next phase of development.

There are five types of meetings that occur between sponsors and the FDA. Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Type B meetings include pre-IND and pre-NDA meetings as well as end of phase meetings such as end-of-phase 2 meetings. A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product, including for example meetings to facilitate early consultations on the use of a biomarker as a new surrogate endpoint that has never been previously used as the primary basis for product approval in the proposed context of use. A Type D meeting is focused on a narrow set of issues (typically limited to no more than two focused topics) and should not require input from more than three disciplines or divisions. Finally, INTERACT meetings are intended for novel products and development programs that present unique challenges in the early development of an investigational product.

Such meetings may be conducted in person, via teleconference/videoconference, or written response only with minutes reflecting the questions that the sponsor posed to the FDA and the agency's responses. The FDA has indicated that its responses, as conveyed in meeting minutes and advice letters, only constitute mere recommendations and/or advice made to a sponsor and, as such, sponsors are not bound by such recommendations and/or advice. Nonetheless, from a practical perspective, a sponsor's failure to follow the FDA's recommendations for design of a clinical program may put the program at significant risk of failure. In September 2023, the FDA issued draft guidance outlining the terms of such meetings in more detail.

Pediatric Studies

Under the Pediatric Research Equity Act, or PREA, applications and certain types of supplements to applications must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The sponsor must submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-phase 2 meeting or as may be agreed between the sponsor and the FDA. Those plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The sponsor and the FDA must reach agreement on a final plan. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical trials, early phase clinical trials, and/or other clinical development programs.

For investigational products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of a sponsor, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, the FDA will meet early in the development process to discuss pediatric study plans with sponsors, and the FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than ninety days after the FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. Pursuant to the Food and Drug Administration Safety and Innovation Act of 2012, or FDASIA, the FDA must send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. FDASIA further requires the FDA to publicly post the PREA Non-Compliance letter and sponsor's response. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although FDA has recently taken steps to limit what it considers abuse of this statutory exemption in PREA by announcing that it does not intend to grant any additional orphan drug designations for rare pediatric subpopulations of what is otherwise a common disease. The FDA also maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population. In May 2023, the FDA issued new draft guidance that further describes the pediatric study requirements under PREA.

Acceptance and Review of an NDA

Assuming successful completion of required clinical testing and other requirements, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things are submitted to the FDA as part of an NDA requesting approval to market the product candidate for one or more indications. The fee required for the submission and review of an application under the PDUFA is substantial (for example, for fiscal year 2026 this application fee is approximately $4.7 million), and the sponsor of an approved application is also subject to an annual program fee, currently set at $442,213 per eligible prescription product. These fees are typically adjusted annually, and exemptions and waivers may be available under certain circumstances, such as where a waiver is necessary to protect the public health, where the fee would present a significant barrier to innovation, or where the sponsor is a small business submitting its first human therapeutic application for review.

The FDA conducts a preliminary review of all applications within 60 days of receipt and must inform the sponsor at that time or before whether an application is sufficiently complete to permit substantive review. This is known as the filing decision. In the event that FDA determines that an application does not satisfy this standard, it will issue a Refuse to File, or RTF, determination to the sponsor. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. In October 2025, the FDA issued internal guidance clarifying that "materially incomplete or inadequately organized" applications that would not permit timely, efficient and complete review will be the subject of an RTF. The internal guidance also provides that the agency will issue an RTF for an application that relies on a single adequate and well-controlled investigation to support approval if prior communications with the FDA determined the need for more than one clinical study and any justification for a single investigation is inadequate.

The FDA has agreed to certain performance goals in the review process of NDAs. Most such applications are meant to be reviewed within ten months from the date of filing, and most applications for "priority review" products are meant to be reviewed within six months of filing. A product that has been designated as a breakthrough therapy may also be eligible for

review within six months if supported by clinical data at the time of submission of the NDA. The review process may be extended by the FDA for three additional months to consider new information or clarification provided by the sponsor to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA submission, including drug component manufacturing such as active pharmaceutical ingredients, finished drug product manufacturing, control testing laboratories, as well as packaging and labeling facilities. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a drug or biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the U.S. prior to being imported or offered for import into the U.S.

Moreover, the FDA will review a sponsor's financial relationship with the principal investigators who conducted the clinical trials in support of the NDA. That is because, under certain circumstances, principal investigators at a clinical trial site may also serve as scientific advisors or consultants to a sponsor and receive compensation in connection with such services. Depending on the level of that compensation and any other financial interest a principal investigator may have in a sponsor, the sponsor may be required to report these relationships to the FDA. The FDA will then evaluate that financial relationship and determine whether it creates a conflict of interest or otherwise affects the interpretation of the trial or the integrity of the data generated at the principal investigator's clinical trial site. If so, the FDA may exclude data from the clinical trial site in connection with its determination of safety and efficacy of the investigational product.

Additionally, before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. The sponsor of the NDA may also have their records, processes, procedures, training, and other aspects reviewed during an inspection. The FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain drug applications, including applications for drugs in a shortage or drugs for which approval is dependent on remediation of conditions identified in the inspection report.

In addition, as a condition of approval, the FDA may require a sponsor to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks.

Finally, the FDA may refer an application for a novel drug to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Expedited Programs

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. None of these expedited programs changes the standards for approval but they may help expedite the development or approval process of product candidates.

Specifically, the FDA may designate a product for fast track review if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. The fast track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, in 2012, Congress enacted the Food and Drug Administration Safety and Improvement Act. This law established a new regulatory scheme allowing for expedited review of products designated as "breakthrough therapies." A product may be designated as a breakthrough therapy if it is intended, either alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed drug represents a significant improvement when compared with other available therapies. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's review clock goal for taking action on a marketing application from ten months to six months.

Further, on June 17, 2025, the FDA announced the creation of a new voucher program to expedite the development and approval of new drug products. Vouchers issued under the new program, which is known as the Commissioner's National Priority Voucher, or CNPV, may reportedly be redeemed by sponsors to shorten the review time of an NDA from approximately ten to twelve months to one to two months. The FDA has indicated that the new CNPV process will convene experts from the FDA's offices for a team-based review rather than using the standard review system of a drug application being sent to numerous FDA offices. Clinical information will be reviewed by a multidisciplinary team of physicians and scientists who will pre-review the submitted information and convene for a one-day meeting. Vouchers under this program will reportedly be given to companies aligned with U.S. national priorities. As with the FDA's other programs for expediting review and approval of new drug products, there is no guarantee it would result in approval of the marketing applications or that such approval, if granted, would be on an expedited basis.

In addition, in September 2025, the FDA introduced a framework intended to streamline the approval of new therapies for ultrarare diseases. The Rare Disease Evidence Principles is intended to allow sponsors to rely on a single-arm trial in support of approval of drugs and biologics that treat rare diseases with very small patient populations and where the disease is linked to a known genetic defect and characterized by progressive functional deterioration leading to disability or death in a short period of time. The targeted diseases should also lack adequate alternative therapies.

Accelerated Approval Pathway

Drug or biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials.

In December 2022, Congress modified certain provisions governing accelerated approval of drug products. Specifically, the new legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded and to submit progress reports on its post-approval studies to the FDA every six months until the study is completed. Moreover, FDORA established expedited procedures authorizing the FDA to withdraw an accelerated approval if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval trial of the product with due diligence, including with respect to "conditions specified by the Secretary." The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the Commissioner or the Commissioner's designee and a written appeal, among other things.

In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The agency indicated that although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. These guidances describe the FDA's latest thinking on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While these guidances are currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

The FDA's Decision on an NDA

The FDA reviews an application to determine, among other things, whether the product is safe and whether it is effective for its intended use(s), with the latter determination being made on the basis of substantial evidence. The term "substantial evidence" is defined under the FDCA as "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the product involved, on the basis of which it could fairly and responsibly be concluded by such experts that the product will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof."

The FDA has interpreted this evidentiary standard to require at least two adequate and well-controlled clinical investigations to establish effectiveness of a new product. Under certain circumstances, however, FDA has indicated that a single trial with certain characteristics and additional information may satisfy this standard. This approach was subsequently endorsed by

Congress in 1998 with legislation providing, in pertinent part, that "If [FDA] determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, FDA may consider such data and evidence to constitute substantial evidence." This modification to the law recognized the potential for FDA to find that one adequate and well controlled clinical investigation with confirmatory evidence, including supportive data outside of a controlled trial, is sufficient to establish effectiveness. In December 2019, FDA issued draft guidance further explaining the studies that are needed to establish substantial evidence of effectiveness. Although the FDA has not yet finalized that guidance, it did issue additional draft guidance in September 2023 that outlines considerations for relying on confirmatory evidence in lieu of a second clinical study. The FDA has not yet finalized these guidances but, in December 2025, the agency signaled that it is considering only requiring one clinical study for approval of most drug products.

After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA will issue either a CRL or an approval letter. To reach this determination, the FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the extensive body of evidence about the product's safety and efficacy in the NDA or BLA. This assessment is also informed by other factors, including: the severity of the underlying condition and how well patients' medical needs are addressed by currently available therapies; uncertainty about how the premarket clinical trial evidence will extrapolate to real-world use of the product in the post-market setting; and whether risk management tools are necessary to manage specific risks. In connection with this assessment, the FDA review team will assemble all individual reviews and other documents into an "action package," which becomes the record for FDA review. The review team then issues a recommendation, and a senior FDA official makes a decision.

A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The CRL may require additional clinical or other data, additional pivotal Phase 3 clinical trial(s) and/or other significant and time consuming requirements related to clinical trials, preclinical studies or manufacturing. If a CRL is issued, the sponsor will have one year to respond to the deficiencies identified by the FDA, at which time the FDA can deem the application withdrawn or, in its discretion, grant the sponsor an additional six month extension to respond. The FDA has committed to reviewing resubmissions in response to an issued CRL in either two or six months depending on the type of information included. Even with the submission of this additional information, however, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. The FDA has taken the position that a CRL is not final agency action making the determination subject to judicial review. Rather, for those seeking to challenge FDA's CRL decision, the agency has indicated that sponsors may request a formal hearing on the CRL or they may file a request for reconsideration or a request for a formal dispute resolution.

An approval letter, on the other hand, authorizes commercial marketing of the product with specific prescribing information for specific indications. That is, the approval will be limited to the conditions of use (e.g., patient population, indication) described in the FDA-approved labeling. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Under the Ensuring Innovation Act, which was signed into law in April 2021, the FDA must publish action packages summarizing its decisions to approve new drugs and biologics within 30 days of approval of such products. While CRLs were previously treated by the FDA as confidential and were only disclosed in action packages for approved products, the agency announced in September 2025 that it will now release CRLs promptly after they are issued to sponsors. Since that announcement, the FDA has posted a number of CRLs on its website.

Post-Approval Requirements and Commitments

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, conditions of NDA approval may include sponsor agreement to PMR or PMC studies, which are designed to further assess drug safety and effectiveness and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. These may include additional studies, registries, data collection, analyses, and/or information.

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

In May 2025, the FDA disclosed plans to expand its use of unannounced inspections of foreign manufacturing facilities that produce drugs and biologics distributed in the U.S. Subsequently, in August 2025, the FDA introduced a “PreCheck” program with the intention of supporting companies as they build new facilities in the U.S. The PreCheck program provides manufacturers with more frequent FDA communication at critical development stages, including facility design, construction, and pre-production. These FDA initiatives flow from an Executive Order issued by President Trump on May 5, 2025, calling for actions to reduce regulatory barriers to pharmaceutical manufacturing in the U.S.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, or complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates the marketing, labeling, advertising and promotion of prescription drug products placed on the market. This regulation includes, among other things, standards and regulations for direct-to-consumer advertising, communications regarding unapproved uses, industry-sponsored scientific and educational activities, and promotional activities involving the Internet and social media. Promotional claims about a product candidate’s safety or effectiveness are prohibited before the product candidate is approved. After approval, a drug product generally may not be promoted for uses that are not approved by the FDA or in a manner that is inconsistent with the product’s prescribing information. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product.

On September 9, 2025, the President issued a Memorandum directing HHS to “ensure transparency and accuracy in direct-to-consumer prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements.” To that end, the FDA announced that it is initiating a rulemaking process “to eliminate the ‘adequate provision’ loophole that allows pharmaceutical advertisements to hide safety information by placing it in another format or location.” In this context, the FDA declared that it will no longer tolerate what it characterized as “deceptive practices” in prescription drug advertising and that the agency would “aggressively deploy” its available enforcement tools, with “heightened scrutiny” of fair balance and disclosures in social media promotions. The FDA also issued a generic “notice letter” directing companies to “remove any noncompliant advertising and bring all promotional communications into compliance.”

In the U.S., healthcare professionals are generally permitted to prescribe drugs for such uses not described in the drug’s labeling, known as off-label uses, because the FDA does not regulate the practice of medicine. However, FDA regulations impose rigorous restrictions on manufacturers’ communications, prohibiting the promotion of off-label uses. It may be permissible, under very specific conditions, for a manufacturer to engage in non-promotional, truthful and non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. In addition,

companies may also promote information that it consistent with the prescribing information and have the ability to proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug under some relatively recent guidance from the FDA. Moreover, with the passage of the Pre-Approval Information Exchange Act, or PIE Act, in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. Previously, such communications were permitted under FDA guidance but the new legislation explicitly provides protection to sponsors who convey certain information about products in development to payors, including unapproved uses of approved products.

In addition, in January 2025, the FDA published final guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses of approved products to healthcare providers. This final guidance calls for such communications to be non-promotional in nature, truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In addition, the distribution of prescription pharmaceutical products is subject to a variety of federal and state laws, the most recent of which is still in the process of being phased into the U.S. supply chain and regulatory framework. The Prescription Drug Marketing Act, or PDMA, was the first federal law to set minimum standards for the registration and regulation of drug distributors by the states and to regulate the distribution of drug samples. Today, both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Congress more recently enacted the Drug Supply Chain Security Act, or DSCSA, which made significant amendments to the FDCA, including by replacing certain provisions from the PDMA pertaining to wholesale distribution of prescription drugs with a more comprehensive statutory scheme. The DSCSA now requires uniform national standards for wholesale distribution and, for the first time, for third-party logistics providers; it also provides for preemption of certain state laws in the areas of licensure and prescription drug traceability. So as not to disrupt supply chains, the FDA has granted certain exemptions from enhanced drug distribution security requirements for eligible trading partners for particular periods of time. For wholesale drug distributors, the final DSCSA deadline was August 27, 2025, marking the date for mandatory transition to a fully electronic, interoperable system for tracking prescription drugs at the package level throughout the United States.

Section 505(b)(2) NDAs

NDAs for most new drug products are based on two full clinical trials which must contain substantial evidence of the safety and efficacy of the proposed new product for the proposed use. These applications are submitted under Section 505(b)(1) of the FDCA. The FDA is, however, authorized to approve an alternative type of NDA under Section 505(b)(2) of the FDCA. This type of application allows the sponsor to rely, in part, on the FDA's previous findings of safety and efficacy for a similar product, or published literature. Specifically, Section 505(b)(2) applies to NDAs for a drug for which the investigations made to show whether or not the drug is safe for use and effective in use and relied upon by the sponsor for approval of the application "were not conducted by or for the sponsor and for which the sponsor has not obtained a right of reference or use from the person by or for whom the investigations were conducted."

Section 505(b)(2) authorizes the FDA to approve an NDA based on safety and effectiveness data that were not developed by the sponsor. NDAs filed under Section 505(b)(2) may provide an alternate and potentially more expeditious pathway to FDA approval for new or improved formulations or new uses of previously approved products. If the 505(b)(2) sponsor can establish that reliance on the FDA's previous approval is scientifically appropriate, the sponsor may eliminate the need to conduct certain preclinical studies or clinical trials of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) sponsor. Products approved under Section 505(b)(2) are often referred to as follow-on products.

Abbreviated New Drug Applications for Generic Drugs

In 1984, with the passage of the Hatch-Waxman Amendments to the FDCA, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, a sponsor

must submit an ANDA to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

Under the Hatch-Waxman Act, the FDA may not approve an ANDA or 505(b)(2) application until any applicable period of regulatory exclusivity for the RLD has expired. The FDCA provides a period of five years of regulatory data exclusivity for a new drug containing a new chemical entity, or NCE. For the purposes of this provision, the FDA has consistently taken the position that an NCE is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. This interpretation was confirmed with enactment of the Ensuring Innovation Act in April 2021. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, a generic or follow-on drug application may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the sponsor may submit its application four years following the original product approval.

The FDCA also provides for a period of three years of regulatory exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the sponsor and are essential to the approval of the application. This three-year exclusivity period often protects changes to a previously approved drug product, such as a new dosage form, route of administration, combination or indication. Three-year exclusivity would be available for a drug product that contains a previously approved active moiety, provided the statutory requirement for a new clinical investigation is satisfied. Unlike five-year NCE exclusivity, an award of three-year exclusivity does not block the FDA from accepting ANDAs or 505(b)(2) applications seeking approval for generic versions of the drug as of the date of approval of the original drug product. The FDA typically makes decisions about awards of data exclusivity shortly before a product is approved.

The FDA must establish a priority review track for certain generic drugs, requiring the FDA to review a drug application within eight months for a drug that has three or fewer approved drugs listed in the Orange Book and is no longer protected by any patent or regulatory exclusivities, or is on the FDA's drug shortage list. The new legislation also authorizes FDA to expedite review of ''competitor generic therapies'' or drugs with inadequate generic competition, including holding meetings with or providing advice to the drug sponsor prior to submission of the application.

In October 2025, the FDA introduced a new program to expedite review of ANDAs and approval of generic drug products. Under this new initiative, a sponsor of an ANDA would qualify for faster review and approval if it conducts bioequivalence studies in the U.S., exclusively sources the active pharmaceutical ingredient in the U.S. and manufactures the finished drug product within the country, as well.

Hatch-Waxman Patent Certification and the 30-Month Stay

As part of the submission of an NDA or certain supplemental applications, NDA sponsors are required to list with the FDA each patent with claims that cover the sponsor's product or an approved method of using the product. Upon approval of a new drug, each of the patents listed in the application for the drug is then published in the Orange Book. The FDA's regulations governing patent listings were largely codified into law with enactment of the Orange Book Modernization Act in January 2021. When an ANDA sponsor files its application with the FDA, the sponsor is required to certify to the FDA concerning any patents listed for the reference product in the Orange Book. Specifically, the ANDA sponsor must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. Moreover, to the extent that the Section 505(b)(2) NDA sponsor is relying on studies conducted for an already approved product, the sponsor also is required to certify to the FDA concerning any patents listed for the NDA-approved product in the Orange Book to the same extent that an ANDA sponsor would.

If the generic drug or follow-on drug sponsor does not challenge the innovator's listed patents, FDA will not approve the ANDA or 505(b)(2) application until all the listed patents claiming the referenced product have expired. A certification that the new generic product will not infringe the already approved product's listed patents or that such patents are invalid or unenforceable is called a Paragraph IV certification. If the ANDA sponsor has provided a Paragraph IV certification to the FDA, the sponsor must also send notice of the Paragraph IV certification to the NDA owner and patent holders once the ANDA has been accepted for filing by the FDA. The NDA owner and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the

earliest of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA application.

Pediatric Studies and Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the U.S. and, if granted, for drug products, provides for the attachment of an additional six months of marketing protection to the term of any existing patent or regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product is effective in the pediatric population studied, rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity or patent protection cover the product are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application. With regard to patents, the six-month pediatric exclusivity period will not attach to any patents for which an ANDA or 505(b)(2) sponsor submitted a Paragraph IV patent certification, unless the NDA sponsor or patent owner first obtains a court determination that the patent is valid and infringed by the proposed product.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Act, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review. The restoration period granted is typically one-half the time between the effective date of an IND and the submission date of an NDA, plus the time between the submission date of an NDA and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved drug product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple drugs for which approval is sought can only be extended in connection with one of the approvals. The U.S. Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Federal and State Data Privacy Laws

There are multiple privacy and data security laws that may impact our business activities, in the U.S. and in other countries where we conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our regulatory risks in the future. In the health care industry generally, under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, the HHS has issued regulations to protect the privacy and security of protected health information, or PHI, used or disclosed by covered entities including certain healthcare providers, health plans and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. While we are not a covered entity, as a business associate, we could be subject to penalties, including criminal penalties, and contractual damages if we knowingly obtain or further disclose PHI from a covered entity, such as a health care provider or clinical research site, and therefore we must ensure the proper authorizations are in place before we, or our vendors or business partners, obtain access to any PHI. Our clinical trials are regulated by the Common Rule, which also includes specific privacy-related provisions. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that may be applicable to our business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. State attorneys general also have authority to enforce state privacy and security laws. New laws and regulations governing privacy and security may be adopted in the future as well.

At the state level, California has enacted legislation that has been dubbed the first "GDPR-like" law in the U.S. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA went into effect on January 1, 2020 and requires covered companies to provide new disclosures to California consumers, provide such consumers rights as it relates to their personal information and new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act, or the CPRA, which went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the

California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA and CCPA may apply to some of our business activities.

In addition to California, at least eighteen other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering additional laws that could go into effect in 2026 and beyond. Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, the State of Washington passed the My Health My Data Act in 2023 which specifically regulated health information that is not otherwise regulated by the HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the privacy or data security laws or regulations described above that are applicable to us, or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a consent decree or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any product candidates we may develop, once approved, are sold in a foreign country, we may be subject to similar foreign laws.

Review and Approval of Drug Products Outside the U.S.

In order to market any product outside of the U.S., a sponsor must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of drug products. Whether or not it obtains FDA approval for a product, the company would need to obtain the necessary approvals by the comparable regulatory authorities of foreign countries or economic areas, such as the 27-member EU, before it can commence clinical trials or marketing of the product in those countries or jurisdictions. The approval process ultimately varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

The EU/European Economic Area, or the EEA, applies harmonized regulatory rules for medicinal products, for the approval process and requirements governing the conduct of clinical trials, and for the regulatory approval of medicinal products. However, pricing and reimbursement for medicinal products varies greatly between countries and jurisdictions and can involve additional testing for health technology assessments.

Non-clinical Studies

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmaco-toxicological) studies must be conducted in compliance with the principles of GLP as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products such as, for example, radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set

of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical Trial Approval in the EU

On January 31, 2022, the Clinical Trials Regulation (EU) No 536/2014, or CTR, became effective in the EU and replaced the prior Clinical Trials Directive 2001/20/EC. The CTR aims to simplify and streamline the authorization, conduct and transparency of clinical trials in the EU. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one Member State of the EU, or an EU Member State, will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the European Medicines Agency, or EMA, and available to clinical trial sponsors, competent authorities of the EU Member States and the public.

The main characteristics of the regulation include: a streamlined application procedure via a single entry point, the "EU Portal and Database"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the appointed reporting EU Member State, whose assessment report is submitted for review by the sponsor and all other competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted, or concerned member states. Part II is assessed separately by each concerned member state. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned member state. However, overall related timelines will be defined by the Clinical Trials Regulation.

The CTR did not change the preexisting requirement that a sponsor must obtain prior approval from the competent national authority of the EU Member State in which the clinical trial is to be conducted. If the clinical trial is conducted in different EU Member States, the competent authorities in each of these EU Member States must provide their approval for the conduct of the clinical trial. Furthermore, the sponsor may only start a clinical trial at a specific clinical site after the applicable ethics committee has issued a favorable opinion. The CTR will apply to any future clinical trials that we conduct in the EU.

Parties conducting certain clinical trials must, as in the U.S., post clinical trial information in the EU at the EudraCT website: https://eudract.ema.europa.eu.

PRIME Designation in the European Union

In March 2016, the EMA launched an initiative, the PRIority MEdicines, or PRIME, scheme, to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIME scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Products from small- and medium-sized enterprises, or SMEs, may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application, or MAA, assessment once a dossier has been submitted. Importantly, a dedicated agency contact and rapporteur from the Committee for Human Medicinal Products, or CHMP, or Committee for Advanced Therapies are appointed early in the PRIME scheme, facilitating increased understanding of the product at the EMA's committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies.

Pediatric Studies

Prior to obtaining a marketing authorization in the EU, sponsors have to demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan, or PIP, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, a class waiver or a deferral for one or more of the measures included in the PIP. The respective requirements for all marketing authorization procedures are set forth in Regulation (EC) No 1901/2006, which is referred to as the Pediatric Regulation. This requirement also applies when a company wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized. The Pediatric Committee of the EMA, or PDCO, may grant deferrals for some medicines, allowing a company to delay development of the medicine in children until there is enough information to demonstrate its effectiveness and safety in adults. The PDCO may also grant waivers when development of a medicine in children is not needed or is not appropriate because (a) the product is likely to be ineffective or unsafe in part or all of the pediatric population; (b) the disease or condition occurs only in adult population; or (c) the product does not represent a significant therapeutic benefit over existing treatments for pediatric population. Before a marketing authorization application can be filed, or an existing marketing authorization can be amended, the EMA determines that companies actually comply with the agreed studies and measures listed in each relevant PIP.

Marketing Authorization

To obtain marketing approval of a product under EU regulatory systems, a sponsor must submit an MAA either under a centralized or decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization by the EC that is valid for all EU member states. The centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

Under the centralized procedure, the CHMP established at the EMA is responsible for conducting the initial assessment of a product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization. Under the centralized procedure in the EU, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional information or written or oral explanation is to be provided by the sponsor in response to questions of the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

The decentralized procedure is available to sponsors who wish to market a product in various EU Member States where such product has not received marketing approval in any EU Member State before. The decentralized procedure provides for approval by one or more other, or concerned, member states of an assessment of an application performed by one member state designated by the sponsor, known as the reference member state. Under this procedure, a sponsor submits an application based on identical dossiers and related materials, including a draft summary of product characteristics, and draft labeling and package leaflet, to the reference member state and concerned member states. The reference member state prepares a draft assessment report and drafts of the related materials within 210 days after receipt of a valid application. Within 90 days of receiving the reference member state's assessment report and related materials, each concerned member state must decide whether to approve the assessment report and related materials.

If a member state cannot approve the assessment report and related materials on the grounds of potential serious risk to public health, the disputed points are subject to a dispute resolution mechanism and may eventually be referred to the EC, whose decision is binding on all member states.

A marketing authorization may be granted only to a sponsor established in the EU. Once the marketing authorization is obtained in all member states of the EU and study results are included in the product information, even when negative, the product is eligible for six months' supplementary protection certificate extension. For orphan-designated medicinal products, the 10-year period of market exclusivity is extended to 12 years.

Periods of Authorization and Renewals in the EU

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk-benefit balance by the EMA or by the competent authority of the relevant EU Member State. To that end, the marketing authorization holder must provide the EMA or the relevant competent authority of the EU Member State with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the EC or the relevant competent authority of the EU Member State decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any marketing authorization that is not followed by the marketing of the medicinal product on the EU market (in the case of the centralized procedure) or on the market of the EU Member State which delivered the marketing authorization within three years after authorization ceases to be valid.

Post-Approval Requirements

As in the U.S., both marketing authorization, or MA, holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the EC, and the competent authorities of EU Member States. The MA holder must, for example, comply with EU pharmacovigilance legislation and its related regulations and guidelines which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. In particular, the MA holder must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for the establishment and maintenance of that system, and oversees the safety profiles of medicinal products and any emerging safety concerns. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory

authorities may also impose specific obligations as a condition of the MA. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The manufacturing process for medicinal products in the EU is also highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable EU laws, including compliance with EU GMP standards when manufacturing medicinal products and active pharmaceutical ingredient.

In the EU, the advertising and promotion of approved products are subject to laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising, and unfair commercial practices. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion, which is prohibited in the EU. Direct-to-consumer advertising of prescription medicines is also prohibited in the EU. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each EU Member State and can differ from one country to another.

The aforementioned EU rules are generally applicable in the EEA.

Failure to comply with EU and EU Member State laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Regulatory Data Exclusivity in the EU

In the EU, innovative medicinal products authorized in the EU on the basis of a full marketing authorization application (as opposed to an application for marketing authorization that relies on data available in the marketing authorization dossier for another, previously approved, medicinal product) are entitled to eight years of data exclusivity. During this period, sponsors for authorization of generics of these innovative products cannot rely on data contained in the marketing authorization dossier submitted for the innovative medicinal product. Innovative medicinal products are also entitled to a total of ten years' market exclusivity. During this ten-year period no generic of this medicinal product can be placed on the EU market. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a NCE so that the innovator gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on an MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

In this context, it should be noted that the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the EC in November 2020. The EC's proposal for revision of several legislative instruments related to medicinal products was published in April 2023 and includes, among other things, provisions that would potentially reduce the duration of regulatory data protection. The European Parliament requested several amendments in April 2024. On December 11, 2025, the European Parliament and Council reached a provisional political agreement on the legislation which is expected to be adopted by mid-2026. Key changes include updating regulatory data exclusivity to a new system with 8 years data exclusivity and reduced market exclusivity period to 1 year which can be extended if specific conditions are fulfilled, adding launch/supply obligations, incentivizing antibiotic innovation with transferable vouchers, and streamlining approval procedures in the EU. If the legislation is finalized in line with the provisional political agreement it will have a profound impact on the pharmaceutical industry.

Pediatric Exclusivity

If a sponsor obtains a marketing authorization in all EU Member States, or a marketing authorization granted in the centralized procedure by the EC, and the study results for the pediatric population are included in the product information, even when negative, the medicine is then eligible for an additional six-month period of qualifying patent protection through extension of the term of the Supplementary Protection Certificate, or SPC, or alternatively a one year extension of the regulatory market exclusivity from ten to eleven years, as selected by the marketing authorization holder.

Access Consortium

In October 2020, the Medicines and Healthcare products Regulatory Agency, or MHRA, joined the Access Consortium along with the Australian Therapeutic Goods Administration of Australia, Health Canada, Health Sciences Authority of Singapore and Swissmedic. The consortium is a coalition of these regulatory authorities that work together to promote greater regulatory collaboration and alignment of regulatory requirements. The consortium's goal is to maximize international co-operation between partners in the consortium, reduce duplication, and increase each agency's capacity to ensure patients have timely access to high quality, safe and effective therapeutic products. The MHRA commenced work-sharing applications with Access partners on January 1, 2021. Access Consortium working group members have regular meetings to exchange information on regulatory issues and challenges faced by the participating regulatory agencies, including issues on clinical trials, marketing authorizations, product manufacturing site inspections, post-marketing surveillance, joint development of technical guidelines or regulatory standards, and collaboration on information platforms. The Access consortium has developed three authorization procedures: the New Active Substance and Biosimilar Work Sharing Initiatives and the Generic Medicine Work Sharing Initiative.

General Data Protection Regulation

There are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the EEA, and the processing of personal data that takes place in the EEA, is subject to the European Union General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, and it imposes heightened requirements on companies that process health and other sensitive data, such as requiring in many situations that a company obtain the consent of the individuals to whom the sensitive personal data relate before processing such data. Examples of obligations imposed by the GDPR on companies processing personal data that fall within the scope of the GDPR include providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, appointing a data protection officer, providing notification of data breaches, and taking certain measures when engaging third-party processors.

The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance.

Following the July 2020 Court of Justice of the European Union judgement invalidating the so-called EU-U.S. Privacy Shield, the EC adopted an adequacy decision for the EU-U.S. Data Privacy Framework in July 2023. This adequacy decision permits U.S. companies who self-certify under the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework, and there is currently one pending litigation against the EU-U.S. Data Privacy Framework before the Court of Justice of the European Union, C-703/25 P – Latombe v. Commission. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the so-called standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business.

On June 23, 2016, the electorate in the UK voted in favor of leaving the EU, commonly referred to as Brexit. Following the withdrawal of the UK from the EU, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the UK and includes parallel obligations to those set forth by GDPR. While the Data Protection Act 2018 in the UK that "implements" and complements the GDPR has achieved Royal Assent on May 23, 2018 and is now effective in the UK, it is still unclear whether transfer of data from the EEA to the UK will remain lawful under GDPR.The UK government has already determined that it considers all EU and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the UK to the EU/EEA remain unaffected. The EC decided in June 2021 that the level of data protection in the UK is "essentially adequate" for purposes of data transfer from the EU to the UK. On December 19, 2025, the EC renewed this decision until December 27, 2031. The UK and the U.S. have also agreed to a U.S.- UK "Data Bridge," which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer personal data from the UK to the U.S. Switzerland has also taken an adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which functions similarly to the EU-U.S. Data Privacy Framework and the U.S.-UK Data Bridge in relation to data transfers from Switzerland to the U.S.). Any changes or updates to these developments have the potential to impact our business.

Beyond the GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow the GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and any eventual sale and distribution of commercial products.

Brexit and the Regulatory Framework in the United Kingdom

As of January 1, 2025, the MHRA is responsible for approving all medicinal products destined for the UK market (Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. The MHRA relies on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the UK's withdrawal from the EU. On April 28, 2025, the UK Parliament adopted amendments to improve and strengthen the UK's clinical trials regulatory regime; they will take effect on April 28, 2026. These changes were needed since the current UK requirements are based upon the now-repealed EU Clinical Trials Directive (2001/20/EC), which has been replaced by the European Clinical Trials Regulation (Regulation EU No 536/2014). Since the UK left the EU prior to the date on which the EU CTR took effect, the UK legal framework did not benefit from the same revisions as occurred at EU level.

As of January 1, 2024, a new international recognition procedure, or the IRP, applies which intends to facilitate approval of pharmaceutical products in the UK. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators, or RRs. The RRs notably include EMA and regulators in the EEA member states for approvals in the European Union centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the United States). The RR assessment must have undergone a full and standalone review. RR assessments based on reliance or recognition cannot be used to support an IRP application. A CHMP positive opinion or a mutual recognition and decentralized procedure positive end of procedure outcome is an RR authorization for the purposes of IRP.

Pharmaceutical Coverage, Pricing and Reimbursement

In the U.S. and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the U.S. such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication. In addition, third-party payors may impose prior authorization or step edit requirements requiring patients to have tried other therapies prior to our products for coverage. Payors may also decline to include our products or product candidates on their formulary, which means that unless healthcare providers seek a medical exception for coverage, the payors will not pay for the product.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product candidate could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Dialysis-related drugs are included in the ESRD PPS bundled payment and are grouped into functional categories such as anemia management and bone and mineral metabolism. In a final ESRD PPS rule published in October 2019, CMS confirmed that TDAPA would be expanded to most new dialysis drugs approved by the FDA after January 1, 2020. The TDAPA provides separate payment for eligible new drugs for two years based on the drug's Average Sales Price, or ASP, that will be in addition to the base rate in order to facilitate the adoption of innovative therapies.

As an oral drug, Auryxia was covered by Medicare under Part D until January 1, 2025, for the treatment of patients with hyperphosphatemia. In January 2011, CMS implemented the ESRD PPS, a prospective payment system for dialysis treatment. Under the ESRD PPS, CMS generally makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at their home. As of January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including Auryxia and all other phosphate lowering medications, are included in the ESRD bundle and separate

Part D Medicare payment for these drugs is no longer available. However, dialysis organizations will receive a TDAPA for claims that include phosphate binders through the end of 2026, or the TDAPA period. Vafseo, which we began selling in January 2025, is also included in the ESRD bundle and ESRD facilities will receive a TDAPA for Vafseo as a new renal dialysis drug meeting certain criteria for a period of two years starting on January 1, 2025. TDAPA provides separate payment based on the drug's ASP that will be in addition to the base rate in order to facilitate the adoption of innovative therapies. If the TDAPA reimbursement amount for Auryxia or Vafseo is lower than anticipated, or if the TDAPA is eliminated, it would have an adverse impact on our revenue. Additionally, after the TDAPA period, CMS currently expects to increase the single bundled payment base rate paid to the dialysis facility for each dialysis treatment to reflect the cost of phosphate lowering medications, including Auryxia and for Vafseo. However, the increase related to Vafseo will only last three years and neither Auryxia nor Vafseo will receive a direct additional payment outside the bundled rate after the TDAPA period. There can be no assurances that any increase in the single bundled payment base rate will be sufficient to adequately reimburse the dialysis facilities for Auryxia or Vafseo at a price that allows us to continue to sell Auryxia or Vafseo at a profit.

In late 2025, legislation was introduced in the U.S. Congress, the Kidney Care Access Protection Act, which seeks to maintain patient access to innovative kidney care treatments, including Vafseo, by addressing reimbursement challenges following TDAPA expiration. There is no guarantee that this legislation will be adopted and, without such legislation, there is a risk that, in the post-TDAPA period, reduced reimbursement could limit provider adoption of Vafseo, restrict patient access and adversely impact our revenue.

In July 2024, Ardelyx filed a complaint in the United States District Court for the District of Columbia against HHS, CMS and other parties, which alleged that CMS's plan to include oral-only phosphate lowering therapies in the ESRD PPS violated its statutory and regulatory authority under the Medicare Improvements for Patients and Providers Act, which established the ESRD PPS bundled payment system for dialysis services. In October 2024, Ardelyx filed a motion for a preliminary injunction to enjoin CMS from including oral-only phosphate lowering therapies in the ESRD PPS. CMS had earlier filed a motion to dismiss the complaint on jurisdictional grounds. On November 8, 2024, the district court denied Ardelyx' motion for a preliminary injunction and it granted the government's motion to dismiss. Thereafter, Ardelyx moved for reconsideration, but the district court also denied that request. On December 26, 2024, Ardelyx filed a notice of appeal with the US Court of Appeals for the DC Circuit. Briefing of the case has been completed and oral argument was held on September 25, 2025.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Outside the U.S., ensuring adequate coverage and payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to governmental control in many countries. Pricing negotiations with governmental authorities can extend well beyond the receipt of regulatory marketing approval for a product and may require a clinical trial that compares the cost effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the EU, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the EU provides options for its EU Member States to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. EU Member States may approve a specific price for a product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

Recently, many countries in the EU have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the EU. The downward pressure on health care costs in general, particularly prescription drugs, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced EU Member States, can further reduce prices. There can be no assurance that

any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Dialysis Organizations Protocols

Dialysis organizations have their own formularies that list primary or preferred therapeutic options in part based on contracting status with drug manufacturers. While a prescriber may make their own independent decision to prescribe what they determine most appropriate for a given patient, any non-formulary therapeutic options are only available through an exception process based on clinical need. Similar to how payor coverage may affect the sales of a product, formulary status within dialysis organizations may affect what products are prescribed within that specific organization. Therefore, if a product is not on a formulary, the prescribers within that organization may be less likely to prescribe that product or may have a difficult time prescribing that product, resulting in less sales. Further, one dialysis organization's determination to add a product to their formulary does not assure that other dialysis organizations will also add the product to theirs. There is always a risk a dialysis organization will not contract with a drug manufacturer for a specific product, resulting in that product not being on that organization's formulary. Additionally, dialysis organizations typically assess a product's efficacy before adding it to their formulary. Their process for assessing a product may differ among organizations and the timing of such assessment could delay adding such treatment to formulary, further affecting product sales.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians, teaching hospitals and other healthcare providers, patient privacy laws and regulations, and other healthcare laws and regulations that may constrain business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government
- HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the U.S. Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making, or offering or promising to make improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment;
- the federal transparency requirements, known as the federal Physician Payments Sunshine Act (renamed the Open Payments Act), under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the CMS within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians, other healthcare providers and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- the PDMA and its implementation regulations, as well as the DSCSA, which regulate the distribution and tracing of prescription drugs and prescription drug samples at the federal level, and set minimum standards for the regulation of drug distributors by the states; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by third-party payors, including private insurers, and state gift ban and disclosure law requirements that differ from the federal Physician Payments Sunshine Act in terms of the nature and type of transfers of value that are reportable and the types of covered recipients.

Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, exclusion from participation in federal and state health care programs, such as Medicare and Medicaid. Ensuring compliance is time consuming and costly. Similar healthcare laws and regulations exist in the EU and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal information.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, such as the Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals, known as the PhRMA Code. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Healthcare Reform in the U.S.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the U.S.

By way of example, the U.S. and state governments continue to propose and pass legislation designed to reduce the cost of healthcare.

In March 2010, the U.S. Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under government health care programs. Other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which will remain in effect through 2031 pursuant to the Coronavirus Aid, Relief and Economic Security Act, or CARES Act. Under current legislation, the actual reductions in Medicare payments may vary up to 4%.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, or the Tax Act, which was signed by the prior administration on December 22, 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. In June 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA after finding that the plaintiffs did not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

Pharmaceutical Prices in the U.S.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the U.S. There have been several recent U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the U.S. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Several states have passed laws allowing for the importation of products from Canada. On January 5, 2023, the FDA approved Florida's plan for Canadian product importation. That state now has authority to import certain products from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each product selected for importation, which must be approved by the FDA. The state will also need to relabel the products and perform quality testing

of the products to meet FDA standards. On May 21, 2025, the FDA announced that it would offer individual states the opportunity to submit a draft proposal for pre-review and meet with the agency to obtain initial feedback from FDA prior to formally submitting their SIP proposal. The intent of these meetings is to assist states in developing their proposals by further clarifying requirements, enhancing the quality of proposals submitted to the agency and ultimately shortening the review timeline.

Further, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The final rule would also eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It originally was set to go into effect on January 1, 2022, but with passage of the Inflation Reduction Act of 2022, or IRA, has been delayed by Congress to January 1, 2032.

The IRA has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition were originally categorically excluded from price negotiation. With passage of the One Big Beautiful Bill Act on July 3, 2025, which was signed into law on July 4, 2025, Congress extended this exemption to drugs and biologics with multiple orphan drug designations.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The law also caps Medicare out-of-pocket drug costs at an estimated $2,000 a year.

On August 15, 2024, HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. On January 17, 2025, HHS announced the selection of 15 additional drugs covered by Part D for the second cycle of negotiations. This second cycle of negotiations with participating drug companies occurred during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027. CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration, and CMS is committed to considering opportunities to bring greater transparency in the negotiation program.

On June 6, 2023, Merck & Co., Inc. filed a lawsuit against HHS and CMS asserting that, among other things, the IRA’s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas Pharma US, Inc., Novo Nordisk Inc., Janssen Pharmaceuticals, Inc., Novartis Pharmaceutical Corporation, AstraZeneca L.P. and Boehringer Ingelheim, Pharmaceuticals, Inc. also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. HHS has generally won the substantive disputes in these cases, or succeeded in getting claims dismissed for lack of standing. Most of these cases are now on appeal. On October 30, 2024, the U.S. Court of Appeals for the Third Circuit heard oral arguments in three of these cases. In April 2025, the U.S. Court of Appeals for the Second Circuit and the U.S. Court of Appeals for the Third Circuit heard arguments in an additional three cases. On May 8, 2025, the U.S. Court of Appeals for the Third Circuit rejected AstraZeneca L.P.’s challenge to the Medicare price negotiation program, finding that the program did not violate the company’s due process rights under the Constitution since there is no protected property interest in selling goods to Medicare beneficiaries at a price higher than what the government is willing to pay in reimbursement. Litigation involving these and other provisions of the IRA will continue with unpredictable and uncertain results.

On April 15, 2025, President Trump issued an Executive Order which directs HHS to take steps to reduce the prices of pharmaceutical products. The new Executive Order repeats many of the proposals advanced during the first Trump Administration, including directing the FDA to streamline and improve its existing drug importation program so as to make it easier for states to obtain approval without sacrificing the safety or quality of drug products. Other provisions of the Executive Order relate to the 340B program. Specifically, one provision calls on the Secretary of HHS to determine the hospital

acquisition cost for covered outpatient drugs at hospital outpatient departments and to consider and propose any appropriate adjustments for Medicare payment. The other provision directs HHS to condition grant funding to certain health centers on those centers passing through the 340B discounts they receive on insulin and injectable epinephrine products to patients who meet certain requirements. With respect to the IRA's Medicare drug pricing program, the Executive Order, among other things, calls for alignment in "the treatment of small molecule prescription drugs with that of biological products, ending the distortion that undermines relative investment in small molecule prescription drugs, coupled with other reforms to prevent any increase in overall costs to Medicare and its beneficiaries."

Further, on May 12, 2025, President Trump issued an additional Executive Order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the U.S. The Executive Order directs the Secretary of HHS to communicate most-favored-nation, or MFN, price targets to pharmaceutical manufacturers to bring prices in line with comparably developed nations. The Executive Order further provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes MFN pricing in the U.S. Subsequently, on May 20, 2025, HHS indicated that the proposed MFN pricing will apply only to brand products without generic or biosimilar competition and the reference foreign countries will include only those in which the branded product similarly does not have generic or biosimilar competition. Second, HHS indicated that the MFN target price will be the lowest price in a country that is a member of the Organization for Economic Co-operation and Development, or OECD, with a gross domestic product, or GDP, per capita of at least 60% of the U.S. GDP per capita. Based on previous estimates, there are likely at least 22 OECD countries that would satisfy this criterion. The implications of these actions remain unclear and are likely to result in litigation if the administration pursues an MFN regulatory pricing requirement.

More recently, on July 31, 2025, the President issued letters to 17 pharmaceutical companies reiterating the requirements of the May 12, 2025, Executive Order and demanding that such companies extend MFN pricing to Medicaid patients, guarantee MFN pricing for newly-launched drug products, return increased revenues abroad to American patients and provide for direct purchasing at MFN pricing. The letters also urged these companies to stipulate that they will not offer other developed nations better prices for new drugs than the prices offered for such products in the U.S. The letters called for engagement with the FDA and CMS within 60 days to implement these changes and threatened to use "every tool in our arsenal" to address what the letter characterized as "abusive drug pricing practices." Subsequently, the administration has announced deals with various pharmaceutical companies to reduce the costs of drugs.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, wholesale distributors, to disclose information about pricing of pharmaceuticals. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription pharmaceutical and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. This may be especially true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

Healthcare Reform and Pharmaceutical Prices in the EU

In the EU, similar political, economic, and regulatory developments to those in the U.S. may affect our ability to profitably commercialize our product candidates, if approved. In many countries, including those of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of an MA. To obtain reimbursement or pricing approval in some countries, pharmaceutical firms may be required to conduct a clinical trial that compares the cost-effectiveness of the product to other available therapies. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or EU Member State level may result in significant additional requirements or obstacles. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU Member States have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could restrict or

regulate post-approval activities and affect the ability of pharmaceutical companies to commercialize their products. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

In the EU, potential reductions in prices and changes in reimbursement levels could be the result of different factors, including reference pricing used by various EU Member States, parallel distribution and parallel trade can further reduce prices. It could also result from the application of external reference pricing mechanisms, which consist of arbitrage between low-priced and high-priced EU Member States. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any product candidates, if approved in those countries.

Health technology assessment, or HTA, of medicinal products in the EU is an essential element of the pricing and reimbursement decision-making process in a number of EU Member States. The outcome of HTA has a direct impact on the pricing and reimbursement status granted to the medicinal product. A negative HTA by a leading and recognized HTA body concerning a medicinal product could undermine the prospects to obtain reimbursement for such product not only in the EU Member State in which the negative assessment was issued, but also in other EU Member States.

In 2011, Directive 2011/24/EU was adopted at the EU level. This directive establishes a voluntary network of national authorities or bodies responsible for HTA in the individual EU Member States. The network facilitates and supports the exchange of scientific information concerning HTAs. Further to this, on December 13, 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted. While the regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The regulation intends to boost cooperation among EU Member States in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Laws Relating to Foreign Trade

We are subject to various federal and foreign laws that govern our international business practices. These laws include the FCPA, which prohibits U.S. companies and their representatives from paying, offering to pay, promising, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate for the purposes of obtaining or retaining business, or to otherwise obtain favorable treatment or influence a person working in an official capacity. In many countries, the health care professionals we regularly interact with may meet the FCPA's definition of a foreign government official. Additionally, interactions with or on the part of our partners, collaborators, contract research organizations, vendors or other agents may also implicate the FCPA. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect their transactions and to devise and maintain an adequate system of internal accounting controls. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents unique challenges in the pharmaceutical industry because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments made by pharmaceutical companies to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

On February 10, 2025, President Trump issued an Executive Order directing the Attorney General to review the guidelines and policies governing the FCPA investigations and enforcement actions. Per the Executive Order, this review will result in new Department of Justice FCPA guidelines intended to enhance American economic competitiveness and to safeguard national security interests. During the 180-day review period, any new FCPA investigations and enforcement actions are to be suspended absent authorization from the Attorney General, and all existing FCPA investigations and enforcement actions will be reviewed. Additionally, after the Attorney General issues revised guidelines, the Executive Order directs her to assess whether "remedial measures" related to past FCPA actions are warranted.

Our international operations could also be subject to compliance with national laws of other countries, such as the United Kingdom Bribery Act. of 2010, or UK Bribery Act. The UK Bribery Act applies to any company "carrying on business" in the UK, irrespective of where the offending conduct occurs. The UK Bribery Act applies to bribery activities both in the public and private sector and prohibits the provision of an "advantage" intended to induce or reward "improper performance" of the recipient's function. The failure by a company to prevent third parties from providing a bribe on its behalf could also

constitute an offense. Penalties under the UK Bribery Act include potentially unlimited fines for companies and criminal sanctions for corporate officers under certain circumstances.

There are local antibribery and anticorruption laws in countries where we are conducting clinical trials, such as Brazil and Russia, and many of these also carry the risk of significant financial or criminal penalties. Our clinical trial operations could also result in enforcement actions by U.S., UK, or other governmental authorities. There are also trade laws within the U.S. and in other regions that regulate the sale, purchase, import, export, reexport, transfer and shipment of goods, currency, products, materials, services and technology. Violations of these laws can lead to serious consequences, including substantial fines.

Other Regulations

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Buying Patterns

We believe the dynamics of Auryxia reimbursement being included in the ESRD bundle under Medicare Part B and Auryxia LoE on March 20, 2025 could result in the buying pattern of certain customers in 2026 and future years being different than historical practices. On January 22, 2026, Teva received tentative approval for its ANDA for Auryxia. Currently, there is only one authorized generic for Auryxia sold by our distributor, but we expect additional generic competition in 2026. If additional generics are approved and enter the market, we expect it will adversely impact our revenue. However, the impact on future Auryxia revenues will depend on many factors, including our ability to maintain contracts with dialysis organizations, the timing and number of additional generics and the pricing of generics and other products on the market that compete with Auryxia.

Employees and Human Capital Resources

As of December 31, 2025, we had 194 employees. None of our employees are represented by any collective bargaining unit. We believe that we maintain good relations with our employees.

We face competition for our personnel from our competitors and other companies throughout our industry. Over the last several years, the challenges in recruiting and retaining employees across the pharmaceutical and biotechnology industries have increased substantially due to current industry job market dynamics.

Retention, growth, training and development of our employees are integral to our success. We offer competitive compensation, including base salary and incentive bonuses. We conduct bi-annual internal and external pay reviews to ensure fair and competitive pay for our employees, which includes an internal pay equity analysis, as well as a review of our employees' pay against external market data. Our company-wide practice around pay transparency includes sharing salary ranges and total rewards information on all job postings and at least annually with employees, which we believe helps to improve recruitment, strengthen employer brand and foster trust and engagement. To foster a stronger sense of ownership and align the interests of employees with shareholders, we grant restricted stock units and common stock options to eligible employees under our broad-based stock incentive program, and employees may purchase stock pursuant to our employee stock purchase plan. In addition, many of our executives participate in our employee stock purchase plan. Further, our benefits packages are designed to attract, motivate and reward talented individuals who possess the skills necessary to support our business objectives, assist in the achievement of our strategic goals and create value for our stockholders. Our compensation program is designed to differentiate us from our competition, incentivize achievement of corporate goals and individual performance and demonstrate our corporate values. In addition, we are committed to developing our team members and provide development and leadership opportunities to our employees to cultivate talent throughout the Company.

We are committed to our employees’ health, safety and well-being. Our work paradigm is flexible and designed to accommodate a range of work profiles. Our workforce is primarily hybrid and fully remote, including field-based, with certain employees being office-based. We offer a wide variety of competitive benefits to support our employees' physical, mental and financial well-being. Our benefits package is comprehensive in coverage and offers options to support all employees in staying healthy, planning for their future and developing their careers. Our management continues to assess and respond to the evolving needs of our workforce.

Environmental, Social and Governance

Our commitment is to ensure that every employee is included, supported and treated fairly. In furtherance of this goal, we conducted an employee engagement survey to identify the strengths and opportunities around our culture and employee experience. The feedback was shared with our Culture Steering Committee, a team whose remit includes supporting and guiding Akebia as an inclusive and culturally intelligent workplace. Over the past four years this team has worked with executive leadership to move forward several initiatives that will enable us to continue to build an inclusive workplace and to work toward our aspiration to have a workforce comprised of talented individuals with different experiences, perspectives

and backgrounds. In 2025, the team developed and implemented a mentorship program to broaden perspectives and development opportunities for employees across the organization. In 2024, this team launched training focused on promoting equal opportunity and mitigating potential bias for all employees.

Our Cambridge office has a Fitwel Certification, a healthy building certification system, and is level two certified. Additionally, we consolidated our office footprint to reduce our use of energy and other resources and have initiated recycling programs, including single stream recycling and recycling cans at every desk. Furthermore, we offer a commuter benefit to all of our hybrid and office-based employees to encourage employees to use public transportation and offer bicycle parking free of charge in the onsite garage.

In addition, we support kidney patient communities where we live and work. We have a copay assistance program that helps to reduce the costs of Auryxia for eligible patients. In 2025, we offered copay assistance to approximately 1,600 patients.

We also have a cross-functional Sponsorship Review Committee that reviews and approves sponsorships and donations based on the relevance of each projects to our purpose, business objectives and the communities we serve. We support and work closely with multiple kidney patient advocacy organizations. We believe our involvement with and support of patient advocacy programs demonstrates our commitment to our purpose of bettering the life of each person impacted by kidney disease.

Available Information

Our website address is www.akebia.com. The information on our website or that may be accessed by links on our website is not incorporated by reference into this Form 10-K. We make available, free of charge and through our website, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and any amendments to any such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission, or SEC.

Corporate Information

Akebia was incorporated in Delaware in 2007 and became a public company in 2014. Our mailing address and principal executive offices and our laboratory are located at 245 First Street, Cambridge, Massachusetts 02142. Our telephone number is (617) 871-2098.

We are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC maintains a website at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, proxy statements, and other information, including amendments and exhibits to such reports, filed or furnished pursuant to the Securities Exchange Act of 1934 are also available free of charge in the “SEC Filings” section of our website located at http://www.akebia.com, as soon as reasonably practicable after the reports are electronically filed with or furnished to the SEC. The information on our website is not part of this Annual Report on Form 10-K.

Item 1A. Risk Factors.

We face a variety of risks and uncertainties in our business. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also become important factors that affect our business, reputation, results of operations, financial condition and stock price which can be materially and adversely affected. If any of the following risks occurs, our business, financial condition, financial statements, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to our Financial Position, Need for Additional Capital and Growth Strategy

We have incurred significant losses since our inception, and anticipate that we will continue to incur losses and cannot guarantee when, if ever, we will become and remain profitable.

Investment in pharmaceutical product development and commercialization is highly speculative because it requires upfront capital expenditures and significant research and development, or R&D, expenses. Despite the investment in assets and R&D, there is significant risk that a product candidate will fail to gain marketing approval or that an approved product will not be commercially viable. Since our inception, we have devoted most of our resources to R&D, including our preclinical and clinical development activities, commercializing Auryxia and Vafseo and providing general and administrative support for these operations. We have funded our operations principally through product sales, payments received from our collaboration and licensing partners, borrowings under term loans, sales of our common stock, including through our employee stock purchase plan, a working capital payment from Vifor (International) Ltd. (now a part of CSL Limited), or CSL Vifor, and a royalty transaction. Prior to our 2018 merger, or the Merger, with Keryx Biopharmaceuticals, Inc., or Keryx, whereby Keryx became our wholly owned subsidiary, we had no products approved for commercial sale and had not generated any revenue from the sale of products. We currently have two commercial products and believe that our existing cash resources and the cash we expect to generate from product, royalty, supply and license revenues are sufficient to fund our current operating plan for at least two years, including to commercialize Vafseo and Auryxia and advance our existing programs. However, we have incurred net losses each year since our inception, including a net loss of $5.3 million for the year ended December 31, 2025, and we cannot guarantee when, if ever, we will become and remain profitable. As of December 31, 2025, we had an accumulated deficit of $1.7 billion.

On March 27, 2024, the United States, or U.S., Food and Drug Administration, or FDA, approved our new drug application, or NDA, for vadadustat under the trade name Vafseo for the treatment of anemia due to chronic kidney disease, or CKD, in adults who have been receiving dialysis for at least three months. However, we expended significant additional resources to obtain the approval of Vafseo, and the commercialization of Vafseo was delayed due to the receipt of a complete response letter, or CRL, from the FDA in March 2022 regarding our NDA, and Vafseo was approved for a narrower indication than we initially pursued, which had and could continue to have an adverse effect on our business.

Our ability to generate product revenue and achieve and maintain profitability depends on our ability to manage expenses and the overall success of Auryxia, Vafseo and any current or future product candidates, including those that may be in-licensed or acquired, which depends on several factors, including:

- obtaining and maintaining adequate or favorable pricing and reimbursement from private and governmental payors for Auryxia, Vafseo and any other product or product candidate, including those that may be in-licensed or acquired;
- obtaining and maintaining market acceptance of Auryxia, Vafseo and any other product candidate, including those that may be in-licensed or acquired;
- the size of any market in which Auryxia, Vafseo and any other product or product candidate, including those that may be in-licensed or acquired, receives approval and obtaining adequate market share in those markets;
- maintaining marketing approvals for Auryxia, Vafseo and any other product, including those that may be in-licensed or acquired;
- obtaining regulatory approval for any potential label expansion for Vafseo, including the timing and scope thereof;
- our ability to maintain contracts with dialysis organizations for the sale of Auryxia and Vafseo in the U.S.;
- actual or perceived advantages or disadvantages of our products or product candidates as compared to alternative treatments, including their respective safety, tolerability and efficacy profiles, the potential convenience and ease of administration and cost;
- maintaining an acceptable safety and tolerability profile of our approved products, including the frequency and severity of any side effects;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, based, in part, on their perception of our clinical trial data and/or the actual or perceived safety, tolerability and efficacy profile;
- patients' adherence or non-adherence to the prescribed treatment regimen;

- the timing and scope of marketing approvals for any product candidate, if approved, including those that may be in-licensed or acquired;
- the timing and number of additional generic versions of Auryxia that enter the market following loss of exclusivity, or LoE, for Auryxia which occurred in March 2025, the pricing of generic versions of Auryxia, the impact of LoE on the product revenue from Auryxia, including the impact on the price of Auryxia;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate supplies of products that are compliant with good manufacturing practices, or GMPs, to support the clinical development and the market demand for Auryxia, Vafseo and any other product and product candidate, including those that may be in-licensed or acquired;
- maintaining adequate inventory levels of Auryxia, Vafseo and any other products or product candidates;
- the potential impact of geopolitical pressures, including tariffs and global trade policies, or the BIOSECURE Act on our ability to conduct our business as currently conducted;
- current and future restrictions or limitations on our approved or future indications and patient populations or other adverse regulatory actions or in the event that the FDA requires Risk Evaluation and Mitigation Strategies, or REMS, or risk management plans that use restrictive risk minimization strategies;
- the effectiveness of our collaborators' and our sales, marketing, manufacturing and distribution strategies and operations;
- competing effectively with any products for the same or similar indications as our products (including generics); and
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents and trade secrets.

Our collaboration, license and other revenue also depends on our partners' ability to successfully market and sell Vafseo and Auryxia in the territories in which they have licensed our products. For example, in May 2023, we entered into a license agreement with MEDICE Arzneimittel Pütter GmbH & Co. KG, or Medice, pursuant to which we granted Medice an exclusive license to develop and commercialize Vafseo for the treatment of anemia in patients with CKD in the European Economic Area, or the EEA, the United Kingdom, or UK, Switzerland and Australia, or collectively, the Medice Territory. Vafseo is currently marketed and sold by Medice in certain countries in the Medice Territory. If Medice's launch of Vafseo in certain countries in the Medice Territory is delayed or their sales are lower than anticipated, we may not receive the revenue that we expect from Medice on the timing anticipated, or at all.

In July 2024, we entered into a Termination and Settlement Agreement with CSL Vifor, or the Vifor Termination Agreement. Pursuant to the Vifor Termination Agreement, we agreed, among other things, to terminate, effective immediately, the Second Amended and Restated License Agreement that we entered into with CSL Vifor in February 2022, as amended in May 2024, or the Vifor License Agreement, pursuant to which we granted CSL Vifor an exclusive license to sell Vafseo to Fresenius Medical Care North America and its affiliates, including Fresenius Kidney Care Group LLC, to certain third-party dialysis organizations approved by us, to independent dialysis organizations that are members of certain group purchasing organizations, or GPOs, and to certain non-retail specialty pharmacies in the U.S., which represents a significant portion of the potential market for Vafseo. As a result, we have regained our rights to sell Vafseo to Fresenius Kidney Care North America and its affiliates and certain other third-party dialysis organizations in the U.S.

Pursuant to the Vifor License Agreement, CSL Vifor contributed $40.0 million to a working capital facility, or Working Capital Fund, established to partially fund our costs of purchasing Vafseo from our contract manufacturers. Pursuant to the terms of the Vifor Termination Agreement, we have agreed to repay the Working Capital Fund to CSL Vifor through quarterly tiered royalty payments ranging from 8% to 14% of our net sales of Vafseo in the U.S., or the WCF Royalty Payments. The WCF Royalty Payments commenced on July 1, 2025, and will continue until the earlier of (i) the cumulative total of the WCF Royalty Payments equals $40.0 million, or (ii) May 31, 2028. The WCF Royalty Payments are subject to minimum true-up milestones of $10.0 million, $20.0 million and $40.0 million, or the WCF Royalty True-Up Payments, on each of May 31, 2026, May 31, 2027 and May 31, 2028, respectively, or the WCF Royalty True-Up Dates. If the cumulative total of the WCF Royalty Payments paid to CSL Vifor on any given WCF Royalty True-Up Date is less than the respective WCF Royalty True-Up Payment, we will pay CSL Vifor a one-time payment equal to the difference between the WCF Royalty True-Up Payment and the cumulative total of the WCF Royalty Payments paid by us through such WCF Royalty True-Up Date. If we are not successful in commercializing Vafseo, including maintaining contracts with dialysis organizations on favorable terms, or at all, our expected revenue related to Vafseo would be adversely impacted, and we may be unable to repay all or part of the WCF Royalty Payments, which could have a material adverse impact on our consolidated financial statements and our ability to achieve and maintain profitability.

In addition, on November 28, 2025, or the APA Closing Date, we entered into an Asset Purchase Agreement, or the Q32 Purchase Agreement, with Q32 Bio Inc. and Q32 Bio Operations Inc., together, Q32, pursuant to which we purchased and assumed from Q32 substantially all assets and liabilities of Q32 and its affiliates related to the research, development, manufacture, and commercialization of Q32's clinical-stage development candidate known as ADX-097, now referred to as

AKB-097, worldwide for the treatment, prevention or diagnosis of any disease or condition in humans. Under the terms of the APA, we (i) made an upfront payment in an amount equal to $7.0 million on the APA Closing Date, (ii) will make an additional upfront payment in an amount equal to $3.0 million on the sixth-month anniversary of the APA Closing Date, (iii) will make certain milestone payments upon the achievement of specified development and regulatory milestone events related to AKB-097 up to an aggregate amount equal to $94.5 million, including a $2.0 million development milestone payment upon the earlier of initiation of a Phase 2 clinical trial and December 31, 2026, (iv) will make certain milestone payments upon the achievement of specified commercial milestone events with respect to the net sales of AKB-097 up to an aggregate amount equal to $487.5 million, and (v) will make certain royalty payments based on the net sales of AKB-097 with royalty percentage tiers ranging from the low single digits to mid-teen percentages. The royalties will expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

Our ability to achieve and maintain profitability also depends on our ability to manage our expenses. We expect to continue to incur substantial additional operating expenses, including additional R&D expenses related to our pipeline, including AKB-097 and praliciguat, and additional R&D and selling, general and administrative expenses for ongoing development, post-marketing requirements and commercialization of Auryxia and Vafseo and any other products, including those that may be in-licensed or acquired, which could lead to operating losses for the foreseeable future. Our prior losses have had, and expected future losses will continue to have, an adverse effect on our stockholders' equity (deficit) and working capital.

In addition to any further costs not currently contemplated in our operating plan, our ability to achieve and maintain profitability and our financial position will depend, in part, on the rate of our future expenditures, the timing of our product, collaboration, license and other revenue, the timing and amount of any repayment of the WCF Royalty Payments, our continued compliance with the terms of the Agreement for the Provision of a Loan Facility, as amended, or the BlackRock Credit Agreement, with Kreos Capital VII (UK) Limited, which are funds and accounts managed by BlackRock Inc., collectively, BlackRock, and our ability to obtain additional funding, should it be needed. In addition, we expect to continue to incur significant expenses if and as we:

- continue our commercialization activities for Auryxia, Vafseo and any other product or product candidate for which we obtain approval, including those that may be in-licensed or acquired;
- seek regulatory approval for any potential label expansion for Vafseo;
- conduct and enroll patients in any clinical trials, including post-marketing studies or any other clinical trials for Auryxia, Vafseo or any other product or product candidate, including those that may be in-licensed or acquired;
- seek marketing approval for any product candidate, including those that may be in-licensed or acquired;
- maintain marketing approvals for Auryxia, Vafseo and any other product, including those that may be in-licensed or acquired;
- manufacture Auryxia, Vafseo and any other product or product candidate, including those that may be in-licensed or acquired, for commercial sale and clinical trials;
- secure and validate manufacturing facilities for any of our products and product candidates;
- conduct discovery and development activities for our products and product candidates or platforms that may lead to the discovery of additional product candidates;
- engage in transactions, including strategic, merger, collaboration, acquisition and licensing transactions, pursuant to which we would market and develop commercial products, or develop and commercialize other product candidates and technologies;
- repay, and pay any associated pre-payment penalties, if applicable, the term loans in an aggregate principal amount of $55.0 million, or the Term Loans, that were made available to us pursuant to the BlackRock Credit Agreement;
- make royalty, milestone or other payments under our current and any future in-licensing agreements, the Q32 Purchase Agreement and the Vifor Termination Agreement;
- maintain, protect and expand our intellectual property portfolio;
- make decisions with respect to our personnel, including the retention of key employees;
- make decisions with respect to our infrastructure, including to support our operations as a fully integrated, publicly traded biopharmaceutical company; and
- experience any additional delays or encounter issues with any of the above.

We have expended and may in the future expend significant resources on our legal proceedings, as described below under Part I, Item 3. Legal Proceedings, including any legal proceedings that may be brought by or against us in the future.

Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency, or the EMA, or other regulatory authorities, or if we otherwise believe it is necessary, to change our manufacturing processes or assays, to

bring on additional manufacturers, to amend or replace our study protocols, to perform studies different from or larger than those currently planned, to conduct any additional clinical trials, whether in order to obtain approval or as a post-approval study, including the post-approval studies required for Vafseo and any other additional clinical trial that we decide to conduct for Vafseo, or if there are any delays in completing any of these activities.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or the associated revenue. Any net losses we may incur in the future could fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter, our product revenue, the progress of our clinical development and our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

In addition, our ability to generate revenue would be negatively affected if dialysis organizations are unwilling to include Auryxia or Vafseo in their formulary or the size of our addressable patient population is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we sought, or the patient population for treatment is narrowed by competition, physician choice, coverage or reimbursement, or payor or treatment guidelines. Even though we generate product revenue from Auryxia and Vafseo in the U.S. and royalties from Riona (ferric citrate hydrate) and Vafseo in Japan, and Vafseo in Europe and other territories where it is approved, and may generate revenue and royalties from the sale of any products that may be approved in the future, including those that may be in-licensed or acquired, we may never generate revenue and royalties that are significant enough for us to become and remain profitable, and we may need to obtain additional financing to continue to fund our operating plan.

We may require substantial additional financing to fund our business. A failure to obtain this necessary capital when needed, or on acceptable terms, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

As of December 31, 2025, our cash and cash equivalents were $184.8 million. We expect to continue to expend substantial amounts of cash for the foreseeable future as we continue to commercialize Auryxia in the U.S.; develop and commercialize Vafseo in the U.S.; and develop and commercialize any other product or product candidate, including those that may be in-licensed or acquired. These expenditures will include costs associated with R&D, manufacturing, potentially obtaining marketing approvals and marketing products approved for sale. In addition, other unanticipated costs may arise. Because the outcomes of our current and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding necessary to successfully complete clinical development for any current or future product candidates or to complete post-marketing studies for Vafseo. Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of conducting clinical trials or any post-marketing requirements or any other clinical trials for Auryxia, Vafseo, praliciguat, AKB-097, and any other product or product candidate, including those that may be in-licensed or acquired;
- the cost and timing of commercialization activities, including product manufacturing, marketing, sales and distribution costs, for Auryxia, Vafseo and any other product or product candidate, including those that may be in-licensed or acquired;
- the results of our meetings with the FDA, the EMA and other regulatory authorities and any consequential effects, including on timing of and ability to obtain and maintain marketing approval, label expansion, study design, study size and resulting operating costs;
- any difficulties or delays in conducting our clinical trials, or enrolling patients in our clinical trials, for Auryxia, Vafseo or any other product candidates;
- the outcome of our efforts to obtain marketing approval for any product candidates, including those that may be in-licensed or acquired, including any additional clinical trials or post-approval commitments imposed by regulatory authorities;
- the timing of, and the costs involved in obtaining, any potential label expansion for Vafseo or marketing approvals for any product candidate, including those that may be in-licensed or acquired, including to fund the preparation, filing and prosecution of regulatory submissions;
- the costs of maintaining marketing approvals for Auryxia, Vafseo or any other product, including those that may be in-licensed or acquired;
- the timing and number of additional generic versions of Auryxia that enter the market following LoE for Auryxia which occurred in March 2025, the pricing of generic versions of Auryxia, the impact of LoE on product revenue from Auryxia, including the impact on the price of Auryxia;
- the cost of securing and validating manufacturing facilities for any of our products and product candidates, including those that may be in-licensed or acquired, and maintaining our manufacturing arrangements for Auryxia and Vafseo

or any other product or product candidate, including those that may be in-licensed or acquired, or securing and validating additional arrangements;

- the costs involved in preparing, filing and prosecuting patent applications and maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation;
- the costs involved in any legal proceedings to which we are a party;
- our status as a publicly traded company on the Nasdaq Capital Market;
- our decisions with respect to personnel;
- our decisions with respect to infrastructure; and
- the extent to which we engage in transactions, including strategic, merger, collaboration, acquisition and licensing transactions, pursuant to which we could develop and market commercial products, or develop other product candidates and technologies.

We may need to obtain substantial additional financing to fund our business. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our R&D programs and/or commercialization efforts.

We believe our existing cash resources and the cash we expect to generate from product, royalty, supply and license revenues are sufficient to fund our current operating plan for at least two years, including to commercialize Vafseo and Auryxia and advance our existing programs. However, if our operating performance deteriorates significantly from the levels expected in our long-term operating plan, including if we do not achieve our future anticipated Vafseo revenue projections, it would have an adverse effect on our liquidity and capital resources and could affect our ability to achieve or maintain profitability or continue as a going concern in the future. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves numerous risks and uncertainties, and actual results could vary as a result of a number of factors, many of which are outside our control. We have based this estimate on assumptions that may be substantially different than actual results, and we could utilize our available capital resources sooner than we currently expect. In addition, if we fail to satisfy any of the covenants under the BlackRock Credit Agreement, and the loan is accelerated, or if certain pre-specified events occur and we are required to make principal payments to BlackRock sooner than we currently anticipate, such event could have a material adverse effect on our business. There can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, or that our cash resources and cash we expect to generate will fund our operating plan for the period anticipated by us, or that additional funding will be available on terms acceptable to us, or at all.

Any additional fundraising efforts may divert our management's attention away from their day-to-day activities, which may adversely affect our ability to develop and commercialize Auryxia, Vafseo and any other products or product candidates, including those that may be in-licensed or acquired. Also, additional funds may not be available to us in sufficient amounts or on acceptable terms or at all. In addition, raising funds in the current economic environment may present additional challenges. For example, any sustained disruption in the capital markets from adverse macroeconomic conditions and an uncertain geopolitical environment, such as tariffs, rising inflation, increasing interest rates, slower economic growth or recession, global trade policies, global supply chain disruptions, ongoing conflicts including the Russia-Ukraine war, hostilities between Israel and Hamas, instability in the Middle East, tensions between China and Taiwan and other emerging geopolitical crises, could negatively impact our ability to raise capital, and we cannot predict the extent or duration of such macroeconomic disruptions. If we are unable to raise additional capital in sufficient amounts when needed or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development and/or commercialization of Auryxia, Vafseo and any other products or product candidates, including those that may be in-licensed or acquired. Any of these events could significantly harm our business, financial condition and prospects.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our products and product candidates on unfavorable terms to us.

We expect to finance future cash needs through product revenue and royalty and license revenue, and we may seek to sell public or private equity, enter into new debt transactions, explore potential strategic transactions or a combination of these approaches or other strategic alternatives. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, our fixed payment obligations may increase, any such securities may have rights senior to those of our common stock, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect the rights of our common stockholders. For example, from September 12, 2024 (the date our shelf registration statement on Form S-3 went effective) through December 31, 2024, we sold 14,271,631 shares of our common stock in an at-the-market offering with gross proceeds of $24.3 million, and during the year ended December 31, 2025, we sold 9,437,364 shares of our common stock under this program with gross proceeds of $18.7 million. In addition, on March 21, 2025, we sold 25,000,000 shares of our common stock in an underwritten public offering with net proceeds of $46.5 million, and on April 22, 2025, we sold an additional 850,000 shares of our common stock in connection with the partial exercise of the underwriters' 30-day option to

purchase additional shares in such underwritten public offering with net proceeds of $1.6 million. Additional debt financing, if available, may involve agreements that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, make capital expenditures, declare dividends, acquire, sell or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic transactions, we may have to relinquish valuable rights to our portfolio and future revenue streams, and enter into agreements that would restrict our operations and strategic flexibility. If we raise additional funds through strategic transactions with third parties, we may have to do so at an earlier stage than otherwise would be desirable. In connection with any such strategic transactions, we may be required to relinquish valuable rights to our product and product candidates, future revenue streams or research programs or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds when needed, we may not be able to pursue planned development and commercialization activities and we may need to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We may not be successful in our efforts to identify, acquire, in-license, discover, develop and commercialize additional products or product candidates or our decisions to prioritize the development of certain product candidates over others may not be successful, which could impair our ability to grow.

Although we continue to focus a substantial amount of our efforts to develop and commercialize Auryxia and Vafseo, a key element of our long-term growth strategy is to develop additional product candidates and acquire, in-license, develop and/or market additional products and product candidates. For example, on November 28, 2025, we acquired AKB-097, a clinical-stage development candidate with the potential to treat rare kidney diseases.

Research programs to identify product candidates require substantial technical, financial and human resources, regardless of whether product candidates are ultimately identified. Our R&D programs, including our rare kidney disease pipeline, may initially show promise, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- the development of product candidates could take longer than anticipated and require additional resources;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates;
- a product candidate may be shown to have harmful side effects, a lack of efficacy or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and/or achieve market acceptance;
- a product candidate we develop and seek regulatory approval for may not be approved by the FDA on a timely basis, or at all;
- product candidates we develop may nevertheless be covered by third party patents or other exclusive rights;
- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer commercially reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third party payors, if applicable.

If any of these events occur, we may be forced to abandon our R&D efforts for one or more of our programs, or we may not be able to identify, discover, develop or commercialize additional product candidates, including those that may be in-licensed or acquired, which may have a material adverse effect on our business.

Because we have limited financial and managerial resources, we have focused on products, research programs and product candidates for specific indications. As a result, we have had to, and in the future may need to, forgo or delay pursuit of opportunities with other product candidates or for other indications, or may out license rights to product candidates, that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities on a timely basis, or at all. Our spending on current and future R&D programs and product candidates for specific indications may not yield any commercially viable products.

Because our internal research capabilities are limited, we may be dependent upon other pharmaceutical and biotechnology companies, academic scientists and institutions, and other researchers to sell or license product candidates, products or technology to us. As a result, our rights to these product candidates may be limited or we may be required to make future payments to such third parties if we are successful in developing such product candidates. For example, under the terms of the Q32 Purchase Agreement, we (i) will make an additional upfront payment to Q32 in an amount equal to $3.0 million on the sixth-month anniversary of the APA Closing Date, (ii) will make certain milestone payments upon the achievement of specified development and regulatory milestone events related to AKB-097 up to an aggregate amount equal to $94.5 million,

including a $2.0 million development milestone payment upon the earlier of initiation of a Phase 2 clinical trial and December 31, 2026, (iii) will make certain milestone payments upon the achievement of specified commercial milestone events with respect to the net sales of AKB-097 up to an aggregate amount equal to $487.5 million, and (iv) will make certain royalty payments based on the net sales of AKB-097 with royalty percentage tiers ranging from the low single digits to mid-teen percentages. The success of this strategy depends partly upon our ability to identify, select, and acquire promising product candidates and products. The process of identifying, selecting, negotiating and implementing a license or acquisition of a product candidate or an approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of a product candidate or an approved product. We have limited resources to identify and execute the acquisition or in-licensing of third party products, businesses, and technologies and integrate them into our current infrastructure.

Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts, such as with respect to the acquisition of our clinical-stage development candidate AKB-097 and the in-license of our clinical-stage development candidate praliciguat. Any product candidate that we acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA, the EMA, the Japanese Pharmaceuticals and Medical Devices Agency, or PMDA, or other regulatory authorities, or post-approval testing or other requirements if approved. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any of our products will be manufactured in a cost effective manner, achieve market acceptance or not require substantial post-marketing clinical trials.

Accordingly, there can be no assurance that we will ever be able to identify, acquire, in-license or develop suitable additional products or product candidates, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential products, product candidates or other programs that ultimately prove to be unsuccessful.

We may engage in strategic transactions to acquire assets, businesses, or rights to products, product candidates or technologies or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense.

As part of our business strategy, we may engage in additional strategic transactions to expand and diversify our portfolio, including through the merger, acquisition or in-license of assets, businesses, or rights to products, product candidates or technologies or through strategic alliances or collaborations, similar to the Merger and our existing and prior collaboration and license arrangements. We may not identify suitable strategic transactions, or complete such transactions in a timely manner, on favorable terms, on a cost-effective basis, or at all. Moreover, we may devote resources to potential opportunities that are never completed or we may incorrectly judge the value or worth of such opportunities. Even if we successfully execute a strategic transaction, we may not be able to realize the anticipated benefits of such transaction and may experience losses related to our investments in such transactions. Integration of an acquired company or assets into our existing business may not be successful and may disrupt ongoing operations, require the hiring of additional personnel and the implementation and integration of additional internal systems and infrastructure, and require management resources that would otherwise focus on developing our existing business. Even if we are able to achieve the long-term benefits of a strategic transaction, our expenses and short-term costs may increase materially and adversely affect our liquidity. Any of the foregoing could have a detrimental effect on our business, results of operations and financial condition. For example, the acquisition of AKB-097 on November 28, 2025 is expected to increase research and development expenses and require significant management attention for integration, which could divert resources from other priorities, raise short-term costs, and adversely affect our liquidity. In addition, on June 4, 2021, we entered into a license agreement, or the Cyclerion Agreement, with Cyclerion Therapeutics Inc., or Cyclerion, pursuant to which Cyclerion granted us an exclusive global license under certain intellectual property rights to research, develop and commercialize praliciguat, an investigational oral, once-daily soluble guanylate cyclase stimulator being evaluated for the treatment of biopsy-confirmed focal segmental glomerulosclerosis, a rare kidney disease, with plans to assess its use in other rare podocytopathies in the future. In December 2024, we entered into an amendment to the Cyclerion Agreement and we now control all clinical and commercial manufacturing of praliciguat, which will be conducted by a third-party manufacturer. Although we needed to do additional work to manufacture product for clinical trials than originally anticipated before we could initiate the trial for praliciguat, on January 6, 2026, we announced that the first patient was dosed in a Phase 2 clinical trial in the U.S. However, even though the clinical trial has started, we may be unsuccessful in developing praliciguat. If any of the assumptions that we made in valuing the transactions, including the costs or timing of development of AKB-097 or praliciguat, or the potential benefits of AKB-097 or praliciguat, were incorrect, we may not recognize the anticipated benefits of the transactions and our business could be harmed.

In addition, future transactions may entail numerous operational, financial and legal risks, including:

- incurring substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- exposure to known and unknown liabilities, including contingent liabilities, possible intellectual property infringement claims, violations of laws, tax liabilities and commercial disputes;

- higher than expected acquisition and integration costs;
- difficulty in integrating operations, processes, systems and personnel of any acquired business;
- increased amortization expenses or, in the case of a write-down of the value of acquired assets, impairment losses, and corresponding adjustments to the estimated useful life of the developed product rights for Auryxia;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain personnel, customers, distributors, vendors and other business partners integral to an in-licensed or acquired product, product candidate or technology;
- potential failure of the due diligence processes to identify significant problems, liabilities or other shortcomings or challenges;
- entry into indications or markets in which we have no or limited development or commercial experience and where competitors in such markets have stronger market positions;
- entry into therapeutic modalities, such as biologics, that differ significantly from our existing small-molecule expertise, potentially requiring the recruitment of personnel with new technical, regulatory, manufacturing, and commercialization capabilities; and
- other challenges associated with managing an increasingly diversified business.

If we are unable to successfully manage any transaction in which we may engage, our ability to develop new products and continue to expand and diversify our portfolio may be limited.

Risks Related to our Financial Arrangements

Our obligations in connection with the BlackRock Credit Agreement and requirements and restrictions in the BlackRock Credit Agreement could adversely affect our financial condition and restrict our operations.

We entered into the BlackRock Credit Agreement, which provides for a senior secured term loan facility, in the aggregate principal amount of $55.0 million, or the Term Loan Facility. The initial tranche of $37.0 million, or the Tranche A Loan, closed on January 29, 2024, or the Closing Date, an additional amount of $8.0 million, or the Tranche B Loan, was drawn on April 19, 2024, and an additional $10.0 million was drawn on February 3, 2025, or the Tranche C Loan and, together with the Tranche A Loan and the Tranche B Loan, the Term Loans. See Note 7, *Indebtedness*, to our consolidated financial statements in Part II, Item 8. Financial Statements and Supplementary Data of this Form 10-K for additional information regarding our obligations under the BlackRock Credit Agreement. The Term Loan Facility has a maturity date of January 29, 2028, or the Maturity Date.

The BlackRock Credit Agreement contains certain representations and warranties, affirmative covenants, negative covenants, financial covenants, events of default and other provisions and conditions that are customarily required for similar financings. The financial covenants under the BlackRock Credit Agreement require us to either (i) maintain cash and cash equivalents, measured as of the last day of each fiscal month, greater than or equal to $15.0 million or (ii) earn consolidated revenue, measured as of the last day of each fiscal month for the trailing twelve-month period, of $150.0 million. Failure to maintain compliance with these or other covenants would result in an event of default under the BlackRock Credit Agreement, which could result in enforcement action, including acceleration of amounts due under the BlackRock Credit Agreement, or limit our ability to make certain payments under the Vifor Termination Agreement.

The Term Loan Facility will accrue interest at a floating annual rate equal to the sum of (x) term Secured Overnight Financing Rate for a tenor of one month (subject to a floor of 4.25% per annum) plus (y) a margin of 6.75% per annum (subject to an overall cap of 15.00% per annum on the all-in interest rate). During the continuance of any payment event of default under the BlackRock Credit Agreement, the interest rate on such overdue sum will automatically increase by an additional 3.0% per annum, and may be subject to an additional late fee of 2.0% of such overdue sum. The Term Loan Facility does not amortize during the period commencing on the Closing Date and ending on December 31, 2026 (as extended at our option), or the Interest Only Period. We are required to pay interest and, after the Interest Only Period, principal on the first calendar day of each month. In the event of certain prespecified events, the repayment schedule will be accelerated. If any of these events occur, and we are required to repay principal sooner than we anticipate, it would have an adverse effect on our business.

In the event there is an acceleration of our and certain of our subsidiaries' liabilities under the BlackRock Credit Agreement as a result of an event of default or otherwise, we may not have sufficient funds or may be unable to arrange for additional financing to repay the liabilities or to make any accelerated payments, and BlackRock could seek to enforce security interests in the collateral securing the BlackRock Credit Agreement, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, our obligations in connection with the BlackRock Credit Agreement could have additional significant adverse consequences, including, among other things:

- restricting our activities, including limitations on transferring certain of our assets, engaging in certain transactions, terminating certain agreements, incurring certain additional indebtedness, creating certain liens, paying cash dividends or making certain other distributions and investments;
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry;
- placing us at a possible competitive disadvantage compared to our competitors who have a smaller amount of debt or competitors with comparable debt at more favorable interest rates; and
- limiting our ability to borrow additional amounts for working capital, capital expenditures, R&D efforts, acquisitions, debt service requirements, execution of our business strategy and other purposes.

Any of these factors could materially and adversely affect our business, financial condition and results of operations.

Our Royalty Interest Acquisition Agreement with HealthCare Royalty Partners IV, L.P. contains various covenants and other provisions, which, if violated, could materially adversely affect our financial condition.

In February 2021, we entered into a royalty interest acquisition agreement, or the Royalty Agreement, with HealthCare Royalty Partners IV, L.P., or HCR, pursuant to which we sold to HCR our right to receive royalties and sales milestones for Vafseo, collectively the Royalty Interest Payments, in each case, payable to us under our Collaboration Agreement dated December 11, 2015, or the TPC Agreement, with Tanabe Pharma Corporation, formerly Mitsubishi Tanabe Pharma Corporation, or TPC, subject to an annual maximum "cap" of $13.0 million, or the Annual Cap, and an aggregate maximum "cap" of $150.0 million, or the Aggregate Cap. Under the Royalty Agreement, we are required to comply with various covenants, including obligations to take certain actions, such as actions with respect to the Royalty Interest Payments, the TPC Agreement, our agreement with TPC for the commercial supply of Vafseo drug product, and our intellectual property. In addition, the Royalty Agreement includes customary events of default upon the occurrence of enumerated events, including failure to perform certain covenants and the occurrence of insolvency events. Upon the occurrence of an event of default, HCR would have the ability to exercise all available remedies in law and equity, which could have a material adverse effect on our financial condition.

Risks Related to Commercialization

Our business is substantially dependent on the commercial success of Auryxia and Vafseo. If we are unable to continue to successfully commercialize Auryxia and Vafseo, our results of operations and financial condition will be materially harmed.

Our business and our ability to generate product revenue largely depend on our, and our collaborators', ability to successfully commercialize Auryxia and Vafseo. Our ability to generate revenue depends on our ability to execute on our commercialization plans, and the size of the market for, and the level of market acceptance of, Auryxia, Vafseo and any other product or product candidate, including those that may be in-licensed or acquired. If we are not able to maintain contracts with dialysis organizations and other customers for the sale of Auryxia and Vafseo on favorable terms, or at all, our revenue and results of operations will be adversely affected. If the size of any market for which a product or product candidate is approved decreases or is smaller than we anticipate, our revenue and results of operations could be materially adversely affected. For example, the approval for Vafseo in the U.S. is limited to the treatment of anemia due to CKD in adults who have been receiving dialysis for at least three months instead of all such adults. This limitation could affect the level of market acceptance of Vafseo.

We had exclusive rights under a series of patents and patent applications to commercialize Auryxia in the U.S. that protected us from generic drug competition until March 20, 2025. Following LoE, the number of generic versions of Auryxia that enter the market, and the timing thereof, will adversely affect our revenue from Auryxia. On February 5, 2025, we entered into an Authorized Generic Distribution and Supply Agreement with Mylan Pharmaceuticals, Inc., or AG Distributor, as amended in September 2025, pursuant to which, since March 20, 2025, they have been selling an authorized generic version of Auryxia. On January 22, 2026, Pharmaceuticals Ltd., or Teva, received tentative approval for its Abbreviated New Drug Application for Auryxia. Currently, there is only one authorized generic for Auryxia sold by our distributor, but we expect additional generic competition in 2026. If additional generic versions of Auryxia are approved and enter the market, we expect it will adversely impact our revenue. However, the impact on future Auryxia revenues will depend on many factors, including our ability to maintain contracts with dialysis organizations, the timing and number of additional generics and the pricing of generics and other products on the market that compete with Auryxia.

Given the concentration of dialysis clinics in large networks, with DaVita, Inc., or DaVita, Fresenius Kidney Care Group LLC, or Fresenius, and U.S. Renal Care, or USRC, accounting for a vast majority of the dialysis population in the U.S., treatment is usually driven by medical protocols that are implemented across the entire network of clinics. Dialysis organizations require large data sets to adopt medical protocols and often have lengthy processes to implement and operationalize the protocol and make the new therapy available for patients. In addition, some dialysis organizations have medical protocols that require specific steps once Vafseo is prescribed that lengthens the time before the patient starts treatment, delaying initial adoption.

If dialysis organizations do not add Vafseo to their medical protocols in a timely manner, or at all, or do not keep Vafseo on their medical protocols, or maintain protocols that delay treatment initiation by requiring additional steps, or if the protocols service smaller populations than the current label, our results of operations could be materially adversely affected. For example, in 2025, physicians initiating and, in some cases, maintaining, patients on therapy within the highly protocolized dialysis environment took longer than we expected. In the year ended December 31, 2025, most Vafseo revenue was driven by mid-sized dialysis organizations. If we are unable to increase sales to the large dialysis organizations and other medium-sized dialysis organizations, our results of operations will be negatively impacted.

Oral-only phosphate binders, including Auryxia, are included in the end-stage renal disease, or ESRD, Prospective Payment System, or PPS, bundle payment, as of January 2025. In addition, dialysis organizations may choose lower cost binders over Auryxia, or binders that may have features or benefits more aligned with the dialysis organization's operational activities, which could negatively impact Auryxia revenue. We believe our revenue growth for Auryxia has been negatively impacted since 2021 primarily as the CKD patient populations we serve experienced both high hospitalization and mortality rates due to COVID-19 and other infectious diseases, and the availability and uses of vaccines, treatments and therapies has increased. Labor shortages and increased costs have also adversely impacted dialysis providers. These impacts have refocused clinical efforts in addressing bone and mineral disorders such as hyperphosphatemia to more acute operational issues to ensure patients receive dialysis treatments. Still some patients have been rescheduled or missed treatments due to labor shortages. In addition, new CKD non-dialysis treatments could slow the progression of CKD non-dialysis patients to dialysis. We believe these factors, among others, have contributed to the continued reduction in the phosphate binder market, which has not experienced growth since early 2020. While we are unable to quantify the impact of these effects on future Auryxia revenues, ongoing impacts from market and patient population challenges could continue to adversely and disproportionately impact CKD patients and the phosphate binder market. Therefore, we expect the impacts from these factors could have a negative impact on our Auryxia revenue for the foreseeable future.

Market acceptance is also critical to our ability to generate significant product revenue. Any product may achieve only limited market acceptance or none at all. If Auryxia, Vafseo or any of our future products is not accepted by the market to the extent that we expect or market acceptance decreases, we may not be able to generate significant product revenue and our business would be materially harmed. For example, an unexpected number of patients initially prescribed Vafseo have discontinued treatment. While we continue to work with dialysis organizations to improve adherence, if a higher than expected number of patient discontinuations persists, or increases, this could negatively impact the market acceptance of Vafseo, and could adversely affect our financial results. Market acceptance of Auryxia, Vafseo or any other approved product depends on a number of factors, including:

- the availability of adequate coverage and reimbursement by, and the availability of discounts, rebates and price concessions to dialysis organizations, third party payors, pharmacy benefit managers, or PBMs, and governmental authorities;
- use at dialysis organizations and their willingness to include or continue to include Auryxia or Vafseo in their formulary or protocols and the scope of such protocols;
- the safety and efficacy of the product, as demonstrated in clinical trials and in the post-marketing setting;
- patients' adherence or non-adherence to the prescribed treatment regimen;
- the prevalence and complications of the disease treated by the product;
- the clinical indications for which the product is approved and the product label approved by regulatory authorities, including any warnings or limitations that may be required on the label as a consequence of potential safety risks associated with the product;
- the countries in which marketing approvals are obtained;
- the claims we and our partners are able to make regarding the safety and efficacy of the product;
- the success of our physician and patient communications and education programs;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety and efficacy of the product in relation to alternative treatments;
- the timing of receipt of marketing approvals and product launch relative to competing products and potential generic entrants;
- the success of, or withdrawal from the market of, competing products;
- the price of competing products;
- relative convenience and ease of administration;
- the frequency and severity of adverse side effects;

- favorable or adverse publicity about our products or favorable or adverse publicity about competing products;
- the effectiveness of our and our partners' sales, marketing, manufacturing and distribution strategies and operations; and
- the restrictions on the use of the product together with other medications, if any.

In addition, our ability to generate net product revenue depends on our ability to control the expenses associated with commercializing a product, including internal expenses, manufacturing costs, rebates, product returns and other adjustments. We do not have control over many of the expenses required to commercialize our products, and if we experience increased costs or expenses, we may not be able to afford the commercial activities required to successfully commercialize our products, which could have an adverse effect on our business. In addition, our net product revenue requires judgment and includes estimates for rebates and product returns, which can fluctuate from quarter-to-quarter and year-over-year. If our net product revenue is lower than anticipated, including as a result of higher expenses or product returns, our business could be harmed.

If we are unable to maintain sales and marketing capabilities or enter into or maintain agreements with third parties, we may not be successful in commercializing Auryxia, Vafseo or any other product candidates that may be approved.

In order to market Auryxia, Vafseo and any other approved product, we intend to continue to invest in sales and marketing, which will require substantial effort and significant management and financial resources. We have built a commercial infrastructure and sales force in the U.S. for Auryxia and Vafseo. If the sales and marketing team cannot successfully commercialize Auryxia or Vafseo, it could have a material adverse effect on our product revenue and our financial condition.

For example, certain restrictions on access for members of our sales force to dialysis organizations have negatively impacted, and may continue to negatively impact, our ability to market Vafseo to healthcare providers, which could ultimately affect our sales of Vafseo. Furthermore, additional restrictions on access to healthcare providers could be imposed in the future, including as a result of outbreaks of infectious diseases. Such restrictions could result in slower adoption of Vafseo, declines or changes in prescription trends and customer orders, and could have a material adverse effect on our business, results of operations, and financial condition.

Additionally, training a sales force to successfully sell and market a new commercial product is expensive and time consuming and could delay any commercial launch or market acceptance of such product. We may underestimate the size of the sales force required for a successful product launch, and we may need to expand our sales and marketing team, which would increase our costs more than we anticipated.

We devote significant effort to recruiting individuals with experience in the sales and marketing of pharmaceutical products. Competition for personnel with these skills is significant and retaining qualified personnel with experience in our industry is difficult. If key sales and marketing employees decide to leave, we may not be able to hire and train new employees quickly enough to meet our needs. At the same time, we may face high turnover, requiring us to expend time and resources to source, train and integrate new employees.

There are risks involved with maintaining our own sales and marketing capabilities, including the following:

- potential inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- potential lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- costs and expenses associated with maintaining our own sales and marketing organization.

If we are unable to maintain our own sales and marketing capabilities, we will not be successful in commercializing Auryxia, Vafseo and any other product candidate that may be approved. Also, if we are unable to maintain our arrangements with third parties with respect to sales and marketing, if we are unsuccessful in entering into additional arrangements with third parties to sell and market our products or we are unable to do so on terms that are favorable to us, or if such third parties are unable to carry out their obligations under such arrangements, it will be difficult to successfully commercialize our product and product candidates, including Vafseo.

Our, or our partners', failure to obtain or maintain adequate coverage, pricing and reimbursement for Auryxia, Vafseo or any other future approved products, could have a material adverse effect on our or our collaboration partners' ability to sell such approved products profitably and otherwise have a material adverse impact on our business.

Market acceptance and sales of any approved products, including Auryxia and Vafseo, depend significantly on the availability of adequate coverage and reimbursement from third party payors and may be affected by existing and future healthcare reform measures. Governmental authorities, dialysis organizations, third party payors, and PBMs decide which drugs they will cover, as well as establish formularies or implement other mechanisms to manage utilization of products and determine

reimbursement levels. We cannot be sure that coverage or adequate reimbursement will be available for Auryxia, Vafseo or any of our potential future products. Even if we obtain coverage for an approved product, third party payors may not establish adequate reimbursement amounts, which may reduce the demand for our product and prompt us to have to reduce pricing for the product. If reimbursement is not available or is limited, we may not be able to successfully commercialize certain of our products. Coverage and reimbursement by a governmental authority, dialysis organization, third-party payor or PBMs may depend upon a number of factors, including the determination that use of a product is:

- a covered benefit under the health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient; and
- cost effective.

Obtaining coverage and reimbursement approval for a product from a governmental authority, dialysis organization, PBM or a third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. In the U.S., there are multiple governmental authorities, PBMs and third-party payors with varying coverage and reimbursement levels for pharmaceutical products, and the timing of commencement of reimbursement by a governmental payor can be dependent on the assignment of codes via the Healthcare Common Procedural Coding System, which codes are assigned on a quarterly basis. Within Medicare, for oral drugs dispensed by pharmacies and also administered in facilities, coverage and reimbursement may vary depending on the setting. Centers for Medicare & Medicaid Services, or CMS, local Medicare administrative contractors, Medicare Advantage and/or Part D plans and/or PBMs operating on behalf of such plans, may have some responsibility for determining the medical necessity of such drugs, and therefore coverage, for different patients. Different reimbursement methodologies may apply, and CMS may have some discretion in interpreting their application in certain settings.

As an oral drug, Auryxia was covered by Medicare under Part D until January 1, 2025, for the treatment of patients with hyperphosphatemia. In January 2011, CMS implemented the ESRD PPS, a prospective payment system for dialysis treatment. Under the ESRD PPS, CMS generally makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at their home. As of January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including Auryxia and all other phosphate lowering medications, are included in the ESRD bundle and separate Part D Medicare payment for these drugs is no longer available. However, dialysis organizations will receive a Transitional Drug Add-on Payment Adjustment, or TDAPA, payment for claims that include phosphate binders through the end of 2026. Vafseo, which we began selling in January 2025, is also included in the ESRD bundle and ESRD facilities will receive a TDAPA for Vafseo as a new renal dialysis drug meeting certain criteria for a period of two years starting on January 1, 2025. TDAPA provides separate payment based on the drug's Average Sales Price, or ASP, that will be in addition to the base rate in order to facilitate the adoption of innovative therapies. If the TDAPA reimbursement amount for Auryxia or Vafseo is lower than anticipated, or if the TDAPA is eliminated, it would have an adverse impact on our revenue. Additionally, after the TDAPA period, CMS currently expects to increase the single bundled payment base rate paid to the dialysis facility for each dialysis treatment to reflect the cost of phosphate lowering medications, including Auryxia and for Vafseo. However, the increase related to Vafseo will only last three years and neither Auryxia nor Vafseo will receive a direct additional payment outside the bundled rate after the TDAPA period. There can be no assurances that any increase in the single bundled payment base rate will be sufficient to adequately reimburse the dialysis facilities for Auryxia at a price that allows us to continue to sell Auryxia or Vafseo at a profit.

In late 2025, legislation was introduced in the U.S. Congress, the Kidney Care Access Protection Act, or KCAPA, which seeks to maintain patient access to innovative kidney care treatments, including Vafseo, by addressing reimbursement challenges following TDAPA expiration. Without such legislation, there is a risk that, in the post-TDAPA period, reduced reimbursement could limit provider adoption of Vafseo, restrict patient access and adversely impact our revenue.

In July 2024, Ardelyx, Inc., or Ardelyx, filed a complaint in the United States District Court for the District of Columbia against the U.S. Department of Health and Human Services, or HHS, CMS and other parties, which alleged that CMS's plan to include oral-only phosphate lowering therapies in the ESRD PPS violated its statutory and regulatory authority under the Medicare Improvements for Patients and Providers Act, which established the ESRD PPS bundled payment system for dialysis services. In October 2024, Ardelyx filed a motion for a preliminary injunction to enjoin CMS from including oral-only phosphate lowering therapies in the ESRD PPS. CMS had earlier filed a motion to dismiss the complaint on jurisdictional grounds. On November 8, 2024, the district court denied Ardelyx's motion for a preliminary injunction and it granted the government's motion to dismiss. Thereafter, Ardelyx moved for reconsideration, but the district court also denied that request. On December 26, 2024, Ardelyx filed a notice of appeal with the U.S. Court of Appeals for the DC Circuit. Briefing of the case has been completed and oral argument was held on September 25, 2025. If Ardelyx is successful in its claims, oral-only phosphate lowering therapies, including Auryxia, may be removed from the ESRD bundle, which could reduce anticipated revenue for Auryxia.

Medicaid reimbursement of drugs varies by state. Private third-party payor reimbursement policies also vary and may or may not be consistent with Medicare reimbursement methodologies. Manufacturers of outpatient prescription drugs may be required to provide discounts or rebates under government healthcare programs or to certain third-party payors in order to obtain coverage of such products.

Additionally, we have and will continue to enter into contracts with dialysis organizations, GPOs, third party payors and/or PBMs offering rebates or discounts on our products in order to obtain favorable formulary status and we may not be able to agree upon commercially reasonable terms with such dialysis organizations, GPOs, third party payors or PBMs, or provide data sufficient to obtain favorable coverage and reimbursement for many reasons, including that we may be at a competitive disadvantage relative to companies with more extensive product lines. In addition, dialysis organizations, GPOs, third party payors, PBMs and/or other entities that purchase our products may impose restrictions on our ability to raise prices for our products over time without incurring additional costs. Three dialysis organizations, DaVita, Fresenius Medical Care Rx and USRC, in the aggregate, accounted for a significant percentage of our gross revenue from Auryxia and Vafseo during the year ended December 31, 2025. If we are not able to maintain supply agreements with these, and other, dialysis organizations for the sale of Vafseo and Auryxia on favorable terms, in a timely basis or at all, our business may be materially harmed.

Due to a variety of factors, including coverage of our products in the ESRD bundle and to support commercial availability of Vafseo in 2025, there were changes to the manner in which we distributed our products, which we implemented in January 2025. This included, for example, reducing the number of mainline wholesalers in our distribution network, distribution of products through specialty distributors, and an increased focus on direct sales through contracts with dialysis organizations. If we are not able to enter into and maintain agreements with wholesalers, specialty distributors, the dialysis organizations and other purchasers for the sale of our products on favorable terms, on a timely basis or at all, our business may be materially harmed. We also began to ship Vafseo directly to certain dialysis clinics, which requires additional oversight and logistics, and if this new distribution model is not successful or requires more resources than we anticipate, it could negatively impact our business. In addition, if dialysis organizations or other purchasers do not purchase as much product as we anticipate or terminate our arrangements, or if due to changes in distribution, dialysis organizations and/or specialty pharmacies are not able to meet market demand causing slower dispensing times and potentially impacting refill rates, it would adversely impact the market opportunity for our products, our product revenues and operating results.

Similar to how payor coverage may affect the sales of a product, formulary status within dialysis organizations may affect what products are prescribed within that specific organization. Therefore, if a product is not on a formulary, the prescribers within that organization may be less likely to prescribe that product or may have a difficult time prescribing that product, resulting in less sales. Further, one dialysis organization’s determination to add a product to their formulary does not assure that other dialysis organizations will also add the product to theirs. There is always a risk a dialysis organization will not contract with a drug manufacturer for a specific product, or will terminate their contract, resulting in that product not being on that organization’s formulary. If any dialysis organization does not add Auryxia or Vafseo to the formulary, or removes Auryxia or Vafseo from the formulary, our business may be materially harmed.

In addition, we may be unable to sell Auryxia or Vafseo to dialysis providers on a profitable basis if CMS significantly reduces the level of reimbursement for dialysis services and providers choose to use alternative therapies or look to re-negotiate their contracts with us. Our profitability may also be affected if our costs of production increase faster than increases in reimbursement levels. Adequate coverage and reimbursement of our products by government and private insurance plans, including Medicare Advantage plans, are central to patient and provider acceptance of any products for which we receive marketing approval. Existing competitive products may enter into sole source agreements with dialysis providers that impact the ability for new product innovations and new competitors may face price pressure based on existing contracts with dialysis providers.

Further, in many countries outside the U.S., a drug must be approved for reimbursement before it can be marketed or sold in that country. In some cases, the prices that we intend to charge for our products are also subject to approval. Approval by the EMA or another regulatory authority does not ensure approval by reimbursement authorities in that jurisdiction, and approval by one reimbursement authority outside the U.S. does not ensure approval by any other reimbursement authorities.

However, the failure to obtain reimbursement in one jurisdiction may negatively impact the ability to obtain reimbursement in another jurisdiction. In addition, we plan to rely on partners to obtain approval by reimbursement authorities outside the U.S. Our partners may not be able to obtain such reimbursement approvals on a timely basis, if at all, and favorable pricing in certain countries depends on a number of factors, some of which are outside of our partners' control. Vafseo was approved in Japan for the treatment of adult patients with anemia due to CKD and is being marketed by TPC in Japan under the trade name Vafseo. Pricing and reimbursement strategy is a key component of TPC’s commercialization plans for Vafseo in Japan. If coverage and reimbursement terms change, TPC may not be able to, or may decide not to, continue commercialization of Vafseo in Japan. Furthermore, Vafseo was approved in Europe and Australia for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis. In Europe, reimbursement is obtained on a country-by-country basis and it is a time consuming process. In May 2023, we entered into the license agreement with Medice, pursuant to which

we granted Medice an exclusive license to develop and commercialize Vafseo for the treatment of anemia in patients with CKD in the Medice Territory. Medice launched and has received pricing and reimbursement for Vafseo in certain countries in Europe and is working on launching and securing pricing and reimbursement for Vafseo in other markets across Europe. There is no guarantee of the timing or extent of reimbursement that they will receive in each country, if at all. If Medice is not able to obtain favorable pricing in the Medice Territory, or if such approvals are delayed, it will affect Medice's sales of Vafseo in the Medice Territory, which could have an adverse effect on our results of operations.

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.

The development and commercialization of new drugs is highly competitive and subject to rapid and significant technological change. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the development and commercialization of Auryxia, Vafseo and any other product or product candidate, including those that may be in-licensed or acquired. Our objective is to successfully commercialize Auryxia and Vafseo and develop and commercialize new products with clinically proven efficacy, convenience, tolerability and/or safety. In many cases, any approved products that we commercialize will compete with existing, market-leading products. If existing or new competitors of Auryxia or Vafseo take market share from us, it could have an adverse impact on our revenue and our business.

We had exclusive rights under a series of patents and patent applications to commercialize Auryxia in the U.S. that protected us from generic drug competition until March 20, 2025. Following LoE, the number of additional generic versions of Auryxia that enter the market, and the timing thereof, will affect our revenue from Auryxia. We and our licensors entered into settlement agreements with all of the third parties who submitted Paragraph IV certification notice letters regarding Abbreviated New Drug Applications, or ANDAs, submitted to the FDA, pursuant to which we granted licenses to market a generic version of Auryxia in the U.S. beginning on March 20, 2025 (subject to FDA approval). In addition, on February 5, 2025, we entered into an Authorized Generic Distribution and Supply Agreement with our AG Distributor, pursuant to which, since March 20, 2025, they have been selling an authorized generic version of Auryxia. On January 22, 2026, Teva received tentative approval for its ANDA for Auryxia. Currently, there is only one authorized generic for Auryxia sold by our distributor, but we expect additional generic competition in 2026. If additional generics are approved and enter the market, we expect it will adversely impact our revenue. However, the impact on future Auryxia revenues will depend on many factors, including our ability to maintain contracts with dialysis organizations, the timing and number of additional generics and the pricing of generics and other products on the market that compete with Auryxia.

Auryxia is competing in the hyperphosphatemia market in the U.S. with other FDA-approved phosphate binders such as Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate), both marketed by Sanofi, PhosLo® and Phoslyra® (calcium acetate), marketed by Fresenius Medical Care North America, Fosrenol® (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, and Velphoro® (sucroferric oxyhydroxide), marketed by Fresenius Medical Care North America, as well as over-the-counter calcium carbonate products such as TUMS® and metal-based options such as aluminum, lanthanum and magnesium. Most of the phosphate binders listed above are now also available in generic forms. In addition, other agents are in development, including OPKO Health Inc.'s Alpharen™ Tablets (fermagate tablets) and Unicycive's RENAZORB™ (lanthanum dioxycarbonate), or could otherwise enter the market that may impact the market for Auryxia. XPHOZAH® (tenapanor), a phosphate absorption inhibitor that is marketed by Ardelyx, is indicated to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy, which may adversely impact the market for Auryxia.

Auryxia is competing in the iron deficiency anemia, or IDA, market in the U.S. with over-the-counter oral iron, ferrous sulfate, other prescription oral iron formulations, including ferrous gluconate, ferrous fumerate, and polysaccharide iron complex, and intravenous iron formulations, including Feraheme® (ferumoxytol injection), Venofer® (iron sucrose injection), Ferrlicit® (sodium ferric gluconate complex in sucrose injection), Injectafer® (ferric carboxymaltose injection), and Triferic® (ferric pyrophosphate citrate). In addition, other new therapies for the treatment of IDA may impact the market for Auryxia, such as Shield Therapeutics plc's Feraccru® (ferric maltol), which is available in Europe for the treatment of IDA and Accrufer® (ferric maltol), which was launched in the U.S. for the treatment of IDA in July 2021.

In Japan, our Japanese sublicensees, Japan Tobacco International (succeeded by Shionogi & Co., Ltd.), or JT, and its subsidiary, Torii Pharmaceutical Co., Ltd., or Torii, commercialize Riona. In the hyperphosphatemia market, Riona competes with Fosrenol® (lanthanum carbonate hydrate) marketed by Bayer Yakuhin Ltd., generic lanthanum carbonate hydrate products, and Phozevel® (tenapor hydrochloride) marketed by Kyowa Kirin Co., Ltd. In the IDA market in Japan, Riona competes with Ferromia® (sodium ferrous citrate) marketed by Alfresa Pharma Corporation and Fero-Gradumet® (dried ferrous sulfate) marketed by Viatris Inc.

Furthermore, Auryxia's commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective, safer or offer greater patient convenience than Auryxia. Other companies

have product candidates in various stages of preclinical or clinical development to treat diseases and complications of the diseases for which we are marketing Auryxia.

Drugs that compete with Vafseo include Epogen® (epoetin alfa) and Aranesp® (darbepoetin alfa), both commercialized by Amgen in the U.S. and Europe, Procrit® (epoetin alfa) and Eprex® (epoetin alfa), commercialized by Johnson & Johnson in the U.S. and Europe, respectively, Mircera® (methoxy PEG-epoetin beta), commercialized by CSL Vifor in the U.S. and Roche Holding Ltd., or Roche, outside of the U.S., Evrenzo® (roxadustat) in Europe commercialized by Astellas Pharma Inc., or Astellas, Eporatio® (epoetin theta) in Europe commercialized by Teva Pharmaceuticals Ltd., Silapo® (epoetin zeta) in Europe commercialized by Stada Arzneimittel AG, Epoetin Alfa Hexal® (epoetin alfa) in Europe commercialized by Hexal AG, Binocrit® (epoetin alfa-biosimilar) in Europe commercialized by Sandoz, and NeoRecormon® (epoetin beta) in Europe commercialized by Roche.

We and our partners may also face competition from potential new anemia therapies. There are several other oral hypoxia-inducible factor prolyl hydroxylase inhibitor product candidates in various stages of development for anemia indications in territories outside the U.S. that may be in direct competition with Vafseo if and when they are approved and launched commercially. These candidates are being developed by companies such as JT and Bayer HealthCare AG, or Bayer. In Europe, roxadustat is approved for the treatment of anemia in patients with CKD.

Furthermore, certain companies are developing potential new therapies for the treatment of renal-related diseases that could potentially reduce injectable erythropoiesis stimulating agent, or ESA, utilization and thus limit the market potential for Vafseo if they are approved and launched commercially. Other new therapies are in development for the treatment of conditions inclusive of renal anemia that may impact the market for anemia-targeted treatment. In addition, other new therapies for the treatment of patients with CKD not on dialysis, or NDD-CKD, may slow the progression of NDD-CKD patients becoming patients with dialysis dependent CKD, or DD-CKD, thereby reducing the DD-CKD patient population which may impact the market opportunity for Vafseo.

In Japan, vadadustat is sold under the name Vafseo, which is approved for patients with CKD, including both DD-CKD and NDD-CKD, and competes with roxadustat, daprodustat and enarodustat. Roxadustat is approved for the treatment of DD-CKD patients and NDD-CKD patients. In addition, daprodustat and enarodustat are approved in Japan for the treatment of anemia due to CKD, and molidustat, Bayer HealthCare AG's product, is approved in Japan for the treatment of renal anemia. In China, roxadustat is commercialized for the treatment of anemia due to CKD in DD-CKD patients and for the treatment of anemia due to CKD in NDD-CKD patients.

A biosimilar is a biologic product that is licensed for marketing based on demonstrating that it is highly similar to an existing, FDA-approved branded biologic product (i.e., a reference biologic product). The patents for the existing, branded biologic product must expire in a given market before biosimilars may enter that market without the risk of being sued for patent infringement. In addition, an application for a biosimilar product can only be approved by the FDA 12 years after the existing, branded product was licensed under a Biologics License Application, or BLA. The patents for epoetin alfa, an injectable ESA, expired in 2004 in the EU, and expired between 2012 and 2016 in the U.S. The introduction of biosimilars into the injectable ESA market in the U.S. will constitute additional competition for Vafseo. In the U.S., Pfizer’s biosimilar version of injectable ESAs, Retacrit® (epoetin alfa-epbx), was approved by the FDA in May 2018 and launched in November 2018 and several biosimilar versions of injectable ESAs are available for sale in the EU.

There are no approved therapies specifically indicated for the treatment of FSGS although an endothelin receptor blocker is in development and under review by the FDA. Current treatment includes glucocorticoid steroids, calcineurin inhibitors, other immunosuppressives such as rituximab, and antihypertensives such as angiotensin-converting enzymes, such as enalapril, and angiotensin II receptor blockers, such as losartan. These treatments may slow kidney failure progression in some patients with FSGS. There are a number of treatments to address FSGS in development. Travere® Therapeutics Inc. developed FILSPARI® (sparsentan), a dual endothelin and angiotensin II receptor antagonist, which is under review by the FDA with a PDUFA target action date of April 13, 2026. There are additional therapies to address FSGS in development including DMX-200 (repagermanium), in Phase 3 development by Dimerix Limited, and other investigational treatments in Phase 3 or Phase 2 development by companies including Apellis Pharmaceuticals, Inc., or Apellis, Boehringer Ingelheim, Sanofi, Vera Therapeutics, or Vera, and Vertex Pharmaceuticals, or Vertex. Since FSGS is heterogenous in nature, we expect a number of therapies will be needed to fully address the needs of the FSGS patient population. Additionally, a combination of therapies may also provide a beneficial impact for some patients.

We are developing AKB-097 for potential treatment of IgAN, LN and C3G. There are other complement inhibitors and medications in development or approved for treatment of these rare kidney diseases. FABHALTA® (iptacopan) is FDA-approved and marketed by Novartis for reduction of proteinuria in adults with primary IgAN. FILSPARI® (sparsentan) is FDA-approved, indicated to slow kidney function decline in adults with primary IgAN. Both FABHALTA and FILSPARI labeling includes a Risk Evaluation and Mitigation Strategy, or REMS. TARPEYO® (budesonide), an FDA-approved medicine used to reduce the loss of kidney function in adults with primary IgAN, is marketed in the U.S. by Calliditas Therapeutics AB, or

Calliditas (acquired by Asahi Kasei Corporation). VANRAFIA™ (atrasentan), marketed by Novartis, is an endothelin receptor antagonist indicated to reduce proteinuria in adults with primary IgAN. In November 2025, the FDA approved VOYXACT® (sibeprenlimab-szsi) to reduce proteinuria in adults with primary IgAN. VOYXACT is a humanized monoclonal antibody that binds to and blocks A PRoliferation-Inducing Ligand, or APRIL.

In November 2025, Vera was granted FDA Priority Review for their BLA for atacicept for the treatment of IgAN. Atacicept is an investigational recombinant fusion protein that binds to B-cell Activating Factor, BAFF, and APRIL cytokines. Vertex is investigating povetacicept, a dual antagonist of the BAFF and APRIL cytokines, for the treatment of IgAN, and initiated a rolling BLA filing for U.S. accelerated approval. A number of complement inhibitors are in development for the treatment of IgAN by companies including Alexion Pharmaceuticals (ULTOMIRIS, ravulizumab, C5 inhibitor, Phase 3), Apellis (EMPAVELI, pegcetacoplan, C3 inhibitor, Phase 2), and Arrowhead Pharmaceuticals, or Arrowhead (ARO-C3, C3 inhibitor, in Phase 1/2).

There are two FDA-approved complement-inhibitor therapies to reduce proteinuria in C3G patients: FABHALTA® (Novartis, iptacopan, Factor B inhibitor) and EMPAVELI® (Apellis, pegcetacoplan, C3 inhibitor). Both FABHALTA and EMPAVELI labeling includes a REMS. Other complement inhibitors are in development by Kira Pharmaceuticals, with KP104 (dual C5 and Factor H inhibitor) in Phase 2 and Arrowhead with ARO-C3 (C3 inhibitor) in Phase 1/2.

There are three FDA-approved therapies for LN: BENLYSTA (belimumab, GSK), LUPKYNIS® (voclosporin, Aurinia Pharmaceuticals) and GAZYVA (obinutuzumab, Genentech/Biogen). Novartis also is developing ianalumab in Phase 3 and complement inhibitor FABHALTA (iptacopan, Factor B inhibitor) in Phase 2.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products. Large and established companies such as Amgen, Roche and GSK, among others, compete in the market for drug products to treat kidney disease. In particular, these companies have greater experience and expertise in conducting preclinical testing and clinical trials, obtaining marketing approvals, manufacturing such products on a broad scale and marketing approved products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we are developing obsolete. Smaller and other early-stage companies may also prove to be significant competitors. In addition, a number of large pharmaceutical companies and small to mid-sized and specialty biotechnology companies have marketed and are developing treatments for rare kidney diseases, including indications we are pursuing with our mid-stage rare kidney disease pipeline. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval, or discovering, developing and commercializing competitive products, before, or more effectively than, we do. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

The commercialization of ferric citrate, branded as Riona in Japan, Vafseo in Europe, Japan and other territories where it is approved, and our current and potential future efforts with respect to the development and commercialization of our products and product candidates outside of the U.S. subject us to a variety of risks associated with international operations, which could materially adversely affect our business.

Our Japanese sublicensee, JT, and its subsidiary, Torii, commercialize Riona, the trade name for ferric citrate hydrate in Japan, as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including DD-CKD and NDD-CKD, and for the treatment of adult patients with IDA in Japan. In Japan and certain other countries in Asia, we granted TPC exclusive rights to commercialize Vafseo, which has been approved and is being marketed by TPC in Japan under the trade name Vafseo. In May 2023, we entered into the license agreement with Medice, pursuant to which we granted Medice an exclusive license to develop and commercialize Vafseo for the treatment of anemia in patients with CKD in the Medice Territory. Pursuant to the license agreement, we transferred the marketing authorization issued by the EMA, UK, the Swiss Agency for Therapeutic Products and the Australian Therapeutic Goods Administration to Medice. On November 12, 2025, we and Medice entered into Amendment #1 to the license agreement, pursuant to which we agreed to supply vadadustat drug substance to Medice pursuant to the terms of a supply agreement dated concurrently with the license agreement amendment and granted Medice the right to manufacture Vafseo tablets using the vadadustat drug substance to be supplied by us. We also granted Averoa SAS, or Averoa, an exclusive license to develop and commercialize ferric citrate in the EEA, Turkey, Switzerland, UK, Balkans, and certain countries in Eastern Europe and the Middle East, or the Averoa Territory, which has been approved by the EMA under the trade name XOANACYL®.

In addition, we have conducted, plan to conduct for AKB-9090, and in the future may conduct, clinical trials outside of the U.S. for any product or product candidate that may be in-licensed or acquired. As a result of these and other activities, we are or

may become subject to additional risks in developing and commercializing Auryxia and Vafseo and our product candidates outside the U.S., including, among others:

- political, regulatory, compliance and economic developments, weakness or instability that could restrict our ability to manufacture, market and sell our products;
- changes in international medical reimbursement policies and programs;
- changes in healthcare policies of foreign jurisdictions;
- trade protection measures, including import or export licensing requirements and tariffs and our compliance therewith;
- our ability to develop or manage relationships with qualified local distributors and trading companies;
- diminished protection of intellectual property in some countries outside of the U.S.;
- differing labor regulations and business practices;
- compliance with laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, the UK Bribery Act or similar local regulation, the EU General Data Protection Regulation, or GDPR, and similar data protection laws, and tax, employment, immigration and labor laws;
- economic weakness, including inflation, increasing interest rates, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, global pandemics, or natural disasters including earthquakes, typhoons, floods and fires.

In addition, we receive revenues from royalty payments converted to U.S. dollars based on net sales of Riona and Vafseo in Japanese yen, the Euro, the Pound Sterling, the Swiss Franc, and may receive payments in other foreign currencies. The exchange rates between these currencies on the one hand, and the U.S. dollar, on the other hand, have changed substantially in recent years and may fluctuate substantially in the future. Our results of operations could be adversely affected over time by certain movements in exchange rates, particularly if these currencies depreciate against the U.S. dollar.

Any of these factors may, individually or as a group, have a material adverse effect on our business and results of operations. As and if we continue to expand our commercialization efforts, we may encounter new risks.

Risks Related to Product Development

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and we will incur additional costs in connection with, and may experience delays in completing, or ultimately be unable to complete, the development of any of our product candidates.

The risk of failure in drug development is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates, including praliciguat and AKB-097, in humans. Preclinical studies and clinical trials are expensive, difficult to design and implement, can take several years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the process.

We may be unable to successfully complete clinical trials of Auryxia, Vafseo and our product candidates or to successfully obtain approval of any potential label expansion for Vafseo or approval of our product candidates, if the results of those trials and studies are not positive or are only modestly positive, or if there are concerns with the product profile due to efficacy or safety. Further, the results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, interim results of a clinical trial do not necessarily predict final results, and results of Phase 3 clinical trials for one indication may not be predictive of results of Phase 3 clinical trials for another indication. For example, we announced positive results from the INNO$_2$VATE program; however, while Vafseo achieved the primary and key secondary efficacy endpoints in each of the two PRO$_2$TECT studies, the PRO$_2$TECT program did not meet the primary major adverse cardiovascular event, or MACE, safety endpoint. Many companies in the biopharmaceutical industry have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we may face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. For example, in March 2022, we received the CRL for Vafseo indicating that the FDA had determined that it could not approve the NDA in its present form, thus delaying

any potential approval of Vafseo. Following submission of the Formal Dispute Resolution Request, or FDRR, to the FDA in 2022, we filed a resubmission to our NDA for vadadustat for the treatment of anemia due to CKD only in adult DD-CKD patients in 2023. On March 27, 2024, the FDA approved our NDA for vadadustat under the trade name of Vafseo for the treatment of anemia due to CKD in adults who have been receiving dialysis for at least three months. However, we expended significant additional resources to obtain the approval of Vafseo, the approved indication is limited to the treatment of anemia due to CKD in adults who have been receiving dialysis for at least three months and the commercialization of Vafseo was delayed, which had and could continue to have an adverse effect on our business.

We have had several lifecycle management and label expansion opportunities under evaluation for Vafseo, one of which is the potential for alternative dosing, and another of which had been label expansion for the treatment of adult patients with NDD-CKD. Following a Type C meeting with the FDA in October 2025, we believe that, based on the FDA feedback, regulatory alignment on a path forward for the design of the VALOR clinical trial for the use of vadadustat to treat anemia in patients with late-stage CKD not on dialysis would require a significantly larger number of patients than proposed, and accordingly would require meaningfully more time and cost to complete than we anticipated. As a result, we do not plan to initiate the VALOR trial, and therefore will not pursue a broad label for Vafseo for adult patients with NDD-CKD. We continue to engage with the FDA regarding smaller subpopulations of CKD non-dialysis dependent patients where we believe we may be able to align on a potential path forward. Based on our communications to date, however, we remain cautious about a path forward. However, we may be required to complete additional clinical trials before seeking approval for label expansion for a potential smaller subgroup of CKD non-dialysis dependent patients, and we may be required to generate additional clinical data before seeking approval for alternative dosing. Clinical trials are time consuming and expensive, and even though Vafseo is approved for adult patients with anemia due to CKD on dialysis for at least three months, we may not be successful in any of our lifecycle management or label expansion opportunities in the timeframe anticipated by us, or at all. In addition, the FDA may not agree with our study design or we may not successfully demonstrate safety and/or efficacy needed to obtain regulatory approval or we may be unable to start a trial when anticipated or successfully complete a trial when anticipated, or at all. If the clinical trials for our label expansion opportunities are not successful or take longer than anticipated, or if we do not obtain FDA approval of label expansion for alternative dosing or for a potential smaller subgroup of CKD non-dialysis dependent patients in a timely manner, or at all, it could impact future revenue and have an adverse effect on our business. Further, if the results of ongoing clinical trials of Vafseo, including our VOCAL clinical trial or the VOICE clinical trial being conducted by USRC, are not positive or are only moderately positive, it could have an adverse effect on our ability to obtain label expansion for alternative dosing or to commercialize Vafseo. In addition, it is impossible to predict when or if any of our other product candidates will prove effective or safe in humans or will receive marketing approval or on what terms.

We may experience numerous unforeseen events during, or as a result of, preclinical development or clinical trials that could delay, prevent or make more challenging our ability to receive or maintain marketing approval or commercialize our product candidates. We may be required to complete additional clinical trials for Auryxia, Vafseo and any other product or product candidate, including those that may be in-licensed or acquired, in order to obtain or maintain required regulatory approvals. Our preclinical studies and clinical trials may take longer to complete than currently anticipated, or may be delayed, suspended, required to be repeated, prematurely terminated or may not successfully demonstrate safety and/or efficacy needed to obtain or maintain regulatory approval for a variety of other reasons, such as:

- the costs may be greater than we anticipate;
- the number of patients required for clinical trials may be larger than we anticipate;
- enrollment in our clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, such as our contract research organizations, or CROs, may fail to comply with regulatory requirements, perform effectively, or meet their contractual obligations to us in a timely manner, or at all, or we may fail to communicate effectively or provide the appropriate level of oversight of such third-party contractors;
- the supply or quality of our starting materials, drug substance and drug product necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators, independent data monitoring committees, institutional review boards, safety committees, or ethics committees, may require that we suspend or terminate our clinical trials for various reasons, including noncompliance with regulatory requirements, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using our product candidate, or a finding that the participants are being exposed to unacceptable health risks;
- clinical trials of our product candidates may produce negative or inconclusive results or results that may be interpreted in a manner different than we interpret them, and we may decide, or regulators may require us, to conduct additional clinical trials, repeat a clinical trial or abandon product development programs;

- lack of adequate funding to continue a clinical trial, including unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials or repeat a clinical trial and increased expenses associated with the services of our CROs and other third parties;
- we may fail to initiate, delay or fail to complete a clinical trial as a result of an Investigational New Drug application, or IND, being placed on clinical hold by the FDA, the EMA, the PMDA, or other regulatory authorities, or for other reasons, such as failure to recruit or enroll suitable patients or patients' failure to return for post-treatment follow up;
- we may determine to expand or otherwise change a clinical trial, including after it has begun;
- clinical trial sites and investigators deviating from the clinical protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial, or failure by us or our CROs to communicate effectively or provide the appropriate level of oversight of such clinical sites and investigators;
- there may be an inability, delay, or failure in identifying, initiating, and maintaining a sufficient number of clinical trial sites, many of which may already be engaged in other clinical programs;
- there may be a delay or failure in reaching agreement with the FDA, the EMA, the PMDA or other regulatory authorities on a clinical trial design upon which we are able to execute;
- there may be a delay or failure in obtaining authorization to commence a clinical trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- there may be delays in reaching, or failure to reach, agreement on acceptable terms with prospective clinical trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- the FDA, the EMA, the PMDA or other regulatory authorities may require us to submit additional data or impose further requirements before permitting us to initiate a clinical trial or during an ongoing clinical trial;
- the FDA, the EMA, the PMDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials;
- third parties with which we work may fail to comply with good practice quality guidelines and regulations, or GxP, including good laboratory practice, good clinical practice, or GCP, and current good manufacturing practice, or cGMP; or
- there may be changes in governmental regulations or administrative actions.

If any of the foregoing occurs, the following may result:

- regulators may require that we conduct additional clinical trials, repeat clinical trials or conduct other studies beyond those that we currently contemplate;
- we may be delayed in obtaining marketing approval for our product candidates;
- we may not obtain marketing approval for our product candidates at all;
- we may obtain approval for indications or patient populations that are not as broad as intended or desired;
- we may obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for any approved product or inhibit our ability to successfully commercialize any approved product;
- a REMS or FDA-imposed risk management plan that use risk minimization strategies to ensure that the benefits of certain prescription drugs outweigh their risks, may be required;
- we may be subject to additional post-marketing restrictions and/or requirements; or
- the product may be removed from the market after obtaining marketing approval.

Our product development costs may also increase if we experience development delays or delays in receiving the requisite marketing approvals. Our preclinical studies or clinical trials may need to be restructured or may not be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize Vafseo for potential future indications or any product candidate that is approved, including those that may be in-licensed or acquired, or allow our competitors to bring products to market before we do. This could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of Auryxia, Vafseo or any other product or product candidate, including those that may be in-licensed or acquired.

Identifying and qualifying patients to participate in clinical trials is critical to the success of our clinical trials. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our clinical trials. AKB-097 and praliciguat are being studied for rare diseases with small patient populations and many of those patients are treated with other therapies or products. Also, there are only a limited number of specialist physicians that regularly treat patients with these rare diseases and major clinical centers that support such treatment are concentrated in a few geographic regions. In addition, other companies are conducting, or have announced plans for, clinical trials that are seeking, or are likely to seek, to enroll patients with these rare diseases. These patients are generally only able to enroll in a single trial at a time. The small population of patients, competition for these patients, the nature of the disease and limited trial sites may make it difficult for us to initiate and enroll enough patients to complete our clinical trials of AKB-097 and praliciguat in a timely and cost-effective manner. Patients may be unwilling to participate in our clinical trials because of concerns about investigational research studies, the time and commitment needed to participate in a study, adverse events observed with the product candidate under study, the current standard of care, competitor products and/or other investigational agents, in each case for the same indications and/or similar patient populations.

In addition, in the case of clinical trials of any product candidate, patients currently receiving treatment with the current standard of care or a competitor product may be reluctant to participate in a clinical trial with an investigational drug. Additionally, it is often more difficult to enroll special or particular subpopulations of patients, such as pediatric or elderly patients, due to a number of factors including parental or other caregiver considerations, concerns and burdens. For example, we began enrolling sites in a post-approval pediatric study for the control of serum phosphorus levels in patients with DD-CKD, or the Hyperphosphatemia Indication, of Auryxia in the second quarter of 2022, which began patient recruitment in the third quarter of 2022, but enrollment of eligible pediatric patients in study sites continues to be very slow despite efforts to do so. We informed the FDA of the enrollment and retention challenges in the trial, and in late August 2025, the FDA recommended that we halt further enrollment in the trial until we have further discussions with the FDA. As a result, we have halted enrollment and have requested a meeting with the FDA.

Finally, competition for clinical trial sites may limit our access to patients appropriate for our clinical trials. As a result, the timeline for recruiting patients and conducting studies may be delayed. These delays could result in increased costs, delays in advancing our development of any product or product candidate, or termination of the clinical trial altogether.

We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics, to complete our clinical trials in a timely manner. Patient enrollment is affected by many factors, including:

- severity of the disease under investigation;
- design of the study protocol;
- size and nature of the patient population;
- eligibility criteria for, and design of, the study in question, including study complexity;
- perceived risks and benefits of the product or product candidate under study, including as a result of adverse effects observed in similar or competing therapies;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product or product candidate being studied in relation to available therapies or other product candidates in development;
- efforts to facilitate timely enrollment in clinical trials;
- participation length and demands on patients and caregivers;
- site staffing shortages and turnover;
- clinical trial sites and investigators failing to perform effectively; and
- patient referral practices of physicians.

We may not be able to initiate or complete clinical trials in a timely manner, or at all, if we cannot enroll a sufficient number of eligible patients to participate in the clinical trials required by regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which may delay approval, or result in failure to maintain or obtain approval, of our products or product candidates, which would have a material adverse effect on our business.

Further, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of the

Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan, or DAP, for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance. On January 27, 2025, in response to an Executive Order issued by President Trump on January 21, 2025, on Diversity, Equity and Inclusion programs, the FDA removed the draft DAP guidance from its website. That action, along with similar actions by the Trump Administration to remove many other healthcare webpages, is currently the subject of ongoing litigation. On July 3, 2025, the U.S. District Court for the District of Columbia ruled that the administration's actions to remove these webpages, including the draft DAP guidance, is unlawful under the Administrative Procedure Act, or APA. The court ordered the restoration of many of these webpages. In late July 2025, the FDA restored the draft DAP guidance to its website with a statement that "information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law." Accordingly, in light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider diversity action plans in connection with its review of marketing applications.

In addition, the regulatory landscape related to clinical trials in the European Union recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

We have conducted and intend to conduct certain of our clinical trials globally. However, there are additional risks unique to conducting trials outside of the U.S., and the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business.

We have conducted and intend to conduct certain of our clinical trials outside of the U.S. The acceptance by the FDA or other regulatory authorities of data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice, (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice, or GCP, regulations and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where foreign clinical trial data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the clinical trial is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the trial through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it could result in the need for additional trials, which could be costly and time consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;

- diminished protection of intellectual property in some countries; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

Auryxia, Vafseo or any other product or product candidate, including those that may be in-licensed or acquired, may cause undesirable side effects or have other properties that may delay or prevent marketing approval or limit their commercial potential.

Undesirable effects caused by, or other undesirable properties of, Auryxia, Vafseo or any other product or product candidate, including those that may be in-licensed or acquired, or competing commercial products or product candidates in development that utilize a common mechanism of action could cause us or regulatory authorities to interrupt, delay or halt clinical trials, could result in a more restrictive label or the delay, denial or withdrawal of marketing approval by the FDA or other regulatory authorities, and could lead to potential product liability claims. In addition, results of our clinical trials could reveal a high frequency of undesirable effects or unexpected characteristics. For example, in March 2022, we received the CRL from the FDA for our NDA for Vafseo in which the FDA concluded that the data in the NDA did not support a favorable benefit-risk assessment of Vafseo for dialysis and non-dialysis patients. The FDA expressed safety concerns noting failure to meet non-inferiority in MACE in the non-dialysis patient population, the increased risk of thromboembolic events, driven by vascular access thrombosis in dialysis patients, and the risk of drug-induced liver injury. As a result, we filed the FDRR and, following the FDRR, we filed a resubmission to our NDA, and the FDA approved Vafseo on March 27, 2024. However, the approved indication is limited to the treatment of anemia due to CKD in adults who have been receiving dialysis for at least three months.

If we or others identify undesirable effects caused by, or other undesirable properties of, Auryxia, Vafseo or any other product or product candidate, including those that may be in-licensed or acquired, or if known undesirable effects are more frequent or severe than in the past, or if any of the foregoing are perceived to have occurred, either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our product candidates may not be approved by regulatory authorities;
- our clinical trials may be put on hold;
- patient recruitment could be slowed, and enrolled patients may not want to complete the clinical trial;
- regulatory authorities may require warnings on the label, such as the warning on Auryxia's label regarding iron overload or the boxed warning on Vafseo's label regarding increased risk of death, myocardial infarction, stroke, venous thromboembolism and thrombosis of vascular access;
- REMS or FDA-imposed risk management plans that use restrictive risk minimization strategies may be required;
- patients' non-adherence to the prescribed treatment regimen;
- we may decide to, or be required to, send drug warnings or safety alerts to physicians, pharmacists and hospitals (or the FDA or other regulatory authorities may choose to issue such alerts), or we may decide to conduct a product recall or be requested to do so by the FDA or other regulatory authority;
- reformulation of the product, additional non-clinical or clinical trials, restrictive changes in labeling or changes to or re-approvals of manufacturing facilities may be required;
- we may be precluded from pursuing additional development opportunities to enhance the clinical profile of a product within its indicated populations, or studying the product or product candidate in additional indications and populations or in new formulations;
- we could be investigated by the government or sued and held liable for harm caused to patients, including in class action lawsuits; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining, whether on a restricted basis or at all, marketing approval and, ultimately, market acceptance or penetration of Auryxia, Vafseo or any other product or product candidate, including those that may be in-licensed or acquired. In addition, any of these events could substantially increase our costs, and could significantly impact our ability to successfully commercialize Auryxia, Vafseo or any other product and product candidate, including those that may be in-licensed or acquired, and generate product revenue.

The patient populations treated with Auryxia and Vafseo have CKD, a serious disease that increases the risk of cardiovascular disease including heart attacks and stroke and, in its most severe form, results in, kidney failure and the need for dialysis or kidney transplant. Many patients with CKD are elderly with comorbidities making them susceptible to significant health risks. Therefore, the likelihood of these patients having adverse events, including serious adverse events is high.

With respect to the global $INNO_2VATE$ Phase 3 program, the incidence of treatment emergent adverse events, or TEAEs, during the Correction and Conversion study in Vafseo-treated patients was 83.8% and 85.5% in darbepoetin alfa treated

patients. During the study, the most common TEAEs reported in Vafseo/darbepoetin alfa treated patients were hypertension (16.2%/ 12.9%) and diarrhea (10.1%/ 9.7%). Serious TEAEs were lower in Vafseo-treated patients at 49.7% compared to 56.5% for darbepoetin alfa treated patients. The incidence of TEAEs during the prevalent dialysis patient study (Conversion) in the Vafseo-treated patients was 88.3%, and 89.3% in darbepoetin alfa treated patients. During the study, the most common TEAEs reported in Vafseo/darbepoetin alfa treated patients were diarrhea (13.0%/ 10.1%), pneumonia (11.0%/ 9.7%), hypertension (10.6%/ 13.8%), and hyperkalemia (9.0%/ 10.8%). Serious TEAEs were slightly lower for Vafseo-treated patients at 55.0% and 58.3% for darbepoetin alfa-treated patients. Patients with DD-CKD experienced an increased risk of thromboembolic events compared to darbepoetin alfa with a time to first event HR of 1.20 (95% CI 0.96 — 1.50) driven by thrombosis of vascular access.

With respect to the global PRO_2TECT Phase 3 program, the incidence of TEAEs during the ESA untreated patients study (Correction) in the Vafseo-treated patients was 90.9%, and 91.6% in darbepoetin alfa-treated patients. During the study, the most common TEAEs reported in Vafseo/darbepoetin alfa-treated patients were end-stage renal disease (34.7%/ 35.2%), hypertension (17.7%/ 22.1.%), hyperkalemia (12.3.%/ 15.6%), urinary tract infection (12.9%/ 12.0%), diarrhea (13.9%/ 10.0%), peripheral oedema (12.5%/ 10.5%), fall (9.6%/ 10%) and nausea (10%/ 8.2%). Serious TEAEs were 65.3% for Vafseo-treated patients and 64.5% for darbepoetin alfa-treated patients. The incidence of TEAEs during the ESA-treated patients study (Conversion) in Vafseo-treated patients was 89.1% and 87.7% in darbepoetin alfa-treated patients. During the study, the most common TEAEs reported in Vafseo/darbepoetin alfa-treated patients were end-stage renal disease (27.5%/ 28.4%), hypertension (14.4%/ 14.8%), urinary tract infection (12.2%/ 14.5%), diarrhea (13.8.%/ 8.8.%), peripheral oedema (9.9%/ 10.1%) and pneumonia (10.0%/ 9.7%). Serious TEAEs were 58.5% for Vafseo-treated patients and 56.6% for darbepoetin alfa-treated patients.

During the conduct of our Phase 3 program for Vafseo, our team and hepatic experts analyzed hepatic cases (unblinded to treatment) and, following the completion of our global Phase 3 clinical program for Vafseo, there was a review of hepatic safety across the Vafseo clinical program, which included eight completed Phase 2 and 3 studies in NDD-CKD patients, 10 completed Phase 1, 2, and 3 studies, and two then-ongoing Phase 3b studies in DD-CKD patients, and 18 completed studies in healthy subjects (17 Phase 1 and one Phase 3). This review consisted of a blinded re-assessment of hepatic events conducted by a separate panel of hepatic experts. While hepatocellular injury attributed to Vafseo was reported in less than 1% of patients, there was one case of severe hepatocellular injury with jaundice, and we cannot guarantee that similar events will not happen in the future. Additionally, the FDA expressed safety concerns related to the risk of drug-induced liver injury in the CRL that it issued in March 2022, and these safety concerns were addressed following the FDRR and resubmission to our NDA.

Serious adverse events related to Vafseo, including those noted in the CRL and label, and any other product candidates could have material adverse consequences on the development and any potential label expansion of Vafseo or the approval of our other product candidates and our business as a whole. Our understanding of adverse events in prior clinical trials of Vafseo or our product candidates may change as we gather more information, the FDA may not agree with our assessment of adverse events and additional unexpected adverse events may be observed in future clinical trials or in the market.

Any of the above safety data or other occurrences could delay or prevent us from achieving or maintaining marketing approval, harm or prevent sales of Auryxia, Vafseo or any other product or product candidate, including those that may be in-licensed or acquired, increase our expenses and impair or prevent our ability to successfully commercialize Auryxia, Vafseo or any other products or product candidates.

In addition, any post-marketing clinical trials conducted, if successful, may expand the patient populations treated with Auryxia, Vafseo or any other product we acquire or for which we receive marketing approval, within or outside of their current indications or patient populations, which could result in the identification of previously unknown undesirable effects, increased frequency or severity of known undesirable effects, or result in the identification of unexpected safety signals. In addition, Vafseo and any other products are commercialized, they will be used in significantly larger patient populations, in less rigorously controlled environments and, in some cases, by less experienced and less expert treating practitioners, than in clinical trials, which could result in increased or more serious adverse effects being reported. As a result, regulatory authorities, healthcare practitioners, third party payors or patients may perceive or conclude that the use of Auryxia, Vafseo or any other products are associated with serious adverse effects, undermining our commercialization efforts.

Risks Related to Regulatory Approval

We may not be able to obtain marketing approval for any potential label expansion for Vafseo or any current or future product candidate, or we may experience significant delays in doing so, any of which would materially harm our business.

Clinical trials, manufacturing and marketing of any product or product candidate are subject to extensive and rigorous review and regulation by numerous governmental authorities in the U.S. and other jurisdictions. Before obtaining marketing approval for the commercial sale of any product candidate, we must demonstrate through rigorous and extensive preclinical development and clinical trials that the product candidate is safe and effective for use in each target indication. This process can take many years and marketing approval may never be achieved. Of the large number of drugs in development in the U.S.

and in other jurisdictions, only a small percentage successfully complete the FDA's and other regulatory jurisdictions' marketing approval processes and are commercialized. Accordingly, even if we are able to obtain the requisite capital to continue to fund our development efforts, we may be unable to successfully obtain regulatory approval for any potential label expansion for Vafseo or for any product candidate, including those that may be in-licensed or acquired. Further, any product candidate may not receive marketing approval in the U.S. even if it is approved in other countries. Each regulatory authority makes their own assessment as to the safety and efficacy of a drug, and the FDA's concern about the safety or efficacy of any product candidate could impact the regulatory authority's decision in another country.

In March 2022, we received the CRL from the FDA regarding our NDA for vadadustat for the treatment of anemia due to CKD. Following a FDRR in 2022, we filed a resubmission to our NDA in 2023. On March 27, 2024, the FDA approved our NDA for vadadustat under the trade name Vafseo for the treatment of anemia due to CKD in adults who have been receiving dialysis for at least three months. However, we expended significant additional resources to obtain the approval of Vafseo, the approved indication is limited to the treatment of anemia due to CKD in adults who have been receiving dialysis for at least three months and the commercialization of Vafseo was delayed, which had and could continue to have an adverse effect on our business.

Vafseo is currently approved as a treatment for anemia due to CKD for dialysis dependent patients in the U.S., European Union, United Kingdom, Switzerland and Australia. In Japan, Vafseo is approved as a treatment for anemia due to CKD in both dialysis dependent and non-dialysis dependent patients and is marketed and sold by our collaborator TPC. In Taiwan and South Korea, Vafseo is approved for the treatment of symptomatic anemia due to CKD in adult patients on chronic maintenance dialysis. We are not permitted to market Vafseo in any additional jurisdictions or other indications until the requisite approval from regulatory authorities in such jurisdiction is received. As a condition to receiving marketing approval for Vafseo in additional territories or for other indications, we may be required by regulatory authorities to conduct additional preclinical studies or clinical trials. For example, we have had several lifecycle management and label expansion opportunities under evaluation for Vafseo, one of which is the potential for alternative dosing, and another of which had been label expansion for the treatment of adult patients with NDD-CKD. However, we may be required to complete additional clinical trials before seeking approval for label expansion, which are time consuming and expensive, and even though Vafseo is approved as a treatment for anemia due to CKD for dialysis dependent patients, we may not be successful in any of our lifecycle management or label expansion opportunities in the timeframe anticipated by us, or at all. For example, we initially submitted a NDA to the FDA for vadadustat in March 2021 and in March 2022 the FDA issued a CRL to our NDA. The FDA concluded that the data in the NDA did not support a favorable benefit-risk assessment of vadadustat for dialysis and non-dialysis patients. The FDA expressed safety concerns, noting failure to meet non-inferiority in MACE in the non-dialysis patient population. While we have since secured FDA approval for use in dialysis patients, we believe there are compelling data supporting a positive benefit-risk profile for the use of Vafseo broadly in U.S. patients with CKD. In addition, following a Type C meeting with the FDA in October 2025, we believe that, based on the FDA feedback, regulatory alignment on a path forward for the design of the VALOR trial for the use of vadadustat to treat anemia in patients with late-stage CKD not on dialysis would require a significantly larger number of patients than proposed, and accordingly would require meaningfully more time and cost to complete than we anticipated. As a result, we do not plan to initiate the VALOR trial, and therefore will not pursue a broad label for Vafseo for adult patients with NDD-CKD. We continue to engage with the FDA regarding smaller subpopulations of CKD non-dialysis dependent patients where we believe we may be able to align on a potential path forward. Based on our communications to date, however, we remain cautious about a path forward. However, the FDA may not agree with our study design or we may not successfully demonstrate safety and/or efficacy needed to obtain regulatory approval or we may be unable to start a trial when anticipated or complete a trial when anticipated or at all. If we do not obtain the approval of label expansion for alternative dosing or for a potential smaller subgroup of CKD non-dialysis patients in a timely manner, or at all, it could impact future revenue and have an adverse effect on our business.

Obtaining marketing approval in the U.S. and other jurisdictions for any product candidate depends upon numerous factors, many of which are subject to the substantial discretion of the regulatory authorities, including that regulatory agencies may not complete their review processes in a timely manner and/or, following completion of the review process, may not grant marketing approval or such marketing approval may be limited. Furthermore, approval of a drug does not ensure successful commercialization. For example, on September 23, 2015, the European Commission, or EC, approved Fexeric (ferric citrate coordination complex) for the control of hyperphosphatemia in adult patients with CKD. Pursuant to the sunset clause under EU law, the EC's approval of Fexeric in the EU was contingent on, among other things, our commencing marketing of Fexeric within three years; although we successfully negotiated an extension to December 23, 2019, we did not commence marketing Fexeric by such date and therefore the Fexeric approval in the EU has ceased to be valid. In April 2024, our partner Averoa submitted its marketing authorization application for ferric citrate in Europe. In March 2025, the Committee for Medicinal Products for Human Use of the European Medicines Agency adopted a positive opinion recommending the EC approve Averoa's marketing authorization, which the EC granted in June 2025. In November 2025, the Medicines and Healthcare Products Regulatory Agency, or MHRA, granted Averoa's UK marketing authorization. However, Averoa has not yet obtained pricing authorization nor commenced sales of ferric citrate in Europe or UK.

Safety concerns with a given product may impact marketing approval. For example, safety concerns associated with the current standard of care for the indications for Vafseo may affect the FDA's or other regulatory authorities' review of the safety results of Vafseo. In addition, these regulatory authorities may not agree with our assessment of adverse events. Further, the policies or regulations, or the type and amount of clinical data necessary to gain approval, may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that our product candidates will never obtain marketing approval in the U.S. or certain other jurisdictions or for some or all of the indications for which we seek approval.

The FDA or other regulatory authorities may delay, limit or deny approval of any product candidate for many reasons including, among others:

- the results of our clinical trials may only be modestly positive, or there may be concerns with the profile due to efficacy or safety;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the relevant regulatory authority for review and/or marketing approval;
- the relevant regulatory authority may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the relevant regulatory authority may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the relevant regulatory authority may not approve any potential label expansion we request for Vafseo;
- the relevant regulatory authority may approve any product candidate for use only in a small patient population or for fewer or more limited indications than we request;
- the relevant regulatory authority may require that we conduct additional clinical trials or repeat one or more clinical trials;
- the FDA or other relevant regulatory authority may require development of a REMS as a condition of approval or post-approval;
- the relevant regulatory authority may grant approval contingent on the performance of costly post-marketing clinical trials;
- the relevant regulatory authority's onsite inspections may be delayed;
- we, or our CROs or other vendors, may fail to comply with GxP or fail to pass any regulatory inspections or audits;
- we or our third-party manufacturers may fail to perform in accordance with the FDA's or other relevant regulatory authority's cGMP requirements and guidance;
- the relevant regulatory authority could deem that our financial relationships with certain principal investigators constitute a conflict of interest, such that the data from those principal investigators may not be used to support our applications;
- as part of any future regulatory process, the FDA may ask an Advisory Committee to review portions of the NDA, the FDA may have difficulty scheduling an Advisory Committee meeting in a timely manner or, if convened, an FDA Advisory Committee could recommend non-approval, conditions of approval or restrictions on approval, and the FDA may ultimately agree with the recommendations;
- the relevant regulatory authority's review process and decision-making regarding any product candidate may be impacted by the results of our and our competitors' clinical trials and safety concerns of marketed products used to treat the same indications as the indications for which Vafseo and any other product candidate are being developed;
- the relevant regulatory authority may not approve the manufacturing processes or facilities of third-party manufacturers with whom we contract; or
- the policies or regulations of the relevant regulatory authority may significantly change in a manner that renders our clinical data insufficient for approval or requires us to amend or submit new clinical protocols.

Moreover, principal investigators for our future clinical trials may serve as scientific advisors or consultants to us and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

In addition, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In Loper Bright Enterprises v. Raimondo, for example, the court overruled Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the APA. Additionally, in Corner Post, Inc. v. Board of Governors of the Federal Reserve System, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, Securities and Exchange Commission v. Jarkesy, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and CMS, that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Further, our ability to develop and market new drug products may be impacted by litigation challenging the FDA's approval of another company's drug product. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states (Missouri, Idaho and Kansas) filed an amended complaint in the U.S. District Court for the Northern District of Texas challenging the FDA's actions. On January 16, 2025, the district court agreed to allow these states to file an amended complaint and continue to pursue this challenge. Thereafter, on September 30, 2025, the district court declined to dismiss the case and, instead, transferred it to the federal district court in the Eastern District of Missouri. Depending on the outcome of this litigation, our ability to develop new drug product candidates and to maintain approval of existing drug products could be delayed, undermined or subject to protracted litigation.

We may not be able to obtain orphan drug exclusivity for praliciguat or any potential future product candidates that we may develop, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the EU. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for a similar product for the same therapeutic indication for that time period. The applicable period is seven years in the U.S. and ten years in the EU. The exclusivity period in the EU can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

We plan to rely on orphan drug exclusivity for praliciguat and may rely on orphan drug exclusivity for potential future product candidates that we may develop. However, we cannot assure you that we will receive orphan drug designation for praliciguat or any of our potential future product candidates. In order for the FDA to grant orphan drug exclusivity to one of our products, the FDA must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which orphan drug exclusivity is sought does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

The FDA Reauthorization Act of 2017, or the FDARA, requires that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. FDARA reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority.

The FDA and Congress may further reevaluate and revise the Orphan Drug Act and its regulations and policies. For example, in September 2021, the Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of orphan drug exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and not the "indication or

use ” for which the product is approved. Subsequently, in another case, a federal district court in Washington, D.C. followed the reasoning of the 11th Circuit decision and that decision was appealed to the U.S. Court of Appeals for the D.C. Circuit. On February 3, 2026, the Consolidated Appropriations Act of 2026 was enacted into law. It overruled these court decisions and codified the FDA’s longstanding interpretation of the scope of orphan drug exclusivity to apply to “the same drug for the same approved use or indication within such [designated] rare disease or condition.” This change, which applies retroactively, expressly authorizes the FDA to approve multiple versions of the same orphan drug for different sub-indications and subpopulations, such as adult and pediatric patients or multiple variations of the same disease that are caused by different genetic variants.

If we are unable to obtain or maintain marketing approval in jurisdictions outside the United States, we and our partners will not be able to market any of our products or product candidates outside of the United States.

In order to market and sell our products and product candidates in the European Union, Japan and many other jurisdictions, we or our partners must obtain or maintain separate marketing approvals and comply with numerous and varying regulatory requirements. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. The approval procedure varies among countries and can involve additional testing. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. The time required to obtain or maintain approval may differ substantially from that required to obtain or maintain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining or maintaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We and our partners may not obtain or maintain approvals from regulatory authorities outside the United States on a timely basis or at all.

Additionally, we and our partners could face heightened risks with respect to obtaining or maintaining marketing authorizations in the UK as a result of the withdrawal of the UK from the EU, commonly referred to as Brexit. The UK is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the MHRA is responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland). On April 28, 2025, the UK Parliament adopted amendments to improve and strengthen the UK’s clinical trials regulatory regime; they will take effect on April 28, 2026. These changes were needed since the current UK requirements are based upon the now-repealed EU Clinical Trials Directive (2001/20/EC), which has been replaced by the European Clinical Trials Regulation (Regulation EU No 536/2014). In anticipation of these new requirements, on October 1, 2025, the MHRA updated its guidance for clinical trials to address, among other things, research transparency requirements for clinical trials, the approvals process, Research Ethics Committee review of clinical trials, simplified arrangements for consent in clinical trials and pharmacovigilance. Since the UK left the EU prior to the date on which the European Trials Regulation took effect, the UK legal framework did not benefit from the same revisions as occurred at EU level.

At the same time, a new international recognition procedure, or IRP, will apply, which intends to facilitate approval of pharmaceutical products in the UK. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA’s specified Reference Regulators, or RRs. The RRs notably include EMA and regulators in the EEA member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the U.S.). However, the concrete functioning of the IRP is currently unclear. Any delay in obtaining, maintaining or an inability to obtain or maintain, any marketing approvals may force us or our partners to restrict or delay efforts to seek regulatory approval in the UK for our product candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the EC in November 2020. The EC’s proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. On April 10, 2024 the European Parliament adopted a position on the proposal requesting several amendments to the package. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term. On June 4, 2025, after almost two years of negotiations among the EU Member States, the Council of the European Union adopted its position on the proposed overhaul of the EU general pharmaceutical legislative framework, which is known as the new Pharma Package. On December 11, 2025, the European Parliament and European Council reached a provisional political agreement on the legislation which is expected to be adopted by mid-2026. The revisions may have a significant impact on the pharmaceutical industry and our business. The new Pharma Package would, among other things, shorten marketing authorization times from 210 to 180 days, and set a baseline period of eight years of data exclusivity and one year of market exclusivity with possible extensions for new indications up to a maximum of 11 years total.

Products approved for marketing are subject to extensive post-marketing regulatory requirements, including post-approval pediatric studies for Auryxia and Vafseo, and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties, including withdrawal of marketing approval, if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, or product candidates, when and if approved.

Marketing approvals may be subject to limitations on the approved indicated uses for which the product may be marketed, other conditions of approval, or contain requirements or commitments for potentially costly post-marketing studies and surveillance to monitor the safety and efficacy of the product, including REMS, or registries or observational studies. For example, in connection with the FDA approvals of Auryxia and Vafseo, we committed to the FDA to conduct certain post-approval studies, including pediatric studies of Auryxia and Vafseo under the Pediatric Research Equity Act of 2003, or PREA, and observational studies of Vafseo related to safety, malignancy and pregnancy. Under PREA, an NDA or supplement to an NDA for certain drug products must contain data to assess the safety and effectiveness of the drug product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. With regard to the Hyperphosphatemia Indication for Auryxia, we initially committed to completing the original post-approval pediatric study and submitting a final report to the FDA by December 31, 2019. However, we did not complete the study according to the original schedule and therefore did not submit the required final report by December 31, 2019. Consequently, we received a notification of noncompliance with PREA. We have since been released from the original post marketing requirement, or PMR, and a new PMR was issued that provided that the final report was due in April 2024. In June 2023 we requested an extension of time for the submission of the final report and such request was denied by the FDA in August 2023. The PMR trial had been actively recruiting patients, but the final report for the trial was due in April 2024, so the trial is considered delayed. We informed the FDA of the enrollment and retention challenges in the trial, and in late August 2025, the FDA recommended that we halt further enrollment in the trial until we have further discussions with the FDA. As a result, we have halted enrollment and have requested a meeting with the FDA. If the FDA finds that we failed to comply with the pediatric study requirement with regard to the Hyperphosphatemia Indication, in violation of applicable law, it could institute enforcement proceedings to seize or enjoin the sale of Auryxia, seek civil penalties or other adverse consequences, which would have a material adverse impact on our ability to commercialize Auryxia and our ability to generate revenues from Auryxia.

In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for Auryxia, Vafseo and any other product for which we receive regulatory approval will be subject to extensive and ongoing regulatory requirements and guidance. These requirements and guidance include manufacturing processes and procedures (including record keeping), the implementation and operation of quality systems to control and assure the quality of the product, submissions of safety and other post-marketing information and reports, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. If we, our contract manufacturing organizations, or CMOs, or other third parties we engage fail to adhere to such regulatory requirements and guidance, we could suffer significant consequences, including product seizures or recalls, loss of product approval, fines and sanctions, reputational damage, loss of customer confidence, shipment delays, inventory shortages, inventory write-offs and other product-related charges and increased manufacturing costs, and our development or commercialization efforts may be materially harmed.

Post-approval discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency or relating to manufacturing operations or processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing, distribution, use or manufacturing of the product;
- withdrawal of the product from the market, or product recalls;
- restrictions on the labeling or marketing of a product;
- fines, restitution or disgorgement of profits or revenues;
- warning or untitled letters or clinical holds;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- REMS; and
- injunctions or the imposition of civil or criminal penalties.

For example, we previously had three limited, voluntary recalls of Auryxia. Any other recalls or any supply, quality or manufacturing issues in the future related to Auryxia or Vafseo could result in significant negative consequences, including

reputational harm, loss of customer confidence, and a negative impact on our financials, any of which could have a material adverse effect on our business and results of operations, and may impact our ability to supply Auryxia in the U.S. or Europe and Vafseo in the U.S., Japan, Europe or in other countries, for commercial and clinical use.

Non-compliance with the FDA, the EMA, the PMDA and other regulatory authorities' requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties.

The FDA's policies and those of other regulatory authorities may change, and additional government regulations may be enacted. We cannot predict the likelihood, nature or extent of government regulations that may arise from future legislation or administrative action, either in the U.S. or in other jurisdictions. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would materially adversely affect our business.

Risks Related to Governmental Regulation and Compliance

We are subject to complex regulatory schemes that require significant resources to ensure compliance and our failure to comply with applicable laws could subject us to government scrutiny or enforcement, potentially resulting in costly investigations, fines, penalties or sanctions, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

In general, a variety of laws apply to us or may otherwise restrict our activities, including the following:

- laws and regulations governing the conduct of preclinical studies and clinical trials in the U.S. and other countries in which we are conducting such studies;
- anti-corruption and anti-bribery laws, including the FCPA, the UK Bribery Act and various other anti-corruption laws in countries outside of the U.S.;
- data privacy laws existing in the U.S., the EU, the UK and other countries in which we operate, including the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, state privacy and data protection laws, such as the California Consumer Privacy Act, or CCPA, as amended by the California Privacy Rights Act of 2020, or CPRA, as well as other state consumer protection laws, GDPR, any additional applicable EU member state, or EU Member State, data protection laws in force from time to time, the retained EU law version of the General Data Protection Regulation as saved into United Kingdom law by virtue of section 3 of the United Kingdom's European Union (Withdrawal) Act 2018;
- federal and state laws requiring the submission of accurate product prices and notifications of price increases;
- federal and state securities laws;
- environmental, health and safety laws and regulations; and
- international trade laws, which are laws that regulate the sale, purchase, import, export, re-export, transfer and shipment of goods, products, materials, services and technology.

In addition, our relationships with healthcare providers, physicians and third party payors expose us to broadly applicable fraud and abuse laws that may constrain the business or financial arrangements and relationships through which we market, sell and distribute Auryxia and Vafseo and any other products for which we may obtain marketing approval. As such, these arrangements are subject to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations at federal, state and international levels. These restrictions include, but are not limited to, the following:

- the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, which among other things, strictly regulates drug product marketing and promotion and prohibits manufacturers from marketing such products for off-label use;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs, and laws requiring notification of price increases;
- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;

- the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, and violations of the FDCA, the federal government pricing laws, and the federal Anti-Kickback Statute trigger liability under the federal False Claims Act;
- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the HITECH, and their respective implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments Act (the former Physician Payments Sunshine Act) requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;
- analogous state laws and regulations, such as state anti-kickback and false claims laws and gift ban and transparency statutes, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by state Medicaid or other programs, or non-governmental third party payors, including private insurers, and which are not preempted by federal laws and often differ from state to state, thus complicating compliance efforts; and
- U.S. state laws restricting interactions with healthcare providers and other members of the healthcare community or requiring pharmaceutical manufacturers to implement certain compliance standards, which vary from state to state.

Because of the breadth of these U.S. laws, and their non-U.S. equivalents, and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reforms have strengthened these laws. For example, the Health Care Reform Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate the law. The Health Care Reform Act also amended the False Claims Act, such that violations of the Anti-Kickback Statute are now deemed violations of the False Claims Act.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines, such as the Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals. Additionally, some state and local laws require the registration and specific training of pharmaceutical sales representatives in the jurisdiction. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA.

Efforts to ensure that our business complies with applicable healthcare laws and regulations involve substantial costs and require us to expend significant resources. One of the potential areas for governmental scrutiny involves federal and state requirements for pharmaceutical manufacturers to submit accurate price reports to the government. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, or potential qui tam complaints, and it is possible that such reviews could result in changes, recalculations, or defense costs that may have adverse legal or financial consequences. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could materially adversely affect our business and would result in increased costs and diversion of management attention and could negatively impact the development, regulatory approval and commercialization of Auryxia or Vafseo, any of which could have a material adverse effect on our business. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

We will incur significant liability if it is determined that we are promoting any "off-label" use of Auryxia, Vafseo or any other product we may develop, in-license or acquire or we are found to have improperly promoted such products through direct-to-consumer advertising, or if it is determined that any of our activities violates the federal Anti-Kickback Statute.

Physicians are permitted to prescribe drug products for uses that differ from those approved by the FDA or other applicable regulatory agencies. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict manufacturer communications regarding unapproved uses of an approved drug. Companies are not permitted to promote drugs for unapproved uses or in a manner that is inconsistent with the FDA-approved labeling. There are also restrictions about making comparative or superiority claims based on safety or efficacy that are not supported by substantial evidence. Accordingly, we may not promote Auryxia in the U.S. for use in any indications other than the Hyperphosphatemia Indication and for the treatment of IDA in adult NDD-CKD patients, and Vafseo for the treatment of anemia due to CKD in adults who have been receiving dialysis for at least three months, and all promotional claims must be consistent with the FDA-approved labeling for Auryxia or Vafseo, as applicable.

Promoting a drug off-label is a violation of the FDCA and can give rise to liability under the federal False Claims Act, as well as under additional federal and state laws and insurance statutes. The FDA, the Department of Justice and other regulatory and enforcement authorities enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained, as well as the false advertising or misleading promotion of drugs. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product. In addition, laws and regulations govern the distribution and tracing of prescription drugs and prescription drug samples, including the Prescription Drug Marketing Act of 1976 and the Drug Supply Chain Security Act, which regulate the distribution and tracing of prescription drugs and prescription drug samples at the federal level and set minimum standards for the regulation of drug distributors by the states. A company that is found to have improperly promoted off-label uses or to have otherwise engaged in false or misleading promotion or improper distribution of drugs will be subject to significant liability, potentially including civil and administrative remedies as well as criminal sanctions. It may also be subject to exclusion and debarment from federal healthcare reimbursement programs.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in January 2025, the FDA published final guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses of approved products to healthcare providers. This final guidance calls for such communications to be non-promotional, truthful, non-misleading, factual, and unbiased and such communications must include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about unapproved use. In addition, under some relatively recent guidance from the FDA and the Pre-Approval Information Securities Exchange Act of 1934, as amended, or the Exchange Act, signed into law as part of the Consolidated Appropriations Act of 2023, or the Consolidated Appropriations Act, companies may also provide information that is consistent with a product's FDA approved-labeling and proactively speak to formulary committee members of payors regarding certain types of data and information for an unapproved drug or unapproved uses of an approved drug. We intend to engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. Although we believe we have put in place a robust compliance program and processes designed to ensure that all such activities are performed in a legal and compliant manner, such program and processes may not be sufficient to deter or detect all violations, and we will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

Further, we will need to ensure full compliance with the administration's recently announced enforcement position on direct-to-consumer, or DTC, prescription drug advertising and related promotional activities. On September 9, 2025, the President issued a Memorandum directing HHS to ensure transparency and accuracy in direct-to-consumer prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements. The same day, the Make America Healthy Again Commission released a report declaring that the FDA, HHS, FTC and DOJ will increase oversight and enforcement under current authorities for violations of direct-to-consumer, or DTC, prescription drug advertising laws. To that end, the FDA announced that it is initiating a rulemaking process to eliminate the adequate provision loophole that allows pharmaceutical advertisements to address safety information by placing it in another format or location. In this context, the FDA declared that it will no longer tolerate what it characterized as deceptive practices in prescription drug advertising and that the agency would aggressively deploy its available enforcement tools, with heightened scrutiny of fair balance and disclosures in social media promotions. The FDA also issued a generic notice letter to a substantial number of companies, including Akebia, directing such companies to remove any noncompliant advertising and bring all promotional communications into compliance. We believe that we maintain a robust compliance program and processes designed to ensure that all promotional advertising activities are performed in a legal and compliant manner. However, given the administration's enforcement position on these issues, we may be at increased risk that the FDA, DOJ or FTC will find our promotional advertising and other

digital campaigns, including social media activities, are not in compliance with fair balance requirements and anticipated rule changes at the FDA and possibly other agencies.

In addition, if a company's activities are determined to have violated the federal Anti-Kickback Statute, this will also give rise to liability under the federal False Claims Act and such violations can result in significant fines, criminal and civil remedies, and exclusion from Medicare and Medicaid. There is increased government focus on relationships between the pharmaceutical industry and physicians, pharmacies (especially specialty pharmacies), and other sources of referrals. Common industry activities, such as speaker programs, insurance assistance and support, relationships with foundations providing copayment assistance, and relationships with patient organizations and patients are receiving increased governmental attention. If any of our relationships or activities is determined to violate applicable federal and state anti-kickback laws, false claims laws, or other laws or regulations, the company and/or company executives, employees, and other representatives could be subject to significant fines and criminal sanctions, imprisonment, and potential exclusion from Medicare and Medicaid, and could harm our reputation or result in significant legal expenses and distraction of management.

Disruptions at the FDA and other government agencies from funding cuts, personnel losses, regulatory reform, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development program and develop and secure approval of our product candidates in a timely manner, which would negatively impact our business.

The FDA and comparable regulatory agencies in foreign jurisdictions, such as the EMA and The Committee for Medicinal Products, play an important role in the development of our product candidates by providing guidance on our clinical development programs and reviewing our regulatory submissions, including INDs, requests for special designations and marketing applications. If these oversight and review activities are disrupted, then correspondingly our ability to develop and secure timely approval of our product candidates could be impacted in a negative manner.

For example, the recent loss and retirement of FDA leadership and personnel and the recent government shutdown could lead to disruptions and delays in FDA guidance, or review and approval of our products and product candidates. Pursuant to President Trump's E.O. 14210, "Implementing the President's 'Department of Government Efficiency' Workforce Optimization Initiative," the Secretary of HHS announced on March 27, 2025, a reorganization and reduction in force across HHS of approximately 20,000 employees (82,000 to 62,000), with FDA's workforce of approximately 20,000 to decrease by 3,500 full-time employees. Subsequently, the FDA indicated that roughly a quarter of those employees who received termination notices had been reinstated. On July 14, 2025, following litigation reaching the U.S. Supreme Court, the administration began to carry out these layoffs across HHS, including the FDA. In November 2025, a Congressional Continuing Resolution ended the government shutdown, providing full-year funding of the FDA through the 2026 federal fiscal year at approximately $7 billion with a slight increase in user fees for drug and device companies.

Further, while the FDA's review of marketing applications and other activities for new drugs and biologics is largely funded through the user fee program established under PDUFA, it remains unclear how the administration's reduction in force and budget cuts will impact this program and the ability of the FDA to provide guidance and review our product candidates in a timely manner. For example, while the FDA reduction in force did not reportedly specifically target FDA reviewers, many operations, administrative and policy staff that help support such reviews were affected and those losses could lead to delays in PDUFA reviews and related activities. As of July 15, 2025, there has been at least one report in which the FDA failed to meet a PDUFA goal date for approval of an NDA due to heavy workload and limited resources. In addition, while currently unclear, there is a risk that the reduction in force and budget cutbacks could threaten the integrity of the PDUFA program itself. That is because, for the FDA to obligate user fees collected under PDUFA in the first place, a certain amount of non-user fee appropriations must be spent on the process for the review of applications plus certain other costs during the same fiscal year.

There is also substantial uncertainty as to how regulatory reform measures being implemented by the Trump Administration across the government will impact the FDA and other federal agencies with jurisdiction over our activities. For example, since taking office, the President has issued several executive orders that could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. These include E.O. 14192, "Unleashing Prosperity Through Deregulation," January 31, 2025; E.O. 14212, "Establishing the President's Make America Healthy Again Commission," February 13, 2025; and E.O. 14219, "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency" Deregulatory Initiative," February 21, 2025. If these or other orders or executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Similarly, actions by the U.S. government have significantly disrupted the operations of U.S. government agencies such as the National Institutes of Health, National Science Foundation, Centers for Disease Control and Prevention and FDA, which have traditionally provided funding for basic research, R&D, and clinical testing. These U.S. government actions have included, among other things, suspending, terminating and withholding of disbursements of funds owed under ongoing contracts,

grants, and other financial assistance agreements; declining to continue multi-year research projects for additional annual budget periods; canceling or delaying solicitations for new contract, grant and other financial assistance awards; canceling or delaying proposal evaluation processes and issuance of such new awards; substantially reducing federal agency staff responsible for managing contract and financial assistance programs; eliminating agency information and resources for facilitating research activity; delaying or terminating federal agency procedures for authorizing international transactions; initiating aggressive enforcement actions that may disrupt the operations of major research universities that are significant contributors to life sciences research in the U.S., and threatening access to federal agency contracts and other funding awards based on companies' otherwise lawful corporate policies and choice of counsel. These U.S. government actions could, directly or indirectly, significantly disrupt, delay, prevent, or increase the costs of our research and product commercialization programs, including our ability to develop new product candidates, conduct clinical trials, implement research collaborations with other companies or institutions, and obtain approvals to market and sell new products.

In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund R&D activities, is subject to the political process, which is inherently fluid and unpredictable. For example, the U.S. government shut down on October 1, 2025, and reopened on November 13, 2025. Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and could impact our ability to access the public markets and obtain necessary capital to properly capitalize and continue our operations.

At the same time, disruptions at the FDA and other government agencies may result from public health events similar to the COVID-19 pandemic. For example, during the pandemic, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Accordingly, if any of the foregoing developments and others impact the ability of the FDA to provide us with guidance regarding our clinical development programs or delay the agency's review and processing of our regulatory submissions, including INDs and NDAs, our business would be negatively impacted. Further, any future government shutdown could impact our ability to access the public markets and obtain necessary capital to properly capitalize and continue our operations.

Compliance with privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which took effect across all member states of the EEA, in May 2018. Following the withdrawal of the UK from the EU, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the UK and includes parallel obligations to those set forth by GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data when required, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, when required, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third party processors. The GDPR increases our obligations as a sponsor in clinical trials in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial patients and investigators. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of the total worldwide annual turnover of a group of companies from the preceding financial year or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU Member States may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data and permits EU Member States to adopt further penalties for violations that are not subject to the administrative fines outlined in the GDPR.

The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S. and, as a result, increases the scrutiny that we should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the U.S. There is ongoing uncertainty about the transfer

mechanisms that companies rely upon to enable the legal transfer of personal data from the EU to other countries. For example, in July 2020, the Court of Justice of the European Union invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S. Although a new Data Privacy Framework has been adopted, as court decisions and regulatory guidance evolves, challenges remain with respect to GDPR compliance. Companies must continue to monitor the regulatory landscape and implement necessary changes, all of which may be costly and may put the company out of compliance while any changes are being implemented.

Following the withdrawal of the UK from the EU, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the UK and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the UK and the EU have determined, through separate "adequacy" decisions, that data transfers between the two jurisdictions are in compliance with the UK Data Protection Act and the GDPR, respectively. The UK and the U.S. have also agreed to a U.S.-UK "Data Bridge", which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the UK to the U.S. In addition to the UK, Switzerland has approved an adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which would function similarly to the EU-U.S. Data Privacy Framework and the U.S.-UK Data Bridge in relation to data transfers from Switzerland to the U.S.). Any changes or updates to these developments have the potential to impact our business.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The EU initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022, and the EC adopted the adequacy decision on July 10, 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the EU to the U.S. However, some privacy advocacy groups have challenged or suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business internationally.

Given the breadth and depth of changes in data protection obligations, complying with the GDPR's requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the EU. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us and could have a material adverse effect on our business, financial condition or results of operations.

Similar privacy and data security requirements are either in place or underway in the U.S. There are a broad variety of data protection laws that may be applicable to our activities, and a range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns. The Federal Trade Commission, or the FTC, and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. For example, the FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the Federal Trade Commission Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement (depending on the nature of the alleged violations). If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements.

Laws also are being considered at both the state and federal levels. For example, the CCPA, which went into effect on January 1, 2020, and the CPRA, which amends CCPA by expanding the scope and applicability, while also introducing new privacy protections, is creating similar risks and obligations as those created by GDPR. In November 2020, California voters passed a ballot initiative for the CPRA, which went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also creates a new agency that is specifically responsible for enforcing the new law and other California privacy laws. Because of this, we may need to engage in additional activities (e.g., data mapping) to identify the personal information we are collecting and the purposes for which such information is collected. In addition, we will need

to ensure that our policies recognize the rights granted to consumers (as that phrase is broadly defined in the CCPA and can include business contact information).

In addition to California, at least 19 other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, the State of Washington passed the My Health My Data Act in 2023 which specifically regulated health information that is not otherwise regulated by the HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states are considering such legislation. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits creates potential risk for our business.

If we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In recent months, the Officer of Civil Rights, or OCR, has been especially active in enforcing the HIPAA rules. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. Additionally, OCR is looking to amend the HIPAA Security Rule, which (if and when finalized) could create additional compliance obligations and risk for our business.

There are also increased restrictions at the federal level relating to transferring sensitive data outside of the U.S. to certain foreign countries. For example, in 2024, Congress passed H.B. 815, which included the Protecting Americans' Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data (including potential health data) to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the Department of Justice recently finalized a rule implementing Executive Order 14117, which creates similar restrictions related to the transfer of sensitive US data to countries such as China. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business.

Given the breadth and depth of changes in data protection obligations, complying with the GDPR's requirements is rigorous and time intensive and requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data collected in the European Union. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities, and could lead to government enforcement actions, private litigation and significant fines and penalties against us, all of which could increase our cost of doing business and have a material adverse effect on our business, financial condition or results of operations. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Further, we cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

Legislative and regulatory healthcare reform may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain for any products that are approved in the U.S. or foreign jurisdictions.

In the U.S. and some foreign jurisdictions, there have been several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of any product candidate, restrict or regulate post-approval activities and affect our ability to profitably sell Auryxia and Vafseo. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we receive for any FDA approved product, such as Auryxia or Vafseo or any reimbursement that physicians receive for administering any approved product.

In the U.S. the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for Auryxia and any other approved products. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA. In addition, other legislative and regulatory changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which will remain in effect through 2031.

Under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010 (PAYGO) sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

The American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, other legislative and regulatory changes have been proposed, but not yet adopted. For example, in July 2019, HHS proposed regulatory changes in kidney health policy and reimbursement. Any new legislative or regulatory changes may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for Auryxia or Vafseo or the frequency with which Auryxia and Vafseo is prescribed or used.

The costs and prices of prescription pharmaceuticals have also been the subject of considerable discussion in the U.S. To date, there have been several recent U.S. congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

In addition, in October 2020, the HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the U.S. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Seven states (Colorado, Florida, Maine, New Hampshire, New Mexico, Texas and Vermont) have passed laws allowing for the importation of drugs from Canada. North Dakota and Virginia have passed legislation establishing workgroups to examine the impact of a state importation program. As of May 2024, five states (Colorado, Florida, Maine, New Hampshire and New Mexico) have submitted Section 804 Importation Program proposals to the FDA. Vermont has submitted a concept letter to HHS. On January 5, 2024, the FDA approved Florida's plan for Canadian drug importation. On December 20, 2024 and June 2, 2025, the FDA granted 6-month and 4-month extensions to Florida's existing SIP authorizations based on Florida's commitment to move forward with the next steps for launching its SIP. Florida has authority to import certain drugs from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each drug selected for importation, which must be approved by the FDA. The state will also need to relabel the drugs and perform quality testing of the products to meet FDA standards. On May 21, 2025, the FDA announced that it would offer individual states the

opportunity to submit a draft proposal for pre-review and meet with the agency to obtain initial feedback from FDA prior to formally submitting their SIP proposal. The intent of these meetings is to assist states in developing their proposals by further clarifying requirements, enhancing the quality of proposals submitted to the agency and ultimately shortening the review timeline.

As an oral drug, Auryxia was covered by Medicare under Part D until January 1, 2025. In January 2011, CMS implemented the ESRD PPS, a prospective payment system for dialysis treatment. Under the ESRD PPS, CMS generally makes a single bundled payment to the dialysis facility for each dialysis treatment that covers all items and services routinely required for dialysis treatments furnished to Medicare beneficiaries in Medicare-certified ESRD facilities or at their home.

As of January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including Auryxia and all other phosphate lowering medications, are included in the ESRD bundle and separate Part D Medicare payment for these drugs is no longer available under Medicare Part D. However, ESRD facilities will receive a TDAPA for Auryxia for a period of at least two years starting on January 1, 2025 based on ASP. After the TDAPA period for Auryxia and other oral-only phosphorus lowering drugs, a permanent adjustment will be made by CMS to the base rate payment for each Medicare dialysis treatment to account for these drug costs. Vafseo, which we began selling in January 2025, is also included in the ESRD bundle and ESRD facilities will receive a TDAPA for Vafseo as a new renal dialysis drug meeting certain criteria for a period of no more than two years starting on January 1, 2025. The TDAPA provides separate payment based on Vafseo's ASP that will be in addition to the base rate to facilitate the adoption of innovative therapies. After the two-year TDAPA period for Vafseo, for a period of three additional years, a Medicare payment adjustment will be made for each dialysis treatment to account for the costs of Vafseo, based on 65% of its ASP. If the TDAPA reimbursement amount for Auryxia or Vafseo is lower than anticipated, or if TDAPA is eliminated, it would have an adverse impact on our revenue. Additionally, after the TDAPA period, CMS currently expects to increase the single bundled payment base rate paid to the dialysis facility for each dialysis treatment to reflect the cost of phosphate lowering medications, including Auryxia and for Vafseo. However, the increase related to Vafseo will only last three years and neither Auryxia nor Vafseo will receive a direct additional payment outside the bundled rate after the TDAPA period. There can be no assurances that any increase in the Medicare bundled payment base rate will be sufficient to adequately reimburse the dialysis facilities for Auryxia or Vafseo at a price that allows us to continue to sell Auryxia or Vafseo at a profit. In late 2025, legislation was introduced in the U.S. Congress, KCAPA, which seeks to maintain patient access to innovative kidney care treatment, including Vafseo, by addressing reimbursement challenges following TDAPA expiration. Without such legislative protection, there is a risk that, in the post-TDAPA period, reduced reimbursement could limit provider adoption of Vafseo, restrict patient access and adversely impact our revenue.

In July 2024, Ardelyx filed a complaint in the United States District Court for the District of Columbia against HHS, CMS and other parties, which alleged that CMS's plan to include oral-only phosphate lowering therapies in the ESRD PPS violated its statutory and regulatory authority under the Medicare Improvements for Patients and Providers Act, which established the ESRD PPS bundled payment system for dialysis services. In October 2024, Ardelyx filed a motion for a preliminary injunction to enjoin CMS from including oral-only phosphate lowering therapies in the ESRD PPS. CMS had earlier filed a motion to dismiss the complaint on jurisdictional grounds. On November 8, 2024, the district court denied Ardelyx's motion for a preliminary injunction and it granted the government's motion to dismiss. Thereafter, Ardelyx moved for reconsideration, but the district court also denied that request. On December 26, 2024, Ardelyx filed a notice of appeal with the US Court of Appeals for the DC Circuit. Briefing of the case has been completed and oral argument was held on September 25, 2025. If Ardelyx is successful in its claims, oral-only phosphate lowering therapies, including Auryxia, may be removed from the ESRD bundle, which could reduce anticipated revenue for Auryxia.

On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. We consider many factors when we implement a price increase for a product, including historical and potential future inflation rates. However, there are many variables that are outside of our control and if we increase the price of Auryxia or Vafseo faster than the pace of inflation, we would be subject to additional rebates under Medicare, which could have a material adverse effect on our product revenues.

With respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. With passage of the One Big Beautiful Bill Act on July 3, 2025, which was signed into law on July 4, 2025, Congress extended this exemption to drugs and

biologics with multiple orphan drug designations. On August 15, 2024, HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, CKD and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. Subsequently, on January 17, 2025, HHS announced its selection of 15 additional drugs covered by Part D for the second cycle of negotiations. This second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027. CMS issued a public statement on January 29, 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The law also caps Medicare out-of-pocket drug costs at an estimated $2,000.

On June 6, 2023, Merck & Co. Inc. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca, Boehringer Ingelheim, and Teva also filed lawsuits in various courts with constitutional and APA claims against the HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. The HHS has generally won the substantive disputes in these cases or succeeded in getting claims dismissed for lack of standing. Most of these cases are now on appeal. On October 30, 2024, the U.S. Court of Appeals for the Third Circuit heard oral argument in three of these cases. On May 8, 2025, the Third Circuit rejected AstraZeneca's challenge to the Medicare price negotiation program, finding that the program did not violate the company's due process rights under the constitution since there is no protected property interest in selling goods to Medicare beneficiaries at a price higher than what the government is willing to pay in reimbursement.

On April 15, 2025, President Trump issued an Executive Order which directs HHS to take steps to reduce the prices of pharmaceutical products. The new Order repeats many of the proposals advanced during the first Trump Administration, including directing the FDA to streamline and improve its existing drug importation program so as to make it easier for states to obtain approval without sacrificing the safety or quality of drug products. Other provisions of the Order relate to the 340B program. Specifically, one provision calls on the Secretary of HHS to determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments and to consider and propose any appropriate adjustments for Medicare payment. The other provision directs HHS to condition grant funding to certain health centers on those centers passing through the 340B discounts they receive on insulin and injectable epinephrine products to patients who meet certain requirements. With respect to the IRA's Medicare drug pricing program, the Order, among other things, calls for alignment in "the treatment of small molecule prescription drugs with that of biological products, ending the distortion that undermines relative investment in small molecule prescription drugs, coupled with other reforms to prevent any increase in overall costs to Medicare and its beneficiaries."

Further, on May 12, 2025, President Trump issued an additional Executive Order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the United States. The Order directs the Secretary of HHS to communicate most-favored-nation, or MFN, price targets to pharmaceutical manufacturers to bring prices in line with comparably developed nations. The Executive Order further provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes MFN pricing in the United States. Thereafter, on May 20, 2025, HHS indicated that the proposed MFN pricing will apply only to brand products without generic or biosimilar competition and the reference foreign countries will include only those in which the branded product similarly does not have generic or biosimilar competition. Second, HHS indicated that the MFN target price will be the lowest price in a country that is a member of the Organization for Economic Co-operation and Development, or OECD, with a gross domestic product, or GDP, per capita of at least 60% of the U.S. GDP per capita. Based on previous estimates, there are likely at least 22 OECD countries that would satisfy this criterion.

On July 31, 2025, the President issued letters to 17 pharmaceutical companies reiterating the requirements of the May 12, 2025, Executive Order and demanding that such companies extend MFN pricing to Medicaid patients, guarantee MFN pricing for newly-launched drug products, return increased revenues abroad to American patients and provide for direct purchasing at MFN pricing. The letters also urged these companies to stipulate that they will not offer other developed nations better prices for new drugs than the prices offered for such products in the U.S. The letters called for engagement with the FDA and CMS within 60 days to implement these changes and threatened to use "every tool in our arsenal" to address what the letter characterized as "abusive drug pricing practices."

On September 30, 2025, the administration announced that Pfizer had agreed to base its pharmaceutical prices in the U.S. on MFN pricing. According to a White House fact sheet, the agreement "will provide every State Medicaid program in the country

access to MFN drug prices" on the company's products, and requires the company "to offer medicines at a deep discount off the list price when selling directly to American patients." Pfizer indicated that the agreement "provides certainty from tariffs" and that the company "will also participate in a direct purchasing platform, TrumpRx.gov, that will allow American patients to purchase medicines…at a significant discount." Thereafter, a number of pharmaceutical companies have entered into agreements with the administration to provide for lower prices on certain pharmaceuticals.

In addition, the industry is awaiting the release of the Global Benchmark for Efficient Drug Pricing, or GLOBE, Model, a proposed rule by CMS that is currently pending review at the Office of Information and Regulatory Affairs within the Office of Management and Budget. Once released, the GLOBE Model proposed rule will provide further insight into how the administration is seeking to advance drug pricing policy and provide an opportunity for interested parties to submit public comment as part of the rulemaking process.

The implications and consequences of these actions and subsequent actions by the Trump Administration to compel an MFN regulatory pricing requirement in the U.S. continue to remain unclear and uncertain and could ultimately result in litigation. However, if an MFN regulatory pricing requirement is implemented in the U.S., it could have an adverse effect on our business.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, wholesale distributors, to disclose information about pricing of pharmaceuticals. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products or put pressure on our product pricing.

It is likely that federal and state legislatures within the U.S. and foreign governments will continue to consider changes to existing healthcare legislation. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for Auryxia or Vafseo and any product candidates for which we receive marketing approval or additional pricing pressures. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for Auryxia, Vafseo and any product candidates for which we receive marketing approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain and maintain coverage and reimbursement approval for Auryxia, Vafseo or any other approved product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

In July 2025, changes to the Medicaid program were enacted as part of new federal legislation, H.R. 1, "One Big Beautiful Bill Act," (Public Law 119-21). These changes include reductions in federal Medicaid funding. As a result, in some states a significant number of individuals may lose Medicaid coverage and become uninsured. These coverage losses could reduce patients' ability to access Auryxia and Vafseo, particularly among low-income individuals receiving dialysis care. If a significant number of patients become uninsured or lose access to Medicaid benefits, our revenues from Auryxia and Vafseo could be adversely affected.

Furthermore, in some countries, including EU Member States, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take a significant amount of time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices, and in certain instances render commercialization in certain markets infeasible or disadvantageous from a financial perspective. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product and/or our product candidates to other available products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third party payors or government authorities may lead to further pressure on the prices or

reimbursement levels. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, the commercial launch of our product and/or product candidates could be delayed, possibly for lengthy periods of time, we or our collaborators may not launch at all in a particular country, we may not be able to recoup our investment in one or more product candidates, and there could be a material adverse effect on our business.

Our reporting and payment obligations under the Medicaid Drug Rebate Program, Medicare and other governmental drug pricing programs are complex and may involve subjective decisions. Any failure to properly comply with those obligations could subject us to penalties and sanctions.

As a condition of reimbursement by various federal and state health insurance programs, we are required to calculate and report certain pricing information to federal and state agencies. The regulations governing the calculations, price reporting and payment obligations are complex and subject to interpretation by various government and regulatory agencies, as well as the courts. Reasonable assumptions have been made where there is lack of regulations or clear guidance and such assumptions involve subjective decisions and estimates. We are required to report any revisions to our calculation, price reporting and payment obligations previously reported or paid. Such revisions could affect our liability to federal and state payors and also adversely impact our reported financial results of operations in the period of such restatement. Further, several states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and several states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers for the untimely, inaccurate, or incomplete reporting of drug pricing information or for otherwise failing to comply with drug price transparency requirements. If we are found to have violated state law requirements, we may become subject to significant penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Uncertainty exists as new laws, regulations, judicial decisions, or new interpretations of existing laws, or regulations related to our calculations, price reporting or payments obligations increases the chances of a legal challenge, restatement or investigation. If we become subject to investigations, restatements, or other inquiries concerning our compliance with price reporting laws and regulations, we could be required to pay or be subject to additional reimbursements, penalties, sanctions or fines, which could have a material adverse effect on our business, financial condition and results of operations. In addition, it is possible that future healthcare reform measures could be adopted, which could result in changes to how we calculate or report certain pricing information to federal and state agencies, or increased pressure on pricing and reimbursement of our products and thus have an adverse impact on our financial position or business operations.

Further, state Medicaid programs may be slow to invoice pharmaceutical companies for calculated rebates resulting in a lag between the time a sale is recorded and the time the rebate is paid. This results in us having to carry a liability on our consolidated balance sheet for the estimate of rebate claims expected for Medicaid patients. If actual claims are higher than current estimates, our financial position and results of operations could be adversely affected.

In addition to retroactive rebates and the potential for 340B Program refunds, if we are found to have knowingly submitted any false price information related to the Medicaid Drug Rebate Program to CMS, we may be liable for civil monetary penalties. Such failure could also be grounds for CMS to terminate our Medicaid drug rebate agreement, pursuant to which we participate in the Medicaid program. In the event that CMS terminates our rebate agreement, federal payments may not be available under government programs, including Medicaid or Medicare Part B, for our covered outpatient drugs.

Additionally, if we overcharge the government in connection with the Federal Supply Schedule pricing program or Tricare Retail Pharmacy Program, whether due to a misstated Federal Ceiling Price or otherwise, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the FDCA and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our collaborators are also subject to similar requirements outside of the U.S. and thus the attendant risks and uncertainties. If our collaborators suffer material and adverse effects from such risks and uncertainties, our rights and benefits for our licensed products could be negatively impacted, which could have a material and adverse impact on our revenues.

With the passage of the CREATES Act, we are exposed to possible litigation and damages by competitors who may claim that we are not providing sufficient quantities of our approved products on commercially reasonable, market-based terms for testing in support of their ANDAs, 505(b)(2) NDAs and biosimilar product applications.

In December 2019, President Trump signed legislation intended to facilitate the development of generic and biosimilar products. The bill, previously known as the CREATES Act, authorizes sponsors of ANDAs, 505(b)(2) NDAs or biosimilar product

applications to file lawsuits against companies holding NDAs or BLAs that decline to provide sufficient quantities of an approved reference drug or biological product on commercially reasonable, market-based terms. Drug or biological products on FDA's drug shortage list are exempt from these new provisions unless the product has been on the list for more than six continuous months or the FDA determines that the supply of the product will help alleviate or prevent a shortage.

To bring an action under the statute, the developer of a product candidate that seeks to develop the product and seek approval under an ANDA, 505(b)(2) NDA, or biosimilar product application must take certain steps to request the reference product from the reference product manufacturer, which, in the case of products covered by a REMS with elements to assure safe use, include obtaining authorization from the FDA for the acquisition of the reference product. If the reference product manufacturer does not provide the reference product and the ANDA, 505(b)(2) NDA, or biosimilar product sponsor does bring an action for failure to provide a reference product, there are certain affirmative defenses available to the reference product manufacturer, which must be shown by a preponderance of evidence, including that the NDA or BLA holder sells the reference product through agents, distributors, or wholesalers and has placed no restrictions, explicit or implicit, on selling the reference product to ANDA, 505(b)(2) or biosimilar sponsors. If the sponsor prevails in litigation, it is entitled to a court order directing the reference product manufacturer to provide, without delay, sufficient quantities of the applicable product on commercially reasonable, market-based terms, plus reasonable attorney fees and costs.

Additionally, the new statutory provisions authorize a federal court to award the product developer an amount "sufficient to deter" the reference product manufacturer from refusing to provide sufficient product quantities on commercially reasonable, market-based terms, up to a certain maximum amount based on revenue earned while in noncompliance, if the court finds, by a preponderance of the evidence, that the reference product manufacturer did not have a legitimate business justification to delay providing the product or failed to comply with the court's order. For the purposes of the statute, the term "commercially reasonable, market-based terms" is defined as (1) the nondiscriminatory price at or below the most recent wholesale acquisition cost for the product, (2) a delivery schedule that meets the statutorily defined timetable, and (3) no additional conditions on the sale.

Although we intend to comply fully with the terms of these statutory provisions, we are still exposed to potential litigation and damages by competitors who may claim that we are not providing sufficient quantities of our approved products on commercially reasonable, market-based terms for testing in support of ANDAs, 505(b)(2) NDA applications or biosimilar product applications. Such litigation would subject us to additional litigation costs, damages and reputational harm, which could lead to lower revenues. The CREATES Act may facilitate future competition with Auryxia or Vafseo and any of our product candidates, if approved, which could impact our ability to maximize product revenue.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the use and disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from the use of hazardous materials by our employees, contractors or consultants, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to our Reliance on Third Parties

We depend on collaborations with third parties for the development and commercialization of Auryxia, an authorized generic version of Auryxia, Riona and Vafseo. If these collaborations are not successful or if our collaborators terminate their agreements with us, we may not be able to capitalize on the market potential of Auryxia, Riona and Vafseo, and our business could be materially harmed.

With respect to Auryxia, we sublicensed the rights to commercialize Riona to JT and Torii in Japan. In addition, we granted Averoa an exclusive license to develop and commercialize ferric citrate in the Averoa Territory. In February 2025, in advance of the market entry of generic competition to our branded Auryxia following LoE, we entered into an Authorized Generic

Distribution and Supply Agreement with our AG Distributor, pursuant to which, since March 2025, our AG Distributor has been selling an authorized generic version of Auryxia. We will be relying on our AG Distributor for the commercialization of this authorized generic. If competition, including from generics other than our AG Distributor, capture sales or if generics other than our authorized generic are sold at a greater discount to Auryxia's price than anticipated, it could materially and adversely affect our expected revenues. In addition, we are responsible for supplying product to our AG Distributor, and if there are challenges within the supply chain, we could be subject to certain penalties, which could be substantial.

With respect to Vafseo, we entered into a collaboration agreement with TPC to develop and commercialize Vafseo in Japan and certain other Asian countries. Furthermore, we granted Medice an exclusive license to develop and commercialize Vafseo for the treatment of anemia in patients with CKD in the Medice Territory.

We may not be able to maintain our collaborations for development and commercialization. For example, on May 13, 2022, Otsuka Pharmaceutical Co. Ltd., or Otsuka, elected to terminate our collaboration agreements related to Vafseo, and we subsequently negotiated a Termination and Settlement Agreement with Otsuka. This termination by Otsuka may have delayed the launch of Vafseo in Europe or other territories previously licensed to Otsuka or adversely affected how we are perceived in scientific and financial communities. In August 2023, Medice informed us that their launch of Vafseo in certain countries in the Medice Territory was going to be later than previously anticipated due to some prerequisite activities required to enable the launch. If we are unable to maintain our collaborations, we may not be able to capitalize on the market potential of our products or product candidates, and our business could be materially harmed.

Our current and any future collaborations may not be successful due to a number of important factors, including the following:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborations may be terminated in accordance with the terms of the collaboration agreements and, if terminated, may make it difficult for us to attract new collaborators or adversely affect how we are perceived in scientific and financial communities, and may result in a need for additional capital and expansion of our internal capabilities to pursue further development or commercialization of the applicable products and product candidates;
- if permitted by the terms of the collaboration agreements, collaborators may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus, availability of funding or other external factors such as a business combination that diverts resources or creates competing priorities;
- if permitted by the terms of the collaboration agreements, collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- a collaborator with marketing and distribution rights to our products may not commit sufficient resources to their marketing and distribution;
- if permitted by the terms of the collaboration agreements, we and our collaborator may have a difference of opinion regarding the development or commercialization strategy for a particular product or product candidate, and our collaborator may have ultimate decision making authority;
- disputes may arise between a collaborator and us that cause the delay or termination of activities related to research, development, supply or commercialization of Auryxia, Riona or Vafseo and any other product candidate, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may not lead to development or commercialization of products and product candidates, if approved, in the most efficient manner or at all;
- inefficiencies or structural changes in internal operations or processes of our collaborators may lead to increased expenses associated with commercializing a product, including manufacturing costs, rebates, product returns and other adjustments which would negatively impact net product revenue;
- a significant change in the senior management team, a change in the financial condition or a change in the business operations, including a change in control or internal corporate restructuring, of any of our collaborators, could result in delayed timelines, re-prioritization of our programs, decreasing resources or funding allocated to support our programs, or termination of the collaborations; and
- collaborators may not comply with all applicable regulatory and legal requirements.

If any of these events occur, the market potential of Auryxia, including our authorized generic, Riona or Vafseo, where approved, and any other products or product candidates, could be reduced, and our business could be materially harmed. Collaborations may also divert resources, including the attention of management and other employees, from other parts of

our business, which could have an adverse effect on other parts of our business, and we cannot be certain that the benefits of the collaboration will outweigh the potential risks.

We may seek to establish additional collaborations and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.

We may decide to enter into additional collaborations, strategic alliances, or joint ventures, or enter into additional licensing arrangements with third parties that we believe will complement or augment our and our partners' development and/or commercialization efforts with respect to Auryxia, Vafseo or any other products or product candidates both within and outside of the U.S. For example, in May 2023, we entered into the license agreement with Medice, pursuant to which we granted Medice an exclusive license to develop and commercialize Vafseo for the treatment of anemia in patients with CKD in the Medice Territory. Additionally, in November 2025, we and Medice entered into Amendment #1 to the license agreement, pursuant to which we agreed to supply vadadustat drug substance to Medice pursuant to the terms of a supply agreement dated concurrently with the license agreement amendment and granted Medice the right to manufacture Vafseo tablets using the vadadustat drug substance to be supplied by us. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, divert management's attention, or disrupt our business.

We may not be successful in entering into additional collaborations as a result of many factors, including the following:

- competition in seeking appropriate collaborators;
- a reduced number of potential collaborators due to recent business combinations in the pharmaceutical industry;
- an inability to negotiate collaborations on acceptable terms, on a timely basis or at all;
- any international rules, regulations, guidance, laws, risks or uncertainties with respect to potential partners outside of the U.S.;
- a potential collaborator's evaluation of Auryxia, Vafseo or any other product or product candidate may differ substantially from ours;
- a potential collaborator's evaluation of our financial stability and resources;
- a potential collaborator's resources and expertise; and
- restrictions due to an existing collaboration agreement.

If we are unable to enter into additional collaborations in a timely manner, or at all, we may have to delay or curtail the commercialization of Auryxia, Vafseo or the development and potential commercialization of any of our product candidates, reduce or delay our development programs, or increase our expenditures and undertake additional development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop or commercialize Auryxia, Vafseo or our product candidates. For example, following the termination of our collaboration agreements with Otsuka in 2022, we incurred additional expenses in connection with the launch of Vafseo in Europe and other countries.

Even if we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, we may not be able to maintain them or they may be unsuccessful, which could delay our timelines or otherwise adversely affect our business.

Royalties from commercial sales of Vafseo under our TPC Agreement will likely fluctuate and will impact our rights to receive future payments under our Royalty Agreement with HCR.

Pursuant to the Royalty Agreement with HCR, we sold to HCR our right to receive the Royalty Interest Payments payable to us under the TPC Agreement, subject to the Annual Cap and the Aggregate Cap. After HCR receives Royalty Interest Payments equal to the Annual Cap in a given calendar year, we will receive 85% of the Royalty Interest Payments for the remainder of that year. After HCR receives Royalty Interest Payments equal to the Aggregate Cap, or we pay the Aggregate Cap to HCR (net of the Royalty Interest Payments already received by HCR), the Royalty Interest Payments will revert back to us, and HCR would have no further right to any Royalty Interest Payments. We received $44.8 million from HCR (net of certain transaction expenses) under the Royalty Agreement.

The royalty revenues under the TPC Agreement may fluctuate considerably because they depend upon, among other things, the rate of growth of sales of Vafseo in the territory covered by the TPC Agreement. Negative fluctuations in these royalty revenues could delay, diminish or eliminate our ability to receive 85% of the Royalty Interest Payments after the Annual Cap is achieved in a given calendar year, or our ability to receive 100% of the Royalty Interest Payments after the Aggregate Cap is achieved.

We rely upon third parties to conduct all aspects of our product manufacturing and commercial distribution, and in many instances only have a single supplier or distributor, and the loss of these manufacturers or distributors, their failure to

supply us on a timely basis, or at all, or their failure to successfully carry out their contractual duties or comply with regulatory requirements, cGMP requirements or guidance could cause delays in or disruptions to our supply chain and substantially harm our business.

We do not have any manufacturing facilities and do not expect to independently manufacture any products or product candidates. We currently rely, and expect to continue to rely, on third-party manufacturers to produce all of our commercial, clinical and preclinical supply. We also utilize third parties for the commercial distribution of Auryxia and Vafseo, including Cardinal Health, Inc. as the exclusive third-party logistics provider, or 3PL, wholesale distributors and certain specialty pharmacy providers. Our reliance on third-party manufacturers, who have control over the manufacturing process, increases the risk that we will not have or be able to maintain or distribute sufficient quantities of Auryxia, Vafseo or any of our product candidates or the ability to obtain such quantities at an acceptable cost or quality, which could delay, prevent or impair our and our partners' development or commercialization efforts.

We currently rely on single source suppliers for each of drug substance and drug product for Auryxia, including for our authorized generic, and commercial supply from other suppliers is not readily available, and our exclusive 3PL for commercial sales of Auryxia and Vafseo. If any of the following occurs, we may not have sufficient quantities of Auryxia, Vafseo or our product candidates to support our clinical trials, commercial distribution, pipeline development or commercialization, which could materially and adversely impact our business and results of operations:

- we are unsuccessful in maintaining our current supply arrangements for commercial quantities of Auryxia and Vafseo, or such arrangements are terminated;
- we are unsuccessful in validating new sites;
- we are unable to maintain adequate inventory levels;
- any of our third-party manufacturers are unable to fulfill the terms of their agreements with us or orders that we place under those agreements due to technical issues, resource constraints, natural disasters or other reasons, including with respect to quality and quantity, or are unable or unwilling to continue to manufacture sufficient quantities or at all on the manufacturing lines included in our regulatory filings;
- any of our third-party manufacturers breach our supply agreements, do not comply with quality or regulatory requirements and guidance, including cGMP or are subject to regulatory review or ceases their operations for any reason; or
- our 3PL fails to perform or encounters any damage or other disruption at their facilities.

If we, or any of our third-party manufacturers or our 3PL cannot or do not perform as agreed or expected, or any of our customers were to experience further shutdowns, delays or other business disruptions, including as a result of resource constraints, catastrophic events, including pandemics, terrorist attacks, wars or other armed conflicts, geopolitical tensions, tariffs, trade agreement disputes, or natural disasters, if they misappropriate our proprietary information, if they terminate their engagements with us, if we terminate our engagements with them, or if there is a significant disagreement, we may be forced to manufacture or distribute the materials ourselves, for which we currently do not have the capabilities or resources, or enter into agreements with other third-party manufacturers or distributors, which we may not be able to do in a timely manner or on favorable or reasonable terms, if at all. If any of these events occur, especially with respect to one of our sole source suppliers, we may not have sufficient quantities of product for the commercial distribution of Auryxia and/or Vafseo or may experience delays in the launch of Vafseo or the development of our product candidates, which could materially and adversely impact our business and results of operation. In addition, if we do not have sufficient quantities of Auryxia, including our authorized generic, or Vafseo to satisfy the requirements of our customer and supply contracts, including inventory levels, we have incurred with respect to Auryxia, and may in the future incur, contractual penalties, which could be substantial.

In some cases, there may be a limited number of qualified replacement manufacturers, or the technical skills or equipment required to manufacture a product or product candidate may be unique or proprietary to the original manufacturer, and we may have difficulty transferring such skills or technology to another third party, or a feasible alternative may not exist. These factors would increase our reliance on our current manufacturers or require us to obtain necessary regulatory approvals and licenses in order to have another third-party manufacture Auryxia or Vafseo. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays and costs associated with the qualification of a new manufacturer and validation of manufacturing processes would negatively affect our ability to supply clinical trials, obtain and maintain marketing approval, or commercialize or satisfy patient demand for Auryxia and Vafseo, where approved, in a timely manner, within budget, or at all.

Moreover, issues that may arise in any scale-up, technology transfer, or continued commercial scale manufacture of our products may lead to significant delays in our development, marketing approval and commercial timelines for new products or affect commercial supply of Auryxia or Vafseo and negatively impact our financial performance. For example, we have

experienced issues in manufacturing Auryxia, including capacity constraints, which have impacted inventory levels, and if we experience manufacturing issues going forward, or incur additional costs, or our actions to prevent future interruptions are not successful, we may experience additional supply issues. If we are unable to produce sufficient quantities of Auryxia drug product to satisfy the requirements of our customer and supply contracts, it could have an adverse impact on our business. In addition, before we can manufacture product at a new site, we may need to validate the process at that site. If the process validation is unsuccessful, or takes longer than we anticipate, we may have to expend additional resources and could experience a supply interruption. Any future supply interruptions, whether related to inventory levels, capacity, quality or quantity, for Auryxia or Vafseo where approved may negatively and materially impact our reputation and financial condition.

Our third-party manufacturers may experience problems with their manufacturing and distribution operations and processes, including, for example, quality issues, such as product specification and stability failures, procedural deviations, improper equipment installation or operation, utility failures, contamination, natural disasters and public health epidemics. We may also encounter difficulties relating to our own quality processes and procedures, including regulatory compliance, lot release, quality control and quality assurance, as well as shortages of qualified personnel. If our third-party manufacturers cannot successfully manufacture material that conforms to our specifications and regulatory requirements and guidance, or if we or our third-party manufacturers experience manufacturing, operations and/or quality issues, including an inability or unwillingness to continue manufacturing our products at all, in accordance with agreed-upon processes or on currently validated manufacturing lines, we may not be able to supply patient demand or maintain marketing approval for Auryxia or Vafseo, and we might be required to expend additional resources to obtain material from other manufacturers. If any of these events occur, our reputation and financial condition would be negatively and materially impacted. In addition, if we have high amounts of write-downs to inventory levels in the future, it could negatively impact our ability to supply Auryxia or Vafseo, and our financial condition could be harmed.

In addition, the cost of obtaining Auryxia and Vafseo is subject to adjustment based on our third-party manufacturers' costs of obtaining raw materials and producing the product. We have limited control over the production costs of Auryxia and Vafseo, including the costs of raw materials, and have seen increases in the production costs of Auryxia and Vafseo, and any significant increase in the cost of obtaining our products could materially adversely affect our revenue for Auryxia and Vafseo.

We rely on third-party manufacturers to manufacture Auryxia and Vafseo for us and comply with cGMP regulations and guidance and other stringent regulatory requirements and guidance enforced by the FDA, EMA, PMDA and other global regulatory authorities. These requirements include, among other things, quality control, cGMP compliance, global regulatory requirements, and the maintenance of records and documentation. The facilities and processes used by our third-party manufacturers to manufacture Auryxia and Vafseo may be inspected by the FDA and other regulatory authorities at any time. Although we have oversight of the manufacturing processes of our third-party manufacturers, we do not ultimately control such manufacturing processes of, and do not have full control over, our third-party manufacturers, including, without limitation, their compliance with cGMP requirements and guidance for the manufacture of certain starting materials, drug substance and finished drug product. Similarly, although we review final production, we do not have full control over the ability of our third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Our third-party manufacturers may also have other clients and other priorities that could affect their manufacturing line capacity or delivery schedules, which are beyond our control.

Moreover, our failure or the failure of our third-party manufacturers or distributors to comply with applicable regulations or guidance, or our failure to oversee or facilitate such compliance, could result in sanctions being imposed on us or our third-party manufacturers or distributors, including, where applicable, clinical holds, fines, injunctions, civil penalties, delays in, suspension of or withdrawal of approvals, license revocation, seizures or recalls of Auryxia or Vafseo in the U.S., Japan or Europe, operating restrictions, receipt of a Form 483 or warning letter, or criminal prosecutions, any of which could significantly and adversely affect the supply of Auryxia or Vafseo. For example, we previously conducted three, limited, voluntary recalls of Auryxia. Any other recalls or any supply, quality or manufacturing issues in the future and any related write-downs of inventory or other consequences could result in significant negative consequences, including reputational harm, loss of customer confidence, and a negative impact on our financials, any of which could have a material adverse effect on our business and results of operations, and may impact our ability to supply Auryxia or Vafseo for clinical and commercial use. Also, if our starting materials, drug substance or drug product are damaged or lost while in our or our third-party manufacturers' or distributors' control, it may adversely impact our ability to supply Auryxia or Vafseo, and we may incur significant financial harm.

If the FDA, EMA or other regulatory authorities withdraws any approval of the facilities being used to manufacture Auryxia, Vafseo or any of our product candidates, we may need to find alternative manufacturing facilities, which would significantly impact our ability to continue commercializing Auryxia or Vafseo, or to develop, obtain marketing approval for or market Vafseo our other product candidates, if approved.

In addition, Auryxia, Vafseo and our product candidates may compete with other products and product candidates for access to third-party manufacturing facilities. A third-party manufacturer or distributor may also encounter delays or operational

issues brought on by sudden internal resource constraints, labor disputes, shifting priorities or shifting regulatory protocols. Certain of these third-party manufacturing facilities may be contractually prohibited from manufacturing Auryxia, Vafseo or our product candidates due to exclusivity provisions in agreements with our competitors. Any of the foregoing could negatively impact our third-party manufacturers' or distributors' ability to meet our demand, which could adversely impact our ability to supply Auryxia, Vafseo or our product candidates, and we may incur significant financial harm.

Our current and anticipated future dependence on third parties for the manufacture and distribution of Auryxia, Vafseo and our product candidates may adversely affect our and our partners' ability to commercialize Auryxia, Vafseo and our product candidates, where approved, on a timely and competitive basis and may reduce any future profit margins.

We rely upon third parties to conduct our clinical trials and certain of our preclinical studies. If they do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain or maintain marketing approval for Auryxia, Vafseo or any of our product candidates, and our business could be substantially harmed.

We do not have the ability to independently conduct certain preclinical studies and clinical trials. We are currently relying, and expect to continue to rely, upon third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our current and future preclinical studies and clinical trials. The third parties upon whom we rely may fail to perform effectively, or terminate their engagement with us, for a number of reasons, including the following:

- if they experience any compliance issues;
- if they experience staffing difficulties;
- if we fail to communicate effectively or provide the appropriate level of oversight;
- if they undergo changes in priorities or corporate structure including as a result of a merger or acquisition or other transaction, or become financially distressed; or
- if they form relationships with other entities, some of which may be our competitors.

If the third parties upon whom we rely to conduct our trials fail to adhere to clinical trial protocols or to regulatory requirements, the quantity, quality or accuracy of the data obtained by the third parties may be compromised. We are exposed to the risk of fraud or other misconduct by such third parties.

Any of these events could cause our preclinical studies and clinical trials, including post-approval clinical trials, to be extended, delayed, suspended, required to be repeated or terminated, or we may receive untitled warning letters or be the subject of an enforcement action, which could result in our failing to maintain marketing approval of Auryxia or Vafseo, or failing to obtain or maintain marketing approval for any other product candidates on a timely basis or at all, any of which would adversely affect our business operations. In addition, if the third parties upon whom we rely fail to perform effectively or terminate their engagement with us, we may need to enter into alternative arrangements, which could delay, perhaps significantly, the development and commercialization of Auryxia, Vafseo or any other product candidates.

Even though we do not directly control the third parties upon whom we rely to conduct our preclinical studies and clinical trials and therefore cannot guarantee the satisfactory and timely performance of their obligations to us, we are nevertheless responsible for ensuring that each of our clinical trials and preclinical studies is conducted in accordance with the applicable protocol, legal and regulatory requirements, including GxP requirements, and scientific standards, and our reliance on these third parties, including CROs, will not relieve us of our regulatory responsibilities. If we or any of our CROs, their subcontractors, or clinical or preclinical trial sites fail to comply with applicable GxP requirements, the clinical data generated in our trials may be deemed unreliable or insufficient, our clinical trials could be put on hold, and/or the FDA, the EMA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical and preclinical trials must be conducted with drug product that meets certain specifications and is manufactured under applicable cGMP regulations. These requirements include, among other things, quality control, quality assurance, and the satisfactory maintenance of records and documentation.

We also rely upon third parties to store and distribute drug product for our clinical trials. For example, we use third parties to store product at various sites in the U.S. to distribute to our clinical trial sites. Any performance failure on the part of our storage or distributor partners could delay clinical development, marketing approval or commercialization, resulting in additional costs and depriving us of potential product revenue.

If the licensor of certain intellectual property relating to Auryxia terminates, modifies or threatens to terminate existing contracts or relationships with us, our business may be materially harmed.

We do not own all of the rights to our product, Auryxia. We have licensed and sublicensed certain rights, patent and otherwise, to Auryxia from Panion & BF Biotech, Inc., or Panion, a third-party, who in turn licenses certain rights to Auryxia from one of the inventors of Auryxia. The license agreement with Panion, or the Panion License Agreement, requires us to meet development milestones and imposes development and commercialization due diligence requirements on us. In

addition, under the Panion License Agreement, we must pay royalties based on a mid-single digit percentage of net sales of product resulting from the licensed technologies, including Auryxia, and pay the patent filing, prosecution and maintenance costs related to the license. If we do not meet our obligations in a timely manner, or if we otherwise breach the terms of the Panion License Agreement, Panion could terminate the agreement, and we would lose the rights to Auryxia. For example, following announcement of the Merger, Panion notified us in writing that Panion would terminate the Panion License Agreement on November 21, 2018 if we did not cure the breach alleged by Panion, specifically, that we failed to use commercially reasonable best efforts to commercialize Auryxia outside the U.S. We disagreed with Panion's claims, and the parties entered discussions to resolve this dispute. On October 24, 2018, prior to the consummation of the Merger, we and Panion entered into a letter agreement, or the Panion Letter Agreement, pursuant to which Panion agreed to rescind any and all prior termination threats or notices relating to the Panion License Agreement and waived its rights to terminate the license agreement based on any breach by us of our obligation to use commercially reasonable efforts to commercialize Auryxia outside the U.S. until the parties executed an amendment to the Panion License Agreement in accordance with the terms of the Panion Letter Agreement, following consummation of the Merger. On April 17, 2019, we and Panion entered into an amendment and restatement of the Panion License Agreement, or the Panion Amended License Agreement, which reflects certain revisions consistent with the terms of the Panion Letter Agreement. See Note 10, *Commitments and Contingencies*, to our consolidated financial statements in Part II, Item 3. Financial Statements and Supplementary Data of this Form 10-K for additional information regarding the Panion Amended License Agreement. Even though we entered into the Panion Amended License Agreement, there are no assurances that Panion will not allege other breaches of the Panion Amended License Agreement or otherwise attempt to terminate the Panion Amended License Agreement in the future. In addition, if Panion breaches its agreement with the inventor from whom it licenses rights to Auryxia, Panion could lose its license, which could impair or delay our ability to develop and commercialize Auryxia.

From time to time, we may have disagreements with Panion, or Panion may have disagreements with the inventor from whom it licenses rights to Auryxia, regarding the terms of the agreements or ownership of proprietary rights, which could impact the commercialization of Auryxia, could require or result in litigation or arbitration, which would be time consuming and expensive, could lead to the termination of the Panion Amended License Agreement, or force us to negotiate a revised or new license agreement on terms less favorable than the original. In addition, in the event that the owners and/or licensors of the rights we license were to enter into bankruptcy or similar proceedings, we could potentially lose our rights to Auryxia or our rights could otherwise be adversely affected, which could prevent us from continuing to commercialize Auryxia.

Manufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our AKB-097 development program or other product candidates.

The manufacturing of biologics is highly complex, and we may experience production issues or interruptions in supply for our AKB-097 development program or other product candidates. The development process may be met with challenges related to successful scale-up of the process to deliver the required inventory to support our clinical trials. Specifically, if we or our third-party CDMOs are unable to procure critical raw materials in a timely manner, successfully scale our manufacturing process, or provide sufficient manufacturing campaign slots to support production, we may not be able to supply the required inventory to allocate to clinical trials and/or commercial supply. Raw material shortages, contamination events, or manufacturing batch failures pose significant risks and could disrupt production and therefore limit downstream supply, ultimately delaying our development timelines and having an adverse effect on our business, financial condition, operations, and product candidates.

We face risks based on our reliance on CDMOs for AKB-097 manufacture as there is increased regulatory scrutiny on aseptic and sterile product manufacture. The manufacturing facilities for AKB-097 on which we rely may not meet the stringent regulatory requirements and this could adversely affect our development and commercialization plans for AKB-097 and other product candidates. Sterile finished good therapeutic products approved for use in clinical trials are required to be manufactured in accordance with cGMP. Such regulations strictly govern manufacturing processes and overarching quality systems to assure robust compliance and quality control of investigational products utilized in clinical trials and commercial products approved for sale. Poor production practices increase the risk of introduction of adventitious agents and/or other contaminants or process changes that may impact the stability of our biologic product candidate which may be undetectable through final product testing. As such, it is critical to implement robust facility and product controls strategies to document that our products have been manufactured and tested in accordance with cGMPs and to demonstrate that our products are safe and efficacious and support our clinical trials and ultimately the potential approval of a BLA for any product candidate.

Our CDMO's facilities and their quality systems must ultimately pass a pre-approval inspection, or PAI, to confirm validity of the information filed in the BLA and to confirm the capability of our CDMOs to manufacture our product in compliance with the applicable regulations. If our or our CDMO's quality systems or facilities involved with the preparation of our product candidates do not pass the PAI, FDA approval of such product candidates will not be granted.

Our CDMOs are subject to routine or for-cause inspections of the facilities that manufacture, test, and/or store our product candidates. Deficiencies identified during these inspections may require remediation potentially impacting or delaying the development or approval of AKB-097 or other product candidates and thereby delaying our clinical trials or the commercial

approval of AKB-097. Additionally, remediation of deficiencies poses the risk of lost product or significant financial impact which also may result in delays to our clinical trials or commercial approval and could materially harm our business.

Changes in and uncertainty surrounding U.S. trade policy on tariffs could have a material adverse impact on our business, financial condition and results of operations.

In 2025, the Trump Administration initiated a series of tariff-related actions against U.S. trading partners. On April 2, 2025, the President issued an executive order announcing a "baseline" reciprocal tariff of 10% on all U.S. trading partners effective April 5, 2025, and higher individualized reciprocal tariffs on 57 countries (with certain product exemptions for pharmaceutical-related products, among others). Previously, the administration had imposed a 25% tariff on Canada and Mexico for goods not covered by the United States-Mexico-Canada Agreement, or USMCA, and tariffs equaling 20% on China. In response, several countries threatened retaliatory measures, including Canada and China, which then imposed retaliatory tariffs. Prior to when the country-specific reciprocal tariffs were scheduled to take effect, the administration delayed the effective date of such tariffs for all countries except China. Several countries, including the United Kingdom, Japan and South Korea, among others, as well as the European Union, have reached deals with the U.S. that include reduced tariff rates and other measures. President Trump also issued an Executive Order detailing new reciprocal tariff rates for individual countries that took effect on August 7, 2025. The new reciprocal rates, which are consistent with the rates reflected in the trade deals already announced, range from 10% to 41%. The new rates do not apply to Canada, China, Mexico and a few other countries.

The U.S. and China reached a tentative agreement that resulted in the suspension of the higher reciprocal tariffs on China until November 10, 2026. For China, the 10% baseline reciprocal tariff announced in April remains in effect, in addition to a minimum of an additional 10%, effective November 10, 2025. For Mexico, the rate remains 25% for goods that are not covered by the USMCA, and for Canada, the rate is 35% for goods that are not covered by the USMCA. Certain countries, including Japan, South Korea and the United Kingdom, as well as the European Union, have reached agreements with the U.S. that cap pharmaceutical tariffs at 15%.

Separately, in April 2025, the U.S. Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 into the impact on U.S. national security of the imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, active pharmaceutical ingredients, and related chemicals. On September 25, 2025, via a post on Truth Social, the President announced that, beginning October 1, 2025, all branded or patented drugs imported in the U.S. would face a 100% tariff. The President indicated that the tariffs could be avoided by building pharmaceutical manufacturing facilities in the U.S. Thereafter, the President delayed the October 1st effective date of these tariffs and announced that the administration had begun preparing tariffs on manufacturers that do not build in the U.S. or enter into a most-favored-nation drug pricing agreement with the administration. Certain trading partners, including the European Union, South Korea and Japan, negotiated exemptions from the Section 232 tariffs on pharmaceuticals.

A host of other U.S. tariff actions remain possible, including an additional 25% tariff on products from countries that do business with Iran.

In February 2026, the U.S. Supreme Court held that the International Emergency Economic Powers Act does not authorize the President to impose tariffs, invalidating both the "reciprocal" tariffs and certain country-specific tariffs. However, the President announced plans to impose new tariffs under other authorities.

We currently manufacture all of our Vafseo drug substance and drug product in China and conduct certain research activities in China. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S. based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on contract development and manufacturing organizations, or CDMOs, and other service providers that operate in China, including our current Vafseo manufacturers.

Our business may be negatively affected by these tariffs and any new tariff actions or trade restrictions and the underlying uncertainty and supply chain disruptions created thereby. The development, testing and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We cannot yet predict the effect of the recently imposed U.S. tariffs on imports, or the extent to which other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

Changes in the geopolitical environment, including U.S. and international trade policies, particularly with respect to China, Europe or Canada, may adversely impact our business and operating results.

Many of our manufacturers and suppliers for Auryxia and Vafseo are located in China, Europe and Canada, and we may continue to rely on foreign CMOs in the future. The manufacturing of our drug product for commercial use of both Auryxia and Vafseo takes place in Canada through a third-party manufacturer, Patheon Inc., or Patheon. The manufacturing for

commercial use of both Auryxia and Vafseo drug substance takes place in France and Spain, respectively. Also, the manufacturing of our drug substance and drug product for commercial supply of Vafseo takes place in China through a third-party manufacturer, STA Pharmaceutical Hong Kong Limited, a subsidiary of WuXi AppTec, or WuXi STA. We also rely on third parties in China for the supply of raw materials used in the manufacture of Vafseo and for certain early-stage research services. Trade tensions and conflicts between the U.S. and China, Europe, Canada or other countries have recently been escalating and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the U.S., China, Europe, Canada or other countries, trade agreement disputes or due to geopolitical unrest and unstable economic conditions. In addition, certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. In addition, the U.S. Department of Commerce's Bureau of Industry and Security, or BIS, published an interim final rule in September 2025, referred to as the "Affiliates Rule," which expands the scope of BIS export restrictions to include entities with 50% or greater ownership, in the aggregate, by one or more entities listed on the BIS entity list. While the Affiliates Rule has been suspended until November 10, 2026 as part of the U.S.-China tentative framework agreement, escalating tensions between the United States and China may prevent or hinder the export of materials or technical information between us and our CDMO and third parties, such as pharmaceutical manufacturers. These third parties may voluntarily require compliance or supply chain requirements that go above and beyond potential legislation to address perceived risk of "pass through," which would make it difficult for us to operate our business.

In addition, on December 18, 2025, as part of the National Defense Authorization Act for Fiscal Year 2026, President Trump signed into law the BIOSECURE Act, which limits U.S. government procurement from and grants to biotechnology companies of concern, or BCCs. Under the BIOSECURE Act, U.S. government agencies cannot (i) buy or obtain biotechnology equipment or services provided by a BCC; (ii) enter into, extend, or renew a contract with any entity using biotechnology equipment or services provided by a BCC to perform a government contract; or (iii) expend loan or grant funds for biotechnology equipment or services provided by a BCC. The BIOSECURE Act does not name specific companies as BCCs but treats any company on the U.S. Department of Defense 1260H list of Chinese Military Companies as a BCC. This list currently includes BGI Group, BGI Genomics Co., Ltd., Forensic Genomics International, and MGI Tech Co., Ltd., but does not include the WuXi entities. The legislation allows for other biotechnology companies, possibly including WuXi entities, to be added to the federal funding prohibitions at a later time.

This law could have the potential to severely restrict the ability of companies like ours to contract with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. Such disruptions could have adverse effects on our ability to commercialize Auryxia and Vafseo or the development of our product candidates and our business operations.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our products and product candidates, affect the demand for our products, the competitive position of our products or product candidates, and import or export of raw materials and finished product candidate used in our preclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China and Canada, including pursuant to our manufacturing service arrangements with WuXi STA and Patheon. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if the U.S., Chinese, European, Canadian or other governments take retaliatory trade actions due to the recent trade tensions, such changes could have an adverse effect on our business, financial condition and results of operations.

Risks Related to our Intellectual Property

If we are unable to adequately protect our intellectual property, third parties may be able to use our intellectual property, which could adversely affect our ability to compete in the market.

Our commercial success will depend in part on our ability, and the ability of our licensors, to obtain and maintain patent protection on our drug product and technologies, and to successfully defend these patents against third party challenges. We seek to protect our proprietary products and technology by filing patent applications in the U.S. and certain foreign jurisdictions. The process for obtaining patent protection is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in a cost effective or timely manner. In addition, we may fail to identify patentable subject matter early enough to obtain patent protection. Further, license agreements with third parties may not allow us to control the preparation, filing and prosecution of patent applications, or the maintenance or enforcement of patents. Such third parties may decide not to enforce such patents or enforce such patents without our involvement. Thus, these patent applications and patents may not, under these circumstances, be prosecuted or enforced in a manner consistent with the best interests of the company.

Our pending patent applications may not issue as patents and may not issue in all countries in which we develop, manufacture or potentially sell our products or in countries where others develop, manufacture and potentially sell products using our technologies. Moreover, our pending patent applications, if issued as patents, may not provide additional protection for our products.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in pharmaceutical and biotechnology patents has emerged to date. Changes in the patent laws or the interpretation of the patent laws in the U.S. and other jurisdictions may diminish the value of our patents or narrow the scope of our patent protection. Accordingly, the patents we own or license may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative drug products or technologies or design around our patented drug products and technologies which may have an adverse effect on our business. If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us, we may have to participate in interference or derivation proceedings in front of the U.S. Patent and Trademark Office, or USPTO, to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that any related patent may expire prior to, or remain in existence for only a short period following, commercialization, which may significantly diminish our ability to exclude others from commercializing products that are similar or identical to ours. The patents we own or license may be challenged or invalidated or may fail to provide us with any competitive advantage. Since we have licensed or sublicensed many patents from third parties, we may not be able to enforce such licensed patents against third party infringers without the cooperation of the patent owner and the licensor, which may not be forthcoming. In addition, we may not be successful or timely in obtaining any patents for which we submit applications.

Generally, the first to file a patent application is entitled to the patent if all other requirements of patentability are met. However, prior to March 16, 2013, in the U.S., the first to invent was entitled to the patent. Since publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, the laws enacted by the Leahy-Smith America Invents Act of 2011, which reformed certain patent laws in the U.S., introduce procedures that permit competitors to challenge our patents in the USPTO after grant, including inter partes review and post grant review. Similar laws exist outside of the U.S. The laws of the European Patent Convention, for example, provide for post-grant opposition procedures that permit competitors to challenge, or oppose, our European patents administratively at the European Patent Office, or EPO.

We may become involved in addressing patentability objections based on third party submission of references, or we may become involved in defending our patent rights in oppositions, derivation proceedings, reexamination, inter partes review, post grant review, interference proceedings or other patent office proceedings or litigation, in the U.S. or elsewhere, challenging our patent rights or the patent rights of others. An adverse result in any such proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged on such a basis in the courts or patent offices in the U.S. and abroad. As a result of such challenges, we may lose exclusivity or freedom-to-operate or patent claims may be narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to prevent third parties from using or commercializing similar or identical products, or limit the duration of the patent protection for our products.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and governmental patent agencies in other jurisdictions also require compliance with a number of procedural, documentary, fee payment (such as annuities) and other similar provisions during the patent application process. While an inadvertent lapse in many cases can be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market sooner than we expect, which would have a material adverse effect on our business.

In addition, patents protecting our product candidate might expire before or shortly after such candidate is commercialized. Thus, our patent portfolio may not provide sufficient rights to exclude others from commercializing products similar or identical to ours.

We also rely on trade secrets and know-how to protect our intellectual property where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, licensees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to adequately protect our trade secrets or other proprietary information. In addition, in some cases, we share certain ownership and publication rights to data relating to some of our products and product candidates with research collaborators, licensees and other third parties. If we cannot maintain the confidentiality of this information, our ability to receive patent protection or protect our trade secrets or other proprietary information will be at risk.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our products and product candidates in all countries throughout the world would be prohibitively expensive. Consequently, the breadth of our intellectual property rights in some countries outside the U.S. may be less extensive than those in the U.S. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the U.S. As a result, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other countries. Competitors may use our technologies in countries where we have not obtained patent protection to develop their own products and, further, may infringe our patents in territories where we have patent protection, but where enforcement is not as strong as in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain countries. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to pharmaceutical and biotechnology products, which could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in countries outside of the U.S. could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage for our products and product candidates from the intellectual property that we develop or license.

The intellectual property that we own or have licensed and related non-patent exclusivity relating to our current and future products is, and may be, limited, which could adversely affect our ability to compete in the market and adversely affect the value of Auryxia, Vafseo or other future products.

The patent rights and related non-patent exclusivity that we own or have licensed relating to Auryxia, Vafseo or other future products, are, or may be limited in ways that may affect our ability to exclude third parties from competing against us. For example, a third party may design around our owned or licensed composition of matter patent claims or market a product for the methods of use not covered by our owned or licensed patents.

Obtaining proof of direct infringement by a competitor for a method of use patent requires us to demonstrate that the competitors make and market a product for the patented use(s). Alternatively, we can prove that our competitors induce or contribute to others in engaging in direct infringement. Proving that a competitor contributes to or induces infringement of a patented method by another has additional proof requirements. For example, proving inducement of infringement requires proof of intent by the competitor. If we are required to defend ourselves against claims or to protect our own proprietary rights against others, it could result in substantial costs to us and the distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us or our partners from marketing and selling Auryxia, Vafseo or other future products, increase the risk that a generic or other similar version of Auryxia, Vafseo or other future products could enter the market to compete with Auryxia, Vafseo or other future products, limit our or our partners' development and commercialization of Auryxia, Vafseo or other future products, or otherwise harm our competitive position and result in additional significant costs.

Moreover, physicians may prescribe a competitive identical product for indications other than the one for which the product has been approved, or “off-label” indications, that are covered by the applicable patents. Although such off-label prescriptions may directly infringe or contribute to or induce infringement of method of use patents, such infringement is difficult to prevent.

In addition, any limitations of our patent protection described above may adversely affect the value of our drug product and may inhibit our ability to obtain a collaboration partner at terms acceptable to us, if at all.

In addition to patent rights in the U.S., we may seek non-patent exclusivity for any approved or future products under other provisions of the FDCA such as new chemical entity, or NCE, exclusivity, or exclusivity for a new use or new formulation, but

there is no guarantee that any products will receive such exclusivity. The FDCA provides a five-year period of non-patent exclusivity within the U.S. to the first sponsor to gain approval of an NDA for an NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which consists of the molecule(s) or ion(s) responsible for the action of the drug substance (but not including those portions of the molecule that cause it to be a salt or ester or which are not bound to the molecule by covalent or similar bonds). Vafseo was granted NCE status following its approval in March 2024 and received a five-year NCE exclusivity. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the sponsor does not own or have a legal right of reference to all the data required for approval.

An ANDA that references an NDA product with NCE exclusivity may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of exclusivity for an NDA, particularly a 505(b)(2) NDA or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the sponsor are deemed by the FDA to be essential to the approval of the application (for example, for new indications, dosages, or strengths of an existing drug). This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. The three-year exclusivity period, unlike five-year exclusivity, does not prevent the submission of a competing ANDA or 505(b)(2) NDA. Instead, it only prevents the FDA from granting final approval to such a product until expiration of the exclusivity period. Five-year and three-year exclusivity will not delay the submission (in the case of five-year exclusivity) or the approval (in the case of three-year exclusivity) of a full NDA submitted under section 505(b)(1) of the FDCA; however, a sponsor submitting a full NDA would be required to conduct all of its own studies needed to independently support a finding of safety and effectiveness for the proposed product, or have a full right of reference to all studies not conducted by the sponsor.

In cases where NCE exclusivity has been granted to a new drug product, the 30-month stay triggered by such litigation is extended by the amount of time such that seven years and six months will elapse from the date of approval of the NDA for that product. Without NCE exclusivity, the 30-month stay on FDA final approval of an ANDA runs from the date on which the sponsor of the reference listed drug receives notice of a Paragraph IV certification from the ANDA sponsor.

In addition to NCE, in the U.S., the FDA has the authority to grant additional regulatory exclusivity protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this pediatric exclusivity may provide an additional six months which are added to the term of any non-patent exclusivity that has been awarded as well as to the regulatory protection related to the term of a relevant patent, to the extent these protections have not already expired.

The FDA also has the authority to grant orphan drug designation to drugs intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. We plan to rely on orphan drug exclusivity for praliciguat and may rely on orphan drug exclusivity for potential future product candidates that we may develop. Orphan drug status currently confers seven years of marketing exclusivity in the U.S. under the FDCA. However, we cannot assure you that we will receive orphan drug designation for praliciguat or any of our potential future product candidates.

In addition, U.S. or foreign regulatory authorities may change their approval policies and new regulations may be enacted regarding non-patent exclusivity. For example, EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the EC in November 2020. The EC's proposal for revision of several legislative instruments related to medicinal products, which may reduce the duration of regulatory data protection and exclusivity periods for orphan drugs, and revise the eligibility for expedited pathways in addition to other changes, was published on April 26, 2023. On April 10, 2024, the European Parliament adopted a position on the proposal requesting several amendments to the package. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term. On June 4, 2025, after almost two years of negotiations among the EU Member States, the Council of the European Union adopted its position on the proposed overhaul of the EU general pharmaceutical legislative framework, which is known as the new Pharma Package. On December 11, 2025, the European Parliament and European Council reached a provisional political agreement on the legislation which is expected to be adopted by mid-2026. The revisions may have a significant impact on the pharmaceutical industry and our business. The new Pharma Package would, among other things, shorten marketing authorization times from 210 to 180 days, and set a baseline period of eight years of data exclusivity and one year of market exclusivity with possible extensions for new indications up to a maximum of 11 years total.

We cannot assure you that Auryxia, Vafseo, praliciguat or any of our other potential future products will obtain such pediatric exclusivity, NCE exclusivity, orphan drug exclusivity or any other market exclusivity in the U.S., EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any non-patent

exclusivity protection. We also cannot assure you that Auryxia, Vafseo or any of our potential future products will obtain patent term extension.

The market entry of one or more generic competitors or any third party's attempt to challenge our intellectual property rights will likely limit Auryxia and Vafseo sales and have an adverse impact on our business and results of operation.

Although the composition and use of Auryxia is currently claimed by 3 issued patents that are listed in the FDA's Orange Book, or OB, and the composition and use of Vafseo is currently claimed by 13 issued patents that are listed in the OB, we cannot assure you that we will be successful in defending against third parties attempting to invalidate or design around our patents or asserting that our patents are invalid or otherwise unenforceable or not infringed, or in competing against third parties introducing generic equivalents of Auryxia, Vafseo or any of our potential future products. If our OB-listed patents are successfully challenged by a third party and a generic version of Auryxia or Vafseo is approved and launched sooner than we anticipate, revenue from Auryxia or Vafseo, respectively, could decline significantly, which would have a material adverse effect on our sales, results of operations and financial condition.

We previously received Paragraph IV certification notice letters regarding ANDAs submitted to the FDA requesting approval for generic versions of Auryxia tablets (210 mg ferric iron per tablet). We filed complaints for patent infringement relating to such ANDAs, and subsequently entered into settlement and license agreements with all such ANDA filers that allowed such ANDA filers to market a generic version of Auryxia in the U.S. as of March 20, 2025. It is possible that we may receive Paragraph IV certification notice letters from additional ANDA filers and may not ultimately be successful in an ANDA litigation.

On January 22, 2026, Teva received tentative approval for its ANDA for Auryxia. Currently, there is only one authorized generic for Auryxia sold by our distributor, but we expect additional generic competition in 2026. If additional generics are approved and enter the market, we expect it will adversely impact our revenue. However, the impact on future Auryxia revenues will depend on many factors, including our ability to maintain contracts with dialysis organizations, the timing and number of additional generics and the pricing of generics and other products on the market that compete with Auryxia. Generic competition for Auryxia, Vafseo or any of our potential future products could have a material adverse effect on our sales, results of operations and financial condition.

Litigation and administrative proceedings, including third party claims of intellectual property infringement and opposition/invalidation proceedings against third party patents, may be costly and time consuming and may delay or harm our drug discovery, development and commercialization efforts.

We may be forced to initiate litigation to enforce our contractual and intellectual property rights, or we may be sued by third parties asserting claims based on contract, tort or intellectual property infringement. Competitors may infringe our patents or misappropriate our trade secrets or confidential information. We may not be able to prevent infringement of our patents or misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S. In addition, third parties may have or may obtain patents in the future and claim that our products or other technologies infringe their patents. If we are required to defend against suits brought by third parties, or if we sue third parties to protect our rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from operating our business. In addition, any legal action against our licensor, licensees or us that seeks damages or an injunction of commercial activities relating to Auryxia, Vafseo or any product candidates or other technologies, including those that may be in-licensed or acquired, could subject us to monetary liability, a temporary or permanent injunction preventing the development, marketing and sale of such products or such technologies, and/or require our licensor, licensees or us to obtain a license to continue to develop, market or sell such products or other technologies. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. We cannot predict whether our licensor, licensees or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. However, there may be patents of third parties of which we are currently unaware with claims to compounds, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Also, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. The pharmaceutical and biotechnology industries are characterized by extensive litigation over patent and other intellectual property rights. We have in the past and may in the future become a party to, or be threatened with, future adversarial litigation or other proceedings regarding intellectual property rights with respect to our product and product candidates. As the pharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

While our product candidates are in preclinical studies and clinical trials, we believe that the use of our product candidates in these preclinical studies and clinical trials in the U.S. falls within the scope of the exemptions provided by 35 U.S.C. Section

271(e), which provides that it shall not be an act of infringement to make, use, offer to sell, or sell within the U.S. or import into the U.S. a patented invention solely for uses reasonably related to the development and submission of information to the FDA. There is an increased possibility of a patent infringement claim against us with respect to commercial products. Our portfolio includes two commercial products: Auryxia and Vafseo. We attempt to ensure that our products and product candidates and the methods we employ to manufacture them, as well as the methods for their use which we intend to promote, do not infringe other parties' patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

FibroGen, Inc., or FibroGen, has filed patent applications in the U.S. and other countries directed to purportedly new methods of using previously known heterocyclic carboxamide compounds for purposes of treating or affecting specified conditions, and some of these applications have since issued as patents. In November 2023, we and our collaboration partner, TPC, entered into a Settlement and Cross License Agreement, or the Settlement Agreement, with FibroGen and its collaboration partner, Astellas. The Settlement Agreement resolves all patent disputes between us, TPC, FibroGen and Astellas in the EU, the contracting states to the European Patent Convention, the UK and Japan, or the Settlement Territory. We may in the future initiate invalidity actions or other legal proceedings with respect to FibroGen patents outside of the Settlement Territory. If we are not successful in such proceedings, FibroGen could try to claim that our products infringe their patent rights.

Third parties, including FibroGen, may in the future claim that our products and product candidates and other technologies infringe upon their patents and may challenge our ability to commercialize Auryxia and Vafseo. Parties making claims against us or our licensees may seek and obtain injunctive or other equitable relief, which could effectively block our or their ability to continue to commercialize Auryxia or Vafseo or further develop and commercialize any product candidates, including those that may be in-licensed or acquired. If any third party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our products or product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product or product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or our intended methods of use, the holders of any such patent may be able to block or impair our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. We may also elect to enter into a license in order to settle litigation or in order to resolve disputes prior to litigation. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our products or product candidates. Should a license to a third party patent become necessary, we cannot predict whether we would be able to obtain a license or, if a license were available, whether it would be available on commercially reasonable terms. If such a license is necessary and a license under the applicable patent is unavailable on commercially reasonable terms, or at all, our ability to commercialize our product or product candidate may be impaired or delayed, which could in turn significantly harm our business.

Further, defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties or redesign our products, which may be impossible or require substantial time and monetary expenditure.

In addition, there may be a challenge or dispute regarding inventorship or ownership of patents or applications currently identified as being owned by or licensed to us. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications.

Various administrative proceedings are also available for challenging patents, including interference, reexamination, inter partes review, and post-grant review proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Competitors may initiate an administrative proceeding challenging our issued patents or pending patent applications, which can be expensive and time consuming to defend. An adverse result in any current or future defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and held not infringed and could put our patent applications at risk of not issuing. In addition, an unfavorable outcome in any current or future proceeding in which we are challenging third party patents could require us to cease using the patented technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all. Even if we are successful, participation in interference or other administrative proceedings before the USPTO or a foreign patent office may result in substantial costs and distract our management and other employees.

We are currently involved in opposition proceedings in the Indian Patent Office. The proceedings may be ongoing for a number of years, may be resolved in a manner adverse to the Company and may involve substantial expense and diversion of

employee resources from our business, which could have an adverse effect on our business. In addition, we may become involved in additional opposition proceedings or other legal or administrative proceedings in the future. For more information, see the other risk factors under “Risks Related to our Intellectual Property”.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and some administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure during discovery. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from potential collaborators, prospective licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees’ former employers. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to our Business and Managing Growth

If we fail to attract, retain and motivate senior management and qualified personnel, we may be unable to successfully develop and commercialize Auryxia, Vafseo or any of our product candidates.

Recruiting and retaining qualified personnel is critical to our success. We are also highly dependent on our executives, certain members of our senior management and certain key personnel. The loss of the services of our executives, senior managers or other employees could impede the achievement of our research, development, regulatory and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Losing members of management and other key personnel could subject us to a number of risks, including the failure to coordinate responsibilities and tasks, the necessity to create new management systems and processes, the impact on corporate culture, and the retention of historical knowledge.

Furthermore, replacing executives, senior managers and other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop and commercialize Auryxia, Vafseo and our product candidates. Our future financial performance and our ability to develop and commercialize Auryxia, Vafseo and our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to hire, train, integrate, and retain additional qualified personnel with sufficient experience. We may be unable to hire, train, retain or motivate these personnel on acceptable terms given the intense competition for our personnel from our competitors and other companies throughout our industry, particularly in our geographic region. The pharmaceutical and biotechnology industries continue to face challenges in recruiting and retaining qualified employees.

In addition, we rely on contractors, consultants and advisors, including scientific and clinical advisors, to assist us in formulating and executing our R&D and commercialization strategy. Our contractors, consultants and advisors may become employed by companies other than ours and may have commitments with other entities that may limit their availability to us. If additional members of management or other personnel leave, or we are unable to continue to attract and retain high quality personnel, our ability to grow and pursue our business strategy will be limited.

We may encounter difficulties in managing our growth, including with respect to our employee base, and managing our partnerships and operations successfully.

In our day-to-day operations, we may encounter difficulties in managing the size of our operations as well as challenges associated with managing our business. We have strategic collaborations for the commercialization of Riona in Japan, the development and commercialization of ferric citrate in Europe, and the development and commercialization of vadadustat, which is now being marketed under the trade name Vafseo by our collaboration partner, TPC, in Japan and potentially other Asian countries and our collaboration partner, Medice, in the Medice Territory. As our operations continue, we expect that we will need to manage our current relationships and enter into new relationships with various strategic collaborators,

consultants, vendors, suppliers and other third parties. These relationships are complex and create numerous risks as we deal with issues that arise.

For example, we supply or have agreed to supply, as applicable, ferric citrate in Europe to Averoa and Vafseo in Japan, Europe and other territories where it is approved for commercial use to TPC and Medice, which will require us to successfully manage our limited financial and managerial resources. In addition, we may not be able to obtain the raw materials or product that we need, or the cost of the raw materials or product may be higher than expected. If we are unable to successfully manage our supply obligations, our ability to commercialize our products or supply such products to our partners could have a material adverse effect on our relationships with our partners and our results of operations.

Our future financial performance and our ability to commercialize Auryxia and Vafseo and to compete effectively and to continue to develop our products and product candidates will depend, in part, on our ability to manage any future growth effectively. This future growth will impose significant added responsibilities on the business and members of management. To manage any future growth, we must continue to implement and improve our managerial, operational and financial systems, procedures and processes. We may not be able to implement these improvements in an efficient or timely manner and may discover deficiencies in existing systems, procedures and processes. Moreover, the systems, procedures and processes currently in place or to be implemented may not be adequate for any such growth. Any expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully managing and, as applicable, growing our Company.

In addition, as we expand our development activities, we expect to grow the teams, infrastructure, and processes necessary to support these efforts. Scaling our development activities will require recruiting, training, and integrating new personnel, as well as enhancing cross-functional coordination, which may introduce additional operational complexity. For example, integrating AKB-097, which we acquired on November 28, 2025, has required, and will continue to require, significant management attention, which could divert resources from other priorities. If we are unable to successfully grow and integrate our teams or adapt our processes to meet the demands of increased development activity, our ability to advance our product candidates and achieve our strategic objectives could be adversely affected.

Furthermore, we may need to adjust the size of our workforce as a result of changes to our expectations for our business, which can result in management being required to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth-related activities and related expenses. Further, we rely on independent third parties to provide certain services to us. We structure our relationships with these outside service providers in a manner that we believe results in an independent contractor relationship, not an employee relationship. If any of our service providers are later legally deemed to be employees, we could be subject to employment and tax withholding liabilities and other additional costs as well as other multiple damages and attorneys' fees.

We previously identified a material weakness in our internal control over financial reporting, which has been remediated. If we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately or timely report our financial results or prevent fraud, and we may conclude that our internal control over financial reporting is not effective, which may adversely affect our business.

We previously identified a material weakness in our internal control over financial reporting as of December 31, 2024 relating to our accounting for inventory and inventory related transactions. A material weakness is a deficiency, or combination of deficiencies, in our internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

Although we have determined that the previously identified material weakness has been remediated as of December 31, 2025, we cannot assure you that we will not identify other material weaknesses in the future, which could negatively impact our results of operations in future periods.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to maintain or implement required new or improved controls, or difficulties encountered in implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any testing by our independent registered public accounting firm may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement.

We cannot assure you that the measures we have taken to date, and the actions we may take in the future, will be sufficient to prevent or avoid potential future material weaknesses. Further, if we are unable to meet the demands that have been placed upon us as a public company, including the rules and regulations of the SEC, we may be unable to accurately report our financial results in future periods, or report them within timeframes required by law or stock exchange regulations. Failure to

comply with the rules and regulations of the SEC, when and as applicable, could also potentially subject us to sanctions or investigations by the SEC, the Nasdaq Stock Market or other regulatory authorities as well as stockholder litigation which, even if resolved in our favor, would require additional financial and management resources and could adversely affect the market price of our common stock. Any failure to maintain or implement required effective internal control over financial reporting, or any difficulties we encounter in their implementation, could result in additional material weaknesses, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock and could also affect our ability to raise capital to fund future business initiatives.

Security breaches and unauthorized use of our information technology systems and information, or the information technology systems or information in the possession of our collaborators, contractors and other third parties, including those arising from the malicious use of artificial intelligence tools to penetrate systems, manipulate data or generate convincing fraudulent communications, could damage the integrity of our clinical trials, impact our regulatory filings, compromise our ability to protect our intellectual property, and subject us to regulatory actions that could result in significant fines or other penalties.

We, our collaborators, contractors and other third parties rely significantly upon information technology, including in certain instances artificial intelligence-based software, and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively. In addition, we and our collaborators, contractors and other third parties rely on information technology networks and systems, including the Internet and artificial intelligence-based software, to process, transmit and store clinical trial data, patient information, and other electronic information, and manage or support a variety of business processes, including operational and financial transactions and records, personal identifying information, payroll data and workforce scheduling information. While these artificial intelligence-based systems can enhance efficiency and analytical capabilities, they may also introduce new vulnerabilities such as algorithmic manipulation, data poisoning, or exploitation of artificial intelligence models to gain unauthorized access or use information in ways that harm our business. We purchase most of our information technology from vendors or service providers, on whom our systems depend. We rely on commercially available systems, software, tools and monitoring to provide security for the processing, transmission and storage of company and customer information.

In the ordinary course of our business, we and our third-party contractors maintain personal and other sensitive data on our and their respective networks, including our intellectual property and proprietary or confidential business information relating to our business and that of our clinical trial patients and business partners. In particular, we rely on CROs and other third parties to store and manage information from our clinical trials, including patient information. We also rely on third parties to manage patient information for Auryxia and Vafseo. Additionally, the use of artificial intelligence based software is increasingly being used in the biopharmaceutical industry. Use of artificial intelligence based software may lead to the release of confidential proprietary information, and adversarial artificial intelligence techniques could be used to reverse-engineer proprietary algorithms, infer sensitive clinical data from anonymized datasets, or bypass existing security controls, which may impact our ability to realize the benefit of our intellectual property. The secure maintenance of this sensitive information is critical to our business and reputation.

Companies and other entities and individuals have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access to systems and information that could impact our business operations, including our clinical trials. These threats can come from a variety of sources, ranging in sophistication from individual hackers to state-sponsored attacks. Attackers have used artificial intelligence and machine learning to launch more automated, targeted and coordinated attacks against targets, including deepfake audio or video impersonations of executives, artificial intelligence-generated spear-phishing campaigns, and automated vulnerability scanning that can rapidly exploit weaknesses before detection. Cyber threats may be broadly targeted, or they may be custom-crafted against our information systems or those of our vendors or third-party service providers. A security incident, cyber attack or other unauthorized access to our systems, could affect our ability to operate our business or the ability of our vendors or third-party service providers to provide services pursuant to their contractual obligations. A security breach, cyberattack or unauthorized access of our clinical data or other data could damage the integrity of our clinical trials, impact our regulatory filings, cause significant risk to our business, compromise our ability to protect our intellectual property, and subject us to regulatory actions, including under the GDPR and CCPA discussed elsewhere in these risk factors and the privacy or security rules under federal, state, or other local laws outside of the U.S. protecting confidential or personal information, that could be expensive to defend and could result in significant fines or other penalties. Cyberattacks can include malware, computer viruses, hacking, social engineering, zero day vulnerabilities or other unauthorized access or other significant compromise of our computer, communications and related systems. Although we take steps to manage and avoid these risks and to be prepared to respond to attacks, our preventive and any remedial actions may not be successful and no such measures can eliminate the possibility of the systems' improper functioning or the improper access or disclosure of confidential or personally identifiable

information such as in the event of cyberattacks. Artificial intelligence-driven attacks can adapt in real time to bypass conventional cybersecurity measures, making detection and response significantly more challenging. Security breaches, whether through physical or electronic break-ins, computer viruses, ransomware, impersonation of authorized users, attacks by hackers, artificial intelligence-generated fraudulent communications or other means, can create system disruptions or shutdowns that impact our business operations or cause the unauthorized disclosure of confidential information.

Although we believe our collaborators, vendors and service providers, such as our CROs, take steps to manage, mitigate and avoid information security risks and respond to attacks, we may be adversely affected by attacks against our collaborators, vendors or service providers, and we may not have adequate contractual remedies against such collaborators, vendors and service providers to remedy any harm to our business caused by such event. Additionally, outside parties may attempt to fraudulently induce employees, collaborators, or other contractors to disclose sensitive information or take other actions, including making fraudulent payments or downloading malware, by using “spoofing” and “phishing” emails, artificial intelligence-generated deep fake communications or other types of attacks. Our employees may be targeted by such fraudulent activities. Outside parties may also subject us to distributed denial of services attacks or introduce viruses or other malware through “trojan horse” programs to our users’ computers in order to gain access to our systems and the data stored therein. Cyber-attacks have become more prevalent and much harder to detect and defend against. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and continuously become more sophisticated, including through the use of artificial intelligence to generate sophisticated spoofed emails, deep fake voice and video, and synthetic identities, and often are not recognized until launched against a target and may be difficult to detect for a long time, we may be unable to anticipate these techniques or to implement adequate preventive or detective measures, and we might not immediately detect such incidents and the damage caused by such incidents.

Such attacks, whether successful or unsuccessful, or other compromises with respect to our information security and the measures we implement to prevent, detect and respond to them, could:

- result in our incurring significant costs related to, for example, rebuilding internal systems, defending against litigation, responding to regulatory inquiries or actions, paying damages or fines, or taking other remedial steps with respect to third parties;
- lead to public exposure of personal information of participants in our clinical trials, Auryxia patients and others;
- damage the integrity of our studies or delay their completion, disrupt our development programs, our business operations and commercialization efforts;
- compromise our ability to protect our trade secrets and proprietary information;
- result in manipulation or falsification of clinical trial data through artificial intelligence-generated synthetic data or altered records, undermining regulatory submissions and scientific validity;
- damage our reputation and deter business partners from working with us; or
- divert the attention of our management and key information technology resources.

Any failure to maintain proper functionality and security of our internal computer and information systems, including failures arising from vulnerabilities in artificial intelligence models or artificial intelligence-enabled systems, could result in a loss of, or damage to, our data or marketing applications or inappropriate disclosure of confidential or proprietary information, interrupt our operations, damage our reputation, subject us to liability claims or regulatory penalties, under a variety of federal, state or other applicable privacy laws, such as HIPAA, the GDPR, or state data protection laws including the CCPA, harm our competitive position and delay the further development and commercialization of our products and product candidates, or impact our relationships with customers and patients.

Our employees, independent contractors, principal investigators, CROs, CMOs, consultants and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading. In addition, laws and regulations governing any international operations we have or may have in the future may require us to develop and implement costly compliance programs.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, CMOs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate applicable laws, including the following:

- FDA and other healthcare authorities’ regulations, including those laws that require the reporting of true, complete and accurate information to regulatory authorities, and those prohibiting the promotion of unapproved drugs or approved drugs for an unapproved use;
- quality standards, including GxP;
- federal and state healthcare fraud and abuse laws and regulations and their non-U.S. equivalents;

- anti-bribery and anti-corruption laws, such as the FCPA and the UK Bribery Act or country-specific anti-bribery or anti-corruption laws, as well as various import and export laws and regulations;
- laws that require the reporting of true and accurate financial information and data; and
- U.S. state and federal securities laws and regulations and their non-U.S. equivalents, including those related to insider trading.

We conducted our global clinical trials for Vafseo, and may in the future conduct additional trials, in countries where corruption is prevalent, and violations of any of these laws by our personnel or by any of our vendors or agents, such as our CROs or CMOs, could have a material adverse impact on our clinical trials and our business and could result in criminal or civil fines and sanctions. We are subject to complex laws that govern our international business practices. These laws include the FCPA, which prohibits U.S. companies and their intermediaries, such as CROs or CMOs, from making improper payments to foreign government officials for the purpose of obtaining or keeping business or obtaining any kind of advantage for the company. The FCPA also requires companies to keep accurate books and records and maintain adequate accounting controls. A number of past and recent FCPA investigations by the Department of Justice and the SEC have focused on the life sciences sector.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. Some of the countries in which we have conducted clinical trials and in which we had CMOs have a history of corruption, which increases our risks of FCPA violations. In addition, the FCPA presents unique challenges in the pharmaceutical industry because in many countries' hospitals are operated by the government, and doctors and other hospital employees are considered foreign government officials. Certain payments made by pharmaceutical companies, or on their behalf by CROs, to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Additionally, the UK Bribery Act applies to our global activities and prohibits bribery of private individuals as well as public officials. The UK Bribery Act prohibits both the offering and accepting of a bribe and imposes strict liability on companies for failing to prevent bribery, unless the company can show that it had "adequate procedures" in place to prevent bribery. There are also local anti-bribery and anti-corruption laws in countries where we have conducted clinical trials, and many of these also carry the risk of significant financial or criminal penalties.

We are also subject to trade control regulations and trade sanction laws that restrict the movement of certain goods, currency, products, materials, services and technology to, and certain operations in, various countries or with certain persons. Our ability to transfer commercial and clinical product and other clinical trial supplies, and for our employees, independent contractors, principal investigators, CROs, CMOs, consultants and vendors ability to travel, between certain countries is subject to maintaining required licenses and complying with these laws and regulations.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state laws, and requirements of non-U.S. jurisdictions, including the GDPR. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us.

The internal controls, policies and procedures, and training and compliance programs we have implemented to deter prohibited practices may not be effective in preventing our employees, contractors, consultants, agents or other representatives from violating or circumventing such internal policies or violating applicable laws and regulations. The failure to comply with laws governing international business practices may impact any future clinical trials, result in substantial civil or criminal penalties for us and any such individuals, including imprisonment, suspension or debarment from government contracting, withdrawal of our products, if approved, from the market, or being delisted from The Nasdaq Capital Market. In addition, we may incur significant costs in implementing sufficient systems, controls and processes to ensure compliance with the aforementioned laws. The laws and regulations referenced above may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements that could adversely affect our business.

Additionally, it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling known or unknown risks or preventing losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, or if any such action is instituted against our employees, consultants, independent contractors, CROs, CMOs, vendors or principal investigators, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, curtailment of our operations, disclosure of our confidential information and imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

Our financial statements include long-lived assets, including goodwill as a result of the Merger. Other long-lived assets, including property and equipment, right-of-use assets or goodwill, could become impaired in the future under certain conditions. Any potential future impairment of property and equipment, our right-of-use assets or goodwill may significantly impact our results of operations and financial condition.

As of December 31, 2025, we had approximately $59.0 million in the aggregate of goodwill from the Merger, $1.2 million of property and equipment and $3.7 million right-of-use assets. In accordance with ASC 350, *Goodwill and Other*, we are required annually for goodwill, or more frequently upon certain indicators of impairment, to review our estimates and assumptions underlying the fair value of our goodwill. In addition, under ASC 360, *Property, Plant and Equipment*, we are required to review our property and equipment and right-of-use assets whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Events giving rise to impairment of long-lived assets are an inherent risk in the pharmaceutical industry and often cannot be predicted.

Conditions that could indicate impairment and necessitate such a review include, but are not limited to, Auryxia's and Vafseo's commercial performance, our inability to execute on our strategic initiatives, the deterioration of our market capitalization such that it is significantly below our net book value, a significant adverse change in legal factors, unexpected adverse business conditions, and an adverse action or assessment by a regulator. To the extent we conclude our long-lived assets have become impaired, we may be required to incur material write-offs relating to such impairment and any such write-offs could have a material impact on our future operating results and financial position. The estimates, judgments and assumptions used in our impairment analyses, and the results of our analyses, are discussed in Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements in Part II, Item 8. Financial Statements and Supplementary Data of this Form 10-K. If these estimates, judgments and assumptions change in the future, additional impairment charges related to plant and equipment, and right-of-use assets or goodwill could be recorded in the future, which could materially impact our financial position, certain of our material agreements, and our future operating results.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Auryxia or Vafseo or affect the development of our product candidates.

We face an inherent risk of product liability as a result of the clinical and commercial use of Auryxia and Vafseo and our product candidates. For example, we may be sued if Auryxia, Vafseo or our product candidates allegedly causes injury or is found to be otherwise unsuitable during clinical trials or commercial use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product or product candidate, negligence, strict liability and breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of Auryxia or Vafseo or affect the development of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for Auryxia or Vafseo;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- delay or termination of clinical trials;
- our inability to continue to develop Auryxia, Vafseo or our product candidates;
- significant costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to study subjects or patients;
- product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- decreased demand for Auryxia or Vafseo;
- loss of revenue;
- the inability to commercialize Auryxia or Vafseo; and
- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the development of our product candidates or commercialization of products we develop. We currently carry product liability insurance that we believe is appropriate for our Company. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have insufficient or no coverage. If we have to pay any amounts awarded by a court or negotiated in a settlement that exceed our

coverage limitations or that are not covered by our insurance, we may not have, or be able to obtain, sufficient capital to pay such amounts. In addition, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost. We also may not be able to obtain additional insurance coverage that will be adequate to cover additional product liability risks that may arise. Consequently, a product liability claim may result in losses that could be material to our business.

We will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we operate in a demanding regulatory environment, and we have and will continue to incur significant legal, accounting, auditing, directors and officers insurance and other expenses. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and certain corporate governance practices. In particular, our compliance with Section 404 of the Sarbanes-Oxley Act has required and will continue to require that we incur substantial accounting-related expenses and expend significant management efforts. Our testing, or the testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls that we would be required to remediate in a timely manner. If we are not able to comply with the requirements of the Sarbanes-Oxley Act, we could be subject to sanctions or investigations by the SEC, the Nasdaq Capital Market or other regulatory authorities, which would require additional financial and management resources and could adversely affect the market price of our securities. Furthermore, if we cannot provide reliable financial reports or prevent fraud, including as a result of remote working by our employees, our business and results of operations would likely be materially and adversely affected.

We cannot predict or estimate the amount of additional costs we may incur to continue to operate as a public company, nor can we predict the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our Ninth Amended and Restated Certificate of Incorporation, as amended, or Charter, and our Second Amended and Restated Bylaws, or Bylaws, as amended to date, contain provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, or DGCL, the personal liability of our directors and executive officers for monetary damages for breach of their fiduciary duties as a director or officer. Our Charter and our Bylaws also provide that we will indemnify our directors and executive officers and may indemnify our employees and other agents to the fullest extent permitted by the DGCL.

In addition, as permitted by Section 145 of the DGCL our Bylaws and our indemnification agreements that we have entered into with our directors and executive officers provide that:

- We will indemnify our directors and officers, as defined in our Bylaws, for serving us in those capacities or for serving other related business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of Akebia and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- The rights conferred in our Bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

Any claims for indemnification made by our directors or officers could impact our cash resources and our ability to fund the business.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

Under Section 382 of the Internal Revenue Code, or Section 382, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. On December 12, 2018, we completed the Merger, which we believe has resulted in an ownership change under Section 382.

Future changes in our stock ownership, many of which are outside of our control, could result in an additional ownership change under Section 382. In addition, the deduction for NOLs arising in taxable years beginning after December 31, 2017 is limited to 80% of current-year taxable income. As a result, if we generate taxable income, our ability to use our pre-change NOL carryforwards to offset federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. At the state level, state NOLs generated in one state cannot be used to offset income generated in another state and there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. taxable income. As described above under "—Risks Related to our Financial Position, Need for Additional Capital and Growth Strategy," we have incurred significant net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. taxable income necessary to utilize our NOLs.

Our Charter designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Charter provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL our Charter or our Bylaws, or (iv) any other action asserting a claim against us, our directors, officers or other employees that is governed by the internal affairs doctrine. Under our Charter, this exclusive forum provision will not apply to claims that are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Exchange Act, or the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Charter described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our Charter inapplicable to, or unenforceable with respect to, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

Risks Related to our Common Stock

Our stock price has been and may continue to be volatile, which could result in substantial losses for holders or future purchasers of our common stock and lawsuits against us and our officers and directors and could result in substantial costs and divert management's attention.

Our stock price has been and will likely continue to be volatile. The stock market in general and the market for similarly situated biopharmaceutical companies specifically have experienced extreme volatility that has often been unrelated to the operating performance of particular companies, such as rising inflation and increasing interest rates. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, including, among others, developments related to and results of our research or clinical trials, developments related to our regulatory submissions and meetings with regulatory authorities, commercialization of Auryxia, Vafseo, and any other product candidates, announcements by us or our competitors of significant transactions or strategic collaborations, market entry of additional generic competition to Auryxia, negative publicity around Auryxia or Vafseo, regulatory or legal developments in the U.S. and other countries, developments or disputes concerning our intellectual property, the recruitment or departure of key personnel, actual or anticipated changes in estimates as to financial results, changes in the structure of healthcare payment systems, market conditions in the biopharmaceutical sector, potential delisting from The Nasdaq Stock Market and other factors beyond our control. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price at which they purchased it.

In addition, securities class actions, shareholder derivative lawsuits and other legal proceedings are often brought against companies for any of the risks described in this Form 10-K following a decline or volatility in the market price of their securities. We could be the target of such litigation or other legal proceedings in the future. Class actions, shareholder derivative lawsuits and other legal proceedings, whether successful or not, could result in substantial costs, damage or settlement awards and such costs and any related settlements or judgments may not be covered by insurance. Monetary damages or any other adverse judgment would have a material adverse effect on our business and financial position. In addition, if other resolution or actions taken as a result of legal proceedings were to restrain our ability to operate or market our products and services, our consolidated financial position, results of operations or cash flows could be materially

adversely affected. We could also suffer an adverse impact on our reputation, negative publicity and a diversion of management's attention and resources, which could have a material adverse effect on our business.

If we fail to comply with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum closing bid price of $1.00 per share and timely filing of all periodic financial reports, or risk delisting, which would have a material adverse effect on our business. If we fail to maintain compliance with Nasdaq's continued listing requirements, it could affect our ability to raise capital on acceptable terms, or at all. In the event we are delisted from Nasdaq, the only established trading market for our common stock would be eliminated, and we would be forced to list our shares on the OTC Markets or another quotation medium, depending on our ability to meet the specific listing requirements of those quotation systems. As a result, an investor would likely find it more difficult to trade or obtain accurate price quotations for our shares. Delisting would likely also reduce the visibility, liquidity, and value of our common stock, reduce institutional investor interest in our Company, and may increase the volatility of our common stock. Delisting could also cause a loss of confidence of potential industry partners, lenders, and employees, which could further harm our business and our future prospects.

The issuance of additional shares of our common stock or the sale of shares of our common stock by any of our directors, officers or significant stockholders will dilute our stockholders' ownership interest in Akebia and may cause the market price of our common stock to decline.

Most of our outstanding common stock can be traded without restriction at any time. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock.

As of December 31, 2025 and based on the amounts reported in the most recent filings made under Section 13(g) of the Exchange Act, BlackRock beneficially owned approximately 7.2% of our outstanding shares of common stock, the Vanguard Group, or Vanguard, beneficially owned approximately 6.0% of our outstanding shares of common stock and State Street Corporation beneficially owned approximately 5.2% of our outstanding shares of common stock. By selling a large number of shares of common stock, BlackRock, Vanguard or State Street Corporation could cause the price of our common stock to decline. In addition, as of December 31, 2025, CSL Vifor beneficially owned 7,571,429 shares of common stock, which have not been registered pursuant to the Securities Act and were issued and sold in reliance upon the exemption from registration contained in Section 4(a)(2) of the Securities Act and Rule 506 promulgated thereunder, but if they are registered in the future, those shares would become freely tradable and, if a large portion of such shares are sold, could cause the price of our common stock to decline.

Further, we entered into a warrant agreement with Kreos Capital VII Aggregator SCSp, or the Warrant Holder, an affiliate of Kreos Capital VII (UK) Limited, pursuant to which (i) we issued a warrant to the Warrant Holder to purchase 3,076,923 shares of our common stock, or the Initial Warrant, at an exercise price per share of $1.30 (subject to standard adjustments for stock splits, stock dividends, rights offerings and pro rata distributions), or the Exercise Price, and (ii) we issued a warrant to the Warrant Holder to purchase 1,153,846 shares of our common stock, at an exercise price per share equal to the Exercise Price. Each warrant is exercisable for eight years from the date of issuance. If any or all of the warrants are exercised, our stockholders could realize dilution, and the value of their shares could decrease. For example, on July 21, 2025, the Warrant Holder exercised its option to purchase 2,115,384 shares of our common stock under the Initial Warrant on a cashless basis at the Exercise Price. A cashless exercise allows the Warrant Holder to convert the warrants into shares of our common stock without the need for a cash payment. Instead of paying cash upon exercise, the Warrant Holder received a reduced number of shares based on a predetermined formula. As a result of the cashless exercise, we issued 1,408,588 shares of our common stock to the Warrant Holder under the Initial Warrant.

We have a significant number of shares that are subject to outstanding options, restricted stock units and other securities convertible into our common stock, and in the future we may issue additional options, restricted stock units, or other securities convertible into our common stock. The exercise or vesting of any such options, restricted stock units, or other securities, and the subsequent sale of the underlying common stock, could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Such sales of our common stock could result in higher than average trading volume and may cause the market price for our common stock to decline.

In addition, we currently have on file with the SEC a shelf registration statement on Form S-3, which allows us to offer and sell up to $250.0 million in registered securities, such as common stock, preferred stock, debt securities, warrants and units, from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale, including a sales agreement prospectus that covers the offering, issuance and sale by us of up to a maximum aggregate offering price of up to $75.0 million of our common stock that may be issued and sold from time to time under a sales agreement with Jefferies LLC, of which $32.0 million remains available for future issuance and sale.

Sales of substantial amounts of shares of our common stock or other securities by our employees or our other stockholders or by us under our shelf registration statement, pursuant to at-the-market offerings or otherwise, could dilute our stockholders, lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities.

Our executive officers, directors and principal stockholders maintain the ability to significantly influence all matters submitted to stockholders for approval.

As of December 31, 2025, our executive officers, directors and principal stockholders, in the aggregate, beneficially owned shares representing a significant percentage of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons could significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our Company on terms that other stockholders may desire.

Provisions in our organizational documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our Charter and our Bylaws contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing certain members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions:

- authorize “blank check” preferred stock, which could be issued by our Board of Directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified Board of Directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our Board of Directors pursuant to a resolution adopted by a majority of the total number of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our Board of Directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our Board of Directors may be filled only by a majority of directors then in office, even though less than a quorum;
- require a supermajority vote of 75% of the holders of our capital stock entitled to vote or the majority vote of our Board of Directors to amend our Bylaws; and
- require a supermajority vote of 85% of the holders of our capital stock entitled to vote to amend the classification of our Board of Directors and to amend certain other provisions of our Charter.

These provisions, alone or together, could delay or prevent hostile takeovers, changes in control or changes in our management.

In addition, Section 203 of the DGCL prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Because we do not anticipate paying any cash dividends on our capital in the foreseeable future, capital appreciation, if any, will be our stockholders’ sole source of gain.

We have never declared or paid cash dividends on our capital stock and we currently intend to retain all of our future earnings, if any, to finance the development and growth of our business. Any payment of cash dividends in the future would be at the discretion of our Board of Directors and would depend on, among other things, our earnings, financial condition, capital requirements, level of indebtedness, statutory and contractual restrictions applying to the payment of dividends and other considerations that the Board of Directors deems relevant. In addition, the terms of the BlackRock Credit Agreement preclude us from paying cash dividends without prior written consent of the lender and future debt agreements may preclude us from paying cash dividends. As a result, capital appreciation, if any, of our common stock will be our stockholders’ sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity.

Cybersecurity Risk Management and Strategy

We have certain processes for assessing, identifying, and managing material risks from cybersecurity threats, which are integrated into our enterprise risk management processes. Specifically, we have processes for:

- **Identifying and Managing Cybersecurity Risks** — We have implemented a cross-functional approach to assessing, identifying and managing material cybersecurity threats and incidents. We periodically review, assess, update and test our policies, standards, processes and practices in a manner intended to address cybersecurity threats and events. The results of such reviews, assessments and tests are evaluated by management and reported to our Audit Committee of the Board of Directors, or the Audit Committee, and our Board of Directors.
- **Technical Safeguards** — We have integrated cybersecurity into our overall information technology operations and designed our processes and systems to help protect our information assets and operations from internal and external cyber threats, protect employee and patient information from unauthorized access or attack as well as secure our networks and systems.
- **Incident Response and Recovery Planning —** To better facilitate our cybersecurity program, our cybersecurity team works collaboratively across our Company to implement programs designed to protect our information systems from cybersecurity threats and to promptly respond to any material cybersecurity incidents. We conduct periodic tabletop exercises, including incident simulations to test these plans and ensure personnel are familiar with their roles and responsibilities in a response scenario.
- **Third-Party Risk Management** — We maintain a risk-based approach to identifying and overseeing material cybersecurity threats presented by third parties and the systems of third parties that could adversely impact our business in the event of a material cybersecurity incident affecting those third-party systems. Also, we engage certain external cybersecurity firms to enhance our cybersecurity oversight and cybersecurity breach detection over third party service providers.
- **Education and Awareness** — We provide training regarding cybersecurity threats as a means to equip our employees and consultants with tools to make employees and consultants aware of and to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices. We also use technology-based tools to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs.

We adjust our cybersecurity policies, standards, processes, and practices as necessary based on the information provided by our assessments, audits and reviews. Such processes include (i) procedural and technical safeguards, (ii) response plans, (iii) periodic tests on our systems, (iv) incident simulations and (v) routine review of our cybersecurity policies and procedures to identify risks and improve our practices. We engage certain external cybersecurity firms to enhance our cybersecurity oversight. We include confidentiality provisions in all contracts with third-party service providers, and data protection provisions in certain contracts with third-party service providers where applicable, to help protect us and our employees and patients from any related vulnerabilities.

Governance

Our Board of Directors is responsible for exercising oversight of management's identification and management of, and planning for, risks from cybersecurity threats. While the full Board of Directors has overall responsibility for risk oversight, the Board of Directors has delegated oversight responsibility related to risks from cybersecurity threats to the Audit Committee of our Board of Directors. The Audit Committee reports to the Board of Directors at least annually, and notifies the Board of Directors as necessary regarding significant new cybersecurity threats or incidents. The Audit Committee meets annually to discuss our approach to overseeing cybersecurity threats with management, including with members of our internal cybersecurity team.

We use an internal management team to run our information technology and cybersecurity functions, which includes our vice president of information technology and information security leads, who have collectively served in various roles in information technology and information security for over 25 years, including at other public companies. Through ongoing communications with this management committee, senior management is informed about and monitors the prevention, detection, mitigation and remediation of cybersecurity threats and incidents in real-time and reports such threats and incidents to the Audit Committee, when appropriate. Management updates the Audit Committee quarterly regarding our

cybersecurity threat risk management and strategy programs. Members of the Audit Committee are also encouraged to regularly engage in ad hoc conversations with management on cybersecurity-related topics and discuss any updates to our cybersecurity risk management and strategy programs. The Audit Committee is notified between such updates regarding significant new cybersecurity threats or incidents that meet pre-established reporting thresholds and any ongoing updates regarding any risk, as needed.

We have not identified any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect our company, including our business strategy, results of operations or financial condition. However, as discussed under “Risk Factor — Risks Related to our Business and Managing Growth” in Part I, Item 1A of this Form 10-K, cybersecurity threats could pose multiple risks to us. As cybersecurity threats become more frequent, sophisticated, and coordinated, it is reasonably likely that we will be required to expend greater resources to continue to modify and enhance our protective measures.

Item 2. Properties

We currently lease approximately 65,167 square feet of office, storage and laboratory space in Cambridge, Massachusetts, which is our corporate headquarters. The lease for our Cambridge, Massachusetts office, storage and lab space expires on September 11, 2026. On January 27, 2026, we entered into a lease agreement pursuant to which we will lease an aggregate of approximately 43,474 square feet, consisting of 28,518 square feet of office space, and 14,956 square feet of laboratory space, in Waltham, Massachusetts. We intend to relocate our corporate headquarters to Waltham in September 2026. We believe our existing facilities are adequate to meet our operational needs.

Item 3. Legal Proceedings

From time to time, we may be involved in legal proceedings arising from the normal course of business activities.

Opposition Proceedings Against Akebia

In September 2018, Dr. Reddy’s Laboratories Limited filed an opposition to our issued Indian Patent No. 287720 covering the composition of matter of vadadustat in the Indian Patent Office. In response to a preliminary opinion, we requested to amend the claims, and the amended claims were published on May 9, 2025. On December 19, 2025, we attended an oral hearing conducted on the basis of the amended claims.

On November 6, 2024, Sandoz AG, or Sandoz, filed an opposition against our issued European Patent No. 3007695 covering vadadustat once daily dosing regimen in the European Patent Office, or the EPO. On March 18, 2025, we timely submitted a Patent Proprietor’s Reply to the Notice of Opposition. Oral proceedings were scheduled for February 24-25, 2026. However, on December 8, 2025, Sandoz withdrew the opposition and the EPO issued a Brief Communication on December 11, 2025, stating that Sandoz is no longer a party to the proceedings. On January 13, 2026, the EPO issued a Brief Communication stating that the oral proceedings are cancelled and the procedure will be continued in writing. On January 15, 2026, the EPO issued a decision to discontinue the opposition proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on The Nasdaq Capital Market under the symbol "AKBA".

Holders

At February 23, 2026, there were approximately 25 holders of record of our common stock. The number of record holders is based upon the actual number of holders registered on our books at such date and does not include shares held in street name by brokers or other nominees, and shares held by persons, partnerships, associations, corporations or other entities whose shares are held by depository trust companies.

Dividends

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying cash dividends in the foreseeable future. In addition, the terms of our BlackRock Credit Agreement preclude us from paying cash dividends without prior written consent and future debt agreements may preclude us from paying cash dividends.

Issuer Purchases of Equity Securities

None.

Recent Sales of Unregistered Securities

We did not sell any securities that were not registered under the Securities Act of 1933, as amended, or the Securities Act, during the year ended, other than pursuant to transactions previously disclosed in our Current Reports on Form 8-K.

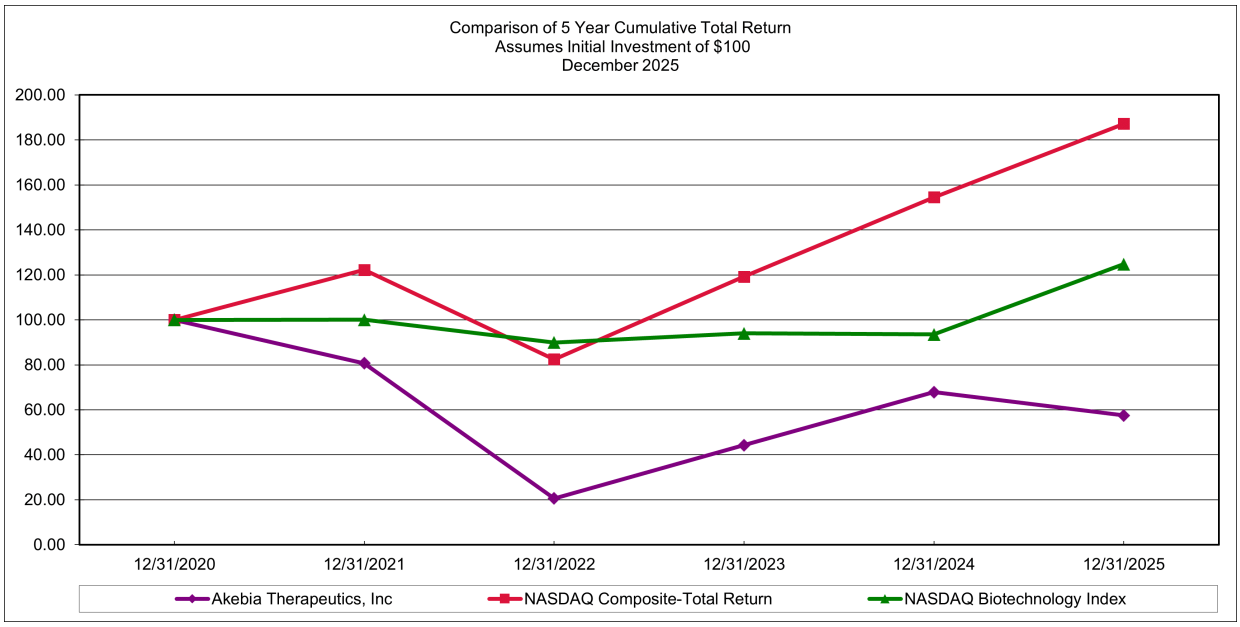
Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Comparative Stock Performance Graph

The following performance graph and related information shall not be deemed to be "soliciting material" or "filed" with the SEC or subject to Regulation 14A or 14C, or to the liabilities of Section 18 of the Exchange Act, except to the extent that we specifically request that this information be treated as soliciting material, or we specifically incorporate it by reference into a filing under the Securities Act, or the Exchange Act.

The following graph* compares the total cumulative returns of our common stock to the Nasdaq** Composite Index and the Nasdaq Biotechnology Index from December 31, 2020 through and including December 31, 2025. The graph assumes $100 was invested on December 31, 2020 in our common stock and each of the indices and that all dividends, if any, are reinvested. The performance shown represents past performance and should not be considered an indication of future performance.



*Prepared by Zack's Investment Research, Inc. Used with permission. All rights reserved. Copyright 1980-2026

**Index Data: Copyright NASDAQ OMX, Inc. Used with permission. All rights reserved.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12, *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*, of this Form 10-K.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Annual Report on Form 10-K, or Form 10-K*, including this management's discussion and analysis of financial condition and results of operations, contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those described in or implied in these forward-looking statements as a result of various factors, including those factors set forth in the "Risk Factors" section included in Part I, Item 1A of this Form 10-K. All references to years, unless otherwise noted, refer to our fiscal years, which end on December 31. For purposes of this section, all references to "we," "us," "our," "Akebia," or the "Company" refer to Akebia Therapeutics, Inc. and its consolidated subsidiaries.*

The following discussion and analysis should also be read in conjunction with the accompanying audited consolidated financial statements and related notes included in Part II, Item 8 of this Form 10-K. This section discusses 2025 and 2024 financial condition, and results of operations and year-to-year comparisons between 2025 and 2024. For discussion of 2024 items and year-over-year comparisons between 2024 and 2023 that are not included in this 2025 Form 10-K, refer to "Item 7. – Management's Discussion and Analysis of Financial Condition and Results of Operations" found in our Form 10-K for the year ended December 31, 2024, that was filed with the Securities and Exchange Commission on March 13, 2025.

Business Overview

We are a fully integrated biopharmaceutical company with two commercial products for patients impacted by kidney disease. We have built a business focused on developing and commercializing innovative therapeutics that we believe serve as a foundation for future growth, including by contributing net product revenue to support the development and advancement of our robust pipeline of mid-stage programs targeting rare kidney diseases and early-stage programs targeting kidney disease and non-kidney focused indications.

We have established the Company as a leader in the kidney community and believe our cross-organizational expertise in kidney disease positions us for success. Chronic kidney disease, or CKD, is a condition in which the kidneys are progressively damaged to the point that they cannot properly filter the blood circulating in the body. This damage causes waste products to build up in the patient's blood, leading to other health problems, including anemia, cardiovascular disease and bone disease. CKD significantly impacts the United States, or U.S., healthcare system, potentially affecting approximately 35.5 million

patients. In 2022, in the U.S. treating Medicare beneficiaries with CKD cost an estimated $95.7 billion, and treating people on dialysis cost an estimated $45.3 billion. Our two commercial products address certain complications of kidney disease.

Our current product portfolio includes:

Vafseo® (vadadustat) is an orally administered medicine that was approved by the U.S. Food and Drug Administration, or the FDA, in March 2024 for the treatment of anemia due to CKD in adult patients on dialysis for at least three months. The current U.S. market opportunity for the treatment of anemia due to CKD in patients with dialysis is approximately $1 billion based on current erythropoiesis stimulating agent, or ESA, pricing. Vafseo is the only oral hypoxia inducible factor, or HIF, based treatment available in the U.S. Vafseo entered the market in January 2025, at which time we had commercial supply agreements for the purchase of Vafseo in place with dialysis organizations caring for nearly 100% of dialysis patients in the U.S. Throughout 2025, we worked closely with dialysis organizations as their medical teams developed, implemented and operationalized protocols to enable prescribers to write Vafseo prescriptions for clinically appropriate patients. Currently, approximately 290,000 dialysis patients in the U.S. have prescribing access to Vafseo.

Vafseo is approved for use in adults in 37 countries and is marketed in certain countries outside the U.S. by our partners. See Part I, Item 1, License and Collaboration Agreements, for details.

Auryxia® (ferric citrate) is an orally administered medicine approved and marketed in the U.S. for two indications: (1) the control of serum phosphorus levels in adult patients with dialysis dependent chronic kidney disease, or DD-CKD, and (2) the treatment of iron deficiency anemia, or IDA, in adult patients with non-dialysis-dependent chronic kidney disease, or NDD-CKD.

Today, we market Auryxia in the U.S. Auryxia became part of our portfolio in 2018 and has historically contributed meaningful revenue to the business. In March 2025, Auryxia reached loss of exclusivity, or LoE. On January 22, 2026, Teva Pharmaceuticals Ltd., or Teva, received tentative approval for its Abbreviated New Drug Application for Auryxia. Currently, there is only one authorized generic for Auryxia sold by our distributor, but we expect additional generic competition in 2026. If additional generics are approved and enter the market, we expect it will adversely impact our revenue.

Ferric citrate is approved for use and marketed in certain countries outside the U.S. by our partners. See Part I, Item 1, License and Collaboration Agreements, for details.

Our development pipeline includes:

Our mid-stage rare kidney disease pipeline assets, praliciguat and AKB-097, are being evaluated to target areas of unmet need. In June 2021, we licensed praliciguat from Cyclerion Therapeutics, Inc., or Cyclerion, via an exclusive global license, which includes certain intellectual property rights to research, develop and commercialize the asset. Praliciguat is an oral, once-daily soluble guanylate cyclase, or sGC, stimulator. We are evaluating praliciguat for the treatment of biopsy-confirmed focal segmental glomerulosclerosis, or FSGS, a rare kidney disease, in a Phase 2 clinical trial. The first patient was dosed in this trial in December 2025. We also plan to assess the use of praliciguat in other rare podocytopathies in the future.

In November 2025, we entered into an asset purchase agreement with Q32 Bio Inc. and Q32 Bio Operations Inc., together Q32, pursuant to which we purchased and assumed substantially all assets and liabilities of Q32 and its affiliates related to the research, development, manufacture and commercialization of Q32's clinical-stage development candidate known as ADX-097, now referred to as AKB-097, an anti-C3d-Factor H fusion protein complement inhibitor. AKB-097 is a potential next-generation complement inhibitor, and we believe AKB-097 has applicability across a wide range of complement-mediated rare kidney diseases. AKB-097 is intended to provide targeted regulation of complement activation at sites of tissue injury while limiting systemic complement inhibition. We expect to initiate a Phase 2 basket study in the second half of 2026 to evaluate AKB-097 for the following indications: IgA Nephropathy, or IgAN; C3 Glomerulopathy, or C3G; and Lupus Nephritis, or LN.

Our early-stage pipeline assets include AKB-9090 and AKB-10108, which are HIF molecules. We plan to initially evaluate AKB-9090 for the treatment of cardiac surgery-related acute kidney injury, or CS-AKI, and we expect to initiate a Phase 1 study in healthy volunteers in the first half of 2026. We may also study AKB-9090 in acute respiratory distress syndrome, or ARDS, as well as other acute treatment indications. AKB-10108 will potentially be evaluated for retinopathy of prematurity, or ROP, in neonates, and other indications, and is currently in preclinical development.

We continue to explore additional commercial and development opportunities to expand our pipeline and portfolio of novel therapeutics through both internal research and external innovation to leverage our fully integrated team.

Factors Affecting Our Performance and Results of Operations

Financial Components

Product Revenue

We generate product revenue from commercial sales of Auryxia and Vafseo to a limited number of customers, including dialysis organizations, wholesale distributors, certain specialty pharmacy providers and our authorized generic distribution partner, Mylan Therapeutics, Inc., or AG Distributor. Our net product revenue includes many variables, including judgments and estimates of discounts, rebates and product returns, which can fluctuate from quarter-to-quarter and year-over-year.

We had exclusive rights under a series of patents and patent applications to commercialize Auryxia in the U.S. that protected us from generic drug competition until March 20, 2025. Following LoE, since March 2025, our AG Distributor has been selling an authorized generic version of Auryxia in the U.S. The impact of LoE on future Auryxia revenues will depend on many factors, including our ability to maintain contracts with dialysis organizations, the timing and number of additional generics and the pricing of generics and other products on the market that compete with Auryxia.

License, Collaboration and Other Revenue

License, collaboration and other revenue includes revenue earned under our agreements with our partners, including license fees, royalty payments and revenue from product we supply.

We expect to continue to generate revenue from our collaboration, license, and supply agreements with Medice, TPC, JT and Torii and any other collaborations into which we have entered or may enter.

Cost of Product and Other Revenue

Cost of product and other revenue includes costs closely correlated or directly related to the costs to manufacture commercial drug substance and drug product, including at our contract manufacturing organizations, or CMOs, as well as indirect costs. Direct and indirect costs include fees for packaging, shipping, insurance and quality assurance, idle capacity charges, changes in reserves for excess inventory, write-offs for inventory that fails to meet specifications or is otherwise no longer suitable for commercial sale, including scrap, changes in our firm purchase commitment liability and royalties due to the licensor of Auryxia related to U.S. and Japan product sales recognized during the period.

Cost of product and other revenue also includes costs to manufacture drug product provided to TPC and Medice for commercial sale of Vafseo in Japan and in the EEA, the UK, Switzerland and Australia, or collectively the Medice Territory, respectively, as well as to our AG Distributor. In addition, cost of product and other revenue includes personnel-related costs, including salaries and bonuses, employee benefits and stock-based compensation attributable to employees in particular functions and associated directly with the manufacturing of our commercial products.

Cost of product and other revenue for a newly launched product does not include the full cost of manufacturing until the initial pre-launch inventory is depleted and additional inventory is manufactured and sold. Until we received regulatory approval for Vafseo in the U.S., we recorded costs incurred to manufacture the U.S. pre-launch inventory, such as raw materials, drug substance and drug product conversion costs as research and development, or R&D, expense.

Cost of goods sold: Amortization of intangible asset - In addition, cost of product and other revenue included the amortization of development product rights for Auryxia through the end of 2024.

Research and Development Expenses

R&D expenses consist primarily of costs incurred for the development of Vafseo and costs associated with our pipeline which includes:

- personnel-related expenses, including salaries, bonuses, employee benefits, stock-based compensation and travel expenses for employees engaged in R&D functions;
- costs associated with feasibility and potential new manufacturing processes and methods for our commercial products;
- regulatory registration and related fees for non-commercial products;
- expenses incurred under agreements with contract research organizations, or CROs, and investigative sites that conduct our clinical trials;
- the cost of acquiring, developing and manufacturing clinical trial materials through CMOs;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies associated with our laboratory space as well as our R&D team;
- acquired in process research and development costs associated with the acquisition of Q32's clinical stage development asset now referred to as AKB-097;

- costs associated with discovery and development for preclinical, clinical and regulatory activities; and
- costs associated with the pre-launch inventory build for Vafseo in the U.S. prior to FDA approval in March 2024 and in Europe prior to the European Commission approval in April 2023.

R&D costs are expensed as incurred. Advance payments made for goods or services to be received in the future for use in R&D activities are recorded as prepaid expenses and other current assets. The prepaid amounts are expensed as the benefits are consumed. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

We cannot determine with certainty the duration and completion costs of our R&D projects, the costs of related clinical development, or if, when, or to what extent we will generate revenue from the commercialization or sale of any of our product candidates.

From inception through December 31, 2025, we have incurred $1.7 billion in R&D expenses. We expect to incur significant R&D expenditures for the foreseeable future as we continue the development of Auryxia, Vafseo, praliciguat, AKB-097 and any other product or product candidate, including those that may be in-licensed or acquired.

A significant portion of our R&D costs have been external costs, which we track on a program-by-program basis as well as costs related to possible new manufacturing processes and methods associated with our commercial products. These external costs include fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials and costs related to acquiring and manufacturing clinical trial materials, including costs paid to CMOs to manufacture clinical trial materials.

We do not track our internal personnel and facilities costs on a program-by-program basis as our personnel are deployed across multiple R&D projects.

Each of our products and product candidates has technical, clinical, regulatory and commercial risk, including those discussed more fully under the heading “Risk Factors” in Part I, Item 1A of this Form 10-K. A change in the outcome of any of the variables with respect to the development of Auryxia, Vafseo or any other product or product candidate could result in a significant change in the costs and timing associated with that development.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation related to commercial, marketing, executive, finance and accounting, information technology, corporate and business development and human resource functions. Other SG&A expenses include costs for marketing initiatives for our commercial products, market research and analysis on our commercial products and potential product candidates, conferences and trade shows, travel expenses, professional services fees (including legal, patent, accounting, audit, tax, and consulting fees), insurance costs, general corporate expenses and allocated facilities-related expenses, including rent and maintenance of facilities.

License Expense

License expense relates to royalties due to Panion & BF Biotech, Inc., or Panion, for sales of Auryxia in the U.S. and Riona in Japan.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income on our interest-bearing accounts, interest expense related to our term loans, accretion of the debt discount on our term loans as well as changes in the fair value of our derivative liability and amortization of the discount on the liability related to the termination fees associated with the termination agreement with BioVectra Inc., or BioVectra, entered into in December 2022, or the BioVectra Termination Agreement. See Note 10, *Commitments and Contingencies,* in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information on the BioVectra Termination Agreement. Other income (expense), net also includes non-cash interest on our liability related to settlement royalties and the amortization of the discount and deferred gain related to our Working Capital Fund (as defined below) liability to Vifor (International) Ltd. (now a part of CSL Limited), or CSL Vifor. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information on our arrangements with CSL Vifor.

Change in Fair Value of Warrant Liability

Change in fair value of warrant liability relates to the change in fair value of our warrant liability related to a warrant agreement with Kreos Capital VII Aggregator SCSp, an affiliate of Kreos Capital VII (UK) Limited, or Kreos. See Note 3, *Fair*

Value of Financial Instruments, and Note 7, *Indebtedness*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information on the warrant liability.

Recent Events

Initiation of Phase 2 Trial in FSGS

In December 2025, we dosed our first patient in a Phase 2 clinical trial of praliciguat for the treatment of biopsy-confirmed FSGS. As a result, in February 2026, pursuant to the terms of a License Agreement, as amended, dated June 3, 2021, by and between us and Cyclerion, or the Cyclerion Agreement, upon such dosing, we paid a $1.0 million regulatory milestone payment to Cyclerion.

See Note 10, *Commitments and Contingencies*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information on the Cyclerion Agreement.

Q32 Asset Purchase Agreement

On November 28, 2025, or the APA Closing Date, we entered into an Asset Purchase Agreement, or the Q32 Purchase Agreement, with Q32, pursuant to which we purchased and assumed from Q32 substantially all assets and liabilities of Q32 and its affiliates related to the research, development, manufacture and commercialization of Q32's clinical-stage development candidate known as ADX-097 (now referred to as AKB-097) worldwide for the treatment, prevention or diagnosis of any disease or condition in humans. AKB-097, which has been evaluated in a Phase 1 clinical trial in healthy volunteers, in a tissue-targeted C3d-Factor H fusion protein complement inhibitor with the potential to treat rare kidney diseases.

Under the terms of the Q32 Purchase Agreement, we (i) made an upfront payment of $7.0 million on the APA Closing Date, (ii) will make an additional upfront payment of $3.0 million on the six-month anniversary of the APA Closing Date, (iii) will make certain milestone payments upon the achievement of specified development and regulatory milestone events related to AKB-097 up to an aggregate amount equal to $94.5 million, including a $2.0 million development milestone payment upon the earlier of initiation of a Phase 2 clinical trial and December 31, 2026, (iv) will make certain milestone payments upon the achievement of specified commercial milestone events with respect to the net sales of AKB-097 up to an aggregate amount equal to $487.5 million, and (v) will make certain royalty payments based on the net sales of AKB-097 with royalty percentage tiers ranging from the low single digits to mid-teen percentages. The royalties will expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

See Note 10, *Commitments and Contingencies*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information on the Q32 Purchase Agreement.

Waltham Lease

In January 2026, we entered into a lease agreement, or the Waltham Lease, pursuant to which we will lease an aggregate of approximately 43,474 square feet, consisting of 28,518 square feet of office space and 14,956 square feet of laboratory space located in Waltham, Massachusetts. We intend to relocate our corporate headquarters to Waltham in September 2026.

See Note 18, *Subsequent Events*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information on the Waltham Lease.

Results of Operations

Comparison of the years ended December 31, 2025 and 2024

(dollars in thousands)	Years ended December 31, 2025	2024	Change $	Change %
Revenues				
Product revenue, net	$ 227,332	$ 152,180	$ 75,152	49 %
License, collaboration and other revenue	8,864	8,000	864	11 %
Total revenues	236,196	160,180	76,016	47 %
Cost of goods sold				
Cost of product and other revenue	39,462	27,135	12,327	45 %
Amortization of intangible asset	—	36,042	(36,042)	(100)%
Total cost of goods sold	39,462	63,177	(23,715)	(38)%
Operating expenses				
Research and development	62,359	37,652	24,707	66 %
Selling, general and administrative	107,480	106,545	935	1 %
License	3,396	3,220	176	5 %
Restructuring	—	58	(58)	(100)%
Total operating expenses	173,235	147,475	25,760	17 %
Operating income (loss)	23,499	(50,472)	73,971	(147)%
Other expense, net	(24,121)	(18,091)	(6,030)	33 %
Change in fair value of warrant liability	(3,099)	(330)	(2,769)	839 %
Loss on extinguishment of debt	—	(517)	517	(100)%
Loss before income taxes	(3,721)	(69,410)	65,689	(95)%
Income tax expense	(1,624)	—	(1,624)	*
Net loss	$ (5,345)	$ (69,410)	$ 64,065	(92)%

*Percentage change not meaningful.

Product Revenue, Net—Net product revenue is derived from sales of Auryxia and Vafseo in the U.S. We distribute Auryxia and Vafseo principally through a limited number of dialysis organizations, wholesale distributors, certain specialty pharmacy providers and our AG Distributor for Auryxia.

Net product revenue was $227.3 million for the year ended December 31, 2025, compared to net product revenue of $152.2 million for the year ended December 31, 2024. The increase was primarily due to Vafseo's entry to the market in January 2025 and an increase in sales volumes of Auryxia.

Auryxia lost exclusivity in the U.S. in March 2025, which may have a negative impact on future Auryxia revenue. Following LoE, our AG Distributor has been selling an authorized generic version of Auryxia in the U.S., which may slightly offset a revenue decline after entry of other generics. However, our ability to generate revenue from sales of Auryxia following entry of other generics will depend on many factors, including our ability to maintain contracts with dialysis organizations, the timing and number of additional generics that enter the market and the pricing of generics and other products on the market that compete with Auryxia.

The following table summarizes our product revenue for the years ended December 31, 2025 and 2024 (in thousands):

Product	Years Ended December 31, 2025	2024
Vafseo[(1)]	$ 45,790	$ —
Auryxia[(2)]	181,542	152,180
Total product revenues	$ 227,332	$ 152,180

(1) Vafseo entered the U.S. market in January 2025.

(2) Includes the authorized generic version of Auryxia sold and distributed by our AG Distributor during the year ended December 31, 2025.

License, Collaboration and Other Revenue—License, collaboration and other revenue was $8.9 million for the year ended December 31, 2025, compared to $8.0 million for the year ended December 31, 2024.

Cost of Goods Sold: Cost of Product and Other Revenue—Cost of product and other revenue was $39.5 million for the year ended December 31, 2025, compared to $27.1 million for the year ended December 31, 2024. The increase was primarily due to higher Auryxia volume during the year ended December 31, 2025. In addition, cost of product and other revenue for the year ended December 31, 2024 was offset by a $12.3 million benefit that we recorded due to our ability to sell inventory previously written-down as excess inventory during the year ended December 31, 2024.

We began capitalizing our Vafseo costs in March 2024, in connection with the FDA's approval of Vafseo for the treatment of anemia due to CKD in adult patients on dialysis for at least three months. Prior to the capitalization of Vafseo inventory costs, such costs were recorded as research and development expenses in the period incurred. Cost of product and other revenue for Vafseo was $3.3 million for the year ended December 31, 2025, comprised of manufacturing and overhead costs as the associated inventory costs such as raw materials, drug substance and drug product conversion costs were expensed previously. If Vafseo inventory sold during the year ended December 31, 2025 was valued at cost, our cost of product and other revenue would have been $6.0 million. As of December 31, 2025, we had $25.0 million of reduced-cost Vafseo inventory. We expect our cost of product and other revenue for Vafseo will increase, reflecting the full cost of manufacturing, subsequent to the utilization of our reduced-cost Vafseo inventory.

Cost of Goods Sold: Amortization of Intangible Asset—Amortization of intangible asset related to the acquired developed product rights for Auryxia, which was amortized using a straight-line method over its estimated useful life of approximately six years. Our intangible asset was fully amortized as of December 31, 2024. We recorded no amortization expense and $36.0 million in amortization expense for the years ended December 31, 2025 and 2024, respectively.

R&D Expenses— R&D expenses were $62.4 million for the year ended December 31, 2025, compared to $37.7 million for the year ended December 31, 2024. The increase was primarily driven by increased clinical trial activities related to Vafseo and our product candidates as well as higher headcount related costs. In addition, we recognized $12.8 million of acquired in process research and development costs associated with the acquisition of AKB-097 from Q32 during the year ended December 31, 2025.

The following table summarizes our R&D expenses for the years ended December 31, 2025 and 2024 (in thousands):

	Years ended December 31,	
	2025	**2024**
Vafseo clinical trial and other external costs	$ 22,371	$ 11,837
IPR&D asset, including transaction costs	12,807	—
External costs for other programs, including feasibility and new processes and methods associated with commercial products	4,651	6,311
Total external R&D expenses	39,829	18,148
Internal personnel, consulting, facilities and other	22,530	19,504
Total R&D expenses	$ 62,359	$ 37,652

We expect to incur significant R&D expenses in future periods in support of ongoing or planned studies with respect to the development of our product candidates as well as Vafseo.

Selling, General and Administrative Expenses—SG&A expenses were $107.5 million for the year ended December 31, 2025, compared to $106.5 million for the year ended December 31, 2024. The increase was primarily due to higher marketing costs in connection with the Vafseo U.S. launch and increased headcount related costs during the year ended December 31, 2025.

License Expenses—License expenses related to royalties due to Panion for sales of Riona in Japan were $3.4 million and $3.2 million for the years ended December 31, 2025 and 2024, respectively.

Restructuring Expenses—There were no restructuring expenses and $0.1 million of restructuring expenses for the years ended December 31, 2025 and 2024, respectively.

Other Expense, Net—Other expense, net, was $24.1 million for the year ended December 31, 2025, compared to $18.1 million for the year ended December 31, 2024. The increase was primarily due to higher non-cash interest expense related to the settlement royalty liability in connection with the Vifor Termination Agreement, which we entered into in July 2024, partially offset by interest income related to our money market funds. See Note 8, *Liability Related to Settlement Royalties, Working*

Capital Fund Liability and Liability Related to Sale of Future Royalties, in the accompanying notes to the audited consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information on our arrangements with CSL Vifor.

Change in Fair Value of Warrant Liability—Change in fair value of warrant liability was $3.1 million and $0.3 million for the years ended December 31, 2025 and 2024, respectively.

Loss on Extinguishment of Debt—During the year ended December 31, 2024, we recorded a $0.5 million loss on the extinguishment of debt in connection with the repayment of the Pharmakon Term Loans.

Income Tax Expense—Income tax expense was $1.6 million for the year ended December 31, 2025. There was no income tax expense for the year ended December 31, 2024.

Liquidity and Capital Resources

As of December 31, 2025, we had cash and cash equivalents of approximately $184.8 million and restricted cash of $1.7 million.

To date, we have funded our operations principally through sales of our common stock, including through our employee stock purchase plan, product sales, payments received from our collaboration and licensing partners, borrowings under term loans, a working capital payment from CSL Vifor also referred to as a Working Capital Fund liability and a royalty transaction. From inception through December 31, 2025, we raised approximately $929.2 million of net proceeds from the sale of equity, including $567.9 million from various underwritten public offerings, $291.3 million from at-the-market, or ATM, offerings, pursuant to our sales agreement with Jefferies LLC, or Jefferies, and prior sales agreements with Cantor Fitzgerald & Co., and $70.0 million from the sale of 7,571,429 shares of common stock to CSL Vifor. During the year ended December 31, 2025, we sold 9,437,364 shares of our common stock under our sales agreement with Jefferies for gross proceeds of $18.7 million ($18.4 million, net of offering expenses).

For the years ended December 31, 2025 and 2024, we incurred net losses of $5.3 million and $69.4 million, respectively. As of December 31, 2025 and 2024, we had an accumulated deficit of $1.7 billion.

We had exclusive rights under a series of patents and patent applications to commercialize Auryxia in the U.S. that protected us from generic drug competition until March 2025. Following LoE, our AG Distributor has been selling an authorized generic version of Auryxia in the U.S., which may slightly offset a revenue decline after entry of other generics. However, our ability to continue to generate revenue from sales of Auryxia following entry of other generics will depend on many factors, including our ability to maintain contracts with dialysis organizations, the timing and number of additional generics that enter the market and the pricing of generics and other products on the market that compete with Auryxia.

We believe our existing cash resources and the cash we expect to generate from product, royalty, supply and license revenues are sufficient to fund our current operating plan for at least two years, including to commercialize Vafseo and Auryxia and advance our existing programs. However, if our operating performance deteriorates significantly from the levels expected in our long-term operating plan, including if we do not achieve our future anticipated Vafseo revenue projections, it would have an adverse effect on our liquidity and capital resources and could affect our ability to achieve and maintain profitability or continue as a going concern in the future. In addition, we may also seek to sell additional private or public equity, enter into new debt transactions, explore potential strategic transactions or a combination of these approaches or other strategic alternatives. If we raise additional funds by issuing equity securities, our shareholders would experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available to us in amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital in sufficient amounts when needed or on attractive terms, we may not be able to pursue development and commercial activities related to Auryxia and Vafseo, or any additional products and product candidates, including those that may be in-licensed or acquired. Any of these events could significantly harm our business, financial condition and prospects.

There can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, or that our cash resources will fund our operating plan for the period of time anticipated by us, or that additional funding will be available on terms acceptable to us, or at all. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves numerous risks and uncertainties, and actual results could vary as a result of a number of factors, many of which are outside our control. We have based this estimate on assumptions that may be substantially different than actual results, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near- and long-term, will depend on many factors including, but not limited to, those described under Part I, Item 1A. Risk Factors under the heading "Risks Related to our Financial Position, Need for Additional Capital and Growth Strategy."

Contractual Obligations and Commitments

Debt Agreements and Other Funding Arrangements

BlackRock Term Loans

On January 29, 2024, or the Closing Date, we entered into the Agreement for the Provision of a Loan Facility, as amended, or the BlackRock Credit Agreement, with Kreos Capital VII (UK) Limited, or Kreos, which are funds and accounts managed by BlackRock Inc., collectively, BlackRock. The BlackRock Credit Agreement provides for a senior secured term loan facility, in the aggregate principal amount of up to $55.0 million, or the Term Loan Facility. The Term Loan Facility was available in three tranches: (i) Tranche A — $37.0 million was funded on the Closing Date and used to repay the Pharmakon Term Loans; (i) Tranche B — $8.0 million was funded on April 19, 2024, and (ii) Tranche C — $10.0 million was funded on February 3, 2025, or the Tranche C Closing Date, collectively, the Term Loans. The Term Loan Facility matures on January 29, 2028, or the BlackRock Maturity Date.

On February 3, 2025, we and Kreos entered into a Second Amendment to the BlackRock Credit Agreement, or the Second Amendment, which, among other things, extended the expiry date of Tranche C from December 31, 2024 to the Tranche C Closing Date, or the Extended Tranche C. Tranche C was available subject to receipt of a certain amount of cumulative gross cash proceeds after the Closing Date in the form of equity or equity linked securities in one or more series of transactions. The terms of the Extended Tranche C are substantially similar to the terms of the original Tranche C, however, interest accrued on the Extended Tranche C as if it was advanced on December 31, 2024.

We are required to make interest-only payments until December 31, 2026 after which, we will begin making equal monthly principal payments. In the event of certain prespecified events, the repayment schedule will be accelerated.

The Term Loan Facility accrues interest at a floating annual rate equal to the sum of (i) term Secured Overnight Financing Rate, or SOFR, for a tenor of one month (subject to a floor of 4.25% per annum) plus (ii) a margin of 6.75% per annum (subject to an overall cap of 15.00% per annum on the all-in interest rate). During the continuance of any payment event of default the interest rate on such overdue sum will automatically increase by an additional 3.0% per annum, and may be subject to an additional late fee of 2.0% of such overdue sum.

All obligations under the Term Loan Facility are secured by substantially all of our existing and after-acquired assets. The BlackRock Credit Agreement requires us to either (i) maintain cash and cash equivalents, measured as of the last day of each fiscal month, greater than or equal to $15.0 million or (ii) earn consolidated revenue, measured as of the last day of each fiscal month for the trailing twelve-month period, of $150.0 million. The BlackRock Credit Agreement contains certain representations and warranties, affirmative and negative covenants that limit our ability to engage in specified types of transactions and other provisions typical within a credit agreement. If an event of default occurs and is continuing under the BlackRock Credit Agreement, BlackRock is entitled to take enforcement action, including acceleration of amounts due which could limit our ability to make certain payments under a Termination and Settlement Agreement with CSL Vifor, or the Vifor Termination Agreement. If we prepay the Term Loans prior to the BlackRock Maturity Date, we will be required to pay a prepayment fee ranging from 1.0% to 4.0% of the amount prepaid.

On the Closing Date, Kreos Capital VII Aggregator SCSp, an affiliate of Kreos, or the Warrant Holder, received a warrant to purchase 3,076,923 shares of our common stock, or the Initial Warrant, at an exercise price per share of $1.30, and upon the borrowing of Tranche C in February 2025, we issued additional warrants to purchase 1,153,846 shares of our common stock at an exercise price per share of $1.30. Each warrant is exercisable for eight years from the date of issuance.

On July 21, 2025, the Warrant Holder exercised its option to purchase 2,115,384 shares of our common stock under the Initial Warrant on a cashless basis at an exercise price per share of $1.30. On July 23, 2025, as a result of the cashless exercise, we issued 1,408,588 shares of our common stock to the Warrant Holder.

See Note 7, *Indebtedness,* in the accompanying notes to the audited consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information.

Liability Related to Settlement Royalties

On July 10, 2024, we and CSL Vifor entered into the Vifor Termination Agreement. Pursuant to the terms of the Vifor Termination Agreement, we pay CSL Vifor decreasing quarterly tiered royalty payments ranging from a high single-digit percentage of our net sales of Vafseo up to $450.0 million to mid-single digit percentage of our net sales of Vafseo above $450.0 million, in each case, in the U.S. during a calendar year, or the Settlement Royalty Payments. The Settlement Royalty Payments commenced upon the first sale of Vafseo by us to a third party for use in the U.S., and will continue until the later of the (i) expiration of the last-to-expire valid claim listed in the FDA Orange Book that would be infringed by the making, using, selling or importing of Vafseo in the U.S. or (ii) the expiration of marketing or regulatory exclusivity for Vafseo in the U.S., or the Settlement Royalty Term. Beginning on July 1, 2027 and throughout the Settlement Royalty Term, we have the option to make a one-time payment to CSL Vifor, or the Royalty Buy-Down Option, upon which the Settlement Royalty Payments will be adjusted as of the date of exercise of the Royalty Buy-Down Option such that we will then only pay CSL Vifor quarterly royalty

payments based on a mid-single digit percentage of our net sales of Vafseo up to $450.0 million in the U.S. during a calendar year in lieu of the above Settlement Royalty Payments. If we exercise the Royalty Buy-Down Option, the WCF Royalty Payments will continue as described below.

The WCF Royalty Payments, as described below, the Settlement Royalty Payments and the Royalty Buy-Down Option are in consideration for the termination of the Vifor License Agreement and all obligations thereunder, and the covenants and agreements set forth in the Vifor Termination Agreement, including the settlement and release of all disputes and claims arising from the Vifor License Agreement.

As a result of the Vifor Termination Agreement, we concluded that CSL Vifor no longer met the definition of a customer and, therefore, the arrangement should not be considered a revenue contract with a customer under ASC 606, *Revenue from Contracts with Customers.* We therefore determined that the $43.3 million received from Vifor in connection with the Vifor License Agreement and related investment agreements should be classified as debt and we are amortizing such amount using the effective interest method over the Settlement Royalty Term. The liability related to settlement royalties and the amortization are based on our current estimates of future royalties expected to be paid over the life of the arrangement. The annual effective interest rate as of December 31, 2025 was 22% which is reflected as interest expense in the consolidated statements of operations and comprehensive loss. We recognized interest expense related to the liability related to settlement royalties of $18.4 million and $9.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, $12.5 million and $54.8 million of the settlement royalties liability is classified as a current and non-current liability, respectively.

See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, in the accompanying notes to the audited consolidated financial statements in Part II, Item 8 of this Form 10-K for further information.

Working Capital Fund Liability (Previously Referred to as Refund Liability to Customer)

In February 2022, we amended our agreement with CSL Vifor and they contributed $40.0 million to a working capital fund, or the Working Capital Fund, established to partially fund our costs of purchasing Vafseo from our contract manufacturers.

Pursuant to the terms of the Vifor Termination Agreement, and generally consistent with the terms of the Vifor License Agreement, we agreed to repay the Working Capital Fund to CSL Vifor through quarterly tiered royalty payments ranging from 8% to 14% of our net sales of Vafseo in the U.S., or the WCF Royalty Payments. The WCF Royalty Payments commenced on July 1, 2025, and will continue until the earlier of (i) the cumulative total of the WCF Royalty Payments equals $40.0 million, or (ii) May 31, 2028, or the WCF Royalty Term. The WCF Royalty Payments are subject to certain minimum true-up milestones.

The Working Capital Fund is considered a debt arrangement with zero coupon interest, and we impute interest on the Working Capital Fund liability at a rate of 15.0% per annum. As of December 31, 2025, $17.4 million and $22.6 million of the Working Capital Fund liability is classified as a current and non-current liability, respectively, based on management's estimated timing of the repayment of the Working Capital Fund liability to CSL Vifor.

See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, in the accompanying notes to the consolidated financial statements in Part II, Item 8 of this Form 10-K for further information.

Liability Related to Sale of Future Royalties

In February 2021, we sold to HealthCare Royalty Partners IV L.P., or HCR, our right to receive royalties and sales milestones for Vafseo in Japan and certain other Asian countries, such countries collectively, the TPC Territory, such payments collectively the Royalty Interest Payments, in each case, payable to us under the Collaboration Agreement dated December 11, 2015, between us and TPC, or the TPC Agreement. The Royalty Interest Payments are subject to an annual maximum “cap” of $13.0 million, after which we will receive 85% of the Royalty Interest Payments for the remainder of that year. The Royalty Interest Payments are also subject to an aggregate maximum “cap” of $150.0 million, after which the Royalty Interest Payments will revert back to us.

We received $44.8 million from HCR, net of certain transaction expenses, which we recorded as a liability at the transaction date. We amortize the liability related to the sale of future royalties using the effective interest method over the life of the arrangement. The annual effective interest rate as of December 31, 2025 was 0%. We retain the right to receive all potential future regulatory milestones for vadadustat under the TPC Agreement. During the year ended December 31, 2025 and 2024, we recorded $1.8 million and $1.9 million of non-cash royalty revenue, respectively. As of December 31, 2025, $1.7 million and $50.6 million of the liability related to the sale of future royalties is classified as a current and non-current liability, respectively.

See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, in the accompanying notes to the consolidated financial statements in Part II, Item 8 of this Form 10-K for further information.

Off-Balance Sheet Arrangements

Letter of Credit

As of December 31, 2025, in connection with the Cambridge Lease (as defined below), we had $1.7 million in a letter of credit outstanding.

Director and Officer Indemnification

We have entered into indemnification agreements with our directors and certain officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. No demands have been made upon us to provide indemnification under such agreements and there are no claims that we are aware of that could have a material effect on our consolidated financial statements.

Contractual Obligations and Commitments Other Than Debt Agreements

We are party to contractual obligations involving commitments to make payments to third parties in the future. Certain contractual obligations are reflected on our consolidated balance sheet as of December 31, 2025, while others are considered future obligations. Our material cash requirements as of December 31, 2025, include contractual obligations and commitments arising in the normal course of business, including leases, license agreements, manufacturing agreements and unconditional purchase commitments which are described in more detail below.

Cambridge Lease

We lease approximately 65,167 square feet of office, storage and laboratory space in Cambridge, Massachusetts under non-cancelable operating leases, collectively the Cambridge Lease. The office, storage and lab lease expires on September 11, 2026.

See Note 9, *Leases*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information.

Waltham Lease

In January 2026, we entered into the Waltham Lease. We intend to relocate our corporate headquarters to Waltham in September 2026.

See Note 18, *Subsequent Events*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information on the Waltham Lease.

License Agreements

Panion License Agreement

We have a license agreement with Panion, under which we are required to pay royalties related to the sale of Auryxia. The royalty payment obligations are contingent upon generating product revenue, and the amount and timing of such payments are not known. See Note 10, *Commitments and Contingencies*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information.

Cyclerion Agreement

In June 2021, we entered into the Cyclerion Agreement, as amended in December 2024, under which we obtained an exclusive global license under certain intellectual property rights to research, develop and commercialize praliciguat, an investigational oral soluble guanylate cyclase stimulator.

Under the Cyclerion Agreement, as amended, Cyclerion is eligible to receive up to an additional aggregate of $197.5 million from us in specified development and regulatory milestone payments on a product-by-product basis. Cyclerion will also be eligible to receive specified commercial milestones as well as tiered royalties ranging from mid-single-digit percentage to twenty percent of net sales, on a product-by-product basis, and subject to reduction upon expiration of patent rights or the launch of a generic product in the territory.

See Note 10, *Commitments and Contingencies*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information.

Q32 Purchase Agreement

On the APA Closing Date, we entered into the Q32 Purchase Agreement with Q32, pursuant to which we purchased and assumed from Q32 substantially all assets and liabilities of Q32 and its affiliates related to the research, development, manufacture and commercialization of Q32's clinical-stage development candidate known as ADX-097 (now referred to as AKB-097) worldwide for the treatment, prevention or diagnosis of any disease or condition in humans. AKB-097, which has been evaluated in a Phase 1 clinical trial in healthy volunteers, in a tissue-targeted C3d-Factor H fusion protein complement inhibitor with the potential to treat rare kidney diseases.

Under the terms of the Q32 Purchase Agreement, we (i) made an upfront payment of $7.0 million on the APA Closing Date, (ii) will make an additional upfront payment of $3.0 million on the six-month anniversary of the APA Closing Date, (iii) will make certain milestone payments upon the achievement of specified development and regulatory milestone events related to AKB-097 up to an aggregate amount equal to $94.5 million, including a $2.0 million development milestone payment upon the earlier of initiation of a Phase 2 clinical trial and December 31, 2026, (iv) will make certain milestone payments upon the achievement of specified commercial milestone events with respect to the net sales of AKB-097 up to an aggregate amount equal to $487.5 million, and (v) will make certain royalty payments based on the net sales of AKB-097 with royalty percentage tiers ranging from the low single digits to mid-teen percentages. The royalties will expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

See Note 10, *Commitments and Contingencies*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information on the Q32 Purchase Agreement.

Manufacturing Agreements

We have various supply arrangements to which we are a party, and we are obligated to pay for drug substance and drug product for commercial use. Under one of our agreements, we are required to purchase a minimum quantity of Auryxia drug substance at a predetermined price. We are also obligated to purchase a certain percentage of the global demand for Vafseo drug substance and drug product based on certain quarterly and annual forecasts we provide to certain suppliers. Our supply agreements for Vafseo drug substance and drug product provide for a volume-based pricing structure. We may also be required to reimburse certain suppliers for reasonable expenses.

See Note 10, *Commitments and Contingencies*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information.

Amounts Due Under Former Manufacturing and Unconditional Purchase Commitments

On December 22, 2022, we terminated any and all existing agreements with BioVectra for the supply of Auryxia drug substance. Under the BioVectra Termination Agreement, we agreed to pay BioVectra a total of $32.5 million consisting of (i) an upfront payment of $17.5 million that was paid in December 2022 and (ii) six quarterly payments of $2.5 million which commenced in April 2024 and were completed in July 2025. In addition, we and BioVectra have released one another from all existing and future claims and liabilities and agreed to return certain materials and documents.

See Note 10, *Commitments and Contingencies*, in the accompanying notes to the consolidated financial statements included in Part II, Item 8 of this Form 10-K for further information.

Other Third Party Contracts

We enter into agreements in the normal course of business with various vendors, which are generally cancellable upon notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of service providers, up to the date of cancellation. In addition, we contract with various organizations to conduct R&D activities with remaining contract costs to us of approximately $82.6 million as of December 31, 2025. The scope of the services under these R&D contracts can be modified upon mutual agreement of the parties, and the contracts or scope of services can be cancelled by us upon written notice. In some instances, the contracts may be cancelled by the third party upon written notice.

Cash Flows

The following table provides a summary of cash flow data for each applicable period:

	Years ended December 31,	
NET CASH PROVIDED BY/(USED IN) *(in thousands)*:	**2025**	**2024**
Operating activities	$ 67,992	$ (40,659)
Investing activities	(7,926)	(33)
Financing activities	72,927	49,663
Net increase in cash, cash equivalents and restricted cash	**$ 132,993**	**$ 8,971**
Cash, cash equivalents and restricted cash — beginning of period	53,550	44,579
Cash, cash equivalents and restricted cash — end of period	**$ 186,543**	**$ 53,550**

Operating Activities

Net cash provided by operating activities during the year ended December 31, 2025 was $68.0 million. Net cash provided by operating activities during the year ended December 31, 2025 consisted of a net loss of $5.3 million and net non-cash adjustments of $56.9 million, including non-cash interest expense of $21.8 million, a charge for the purchase of an in-process research and development, or IPR&D, asset of $12.8 million related to the Q32 Purchase Agreement and a reduction of $16.5 million in working capital.

Net cash used in operating activities during the year ended December 31, 2024 was $40.7 million. Net cash used in operating activities during the year ended December 31, 2024 consisted of a net loss of $69.4 million and non-cash adjustments of $68.4 million, including amortization of our intangible asset of $36.0 million, and a reduction of $39.7 million in working capital.

Investing Activities

Net cash used in investing activities was $7.9 million for the year ended December 31, 2025, which primarily consisted of the purchase of an IPR&D asset, including transaction costs, related to the Q32 Purchase Agreement.

Net cash used in investing activities was immaterial for the year ended December 31, 2024.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2025 was $72.9 million, which primarily consisted of proceeds of $10.0 million from the issuance of debt under the BlackRock Credit Agreement and net proceeds of $66.4 million from the sale of common stock from our March 2025 underwritten public offering and under our ATM facility.

Net cash provided by financing activities for the year ended December 31, 2024 was $49.7 million, which primarily consisted of proceeds of $45.0 million from the issuance of debt under the BlackRock Credit Agreement and net proceeds of $42.5 million from the sale of common stock under our ATM facility, partially offset by principal payments of debt of $37.1 million primarily related to the Pharmakon Term Loans which were repaid in January 2024.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements not yet adopted, see Note 2, *Summary of Significant Accounting Policies,* to our consolidated financial statements included in Part II, Item 8 of this Form 10-K.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements included elsewhere in this Form 10-K, which consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, including the current or long-term classification of such assets, liabilities and expenses, classification of the expenses and the related disclosure of contingent assets and liabilities. We monitor our estimates on an ongoing basis for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

While our significant accounting policies are described in more detail in Note 2, *Summary of Significant Accounting Policies*, to our consolidated financial statements in Part II, Item 8 of this Form 10-K, we believe the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements and to understanding of our results of operations.

Product Revenue, Net

We recognize revenue on product sales when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

The most significant estimate we are required to make is related to commercial and government rebates, chargebacks, discounts and fees (collectively considered variable consideration). Revenue from product sales is recorded at the net sales price (transaction price), which includes estimates of variable consideration, which are described below. We track available information regarding changes, if any, to the payor mix for our products, to our contractual terms with third-party payors and to applicable governmental programs and regulations and levels of our products in the distribution channel. We adjust our estimated rebates based upon new information as it becomes available, including information regarding actual rebates for our products and forecasted customer buying and payment demands. Claims by third-party payors for government rebates are submitted to us significantly after the related sales, potentially resulting in adjustments in the period in which the new information becomes known. Our adjustments to revenue related to prior period sales have not been significant.

Further details on the variable consideration components or provisions include:

- *Commercial Rebates*—We contract with dialysis organizations, wholesale distributors and certain specialty pharmacy providers for the payment of rebates with respect to utilization of our products. We estimate commercial rebates based upon our customers' actual purchase level during the quarterly or annual rebate purchase period, and the corresponding contractual rebate tier we expect each customer to achieve. The provision for commercial rebates is recorded in accrued expenses and other current liabilities in our consolidated balance sheets.
- *Trade Discounts and Allowances*—Discounts that include incentive fees are explicitly stated in our contracts. In addition, we compensate (through trade discounts and allowances) our customers for sales order management, data and distribution services.
- *Product Returns*—Consistent with industry practice, subject to certain caps for certain customers, we generally offer customers a limited right of return which allows for the product to be returned when the product expiry is within an allowable window, when the quantity delivered is different than quantity ordered, the product is damaged in transit prior to receipt by the customer, or is subject to a recall. This right of return generally lapses once the product is provided to a patient. We estimate the amount of our product sales that may be returned for credit by our customers. Product return provisions are estimated primarily based on our gross sales multiplied by an estimated return rate calculated using our historical actual rate of return for product sales as well as recent trends on lots still subject to the return window. In addition, certain customers are subject to an annual cap on returns of 2% of gross sales in any given year.
- *Chargebacks and Discounts*—Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. Provisions for chargebacks consist of credits that we expect to issue for units that remain in the distribution channel at each reporting period end that we expect will be sold to qualified healthcare providers and chargebacks that customers have claimed but for which we have not yet issued a credit.
- *Government Rebates*—We are subject to discount obligations under state Medicaid programs and other government programs. We estimate Medicaid and other government programs rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel at the end of each reporting period.
- *Other Incentives*—Other incentives that we offer include voluntary patient assistance programs such as our co-pay assistance program, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on actual claims processed during a given period, as well as historical utilization data to estimate the amount we expect to receive associated with product that has been recognized as revenue, but remains in in the distribution channel at the end of each reporting period.

Overall, these provisions reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the respective underlying contracts. Our calculation of the provisions, include estimates and judgments that

materially affect our recognition of net product revenues. Changes in our estimates of net product revenues could have a material effect on net product revenues recorded in the period in which we determine that change occurs.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

We had cash, cash equivalents and short-term marketable securities of $184.8 million and $51.9 million at December 31, 2025 and 2024, respectively, which consisted of cash and money market funds. Interest income is sensitive to changes in the general level of interest rates. However, due to the nature of these investments, a change in market interest rates of 1% would not be expected to have a material impact on our financial condition or results of operations for either period.

Foreign Exchange Risk

We are exposed to market risk related to exchange rates. The majority of our revenues for the years ended December 31, 2025, 2024 and 2023 was received in U.S. dollars, including revenues we received from royalty payments converted to U.S. dollars based on the net sales of Riona® and Vafseo™, in Japanese yen and the Euro, respectively. Our exchange rate risk arises from such foreign currency net sales. As a result, we are exposed to movements in the exchange rates of the Japanese yen and the Euro against the U.S. dollar. During the years ended December 31, 2025, 2024 and 2023, the impact of foreign currency exposure was immaterial and thus did not have a significant impact on our consolidated financial statements.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Akebia Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Akebia Therapeutics, Inc. (the Company) as of December 31, 2025 and 2024, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2025, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 26, 2026, expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Product Revenue, Net

Description of the Matter

During the year ended December 31, 2025, the Company recorded net product revenue of $227.3 million. As described in Note 2 to the consolidated financial statements under the caption “Product Revenue, net”, revenue from product sales includes estimates of variable consideration for which provisions are established, including provisions for commercial rebates.

Auditing the Company’s accounting for variable consideration related to commercial rebates on product sales was especially challenging due to the varying contractual terms within each customer contract and because the amounts are material to the consolidated financial statements and related disclosures.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated and tested the design and the operating effectiveness of internal controls over the Company’s process to determine provisions for commercial rebates on product sales. This included testing controls over the Company’s process to evaluate the contractual terms of contracts with customers, including evaluation of commercial rebates and determining the appropriate revenue recognition. We also tested the Company’s controls over evaluating the completeness and accuracy of the data used in the process.

To test the Company’s accounting for provisions for commercial rebates on product sales, our audit procedures included, among others, inspecting agreements with significant customers to validate the contractual terms of contracts with customers, including the identification of commercial rebates. We also tested the completeness and accuracy of the underlying data used in the calculations, including testing the mathematical accuracy of the Company’s calculations, and testing the accuracy of variable consideration by tracing key terms to the contracts with customers.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2013.

Boston, Massachusetts
February 26, 2026

AKEBIA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

(dollars in thousands, except per share amounts)	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 184,844	$ 51,870
Inventories	15,610	16,243
Accounts receivable, net	47,031	34,368
Prepaid expenses and other current assets	5,470	11,350
Total current assets	252,955	113,831
Property and equipment, net	1,222	2,200
Operating right-of-use assets	3,663	8,218
Goodwill	59,044	59,044
Other long-term assets	59,681	37,377
Total assets	$ 376,565	$ 220,670
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 21,185	$ 15,180
Accrued expenses and other current liabilities	121,716	63,460
Short-term deferred revenue	2,681	—
Working Capital Fund liability, current portion	17,356	2,274
Total current liabilities	162,938	80,914
Long-term operating lease liabilities	—	3,547
Long-term debt, net	48,250	38,693
Liability related to settlement royalties, net of current portion	54,750	46,697
Liability related to sale of future royalties, net of current portion	50,608	52,066
Working Capital Fund liability, net of current portion	22,606	38,013
Warrant liability	2,980	5,176
Other long-term liabilities	1,823	4,749
Total liabilities	343,955	269,855
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Preferred stock $0.00001 par value, 25,000,000 shares authorized; no shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock: $0.00001 par value; 350,000,000 shares authorized at December 31, 2025 and 2024; 265,424,818 and 224,848,992 shares issued and outstanding at December 31, 2025 and 2024, respectively	2	2
Additional paid-in capital	1,716,307	1,629,167
Accumulated other comprehensive income	6	6
Accumulated deficit	(1,683,705)	(1,678,360)
Total stockholders' equity (deficit)	32,610	(49,185)
Total liabilities and stockholders' equity (deficit)	$ 376,565	$ 220,670

The accompanying notes are an integral part of these consolidated financial statements.

AKEBIA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(dollars in thousands, except per share amounts)	Years Ended December 31, 2025	2024	2023
Revenues:			
Product revenue, net	$ 227,332	$ 152,180	$ 170,301
License, collaboration and other revenue	8,864	8,000	24,322
Total revenues	236,196	160,180	194,623
Cost of goods sold:			
Cost of product and other revenue	39,462	27,135	38,107
Amortization of intangible asset	—	36,042	36,042
Total cost of goods sold	39,462	63,177	74,149
Operating expenses:			
Research and development	62,359	37,652	63,079
Selling, general and administrative	107,480	106,545	100,233
License	3,396	3,220	3,237
Restructuring	—	58	181
Total operating expenses	173,235	147,475	166,730
Income (loss) from operations	23,499	(50,472)	(46,256)
Other income (expense):			
Interest expense	(24,179)	(18,185)	(6,032)
Other income	58	94	887
Change in fair value of warrant liability	(3,099)	(330)	—
Loss on extinguishment of debt	—	(517)	—
Loss on termination of lease	—	—	(524)
Loss before income taxes	(3,721)	(69,410)	(51,925)
Income tax expense	(1,624)	—	—
Net loss	$ (5,345)	$ (69,410)	$ (51,925)
Comprehensive loss	$ (5,345)	$ (69,410)	$ (51,925)
Net loss per share:			
Basic and diluted	$(0.02)	$(0.33)	$(0.28)
Weighted average number of common shares outstanding:			
Basic and diluted	257,157,782	210,946,658	187,465,448

The accompanying notes are an integral part of these consolidated financial statements.

Akebia Therapeutics, Inc.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(dollars in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' (Deficit) Equity
Balance at December 31, 2022	**184,135,714**	**$ 2**	**$ 1,562,247**	**$ 6**	**$ (1,557,025)**	**$ 5,230**
Issuance of common stock, net of issuance costs	6,189,974	—	6,708	—	—	6,708
Proceeds from sale of stock under employee stock purchase plan	200,194	—	85	—	—	85
Stock-based compensation expense	—	—	9,317	—	—	9,317
Restricted stock unit vesting	4,054,407	—	—	—	—	—
Exercise of options	2,250	—	1	—	—	1
Net loss	—	—	—	—	(51,925)	(51,925)
Balance at December 31, 2023	**194,582,539**	**$ 2**	**$ 1,578,358**	**$ 6**	**$ (1,608,950)**	**$ (30,584)**
Issuance of common stock, net of issuance costs	27,532,942	—	42,495	—	—	42,495
Proceeds from sale of stock under employee stock purchase plan	189,732	—	153	—	—	153
Stock-based compensation expense	—	—	7,775	—	—	7,775
Restricted stock unit vesting	2,099,540	—	—	—	—	—
Exercise of options	444,239	—	386	—	—	386
Net loss	—	—	—	—	(69,410)	(69,410)
Balance at December 31, 2024	**224,848,992**	**$ 2**	**$ 1,629,167**	**$ 6**	**$ (1,678,360)**	**$ (49,185)**
Warrants exercised, cashless	1,408,588	—	7,494	—	—	7,494
Issuance of common stock, net of issuance costs	35,287,364	—	66,449	—	—	66,449
Proceeds from sale of stock under employee stock purchase plan	187,422	—	230	—	—	230
Stock-based compensation expense	—	—	11,283	—	—	11,283
Restricted stock unit vesting	2,486,599	—	—	—	—	—
Exercise of options	1,205,853	—	1,684	—	—	1,684
Net loss	—	—	—	—	(5,345)	(5,345)
Balance at December 31, 2025	**265,424,818**	**$ 2**	**$ 1,716,307**	**$ 6**	**$ (1,683,705)**	**$ 32,610**

The accompanying notes are an integral part of these consolidated financial statements.

Akebia Therapeutics, Inc.
CONSOLIDATED STATEMENT OF CASH FLOWS

(dollars in thousands)	Years Ended December 31, 2025	2024	2023
Operating Activities:			
Net loss	$ (5,345)	$ (69,410)	$ (51,925)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	1,269	1,462	1,585
Amortization of intangible asset	—	36,042	36,042
Bad debt expense	1,479	876	—
Change in fair value of warrant liability	3,099	330	—
Non-cash royalty revenue related to sale of future royalties	(1,768)	(1,895)	(1,977)
Non-cash research and development expense	—	—	782
Non-cash interest expense	21,808	13,069	(2,228)
Non-cash operating lease expense	4,555	4,198	4,219
Non-cash loss on extinguishment of debt	—	294	—
Non-cash write-off on termination of lease	—	—	(825)
Charge for purchase of IPR&D asset	12,807	—	—
Write-down of inventory	2,505	4,208	1,580
Change in excess inventory purchase commitments	—	2,068	1,533
Stock-based compensation expense	11,283	7,775	9,317
Gain on the sale of property and equipment	(172)	—	—
Change in fair value of embedded debt derivative	—	—	(760)
Changes in operating assets and liabilities:			
Accounts receivable	(14,142)	4,046	994
Inventory	(23,125)	(28,401)	(2,542)
Prepaid expenses and other current assets	7,579	8,893	11,839
Other long-term assets	(2,622)	622	(1,361)
Accounts payable	3,082	(1,364)	(5,244)
Accrued expense and other current liabilities	48,530	(12,777)	(10,021)
Operating lease liabilities	(5,399)	(4,491)	(4,963)
Deferred revenue	2,681	—	(3,738)
Other long-term liabilities	(112)	(6,204)	(5,691)
Net cash provided by (used in) operating activities	**67,992**	**(40,659)**	**(23,384)**
Investing Activities:			
Purchase of equipment	(291)	(33)	—
Proceeds from the sale of property and equipment	172	—	—
Purchase of IPR&D asset, including transaction costs	(7,807)	—	—
Net cash used in investing activities	**(7,926)**	**(33)**	**—**
Financing Activities:			
Proceeds from the issuance of debt	10,000	45,000	—
Payments of issuance costs related to BlackRock Credit Agreement	(63)	(1,272)	—
Proceeds from the issuance of common stock, net of issuance costs	66,449	42,495	6,708
Proceeds from the sale of stock under employee stock purchase plan	230	154	85
Proceeds from the exercise of common stock options	1,684	385	1
Repayment of WCF liability	(1,146)	—	—
Repayment of liability related to settlement royalties	(3,765)	—	—
Repayment of term debt	(462)	(37,099)	(32,000)
Net cash provided by (used in) financing activities	**72,927**	**49,663**	**(25,206)**
Increase (decrease) in cash, cash equivalents and restricted cash	132,993	8,971	(48,590)
Cash, cash equivalents and restricted cash at beginning of the period	53,550	44,579	93,169
Cash, cash equivalents and restricted cash at end of the period	**$ 186,543**	**$ 53,550**	**$ 44,579**
Supplemental cash flow information			
Issuance of warrants in connection with BlackRock Credit Agreement	$ 2,199	$ 4,846	$ —
Cashless exercise of warrants in connection with BlackRock Credit Agreement	7,494	—	—
Purchase of IPR&D asset included in accrued expenses and other current liabilities	5,000	—	—
Cash paid for interest	6,080	5,035	6,059

The accompanying notes are an integral part of these consolidated financial statements.

Akebia Therapeutics, Inc.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. NATURE OF BUSINESS

Organization

Akebia Therapeutics, Inc., referred to as Akebia or the Company, was incorporated in the State of Delaware in 2007 and became a public company in 2014. Akebia is a fully integrated commercial-stage biopharmaceutical company focused on developing and commercializing innovative therapeutics.

The Company has two products approved by the Food and Drug Administration, or FDA, in the United States, or U.S. Vafseo® (vadadustat) is an oral hypoxia-inducible factor prolyl hydroxylase, or HIF-PH, inhibitor. Vafseo (vadadustat) Tablets were approved in the U.S. in March 2024 for the treatment of anemia due to chronic kidney disease, or CKD, in adults who have been receiving dialysis for at least three months. Vafseo entered the U.S. market in January 2025. Auryxia® (ferric citrate) is an orally administered medicine approved and marketed in the U.S. for two indications: (i) the control of serum phosphorus levels in adult patients with dialysis dependent chronic kidney disease, or DD-CKD, and (ii) the treatment of iron deficiency anemia, or IDA, in adult patients with non-dialysis dependent chronic kidney disease, or NDD-CKD. Auryxia lost exclusivity in the U.S. in March 2025.

Vafseo is also approved for the treatment of symptomatic anemia associated with CKD in the European Economic Area, or EEA, the United Kingdom, or the UK, Switzerland, Australia, South Korea and Taiwan in adult patients on chronic maintenance dialysis and in Japan for adult dialysis-dependent and non-dialysis patients. Vafseo is marketed and sold by the Company's collaboration partners in certain countries.

Ferric citrate is also approved in Japan, and is marketed and sold by the Company's collaboration partner, as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including DD-CKD and NDD-CKD, and for the treatment of adult patients with IDA under the trade name Riona (ferric citrate hydrate).

Since its inception, the Company has devoted most of its resources to research and development, or R&D, including its preclinical and clinical development activities, commercializing Auryxia and Vafseo and providing general and administrative support for these operations. The Company's mid-stage rare kidney disease pipeline assets, praliciguat and AKB-097, are being evaluated to target areas of unmet need. The Company's early-stage pipeline assets include AKB-9090 and AKB-10108, which are HIF molecules. In addition, the Company continues to explore additional development opportunities to expand its pipeline and portfolio of novel therapeutics through both internal research and external innovation to leverage its fully integrated team.

As of December 31, 2025, the Company had cash and cash equivalents of approximately $184.8 million. Based on its current operating plan, the Company believes that its cash resources and the cash the Company expects to generate from product, royalty, supply and license revenues will be sufficient to fund its current operating plan through at least twelve months from the filing of this Annual Report on Form 10-K, or Form 10-K. However, if the Company’s operating performance deteriorates significantly from the levels expected in the Company’s operating plan, including if the Company does not achieve its future anticipated Vafseo revenue projections, it would affect the Company’s liquidity and its ability to continue as a going concern in the future. The Company expects to finance future cash needs through product and license, collaboration and other revenue, including royalties and revenue from supply agreements. In addition, the Company may seek to sell public or private equity, enter into new debt transactions, explore potential strategic transactions, consider other cash-generating or saving measures or a combination of these approaches or other strategic alternatives. There can be no assurance that the current operating plan will be achieved in the time frame anticipated by the Company or that its cash resources will fund its operating plan for the period of time anticipated by the Company, or that additional funding will be available on terms acceptable to the Company, or at all.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the U.S., or GAAP. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Update, or ASU, of the Financial Accounting Standards Board, or FASB.

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany balances and transactions have been eliminated in the consolidated financial statements herein.

Certain monetary amounts, percentages and other figures included elsewhere in these consolidated financial statements have been subject to rounding adjustments. Accordingly, figures shown as totals in certain tables may not be the arithmetic aggregation of the figures that precede them, and figures expressed as percentages in the text may not total 100% or, as applicable, when aggregated, may not be the arithmetic aggregation of the percentages that precede them.

Use of Estimates

The preparation of financial statements in conformity with GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, revenue and expenses, classification of the expenses, assets and liabilities and the disclosure of contingent assets and liabilities as of and during the reported period. On an ongoing basis, management evaluates its estimates. Management bases its estimates and assumptions on historical experience when available and on various factors, including expected business and operational changes, sensitivity and volatility associated with the assumption that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of the assets and liabilities that are not readily apparent from other sources. In certain circumstances, management must apply significant judgment in this process. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management selects an amount that falls within that range of reasonable estimates. Although, the Company regularly assesses these estimates, actual results could differ materially from these estimates. Changes in estimates are recorded in the period they become known.

Significant estimates and judgments reflected in these consolidated financial statements include, but are not limited to: accrued expenses, other long-term liabilities, a liability related to settlement royalties, revenues, including various rebates, returns and provisions related to product sales, inventories, classification of expenses between cost of goods sold, R&D and selling, general and administrative, long-term assets, including the Company's right-of-use assets and goodwill.

Cash, Cash Equivalents and Restricted Cash

In determining its cash, cash equivalents and restricted cash, the Company considers only those highly liquid investments, readily convertible to cash within 90 days from the date of purchase to be cash equivalents. As of December 31, 2025, cash and cash equivalents primarily included cash on hand and money market funds.

Restricted cash represents amounts required to secure the outstanding letter of credit in connection with the Company’s office and laboratory space in Cambridge, Massachusetts, or the Cambridge Lease. Restricted cash is included in "prepaid expenses and other current assets" in the consolidated balance sheet as of December 31, 2025 and in “other long-term assets” in the consolidated balance sheet as of December 31, 2024.

The following table reconciles cash, cash equivalents and restricted cash reported within the Company's consolidated balance sheets to the total amounts reported in the consolidated statements of cash flows:

	December 31,		
Reconciliation of cash, cash equivalents and restricted cash (in thousands)	**2025**	**2024**	**2023**
Cash and cash equivalents	$ 184,844	$ 51,870	$ 42,925
Restricted cash	1,699	1,680	1,654
Total cash, cash equivalents and restricted cash	$ 186,543	$ 53,550	$ 44,579

Fair Value of Financial Instruments

Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, management considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability. ASC Topic 820, *Fair Value Measurement*, establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. To the extent the valuation is based on models or inputs that are less observable in the market, the determination of fair values requires more judgment. A financial instrument categorization within the fair value hierarchy is based upon the lowest level of input that is significant to the fair value measurement. The three levels of inputs that may be used to measure fair value are:

- **Level 1** – unadjusted quoted prices in active markets for identical assets or liabilities to the reporting entity at the measurement date.
- **Level 2** – quoted prices for similar assets or liabilities in markets that are not active, or for which all significant inputs are observable, either directly or indirectly, for substantially the full term of the asset or liability.

- **Level 3** – unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at the measurement date.

Accounts Receivable

The Company's accounts receivable represent amounts due to the Company from product sales and from its collaboration, license and other agreements. Royalties that have not been invoiced as of the balance sheet date are recorded as unbilled accounts receivable. Accounts receivable arising from product sales primarily represent amounts due from the Company's customers, net of allowances for customer discounts and chargebacks. The Company deducts trade allowances for prompt payment, among other certain discounts or chargebacks, from its accounts receivable based on its experience that the Company's customers will earn these discounts and fees.

Concentrations of Risk and Off-Balance Sheet Risk

Credit Risk

Cash, cash equivalents and accounts receivable are the only financial instruments that potentially subject the Company to concentrations of credit risk. The Company maintains cash accounts principally at two financial institutions in the U.S., which at times, may exceed the Federal Deposit Insurance Corporation's limits. The Company has not experienced any losses from cash balances in excess of the insurance limit. The Company's management does not believe the Company is exposed to significant credit risk at this time due to the financial condition of the financial institutions where its cash is held.

The Company makes judgments as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding receivables and the overall quality and age of those invoices not specifically reviewed as well as historical payment patterns and existing economic factors. The Company believes that credit risks associated with its customers and collaboration partners are not significant. The Company's allowance for credit losses was $2.7 million and $1.2 million as of December 31, 2025 and 2024, respectively.

The following table summarizes the activity related to the Company's allowance for credit losses (in thousands):

	Year Ended December 31,		
	2025	**2024**	**2023**
Beginning balance	$ 1,212	$ 1,029	$ 1,106
Provision for bad debts	1,479	877	(77)
Recoveries/(write-offs)	—	(695)	—
Ending balance	$ 2,691	$ 1,212	$ 1,029

Gross revenues and accounts receivable from each of the Company's customers or collaboration partners who individually accounted for 10% or more of total gross revenues and/or 10% or more of total gross accounts receivable consisted of the following:

	% of Total Gross Revenues		
	Years Ended December 31,		
Customer	**2025**	**2024**	**2023**
Fresenius Medical Care Rx	30%	48%	40%
U.S. Renal Care	29%	*	*
DaVita, Inc.	25%	*	*
Cencora, Inc.	*	19%	21%
McKesson Corporation	*	12%	11%
Cardinal Health, Inc.	*	*	10%

	% of Gross Accounts Receivable	
	December 31,	
Customer	2025	2024
U.S. Renal Care	42%	*
DaVita, Inc.	29%	16%
Fresenius Medical Care Rx	*	42%
Cencora, Inc.	*	13%

**Percentage less than 10% threshold.*

Off-Balance Sheet Accounts

The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangement. See Note 9, *Leases,* for further details.

Manufacturing and Distribution Risk

The Company is dependent on third-party manufacturers, logistics companies and distributors to supply products for commercial activities associated with its products and product candidates, as applicable. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients, or APIs, and formulated drugs related to the Company's product and product candidate activities. These activities, including the commercialization of Auryxia and Vafseo, could be adversely affected by a significant interruption in the supply of APIs and formulated drugs or distribution of finished product to the market.

Inventories, including Pre-Launch Inventories

The Company values its inventories at the lower-of-actual cost or net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials, manufacturing services and overhead, on a first-in, first-out basis. Inventory expected to be utilized beyond one year is recorded in inventories, long-term on the consolidated balance sheets.

Prior to obtaining regulatory approval for an investigational product candidate, the Company expenses costs relating to production of pre-launch inventory as R&D expense in its consolidated statements of operations and comprehensive loss in the period incurred. After regulatory approval has been received, the Company capitalizes such inventory costs. Products used in clinical trials are expensed as R&D expense in the statement of operations and comprehensive loss.

The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and writes down any excess or obsolete inventory to its net realizable value in the period in which the impairment is identified through cost of product and other revenue in the consolidated statements of operations and comprehensive loss.

Additionally, the Company’s product is subject to strict quality control and monitoring that is performed throughout the manufacturing process, including release of work-in-process to finished goods. In the event that certain batches or units of product do not meet quality specifications, the Company will record a write-down of any potential unmarketable inventory to its estimated net realizable value and record the expense as cost of product and other revenue in the consolidated statements of operations and comprehensive loss.

The Company prepays for certain manufacturing costs, including raw materials and drug substance, to its CMOs which are included in prepaid expenses and other current assets on the consolidated balance sheets.

Property and Equipment

Property and equipment are recorded at cost, less accumulated depreciation. Expenditures for repairs and maintenance are expensed as incurred. Depreciation expense is recognized using the straight-line method over the estimated useful lives, which are typically:

Asset Category	Estimated Useful Life
Computer equipment and software	3 years
Furniture and fixtures	5 years - 7 years
Laboratory and other equipment	7 years
Leasehold improvements	Shorter of the useful life or remaining lease term

Maintenance and repairs to an asset that do not improve or extend its life are charged to operations. When assets are retired or otherwise disposed of, the assets and related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is reflected in the Company's consolidated statements of operations and comprehensive loss.

Intangible Asset

The Company maintained a definite-lived intangible asset related to developed product rights for Auryxia. The intangible asset was initially recorded at fair value and was stated net of accumulated amortization. The Company amortized its intangible asset that had a finite life using the straight-line method over the estimated useful life of six years. The Company's intangible asset was fully amortized as of December 31, 2024.

Goodwill

Goodwill reflects the excess purchase price over the fair value of the net tangible and intangible assets acquired in a business combination.

Goodwill is evaluated for impairment on an annual basis, and more frequently if indicators are present or changes in circumstances suggest that impairment may exist. The Company compares the fair value of its reporting unit to its carrying value. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of its reporting unit, the Company would record an impairment loss equal to the difference. The Company operates in one operating segment which the Company considers to be the only reporting unit.

Impairment of Long-Lived Assets and Intangible Asset Subject to Amortization

Long-lived assets primarily include property and equipment, right of use assets and an intangible asset. The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such asset groups may not be recoverable. The recoverability of asset groups to be held and used is measured by a comparison of the carrying amount of an asset group to the future undiscounted net cash flows expected to be generated by the asset group. If such asset groups are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset group exceeds the fair value of the asset group.

The Company did not recognize any impairment losses on long-lived assets for the years ended December 31, 2025, 2024 and 2023.

Leases

The Company made an accounting policy election not to recognize leases with an initial term of twelve months or less within its consolidated balance sheets and to recognize those lease payments as an expense on a straight-line basis in its consolidated statements of operations and comprehensive loss. The Company also made the accounting policy election not to separate the non-lease components from the lease components for its building leases and, rather, account for each non-lease component and lease component as a single component.

The Company determines if an arrangement is a lease at inception. An arrangement is determined to contain a lease if the contract conveys the right to control the use of an identified property, plant or equipment for a period of time in exchange for consideration. If the Company can benefit from the various underlying assets of a lease on their own or together with other resources that are readily available, or if the various underlying assets are neither highly dependent on nor highly interrelated with other underlying assets in the arrangement, they are considered to be a separate lease component. In the event multiple underlying assets are identified, the lease consideration is allocated to the various components based on each of the component’s relative fair value.

Operating lease assets represent the Company’s right to use an underlying asset for the lease term and operating lease liabilities represent its obligation to make lease payments arising from the leasing arrangement. The right-of-use asset and operating lease liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. The Company uses the implicit rate when readily determinable and uses an estimate of its incremental borrowing rate when the implicit rate is not readily determinable based upon the available information at the commencement date of lease inception. The incremental borrowing rate is determined using a credit rating scoring model to estimate the Company’s credit rating, adjusted for collateralization. The calculation of the right-of-use asset includes any lease payments made and excludes any lease incentives. If a lease includes an option to extend or terminate the lease, the Company reflects the option in the lease term if it is reasonably certain the Company will exercise the option.

The Company’s operating leases are reflected in operating right-of-use assets, accrued expenses and other current liabilities and long-term operating lease liabilities in its consolidated balance sheets.

Liability Related to Sale of Future Royalties

The Company accounts for the liability related to sale of future royalties as a debt financing, amortized under the effective interest rate method over the estimated life of the related expected royalty stream. The liability related to sale of future royalties and the debt amortization are based on the Company's current estimates of future royalties expected to be paid over the life of the arrangement. The Company will periodically assess the expected royalty payments. To the extent the Company's estimates of future royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, the Company will adjust the effective interest rate and recognize related non-cash interest expense on a prospective basis. In the event the Company's estimates of future royalties are less than the proceeds from the sale of future royalties, the Company will not recognize related non-cash interest expense. Non-cash royalty revenue is reflected as royalty revenue within license, collaboration and other revenue, and non-cash amortization of debt is reflected as interest expense in the consolidated statements of operations and comprehensive loss. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for more information.

Working Capital Fund Liability (Previously Referred to as Refund Liability to Customer)

The Company accounts for the Working Capital Fund liability as a debt arrangement, which is recorded at net present value. When the funds were received, the Company recorded an initial discount on the Working Capital Fund liability and a corresponding deferred gain to the Working Capital Fund liability. The discount on the Working Capital Fund liability is being amortized to interest expense on the consolidated statement of operations and comprehensive loss and the deferred gain is being amortized to other income on the consolidated statement of operations and comprehensive loss over the expected term of the arrangement. On a quarterly basis, the Company reassesses the effective rate and will adjust the rate prospectively, if needed. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for more information.

Liability Related to Settlement Royalties

The Company accounts for the liability related to settlement royalties as a liability, amortized using the effective interest method over the term of the arrangement. The liability related to settlement royalties and the amortization are based on the Company's current estimates of future royalties expected to be paid over the life of the arrangement. To the extent the Company's estimates of future royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, the Company will adjust the effective interest rate and recognize related non-cash interest expense on a prospective basis. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for more information.

Warrant Liability

The Company accounts for the warrant liability under ASC 815, *Derivatives and Hedging*, as it could potentially require net cash settlement outside of the Company's control. The warrant liability is measured at fair value each reporting period and when a warrant is exercised, with changes in fair value presented within the consolidated statements of operations and comprehensive loss. See Note 7, *Indebtedness*, for more information.

Excess Firm Purchase Commitment Liability

At each reporting period, the Company assesses whether there are excess firm non-cancelable purchase commitment liabilities, resulting from supply agreements with third-party CMOs. The determination of excess firm purchase commitment liabilities requires judgment, including consideration of many factors, such as estimates of future product demand, current and future market conditions, impact of the Company's loss of exclusivity, expiration and utilization of drug substance under firm purchase commitments, and contractual minimums. Any changes in the firm purchase commitment liability are recorded in cost of product and other revenue in the consolidated statements of operations and comprehensive loss.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, which applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when, or as, the performance obligation is satisfied.

The Company does not include a financing component to its estimated transaction price at contract inception unless it estimates that certain performance obligations will not be satisfied within one year. Additionally, the Company recognizes the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that the Company otherwise would have recognized is one year or less.

Product Revenue, Net

The Company recognizes product revenues on sales of Auryxia and Vafseo primarily attributable to a limited number of customers, including dialysis organizations, wholesale distributors, certain specialty pharmacy providers and its authorized generic distribution partner, in the U.S., which accounts for the largest portion of the Company's total revenue. These customers resell the Company’s product to health care providers and patients. In addition to distribution agreements with customers, the Company enters into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks and discounts with respect to the purchase of the Company’s products. The Company’s payment terms are consistent with prevailing practice in the respective markets in which the Company does business. Most of the Company’s customers make payments based on contract terms, which are not affected by contingent events that could impact the transaction price. Payment terms fall within the one-year guidance for the practical expedient, which allows the Company to forgo adjustment of the contractual payment amount of consideration for the effects of a significant financing component.

The Company recognizes revenue on product sales when the customer obtains control of the Company’s products, which occurs at a point in time, typically upon receipt of the product by the Company's customer. The Company expenses incremental costs of obtaining a contract, such as sales commissions, as and when incurred, if the expected amortization period of the asset that it would have recognized is one year or less. Sales commissions are recorded in selling, general and administrative expense in the statements of operations and comprehensive loss.

Revenue from product sales is recorded at the net sales price, or Transaction Price, which includes estimates of variable consideration for which provisions are established and which result from discounts, returns, chargebacks, rebates, co-pay assistance and other allowances offered within contracts between the Company and its customers, health care providers, payors and other indirect customers relating to the Company’s sales of its products. When appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in ASC 606 for relevant factors such as the Company’s historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns.

The amount of variable consideration that is included in the Transaction Price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company’s estimates. The provisions are classified as reductions to accounts receivable, net of payable, if the trade discount and/or allowance will be credited to the customer or accrued expenses and other current liabilities or other long-term liabilities, if payable to a third-party in the consolidated balance sheets.

Commercial Rebates—The Company contracts with dialysis organizations, wholesale distributors and certain specialty pharmacy providers for the payment of rebates with respect to utilization of Auryxia and Vafseo. The Company estimates commercial rebates based upon customers' actual purchase level during the quarterly or annual rebate purchase period, and the corresponding contractual rebate tier each customer is expected to achieve. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of an accrued liability.

Trade Discounts and Allowances—The Company generally provides customers with prompt pay discounts and pays fees for sales order management, data and distribution services, which are explicitly stated in its contracts. Trade discounts and allowances are recorded as a reduction of revenue within the consolidated statements of operations and comprehensive loss in the period the related product revenue is recognized. The Company estimates that, based on its

experience, its customers will earn these discounts and fees, and the Company will deduct the full amount of these discounts and fees from its gross product revenues and accounts receivable at the time such revenues are recognized.

Product Returns—Consistent with industry practice, subject to certain caps for certain customers, the Company generally offers customers a limited right of return which allows for the product to be returned when the product expiry is within an allowable window, when the quantity delivered is different than quantity ordered, the product is damaged in transit prior to receipt by the customer or is subject to a recall. This right of return generally lapses once the product is provided to a patient or generally, if the bottle has been opened. The Company estimates the amount of its product sales that may be returned and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return provision using its own historical return information as well as recent trends on lots still subject to the return window. In addition, certain customers are subject to an annual cap on returns of 2% of gross sales in any given year.

Provider Chargebacks and Discounts—Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These provisions are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the customer's resale of the product. Provisions for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel at each reporting period end that the Company expects will be sold to qualified healthcare providers, and chargebacks that customers have claimed but for which the Company has not yet issued a credit.

Government Rebates—The Company is subject to discount obligations under state Medicaid programs and other government programs. The Company estimates its Medicaid and other government programs rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These provisions are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities in the consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel at the end of each reporting period.

Other Incentives—The Company offers a voluntary patient co-pay assistance program, which provides financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on actual claims processed during a given period plus an estimate of the amount the Company expects to pay based on historical utilization rates for the product that has been recognized as revenue but is estimated to be remaining in in the distribution channel at the end of each reporting period.

License, Collaboration and Other Revenues

The Company enters into license and collaboration agreements within the scope of ASC 606, under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include the following: (i) non-refundable, up front licenses fees associated with the licensing of intellectual property; (ii) development, regulatory and commercial milestone payments; (iii) drug product the Company supplies in connection with certain license and collaboration agreements and (iv) royalties earned on net sales of licensed products.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company implements the five-step model noted above. As part of the accounting for these arrangements, the Company develops assumptions that require judgment to determine whether the individual promises should be accounted for as separate performance obligations or as a combined performance obligation, and to determine the stand-alone selling price for each performance obligation identified in the contract. A deliverable represents a separate performance obligation if both of the following criteria are met: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer, and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates and probabilities of technical and regulatory success.

Licenses of Intellectual Property

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments

At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. The Company evaluates factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to assess the milestone as probable of being achieved. There is considerable judgment involved in determining whether a milestone is probable of being reached at each specific reporting period. Milestone payments that are not within the control of the Company or the customer, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenues as, or when, the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration, license and other revenue in the period of adjustment.

Drug Product Supply

Collaboration and license arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as a separate performance obligation. If the Company is entitled to additional payments when the licensee exercises these options, any payments are recorded in license, collaboration and other revenues when the licensee obtains control of the goods, which is generally upon delivery.

Royalties

The Company will recognize sales-based royalties, including milestone payments based on the level of net sales, at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Collaborative Arrangements

The Company records the elements of its collaboration agreements that represent joint operating activities in accordance with ASC Topic 808, *Collaborative Arrangements,* or ASC 808. Accordingly, the elements of the collaboration agreements that represent activities in which both parties are active participants and to which both parties are exposed to the significant risks and rewards that are dependent on the commercial success of the activities are recorded as collaborative arrangements. The Company considers the guidance in ASC 606-10-15, *Revenue from Contracts with Customers – Scope and Scope Exceptions*, in determining the appropriate treatment for the transactions between the Company and its collaborative partners and the transactions between the Company and third parties. Generally, the classification of transactions under the collaborative arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. To the extent product revenue is generated from the collaboration, the Company recognizes its share of the net sales on a gross basis if the Company is deemed to be the principal in the transactions with customers, or on a net basis if the Company is instead deemed to be the agent in the transactions with customers, consistent with the guidance in ASC 606.

Cost of Product and Other Revenue

Cost of product and other revenue includes costs closely correlated or directly related to the costs to manufacture commercial products, including costs paid to the Company's contract manufacturing organizations, or CMOs, as well as indirect costs. Direct and indirect costs include fees for packaging, shipping, insurance and quality assurance, idle capacity charges, routine testing costs, routine ongoing efforts to improve existing commercial products, reserves for excess inventory, write-offs for inventory that fails to meet specifications or is otherwise no longer suitable for commercial sale, including scrap,

changes in firm purchase commitment liability and royalties due to the licensor of Auryxia related to U.S. and Japan product sales recognized during the period. In addition, cost of product and other revenue includes the amortization of development product rights for the Auryxia intangible asset. The Company also includes personnel-related costs, including salaries and bonuses, employee benefits and stock-based compensation attributable to employees in particular functions and associated directly with the manufacturing of our commercial products.

Further, the Company includes in cost of product and other revenue costs to manufacture drug product provided to customers for which it has a license agreement or authorized generic distribution and supply agreement. Cost of goods sold for a newly launched product may not include the full cost of manufacturing until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold.

Until the Company received regulatory approval for Vafseo in the U.S. in March 2024, the Company recorded expenses incurred for the manufacture of pre-launch inventory that would support a U.S. launch as R&D expense. The costs associated with the pre-launch inventory for the Medice Territory were expensed to R&D through April 2023 when marketing authorization was received.

Research and Development Expenses

R&D costs are expensed as incurred. Internal R&D expenses are comprised of costs incurred in providing R&D activities, including salaries and bonuses, employee benefits, stock-based compensation for personnel engaged in R&D activities. In addition, they include facility costs, including the laboratory and an allocation of office space for utilization by R&D staff, depreciation expense on the laboratory equipment as well as other direct costs such as lab supplies and equipment.

External R&D costs include development of potential new manufacturing processes and methods for both commercial and non-commercial products, conceptual formulation and design of possible product and process alternatives, research compounds and clinical manufacturing costs, costs incurred for consultants and other outside services, such as data management and statistical analysis support and materials and supplies used in support of the clinical and preclinical programs and costs paid to clinical resource organizations, or CRO, including investigative sites that conduct the Company's clinical trials.

Non-refundable advance payments for goods and services are recorded in prepaid and other current assets in the consolidated balance sheets and expensed when the activity is performed or when the goods are received. In addition, the costs associated with pre-launch inventory, including the cost of raw materials, costs paid to contract manufacturers for inventory manufacturing, freight and custom charges for Vafseo were expensed as R&D prior to regulatory approval.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation related to commercial, marketing, executive, finance and accounting, information technology, corporate and business development and human resource functions. Other SG&A expenses include costs for marketing initiatives for the Company's commercial products, market research and analysis on the Company's commercial products and potential product candidates, conferences and trade shows, travel expenses, professional services fees (including legal, patent, accounting, audit, tax, and consulting fees), insurance costs, general corporate expenses and allocated facilities-related expenses, including rent and maintenance of facilities. Costs associated with advertising are expensed in the period incurred and are included in selling, general and administrative expenses. For the years ended December 31, 2025, 2024 and 2023, advertising expenses totaled $7.6 million, $4.6 million and $1.0 million, respectively.

Patent Costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Such amounts incurred are classified as SG&A expenses in the accompanying consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

The Company’s stock-based compensation program allows for grants of common stock options, restricted stock awards, performance-based restricted stock units, or PSUs, stock appreciation rights, or SARs and restricted stock units. Grants are awarded to employees and non-employees, including directors.

The Company accounts for its stock-based compensation awards in accordance with ASC Topic 718, *Compensation—Stock Compensation*, or ASC 718. ASC 718 requires all stock-based payments to employees and non-employees, including modifications to existing stock awards, to be recognized in the statements of operations and comprehensive loss based on their fair values. The Company estimates the fair value of options granted using the Black-Scholes option pricing model, or Black-Scholes. The Company uses the market price at the time of grant to determine the fair value of restricted stock awards and performance-based restricted stock awards.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Prior to 2017, due to the lack of company-specific historical and implied volatility data for trading the Company's stock in the public market, the Company had based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility was calculated based on a period of time commensurate with the expected term assumption. The Company uses the simplified method as prescribed by the Securities and Exchange Commission, or SEC, Staff Accounting Bulletin No. 107, *Share-Based Payment*, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock. The Company recognizes forfeitures as they occur.

The Company's stock-based awards are subject to either service or performance-based vesting conditions. Compensation expense related to awards to employees and non-employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term, and is adjusted for pre-vesting forfeitures in the period in which the forfeitures occur. Compensation expense related to awards to employees and non-employees with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable.

For awards with performance conditions in which the award does not vest unless the performance condition is met, the Company recognizes expense if, and to the extent that, the Company estimates that achievement of the performance condition is probable. If the Company concludes that vesting is probable, it recognizes expense from the date it reaches this conclusion through the estimated vesting date.

For market-based awards, the Company recognizes expense on a straight-line basis over the requisite service period, regardless of whether the market condition has been satisfied. Market-based performance stock unit awards vest upon the achievement of the performance target. Forfeitures are accounted for as incurred. The Company estimates the fair value of these awards as of the grant date using a Monte Carlo simulation that incorporates option-pricing inputs. This simulation covers the period from the grant date through the end of the derived requisite service period. Volatility as of the grant date is estimated based on historical daily volatility of the Company's common stock over a period of time, which is equivalent to the expected term of the award. The risk-free interest rate is based on the U.S. Treasury Note rate, as of the week the award is issued, with a duration that most closely resembles the expected term of the award.

Income Taxes

Income taxes are recorded in accordance with FASB Topic 740, *Income Taxes*, or ASC 740, which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. All deferred taxes as of December 31, 2025, 2024 and 2023 are classified as non-current within the income tax provision. See Note 15, *Income Taxes*, for further information.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of December 31, 2025, 2024 and 2023, the Company does not have any significant uncertain tax positions. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

Business Combinations and Asset Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying a screen test to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create

outputs which would meet the requirements of a business. If determined to be an asset acquisition, the Company accounts for the transaction under ASC 805-50, which requires the acquiring entity in an asset acquisition to recognize assets acquired and liabilities assumed based on the cost to the acquiring entity on a relative fair value basis, which includes transaction costs in addition to consideration given. Goodwill is not recognized in an asset acquisition and any excess consideration transferred over the fair value of the net assets acquired is allocated to the identifiable assets based on relative fair values. In-process research and development, or IPR&D, projects with no alternative future use are recorded in R&D expense upon acquisition, and contingent consideration obligations incurred in connection with an asset acquisition are recorded when it is probable that they will occur and they can be reasonably estimated.

Net Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, common stock options, stock appreciation rights, warrants and RSUs as well as restricted stock, if the Company was to issue any, are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented. Diluted net income per share is calculated by dividing the net income by the weighted-average common shares outstanding for the period, including any dilutive effect from outstanding options, warrants, restricted stock and RSUs using the treasury stock method.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or CODM, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company operates its business in a single segment and as one reporting unit, which is how its chief operating decision maker (who is the Company's president and chief executive officer) reviews financial performance and allocates resources. The Company views its operations as and manages its business in one operating segment.

New Accounting Pronouncements - Recently Adopted

In December 2023, the FASB issued ASU 2023-09, *Income Taxes* (Topic 740): *Improvements to Income Tax Disclosures*. ASU 2023-09 requires public companies to annually (i) disclose specific categories in the rate reconciliation and (ii) provide additional information for reconciling items that meet a quantitative threshold (if the effect of those reconciling items is equal to or greater than 5 percent of the amount computed by multiplying pretax income or loss by the applicable statutory income tax rate). ASU 2023-09 is effective for the annual reporting periods in fiscal years beginning after December 15, 2024. See Note 15, *Income Taxes*, for further information.

New Accounting Pronouncements - Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires new tabular disclosures in the notes to consolidated financial statements, disaggregating certain cost and expense categories within relevant captions on the consolidated statements of operations and comprehensive loss. The prescribed cost and expense categories requiring disaggregated disclosures include purchases of inventory, employee compensation, depreciation and intangible asset amortization, along with certain other expense disclosures already required by U.S. GAAP that would need to be integrated within the new tabular disaggregated expense disclosures. Additionally, the amendments also require the disclosure of total selling expenses and an entity's definition of those expenses. ASU 2024-03 will be effective for annual reporting periods in fiscal years beginning after December 15, 2026, and interim reporting periods in fiscal years beginning after December 31, 2027. Early adoption is permitted and the amendments should be applied on a prospective basis. Retrospective application is permitted. The Company is currently reviewing the impact that the adoption of ASU 2024-03 may have on its expense disclosures in the notes to the consolidated financial statements.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*. ASU 2025-05 provides a practical expedient that all entities can use when estimating expected credit losses for current accounts receivable and current contract assets arising from transactions accounted for under ASC 606, *Revenue from Contracts with Customers*. Under this practical expedient, an entity is allowed to assume that the current conditions it has applied in determining credit loss allowances for current accounts receivable and current contract assets remain unchanged for the remaining life of those assets. ASU 2025-05 is effective for fiscal years beginning after December 15, 2025, and interim reporting periods in those years. Entities that elect the practical expedient and, if applicable, make the accounting policy election are required to apply the amendments prospectively. The Company is

currently evaluating ASU 2025-05 and does not expect it to have a material effect on the Company's consolidated financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software*, which removes all references to prescriptive and sequential software development stages (referred to as "project stages"). An entity will be required to start capitalizing software costs when (i) management has authorized and committed to funding the software project and (ii) it is probable that the project will be completed and the software will be used to perform the function intended (referred to as the "probable-to-complete recognition threshold"). ASU 2025-06 is effective for fiscal years beginning after December 15, 2027, and interim reporting periods within those annual periods. Early adoption is permitted as of the beginning of the annual reporting period. The Company is currently evaluating ASU 2025-06 and does not expect it to have a material effect on the Company's consolidated financial statements.

3. FAIR VALUE MEASUREMENTS

The tables below present certain assets and liabilities measured at fair value categorized by the level of input used in the valuation of each asset and liability (in thousands):

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 172,689	$ —	$ —	$ 172,689
Long-term liability:				
Warrant liability	$ —	$ 2,980	—	$ 2,980

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Long-term liability:				
Warrant liability	$ —	$ 5,176	—	$ 5,176

Cash and cash equivalents —Money market funds included within cash and cash equivalents are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets. As of December 31, 2024, the Company did not have any money market funds included in cash equivalents.

Warrant liability – The warrant liability is classified within Level 2 of the fair value hierarchy because it is valued using inputs which are observable either directly or indirectly. The fair value was calculated using the Black-Scholes option pricing model using the following key inputs: volatility, risk-free rate, dividend yield and expected term.

4. INVENTORIES

Inventories consists of the following (in thousands):

	December 31,	
Inventories, current:	2025	2024
Work-in-process	$ 12,651	$ 12,031
Finished goods	2,959	4,212
Inventories, current	$ 15,610	$ 16,243
Long-term inventories included in other long-term assets:		
Raw materials	50	381
Work-in-process	57,290	34,572
Finished goods	1,789	—
Inventories, long-term	59,129	34,953
Total inventories	$ 74,739	$ 51,196

Inventory written down as a result of excess, obsolescence, scrap or other reasons charged to cost of product and other revenue in the consolidated statements of operations and comprehensive loss was $2.5 million, $4.2 million and $1.6 million during the years ended December 31, 2025, 2024 and 2023, respectively. For the years ended December 31, 2024 and 2023, the Company realized $12.3 million and $4.3 million, respectively, of lower cost of product and other revenue due to the Company's ability to sell inventory previously written down to zero, its then net realizable value.

5. INTANGIBLE ASSET AND GOODWILL

Intangible Asset

The Company maintained a definite-lived intangible asset related to developed product rights for Auryxia. The intangible asset was initially recorded at fair value and was stated net of accumulated amortization. The Company amortized the intangible asset using the straight-line method over the estimated useful life of six years. The intangible asset was fully amortized as of December 31, 2024. The Company recorded $36.0 million in amortization expense during each of the years ended December 31, 2024 and 2023 related to the developed product rights for Auryxia.

Goodwill

As of December 31, 2025 and 2024, the Company had goodwill of $59.0 million recorded in connection with the December 2018 merger with Keryx Biopharmaceuticals, Inc., or Keryx. The Company has not identified any goodwill impairment to date.

6. ADDITIONAL BALANCE SHEET DETAIL

Prepaid expenses and other current assets are as follows (in thousands):

	December 31,	
Description	**2025**	**2024**
Prepaid manufacturing	—	4,029
Restricted cash	1,699	—
Other	3,771	7,321
Total prepaid expenses and other current assets	5,470	11,350

Prepaid manufacturing expenses include advance payments to contract manufacturing organizations, or CMOs, for APIs or drug substance. Such amounts are reclassified to work-in-process inventory upon the quality release of the batches and transfer of title to the Company from the CMO.

Other prepaid expenses and other current assets, among other things, include capitalized implementation costs, prepaid insurance and prepaid information technology costs.

Other long-term assets are as follows (in thousands):

	December 31,	
Description	**2025**	**2024**
Long-term inventories	$ 59,129	$ 34,953
Restricted cash	—	1,680
Other	552	744
Total other long-term assets	$ 59,681	$ 37,377

See Note 4, *Inventories*, for further information on long-term inventories.

Accrued expenses and other current liabilities are as follows (in thousands):

Description	December 31, 2025	2024
Product revenue allowances	$ 7,916	$ 9,657
Product rebates	64,674	6,070
Product return provisions, current portion	2,375	5,295
Compensation and related benefits	11,018	9,194
Operating lease liabilities, current portion	3,548	5,400
Royalties due to Panion & BF Biotech, Inc.	3,924	3,543
Liability related to sale of future royalties, current portion	1,664	2,039
Professional fees	1,597	1,452
Accrued manufacturing costs	1,808	1,468
BioVectra, Inc. termination fees, current portion	—	7,204
Settlement royalties liability, current portion	12,516	5,924
Clinical trial costs	1,188	1,885
Restructuring costs, current portion	—	489
Payments due to Q32	5,000	—
Other	4,488	3,840
Total accrued expenses and other current liabilities	$ 121,716	$ 63,460

7. INDEBTEDNESS

Entry into BlackRock Loan Facility

On January 29, 2024, or the Closing Date, the Company entered into the Agreement for the Provision of a Loan Facility, or the BlackRock Credit Agreement, with Kreos Capital VII (UK) Limited, or Kreos, which are funds and accounts managed by BlackRock Inc., collectively, BlackRock, and provides for a senior secured term loan facility in the aggregate principal amount of up to $55.0 million, or the Term Loan Facility. The Term Loan Facility was available in three tranches: (i) Tranche A — $37.0 million was funded on the Closing Date and used to repay the Pharmakon Term Loans (as defined below); (ii) Tranche B — $8.0 million was funded on April 19, 2024, or the Tranche B Closing Date; and (iii) Tranche C — $10.0 million was funded on February 3, 2025, or the Tranche C Closing Date, collectively the Term Loans.

On February 3, 2025, the Company and Kreos entered into a Second Amendment to the BlackRock Credit Agreement, or the Second Amendment, which, among other things, extended the expiry date of Tranche C from December 31, 2024 to the Tranche C Closing Date, or the Extended Tranche C. Tranche C was available subject to receipt of a certain amount of cumulative gross cash proceeds after the Closing Date in the form of equity or equity linked securities in one or more series of transactions. The terms of the Extended Tranche C are substantially similar to the terms of the original Tranche C, however, interest accrued on the Extended Tranche C as if it was advanced on December 31, 2024.

On the Closing Date, the Company received $34.5 million on Tranche A, after deducting debt issuance costs, fees and expenses. On the Tranche B Closing Date, the Company received $7.5 million, after deducting debt issuance costs, fees and expenses. On the Tranche C Closing Date, the Company received $9.3 million, after deducting debt issuance costs, interest, fees and expenses.

The BlackRock Term Loan Facility had an initial maturity date of March 31, 2025, which was automatically extended to January 29, 2028, after the Company received FDA approval for Vafseo, or the BlackRock Maturity Date. The Company is required to make interest-only payments until December 31, 2026, or the BlackRock Interest Only Period, after which the Company will begin paying equal monthly principal on the first calendar day of each month. In the event of certain prespecified events, the repayment schedule will be accelerated.

The Term Loan Facility will accrue interest at a floating annual rate equal to the sum of (i) the term Secured Overnight Financing Rate, or SOFR, for a tenor of one month (subject to a floor of 4.25% per annum) plus (ii) a margin of 6.75% per annum (subject to an overall cap of 15.00% per annum on the all-in interest rate). As of December 31, 2025, the Company's interest rate was 11.00%. During the years ended December 31, 2025 and 2024, the Company recognized interest expense of $8.4 million and $7.1 million, respectively.

During the continuance of any payment event of default under the BlackRock Credit Agreement, the interest rate on such overdue sum will automatically increase by an additional 3.0% per annum, and may be subject to an additional late fee of

2.0% of such overdue sum. The Term Loan Facility also includes transaction fees ranging from 1.00% to 1.25% of the draw down amount as well as exit fees of 0.75% of the amount funded to the relevant tranche.

If the Company prepays the outstanding loan prior to maturity, it will be required to pay a prepayment fee ranging from 1.0% to 4.0% of the amount prepaid.

As of December 31, 2025, future principal payments under the BlackRock Credit Agreement are as follows (in thousands):

Years ended December 31,	Amounts
2026	—
2027	50,558
2028	1,881
Total before unamortized discount and issuance costs	52,439
Less: unamortized discount and issuance costs	(4,189)
Total term loans	$ 48,250

The BlackRock Term Loan Facility is secured by substantially all of the existing and after-acquired assets of the Company, including intellectual property. The BlackRock Credit Agreement requires the Company to (i) maintain a minimum aggregate cash balance of $15.0 million in one or more controlled accounts or (ii) trailing twelve-month revenue of $150.0 million, both of which are measured monthly. The BlackRock Credit Agreement contains certain representations and warranties, affirmative and negative covenants that limit the Company's ability to engage in specified types of transactions and other provisions typical within a credit agreement. If an event of default occurs and is continuing under the BlackRock Credit Agreement, BlackRock is entitled to take enforcement action, including acceleration of amounts due and it could limit the Company's ability to make certain payments under the Vifor Termination Agreement (as defined below).

On July 10, 2024, in connection with the Termination and Settlement Agreement entered into between the Company and CSL Vifor (as defined below), or the Vifor Termination Agreement, the Company and Kreos entered into a First Amendment to the BlackRock Credit Agreement, which amended certain provisions of the BlackRock Credit Agreement. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for further information on the Vifor Termination Agreement.

Warrant

On the Closing Date, Kreos Capital VII Aggregator SCSp, an affiliate of Kreos, or the Warrant Holder, received a warrant to purchase 3,076,923 shares of the Company’s common stock, at an exercise price per share of $1.30, or the Initial Warrant. On the Tranche C Closing Date, the Company issued the Warrant Holder an additional warrant to purchase 1,153,846 shares of the Company’s common stock at an exercise price per share of $1.30, or the Tranche C Warrant. Each warrant is exercisable for eight years from the date of issuance.

On July 21, 2025, the Warrant Holder exercised its option to purchase 2,115,384 shares of the Company's common stock under the Initial Warrant on a cashless basis at an exercise price per share of $1.30. A cashless exercise allows the Warrant Holder to convert the warrants into shares of the Company's common stock without the need for a cash payment. Instead of paying cash upon exercise, the Warrant Holder received a reduced number of shares based on a predetermined formula. On July 23, 2025, as a result of the cashless exercise, the Company issued 1,408,588 shares of common stock to the Warrant Holder under the Initial Warrant.

The Initial Warrant and the Tranche C Warrant are liabilities classified under ASC 815, *Derivatives and Hedging*, as they could potentially require net cash settlement outside of the Company’s control. The Initial Warrant and the Tranche C Warrant are measured at fair value each reporting period and when a warrant is exercised, with the changes in fair value presented within the consolidated statements of operations and comprehensive loss. The fair value of the warrant liability was $3.0 million and $5.2 million as of December 31, 2025 and 2024, respectively. See Note 3, *Fair Value of Financial Instruments*, for information on the fair value determination.

Other Agreements Accounted for as Debt

The Company has a liability related to settlement royalties and a Working Capital Fund liability with Vifor (International) Ltd. (now a part of CSL Limited), or CSL Vifor, and a liability related to the sale of future royalties, which are accounted for as debt arrangements. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for further information.

Pharmakon Term Loan (Extinguished January 29, 2024)

On November 11, 2019, the Company, with Keryx as guarantor, entered into a loan agreement, or Pharmakon Loan Agreement, which consisted of a secured term loan facility in an aggregate amount of up to $100.0 million, or Pharmakon Term Loans.

On the Closing Date, using the proceeds from the BlackRock Credit Agreement, the Company paid the then outstanding principal balance on the Pharmakon Term Loans of $35.0 million, plus the outstanding interest and a prepayment fee of $0.2 million. During the year ended December 31, 2024, the Company recorded a debt extinguishment loss of $0.5 million.

The Company recognized immaterial interest expense and $6.0 million of interest expense related to the Pharmakon Loan Agreement during the years ended December 31, 2024 and 2023, respectively.

8. LIABILITY RELATED TO SETTLEMENT ROYALTIES, WORKING CAPITAL FUND LIABILITY AND LIABILITY RELATED TO SALE OF FUTURE ROYALTIES

Vifor License Agreement

Summary of Agreement

On February 18, 2022, the Company entered into a Second Amended and Restated License Agreement, or the Vifor License Agreement, with CSL Vifor, which amended and restated the License Agreement dated as of May 12, 2017, or the Original License Agreement. The Vifor License Agreement granted CSL Vifor an exclusive license to sell Vafseo to Fresenius Medical Care North America and its affiliates, including Fresenius Kidney Care Group LLC, to certain third-party dialysis organizations approved by the Company, to independent dialysis organizations that were members of certain group purchasing organizations and certain non-retail specialty pharmacies, collectively, the Supply Group, in the U.S.

The Vifor License Agreement was structured as a profit share arrangement between the Company and CSL Vifor in which the Company would receive approximately 66% of the profit, net of certain pre-specified costs. In addition, CSL Vifor made an upfront payment to the Company of $25.0 million in February 2022 in connection with the amendment and restatement of the Vifor License Agreement, which was previously recorded as long-term deferred revenue in the consolidated balance sheets.

Investment Agreements

In connection with the Original License Agreement, in May 2017, the Company sold an aggregate of 3,571,429 shares of the Company's common stock, or 2017 Shares, to CSL Vifor at a price per share of $14.00 for a total of $50.0 million.

In February 2022, in connection with the Vifor License Agreement, the Company sold an aggregate of 4,000,000 shares of its common stock, or 2022 Shares, to CSL Vifor at a price per share of $5.00 for a total of $20.0 million.

The $18.3 million, which represented the premiums over the closing stock price, or $4.7 million for the 2017 Shares and $13.6 million for the 2022 Shares, was previously recorded as long-term deferred revenue in the consolidated balance sheets as it represented consideration related to the Vifor License Agreement.

The 2017 Shares and 2022 Shares are subject to standstill agreements and are subject to voting agreements. The 2017 Shares and 2022 Shares have not been registered pursuant to the Securities Act of 1933, as amended, or the Securities Act, and were issued and sold in reliance upon the exemption from registration contained in Section 4(a)(2) of the Securities Act and Rule 506 promulgated thereunder as the transaction did not involve any public offering within the meaning of Section 4(a)(2) of the Securities Act.

Vifor Termination Agreement

On July 10, 2024, the Company and CSL Vifor entered into the Vifor Termination Agreement, pursuant to which the Company and CSL Vifor agreed, among other things, to terminate, effective immediately, the Vifor License Agreement.

Pursuant to the terms of the Vifor Termination Agreement, the Company will pay CSL Vifor decreasing quarterly tiered royalty payments ranging from a high single-digit percentage of the Company's net sales of Vafseo up to $450.0 million to mid-single digit percentage of the Company's net sales of Vafseo above $450.0 million, in each case, in the U.S. during a calendar year, or the Settlement Royalty Payments. The Settlement Royalty Payments commenced upon the first sale of Vafseo by the Company to a third party for use in the U.S., and will continue until the later of the (i) expiration of the last-to-expire valid claim listed in the FDA Orange Book that would be infringed by the making, using, selling or importing of Vafseo in the U.S. or (ii) the expiration of marketing or regulatory exclusivity for Vafseo in the U.S., or the Settlement Royalty Term. Beginning on July 1, 2027 and throughout the Settlement Royalty Term, the Company has the option to make a one-time payment to CSL Vifor, or the Royalty Buy-Down Option, upon which the Settlement Royalty Payments will be adjusted as of the date of exercise of the Royalty Buy-Down Option such that the Company will then only pay CSL Vifor quarterly royalty payments based on a mid-single digit percentage of the Company's net sales of Vafseo up to $450.0 million in the U.S. during a calendar

year in lieu of the above Settlement Royalty Payments. If the Company exercises the Royalty Buy-Down Option, the WCF Royalty Payments, as described below, will continue as described above.

The WCF Royalty Payments, as described below, the Settlement Royalty Payments and the Royalty Buy-Down Option are in consideration for the termination of the Vifor License Agreement and all obligations thereunder, and the covenants and agreements set forth in the Vifor Termination Agreement, including the settlement and release of all disputes and claims arising from the Vifor License Agreement.

As a result of the Vifor Termination Agreement, the Company reassessed whether the Vifor License Agreement still met the criteria to be considered a contract within the scope of ASC 606, *Revenue from Contracts with Customers,* and concluded that CSL Vifor no longer met the definition of a customer and, therefore, the arrangement should not be considered a revenue contract with a customer under ASC 606. The Company therefore determined that the consideration received from CSL Vifor of $43.3 million, comprised of the up-front payment of $25.0 million and the premiums paid by CSL Vifor for the 2017 Shares and 2022 Shares of $4.7 million and $13.6 million, respectively, should be classified as debt. Accordingly, the Company recorded the $43.3 million as a liability and is amortizing such amount using the effective interest method over the Settlement Royalty Term. The liability related to settlement royalties and the amortization are based on the Company's current estimates of future royalties expected to be paid over the life of the arrangement. To the extent the Company's estimates of future royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, the Company will adjust the effective interest rate and recognize the related non-cash interest expense on a prospective basis. On a quarterly basis, the Company reassesses the expected royalty payments.

The annual effective interest rate as of December 31, 2025 was 22.3% which is reflected as interest expense in the consolidated statements of operations and comprehensive loss. The Company recognized interest expense of $18.4 million and $9.3 million for the years ended December 31, 2025 and 2024, respectively, related to the settlement royalties liability. As of December 31, 2025 and 2024, the balances related to the settlement royalties liability were as follows (in thousands):

	December 31,	
Description	**2025**	**2024**
Current portion (included in accrued expenses and other current liabilities)	$ 12,516	$ 5,924
Long-term portion	54,750	46,697
Total settlement royalties liability	$ 67,266	$ 52,621

Working Capital Fund Liability (Previously Referred to as Refund Liability to Customer)

Pursuant to the Vifor License Agreement, CSL Vifor contributed $40.0 million to a working capital fund, or Working Capital Fund, established to partially fund the Company's costs of purchasing Vafseo from its contract manufacturers.

The Working Capital Fund is considered a debt arrangement with zero coupon interest and the Company imputes interest on the Working Capital Fund liability at a rate of 15.0% per annum, which was determined based on certain factors, including the Company's credit rating, comparable securities yield and the expected repayment period. On March 18, 2022, when the $40.0 million was received from CSL Vifor, the Company recorded an initial discount on the Working Capital Fund liability and a corresponding deferred gain to the Working Capital Fund liability in the consolidated balance sheet.

On May 3, 2024, the Company and CSL Vifor entered into Amendment #1 to the Vifor License Agreement, or the Amendment. Pursuant to the Amendment, and as modified by the Vifor Termination Agreement, the Company and CSL Vifor agreed to modify the method of repayment of the Working Capital Fund such that the Working Capital Fund will be repaid through quarterly tiered royalty payments ranging from 8% to 14% of the Company's net sales of Vafseo in the U.S., or the WCF Royalty Payments. The WCF Royalty Payments commenced on July 1, 2025, and will continue until the earlier of (i) the cumulative total of the WCF Royalty Payments equals $40.0 million, or (ii) May 31, 2028, or the WCF Royalty Term. The WCF Royalty Payments are subject to minimum true-up milestones of $10.0 million, $20.0 million and $40.0 million, or the WCF Royalty True-Up Payments, on each of May 31, 2026, May 31, 2027 and May 31, 2028, respectively, or the WCF Royalty True-Up Dates. If the cumulative total of the WCF Royalty Payments paid to CSL Vifor on any given WCF Royalty True-Up Date is less than the respective WCF Royalty True-Up Payment, the Company will pay CSL Vifor a one-time payment equal to the difference between the WCF Royalty True-Up Payment and the cumulative total of the WCF Royalty Payments paid by the Company through such WCF Royalty True-Up Date. The Company determined that the terms of the Amendment are not substantially different than the terms of the Vifor License Agreement, and therefore the Amendment was accounted for as a modification. The Company concluded that the 15% discount rate remains appropriate. On a quarterly basis, the Company reassesses the effective rate and will adjust the rate prospectively, if needed.

The discount on the Working Capital Fund liability is being amortized to interest expense using the effective interest method over the WCF Royalty Term. The deferred gain is being amortized to interest income on a straight-line basis over the WCF

Royalty Term. The amortization of the discount was $4.7 million, $3.8 million and $3.1 million for the years ended December 31, 2025, 2024 and 2023, respectively. The amortization of the deferred gain was $3.9 million, $3.6 million and $4.0 million for the years ended December 31, 2025, 2024 and 2023, respectively.

As of December 31, 2025 and 2024, the balances related to the Working Capital Fund liability were as follows (in thousands):

	December 31,	
Description	**2025**	**2024**
Current portion	$ 17,356	$ 2,274
Long-term portion	22,606	38,013
Total Working Capital Fund liability	$ 39,962	$ 40,287

Liability Related to Sale of Future Royalties

In February 2021, the Company entered into a royalty interest acquisition agreement, or the Royalty Agreement, with HealthCare Royalty Partners IV, L.P., or HCR, pursuant to which the Company sold to HCR its right to receive royalties and sales milestones for Vafseo in Japan and certain other Asian countries, such countries collectively, the TPC Territory, and such payments collectively the Royalty Interest Payments, in each case, payable to the Company under the Company's Collaboration Agreement, or the TPC Agreement, with Tanabe Pharma Corporation, or TPC. The Royalty Interest Payments are subject to an annual maximum “cap” of $13.0 million, after which the Company will receive 85% of the Royalty Interest Payments for the remainder of that year. The Royalty Interest Payments are also subject to an aggregate maximum “cap” of $150.0 million, after which the Royalty Interest Payments will revert back to the Company.

The Company retains the right to receive all potential future regulatory milestones for Vafseo under the TPC Agreement. The Royalty Agreement will terminate on the earlier of the date on which HCR has received (i) the last Royalty Interest Payment or (ii) payment by the Company of an amount equal to the Aggregate Cap minus the aggregate amount of all Royalty Interest Payments actually received by HCR.

At the transaction date, the Company recognized the proceeds received from HCR of $44.8 million (net of certain transaction expenses) as a liability and is amortizing it using the effective interest method over the life of the arrangement. The liability related to sale of future royalties and the debt amortization are based on the Company’s current estimates of future royalties expected to be paid over the life of the arrangement. To the extent the Company’s estimates of future royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, the Company will adjust the effective interest rate and recognize related non-cash interest expense on a prospective basis. In the event the Company's estimates of future royalties are less than the proceeds from the sale of future royalties, the Company will not recognize related non-cash interest expense. On a quarterly basis, the Company assesses the expected royalty payments. The annual effective interest rate as of December 31, 2025 was 0% and, therefore the Company did not recognize any non-cash interest expense in the consolidated statements of operations and comprehensive loss. As a result of the Company's ongoing involvement in the cash flows related to the royalties and sales milestones in the TPC Territory, the Company will continue to account for the royalties received as non-cash royalty revenue which is reflected within license, collaboration and other revenue in the consolidated statements of operations and comprehensive loss.

During the years ended December 31, 2025, 2024 and 2023, the Company paid $1.8 million, $2.0 million and $2.0 million of royalties to HCR, respectively. As of December 31, 2025 and 2024, the balances related to the liability related to the sale of future royalties were as follows (in thousands):

	December 31,	
Description	**2025**	**2024**
Current portion (included in accrued expenses and other current liabilities)	$ 1,664	$ 2,039
Long-term portion	50,608	52,066
Total liability related to sale of future royalties	$ 52,272	$ 54,105

The Royalty Agreement requires the Company to take certain actions, including actions with respect to the Royalty Interest Payments, the TPC Agreement, and the Company's intellectual property. The Royalty Agreement also contains certain representations and warranties, covenants, indemnification obligations, events of default and other provisions that are customary for a royalty monetization transaction of this nature. In addition, the Company granted HCR a precautionary security interest in connection with the Royalty Interest Payments.

9. LEASES

Cambridge Lease

Under the Cambridge Lease, the Company leases approximately 65,167 square feet of office, storage and laboratory space in Cambridge, Massachusetts. The term of the Cambridge Lease with respect to the 59,216 square feet of office and storage space expires on September 11, 2026, with one five-year extension option available. The term of the Cambridge Lease with respect to the 5,951 square feet of the laboratory space expires on September 11, 2026, with one two-year extension option available. In addition to rent, the Company is required to pay additional amounts for taxes, insurance, maintenance, and other operating expenses.

The Cambridge Lease is non-cancelable and is classified as an operating lease. The renewal options with respect to the office, storage and the lab space of the Cambridge Lease were not included in the calculation of the right-of-use asset and operating lease liability as the renewals were not reasonably certain. The Cambridge Lease does not contain residual value guarantees. The components of lease right-of-use assets and lease liabilities are included in the consolidated balance sheets. Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company used its incremental borrowing rate when measuring operating lease liabilities. In arriving at the operating lease liabilities, the Company applied incremental borrowing rates ranging from 6.65% to 6.94%, which were based on the remaining lease term at either the date of adoption of ASC 842, *Leases*, or the effective date of any subsequent lease term extensions. As of December 31, 2025, the remaining lease term for the Cambridge Lease was 0.70 years.

Operating lease costs were $5.0 million for each of the years ended December 31, 2025 and 2024 and $5.7 million for the year ended December 31, 2023. Cash paid for amounts included in the measurement of operating lease liabilities were $5.8 million, $5.7 million and $5.9 million for the years ended December 31, 2025, 2024 and 2023, respectively. The security deposit in connection with the Cambridge Lease is $1.7 million in the form of a letter of credit, which is included as restricted cash in prepaid expenses and other current assets in the Company's consolidated balance sheet as of December 31, 2025 and in other long-term assets in the Company's consolidated balance sheet as of December 31, 2024.

Sublease and Former Boston Lease

Previously, the Company leased 27,924 square feet of office space in Boston, Massachusetts, or the Boston Lease, under a non-cancelable operating lease that was set to expire in July 2031. The Company subleased the entire Boston Lease, effective October 2019 through February 2023. The Company recorded no rental income for each of the years ended December 31, 2025 and 2024 and $0.3 million in rental income as other income in the consolidated statements of operations and comprehensive loss during the year ended December 31, 2023.

In May 2023, pursuant to a Lease Assignment Agreement, or the Lease Assignment Agreement, the Company assigned all of its rights, title, and interest in, to, and under the Boston Lease to LG Chem Life Sciences Innovation Center, Inc., or LG Chem, and made a payment to LG Chem of $1.3 million. As of May 2023, LG Chem assumed all of the rights and obligations of the Company under the Boston Lease and the Company has no further obligations for rent or other payments under the Boston Lease. In accordance with ASC 842, *Leases*, the Company wrote off the right-of-use asset and lease liability associated with the Boston Lease, and recognized the difference between the right-of-use asset and the lease liability offset by the $1.3 million payment as a loss on lease termination in the consolidated statements of operations and comprehensive loss of $0.5 million during the year ended December 31, 2023.

Future Lease Commitments

Future commitments under the non-cancelable Cambridge Lease are as follows (in thousands):

	Operating Lease
2026	$ 3,613
Less: present value adjustment	(65)
Current operating lease liabilities	$ 3,548

See Note 18, *Subsequent Events*, for information regarding the Waltham Lease (as defined below).

10. COMMITMENTS AND CONTINGENCIES

Manufacturing and Unconditional Purchase Commitment Agreements

Siegfried Manufacturing

The Company's contractual obligations include a commercial supply agreement with Siegfried Evionnaz, or Siegfried, to supply commercial drug substance for Auryxia. The Company and Siegfried entered into a Master Manufacturing Services and Supply Agreement, most recently amended in February 2023, or the Siegfried Agreement, under which the Company has agreed to

purchase a minimum quantity of drug substance of Auryxia, annually at a predetermined price. As of December 31, 2025, the Company had a minimum total commitment of approximately $0.8 million through the end of 2026.

The term of the Siegfried Agreement expires on December 31, 2026. The Siegfried Agreement provides the Company and Siegfried with certain early termination rights.

The Company regularly reviews its estimate of the excess firm purchase commitment liability which relates to the amount of minimum purchase commitments under the Siegfried Agreement that exceed the current forecast, including review of assumptions of expected future demand and expiry of inventory. The excess firm purchase commitment liability was $0.8 million and $3.6 million as of December 31, 2025 and 2024, respectively. The Company did not record a charge to cost of product and other revenue related to the change in the excess firm purchase commitment liability during the year ended December 31, 2025. During the years ended December 31, 2024 and 2023, the Company recorded $2.1 million and $1.5 million, respectively, to costs of product and other revenue related to the change in the excess firm purchase commitment liability.

Patheon Manufacturing

In March 2020, the Company entered into a Supply Agreement with Patheon Inc., or Patheon, or the Patheon Agreement, under which Patheon agreed to manufacture Vafseo drug product for commercial use under a volume-based pricing structure through June 30, 2023, with the agreement renewing annually unless either party gives the other party eighteen months' prior written notice. Under the Patheon Agreement, the Company agreed to purchase from Patheon a certain percentage of the estimated global demand for Vafseo drug product based on certain quarterly and annual forecasts provided by the Company. As of December 31, 2025, the Company has committed to purchase $1.1 million of Vafseo drug product from Patheon through the end of 2026, however, as estimated global demand fluctuates, the Company may have additional future obligations under the Patheon Agreement.

WuXi STA Manufacturing

In April 2020, the Company entered into a Supply Agreement with STA Pharmaceutical Hong Kong Limited, a subsidiary of WuXi AppTec, or WuXi STA, or, as amended, the WuXi STA DS Agreement. Under the WuXi STA DS Agreement, WuXi STA will manufacture Vafseo drug substance for commercial use under a volume-based pricing structure through April 2, 2029. Pursuant to the WuXi STA DS Agreement, the Company has agreed to purchase a certain percentage of the global demand for Vafseo drug substance from WuXi STA. As of December 31, 2025, the Company has committed to purchase $69.2 million of Vafseo drug substance from WuXi STA through the end of 2027, however, as estimated global demand fluctuates, the Company may have additional future obligations under the WuXi STA DS Agreement.

On February 10, 2021, the Company entered into a Supply Agreement with WuXi STA, which was amended on October 15, 2024, or the WuXi STA DP Agreement, under which WuXi STA will manufacture and supply Vafseo drug product for commercial purposes under a volume-based pricing structure through January 1, 2032. The Vafseo drug product price is reviewed annually by the Company and WuXi STA. The Company also reimburses WuXi STA for certain reasonable expenses. Pursuant to the WuXi STA DP Agreement, the Company has agreed to purchase a certain percentage of global demand for Vafseo drug product from WuXi STA. The WuXi STA DP Agreement may be renewed or extended by mutual agreement of the Company and WuXi STA with at least eighteen months' prior written notice. The WuXi STA DP Agreement allows the Company to terminate the relationship on 180 calendar days' prior written notice to WuXi STA for any reason. In addition, each party has the ability to terminate the WuXi STA DP Agreement upon the occurrence of certain conditions. As of December 31, 2025, the Company has committed to purchase $1.8 million of Vafseo drug product from WuXi STA through the first half of 2026, however, as estimated global demand fluctuates, the Company may have additional future obligations under the WuXi STA DP Agreement.

Esteve - Assigned Supply Agreement

On April 9, 2019, the Company entered into a Supply Agreement with Esteve Química, S.A., or Esteve, or the Esteve Agreement, under which Esteve would manufacture Vafseo drug substance for commercial use under a volume-based pricing structure. On December 16, 2022, the Company, TPC and Esteve executed the Esteve Assignment Agreement, pursuant to which the Esteve Agreement was assigned to TPC. The Esteve Assignment Agreement transferred the rights and obligations of the Esteve Agreement to TPC, specifically including the obligations under certain purchase orders issued by the Company and accepted by Esteve.

As of December 31, 2025, the Company has no minimum commitments with Esteve, however, the Company may have future obligations with Esteve.

BioVectra - Former Manufacturing and Unconditional Purchase Commitments

Under the Manufacture and Supply Agreement with BioVectra, Inc., or BioVectra, and the Amended and Restated Product Manufacture and Supply and Facility Construction Agreement with BioVectra, the Company agreed to purchase minimum

quantities of Auryxia drug substance annually at predetermined prices as well as reimburse BioVectra for certain costs in connection with construction of a new facility for the manufacture and supply of Auryxia drug substance.

On December 22, 2022, the Company and BioVectra entered into a termination agreement, or the BioVectra Termination Agreement, pursuant to which the parties agreed, among other things, to terminate, effective immediately, any and all existing agreements entered into between the parties in connection with the manufacture and supply, by BioVectra to the Company, of Auryxia drug substance. Under the terms of the BioVectra Termination Agreement, each of the Company and BioVectra released one another from all existing and future claims and liabilities and the return of certain materials and documents. In addition, the Company agreed to pay BioVectra a total of $32.5 million consisting of (i) an upfront payment of $17.5 million and (ii) six quarterly payments of $2.5 million which commenced in April 2024 and were completed in July 2025, totaling $15.0 million. The upfront payment of $17.5 million was made during the quarter ended December 31, 2022 and was recorded in cost of product and other revenue. In accordance with ASC 420, *Exit or Disposal Cost Obligations*, the Company recognized a liability and corresponding expense for the remaining termination fees based on estimated fair value as of December 22, 2022. The Company imputed interest on the liability for the remaining termination fees at a rate of 17.0% per annum, which was determined based on certain factors, including the Company's credit rating, comparable securities yield and expected repayment period of the remaining termination fees. The Company recorded an initial discount on the remaining termination fees in the consolidated balance sheet on the date of the termination. This resulted in the recording of a liability and corresponding charge to cost of goods sold of $11.2 million during the quarter ended December 31, 2022. The discount on the liability balance was amortized to interest expense using the effective interest rate method over the term of the liability. The amortization of the discount was $0.3 million, $1.6 million and $1.9 million for the years ended December 31, 2025, 2024 and 2023, respectively.

License Agreements

Panion License Agreement

On April 17, 2019, the Company and Panion & BF Biotech, Inc., or Panion, entered into a second amended and restated license agreement, or Panion Amended License Agreement, which amended and restated in full the license agreement between the Company and Panion. The Panion Amended License Agreement provides the Company with an exclusive license under Panion-owned know-how and patents covering the rights to sublicense, develop, make, use, sell, offer for sale, import and export ferric citrate worldwide, excluding certain Asian-Pacific countries, or the Licensor Territory. The Panion Amended License Agreement also provides Panion with an exclusive license under Company-owned patents covering the rights to sublicense (with the Company's written consent), develop, make, use, sell, offer for sale, import and export ferric citrate in certain countries in the Licensor Territory. Under the Panion Amended License Agreement, Panion is eligible to receive from the Company or any sublicensee royalty payments based on a mid-single digit percentage of sales of ferric citrate in the Company's licensed territories. The Company is eligible to receive from Panion or any sublicensee royalty payments based on a mid-single digit percentage of net sales of ferric citrate in Panion's licensed territories.

The Panion Amended License Agreement terminates upon the expiration of each of the Company's and Panion's obligations to pay royalties thereunder. In addition, the Company may terminate the Panion Amended License Agreement (i) in its entirety or (ii) with respect to one or more countries in the Company's licensed territory, in either case upon ninety days' notice. The Company and Panion also each have the right to terminate the Panion Amended License Agreement upon the occurrence of a material breach of the Panion Amended License Agreement by the other party, subject to certain cure provisions, or certain insolvency events. The Panion Amended License Agreement also provides that, on a country-by-country basis, until the second anniversary of the expiration of the obligation of the Company or Panion, as applicable, to pay royalties in a country in which such party has ferric citrate for sale on the date of such expiration, neither the other party nor its affiliates will, directly or indirectly, sell, distribute or otherwise commercialize or supply or cause to supply ferric citrate to a third party for sale or distribution in such country.

The Panion Amended License Agreement includes customary terms relating to, among others, indemnification, confidentiality, remedies, and representations and warranties. In addition, the Panion Amended License Agreement provides that each of the Company and Panion has the right, but not the obligation, to conduct litigation against any infringer of certain patent rights under the Panion Amended License Agreement in certain territories.

During the years ended December 31, 2025, 2024 and 2023, the Company incurred approximately $11.3 million, $9.1 million and $10.0 million, respectively, in royalty payments due to Panion relating to the Company's sales of Auryxia in the U.S. and Japan Tobacco, Inc. and its subsidiary Torii Pharmaceutical Co., Ltd., collectively, JT and Torii's, net sales of Riona in Japan.

Cyclerion Agreement

In June 2021, the Company entered into a license agreement, or the Cyclerion Agreement, with Cyclerion Therapeutics Inc., or Cyclerion, under which the Company obtained an exclusive global license under certain intellectual property rights to research, develop and commercialize praliciguat, an investigational oral soluble guanylate cyclase stimulator.

Under the terms of the Cyclerion Agreement, the Company made an upfront payment of $3.0 million to Cyclerion, which was paid during the second quarter of 2021. Substantially all of the fair value of the assets acquired in conjunction with the Cyclerion Agreement was concentrated in the acquired license. As a result, the Company accounted for this transaction as an asset acquisition under ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The $3.0 million upfront payment was charged to research and development expense at acquisition in June of 2021, as it relates to a development stage compound with no alternative future use.

In December 2024, the Company and Cyclerion entered into Amendment #1 to the Cyclerion Agreement, pursuant to which the Company agreed to pay Cyclerion (i) $1.25 million, which was paid in December 2024, and (ii) $0.5 million, which was paid in September 2025. In addition, the parties agreed to the reduction of certain development milestones and the increase of certain royalty rates on net sales and sublicense income. During the year ended December 31, 2024, the Company recorded the $1.25 million payment and $0.5 million payment to research and development expense in accordance with ASC 730, *Research and Development*, as praliciguat remains a development stage compound with no alternative future use. Furthermore, the only contingency as it related to the $0.5 million payment made in September 2025 was the passage of time.

Under the Cyclerion Agreement, as amended, Cyclerion is eligible to receive up to an additional aggregate of $197.5 million from the Company in specified development and regulatory milestone payments on a product-by-product basis. In December 2025, the Company incurred a $1.0 million development milestone in connection with the initiation of a Phase 2 clinical trial for praliciguat in the U.S., which was charged to research and development expense during the year ended December 31, 2025. The $1.0 million development milestone payment is included in accrued expenses and other current liabilities in the accompanying consolidated balance sheet as of December 31, 2025. Cyclerion will also be eligible to receive specified commercial milestones as well as tiered royalties ranging from a mid-single-digit percentage to twenty percent of net sales, on a product-by-product basis, and subject to reduction upon expiration of patent rights or the launch of a generic product in the territory.

Unless earlier terminated, the Cyclerion Agreement will expire on a product-by-product and country-by-country basis upon the expiration of the last royalty term, which ends upon the longest of (i) the expiration of the patents licensed under the Cyclerion Agreement, (ii) the expiration of regulatory exclusivity for such product and (iii) ten years from first commercial sale of such product. The Company may terminate the Cyclerion Agreement in its entirety or only with respect to a particular licensed compound or product upon 180 days' prior written notice to Cyclerion. The parties also have customary termination rights, subject to a cure period, in the event of the other party's material breach of the Cyclerion Agreement or in the event of certain additional circumstances.

Q32 Agreement

On November 28, 2025, or the APA Closing Date, the Company entered into an Asset Purchase Agreement, or the Q32 Purchase Agreement, with Q32 Bio Inc. and Q32 Bio Operations Inc, or together, Q32, pursuant to which Q32 sold and assigned to the Company, and the Company purchased and assumed from Q32 substantially all assets and liabilities of Q32 and its affiliates related to the research, development, manufacture and commercialization of Q32's clinical-stage development candidate known as ADX-097 (now referred to as AKB-097) worldwide for the treatment, prevention or diagnosis of any disease or condition in humans. AKB-097, which has been evaluated in a Phase 1 clinical trial in healthy volunteers, is a tissue-targeted C3d-Factor H fusion protein complement inhibitor with the potential to treat rare kidney diseases.

Under the terms of the Q32 Purchase Agreement, the Company (i) made an upfront payment of $7.0 million on the APA Closing Date, (ii) will make an additional upfront payment of $3.0 million on the six-month anniversary of the APA Closing Date, (iii) will make certain milestone payments upon the achievement of specified development and regulatory milestone events related to AKB-097 up to an aggregate amount equal to $94.5 million, including a $2.0 million development milestone payment upon the earlier of initiation of a Phase 2 clinical trial and December 31, 2026, (iv) will make certain milestone payments upon the achievement of specified commercial milestone events with respect to the net sales of AKB-097 up to an aggregate amount equal to $487.5 million, and (v) will make certain royalty payments based on the net sales of AKB-097 with royalty percentage tiers ranging from the low single digits to mid-teen percentages. The royalties will expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

The transaction was accounted for as an asset acquisition as the acquired assets did not meet the definition of a business. The Company did not acquire any outputs and there was not an acquired substantive process in place to create outputs. The total purchase consideration of $12.8 million was composed of the $7.0 million upfront payment, the $3.0 million additional upfront payment, the $2.0 million development milestone payment and $0.8 million of direct transaction costs. The only contingency as it relates to the $2.0 million milestone payment upon the earlier of initiation of a Phase 2 clinical trial and December 31, 2026 is the passage of time.

The fair value was allocated to IPR&D assets with no alternative future use for these assets at the closing of the acquisition. As a result, the Company recorded a charge of $12.8 million related to acquired IPR&D expense on the consolidated statements of operations and comprehensive loss during the year ended December 31, 2025. The $3.0 million additional upfront payment and the $2.0 million development milestone payment are included in accrued expenses and other current liabilities in the consolidated balance sheet as of December 31, 2025.

Other Third Party Contracts

The Company contracts with various organizations to conduct R&D activities with remaining contract costs to the Company of approximately $82.6 million at December 31, 2025. The scope of the services under these R&D contracts can be modified upon mutual agreement of the parties, and the contracts or scope of services can be cancelled by the Company upon written notice. In some instances, the contracts may be cancelled by the third party upon written notice.

Litigation and Related Matters

The Company is involved from time to time in various legal proceedings arising in the normal course of business. The Company provides disclosure when a loss in excess of any reserve is reasonably possible, and if estimable, the Company discloses the potential loss or range of possible loss. Significant judgment is required to assess the likelihood of various potential outcomes and the quantification of loss in those scenarios. Changes in the Company's estimates could have a material impact and are recorded as litigation progresses and new information comes to light. Although the outcomes of potential legal proceedings are inherently difficult to predict, the Company does not expect the resolution of current legal proceedings to have a material adverse effect on its financial position, results of operations or cash flows of the Company.

Guarantees and Indemnifications

As permitted under Delaware law, the Company may indemnify its officers, directors and employees for certain events or occurrences that happen by reason of their relationship with, or position held at, the Company. The Company may also be subject to indemnification obligations by law with respect to the actions of its employees under certain circumstances and in certain jurisdictions. The Company maintains director and officer liability insurance coverage that is intended to cover a portion of amounts that may be due with respect to indemnification after a deductible is met. Further, the Company is a party to a variety of agreements in the ordinary course of business under which it may be obligated to indemnify third parties with respect to certain matters. For the years ended December 31, 2025, 2024 and 2023, the Company did not experience any losses related to these indemnification obligations, and no claims were outstanding as of December 31, 2025. The Company does not have any claims related to these indemnification obligations and consequently concluded that the fair value of these obligations is negligible and no related accruals were recorded.

11. PRODUCT REVENUE AND PROVISIONS FOR VARIABLE CONSIDERATION

Until Vafseo's market entry in January 2025, the Company's only source of product revenue was from the U.S. sales of Auryxia. The following table presents net product revenue for Vafseo and Auryxia (in thousands):

	Years Ended December 31,		
Product	**2025**	**2024**	**2023**
Vafseo	$ 45,790	$ —	$ —
Auryxia[(1)]	181,542	152,180	170,301
Total product revenues	$ 227,332	$ 152,180	$ 170,301

(1) Includes the authorized generic version of Auryxia sold and distributed by the Company's authorized generic distribution partner, Mylan Therapeutics, Inc., or AG Distributor, during the year ended December 31, 2025.

The following table presents changes in the Company's contract assets and liabilities related to the Company's sales to its AG Distributor (in thousands):

	Year Ended December 31, 2025			
	Balance at Beginning of Period	**Additions**	**Deductions**	**Balance at End of Period**
Contract assets:				
Accounts receivable	$ —	$ 12,006	$ (11,812)	$ 194
Contract liabilities:				
Deferred revenue	$ —	$ 10,675	$ (7,994)	$ 2,681

Product revenue allowance and provision categories were as follows:

(in thousands)	Chargebacks and Discounts	Rebates, Fees and other Deductions	Returns	Total
Balance at December 31, 2022	$ 1,259	$ 26,252	$ 10,923	$ 38,434
Provisions related to sales in current year	11,138	79,648	6,181	$ 96,967
Adjustments related to prior year sales	(304)	(1,506)	1,648	$ (162)
Credits/payments made	(10,486)	(81,403)	(11,836)	$ (103,725)
Balance at December 31, 2023	$ 1,607	$ 22,991	$ 6,916	$ 31,514
Current provisions related to sales in current year	9,225	44,914	4,862	59,001
Adjustments related to prior year sales	(94)	(2,056)	(540)	(2,690)
Credits/payments made	(9,302)	(50,123)	(4,796)	(64,221)
Balance at December 31, 2024	$ 1,436	$ 15,726	$ 6,442	$ 23,604
Current provisions related to sales in current year	4,051	81,019	634	85,704
Adjustments related to prior year sales	69	143	(1,631)	(1,419)
Credits/payments made	(4,403)	(24,299)	(2,094)	(30,796)
Balance at December 31, 2025	$ 1,153	$ 72,589	$ 3,351	$ 77,093

Chargebacks, discounts and estimated product returns are recorded as a reduction of revenue in the period the related product revenue is recognized in the consolidated statements of operations and comprehensive loss. Chargebacks are recorded as a reduction to accounts receivable while discounts, rebates, fees and other deductions are recorded with a corresponding increase to accrued expenses and other current liabilities or accounts payable in the consolidated balance sheets. Estimated product returns on product sales that are not expected to be returned within one year are recorded as other long-term liabilities in the consolidated balance sheets.

Accounts receivable, net related to product sales was approximately $44.4 million and $32.4 million as of December 31, 2025 and 2024, respectively.

12. LICENSE, COLLABORATION AND OTHER REVENUE

The Company recognized the following revenues from its license, collaboration and other revenue agreements (in thousands):

		Years Ended December 31,		
Entity	**Description**	**2025**	**2024**	**2023**
Medice	License and Product Supply of Vafseo in EU	$ 411	$ 22	$ 10,968
TPC, formerly known as Mitsubishi Tanabe Pharma	License and Product Supply of Vafseo in Japan	2,794	2,612	5,735
JT and Torii	License and royalties related to the sale of Riona in Japan	5,659	5,366	5,394
Otsuka	Terminated U.S. and International Agreements	—	—	2,225
Total License, Collaboration and Other Revenue		$ 8,864	$ 8,000	$ 24,322

The following table presents changes in the Company's contract assets and liabilities related to license, collaboration and other revenue agreements (in thousands):

	Year Ended December 31, 2025			
	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract assets:				
Accounts receivable[1]	$ 2,010	$ 8,894	$ (8,513)	$ 2,391
Contract liability:				
Deferred revenue	$ —	$ —	$ —	$ —

	Year Ended December 31, 2024			
	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract assets:				
Accounts receivable[1]	$ 3,333	$ 8,562	$ (9,885)	$ 2,010
Contract liabilities:				
Deferred revenue (long-term)[2]	$ 43,296	$ —	$ (43,296)	$ —

(1) Excludes accounts receivable from product sales of Auryxia and Vafseo which are included in the accompanying consolidated balance sheets as of December 31, 2025 and 2024.

(2) See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for further information.

During the years ended December 31, 2025, 2024 and 2023, the Company recognized the following revenues as a result of changes in the contract asset and contract liability balances in the respective periods (in thousands):

	Years Ended December 31,		
Revenue Recognized in the Period from:	2025	2024	2023
Deferred revenue - beginning of the period	$ —	$ —	$ 3,738

During each of the years ended December 31, 2025, 2024 and 2023, the Company recognized no revenue from performance obligations satisfied in previous periods.

Medice License Agreement

On May 24, 2023, or the Medice Effective Date, the Company and MEDICE Arzneimittel Pütter GmbH & Co. KG, or Medice, entered into a License Agreement, or the Medice License Agreement, pursuant to which the Company granted to Medice an exclusive license to develop and commercialize Vafseo for the treatment of anemia in adult patients with CKD in the EEA, the UK, Switzerland and Australia, or collectively, the Medice Territory.

Under the Medice License Agreement, the Company received an up-front payment of $10.0 million and is eligible to receive the following payments:

(i) commercial milestone payments up to an aggregate of $100.0 million, and

(ii) tiered royalties ranging from 10% to 30% of Medice's annual net sales of Vafseo in the Medice Territory, subject to reduction in certain circumstances.

The royalties will expire on a country-by-country basis upon the latest to occur of (a) the date of expiration of the last-to-expire valid claim of any Company, Medice or joint patent that covers Vafseo in such country in the Medice Territory, (b) the date of expiration of data or regulatory exclusivity for Vafseo in such country in the Medice Territory and (c) the date that is twelve years from first commercial sale of Vafseo in such country in the Medice Territory.

Under the Medice License Agreement, the Company retains the right to develop Vafseo for non-dialysis patients with anemia due to CKD in the Medice Territory. If the Company develops Vafseo for non-dialysis patients and Vafseo receives marketing approval in the Medice Territory, Medice will commercialize Vafseo for both indications in the Medice Territory. In this instance, the Company would receive 70% of the net product margin of any sales of Vafseo in the non-dialysis patient population, unless Medice requests to share the cost of the development necessary to gain approval to market Vafseo for non-dialysis patients in the Medice Territory and the parties agree on alternative financial terms. If the Company develops

Vafseo for non-dialysis patients, the Company has determined that the activities under the Medice License Agreement represent joint operating activities in which both parties are active participants and of which both parties are exposed to significant risks and rewards that are dependent on the success of the activities. Accordingly, if the Company develops Vafseo for non-dialysis patients the Company will account for the joint activities in accordance with ASC No. 808, *Collaborative Arrangements*, or ASC 808. Additionally, the Company has determined that in the context of the development of Vafseo for non-dialysis patients, Medice does not represent a customer as contemplated by ASC 606. As a result, the activities conducted pursuant to development activities for Vafseo for non-dialysis patients will be accounted for as a component of the related expense in the period incurred.

The Medice License Agreement expires on the date of expiration of all payment obligations due thereunder with respect to Vafseo in the last country in the Medice Territory, unless earlier terminated in accordance with the terms of the Medice License Agreement. Either party may, subject to a cure period, terminate the Medice License Agreement in the event of the other party's uncured material breach. Medice has the right to terminate the Medice License Agreement in its entirety for convenience upon twelve months' prior written notice delivered on or after the date that is twelve months after the Medice Effective Date.

The Company evaluated the elements of the Medice License Agreement in accordance with the provisions of ASC 606 and concluded Medice is a customer. The Company identified one performance obligation in connection with its obligations under the Medice License Agreement, which is the license, or License Performance Obligation. The transaction price at inception was comprised of the up-front payment of $10.0 million, of which the Company received $8.6 million during the quarter ended June 30, 2023. The remaining $1.4 million was withheld by the German Federal Tax Office and was included in prepaid expenses and other current assets as of December 31, 2024 in the consolidated balance sheet. The $1.4 million was received during the year ended December 31, 2025.

Pursuant to the terms of the Medice License Agreement, the up-front payment of $10.0 million is non-refundable and non-creditable against any other amount due to the Company and was allocated to the License Performance Obligation, which was satisfied as of the Medice Effective Date. As such, the Company recognized the $10.0 million up-front payment as license, collaboration and other revenue in the consolidated statement of operations and comprehensive loss during the year ended December 31, 2023.

In accordance with ASC 606, the Company will recognize sales-based royalties and milestone payments at the later of when the performance obligation is satisfied or the related sales occur. During the years ended December 31, 2025, 2024 and 2023, the Company recognized $0.1 million in revenue from Medice royalties, immaterial revenue from Medice royalties and no revenue from Medice royalties, respectively. As of December 31, 2025, there were $0.1 million contract assets, and no accounts receivable, payables or deferred revenue in connection with the Medice License Agreement.

Medice Letter Agreement

On December 6, 2023, the Company and Medice entered into a letter agreement, or the Medice Letter Agreement, pursuant to which the Company agreed to sell to Medice a partial batch of Vafseo in order to achieve packaging validation for the Medice Territory. The Company previously recognized revenue under this arrangement when risk of loss passed to Medice and delivery occurred. During the year ended December 31, 2023, the Company recognized $1.0 million in collaboration, license and other revenue under the Medice Letter Agreement.

Supply of Drug Product to Medice

On September 13, 2024, the Company and Medice entered into a supply agreement, or the Medice Supply Agreement, under which the Company supplies Vafseo drug product to Medice for commercial and developmental use in the Medice Territory. The Company recognizes revenue under this arrangement when risk of loss passes to Medice, delivery has occurred, and Medice has accepted the product. The Company recognized $0.3 million of revenue under the Medice Supply Agreement during the year ended December 31, 2025. The Company did not recognize any revenue under the Medice Supply Agreement during the years ended December 31, 2024 or 2023. As of December 31, 2025, there were $0.3 million accounts receivable and no contract assets, payables or deferred revenue in connection with the Medice Supply Agreement.

Supply of Drug Substance to Medice

On November 12, 2025, the Company and Medice entered into Amendment #1 to the License Agreement, or the Medice Amendment. Pursuant to the Medice Amendment, the Company agreed to supply vadadustat drug substance to Medice pursuant to the terms of a supply agreement dated concurrently with the Medice Amendment and granted Medice the right to manufacture Vafseo tablets using the vadadustat drug substance to be supplied by the Company. In addition, the Medice Amendment provides that any know-how or patent rights arising out of Medice’s manufacture of Vafseo tablets will be owned by the Company.

The Company did not recognize any revenue related to the supply of vadadustat drug substance to Medice during the years ended December 31, 2025, 2024 or 2023.

TPC Collaboration Agreement

On December 11, 2015, the Company and TPC entered into the TPC Agreement, providing TPC with exclusive development and commercialization rights to Vafseo in the TPC Territory, which was amended effective as of December 2, 2022. In addition, the Company supplies Vafseo to TPC for both clinical and commercial use in the TPC Territory. In February 2021, the Company entered into the Royalty Agreement with HCR, whereby the Company sold its right to receive royalties and sales milestones under the TPC Agreement, subject to certain caps and other terms and conditions. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties,* for more information.

Unless earlier terminated, the TPC Agreement will continue in effect on a country-by-country basis until the later of the following: expiration of the last-to-expire patent covering Vafseo in such country in the TPC Territory; expiration of marketing or regulatory exclusivity in such country in the TPC Territory; or ten years after the first commercial sale of Vafseo in such country in the TPC Territory. TPC may terminate the TPC Agreement upon twelve months' notice at any time after the second anniversary of the effective date of the TPC Agreement. Either party may terminate the TPC Agreement upon the material breach of the other party that is not cured within a specified time period or upon the insolvency of the other party.

Under the TPC Agreement, TPC is required to make certain milestone payments to the Company aggregating up to approximately $225.0 million upon the achievement of specified development, regulatory and commercial events. The Company has received $10.0 million in development milestone payments. Of the $40.0 million in regulatory milestone payments the Company is eligible for, the Company received $10.0 million in relation to the Japanese NDA filing in the third quarter of 2019 and $15.0 million following regulatory approval of Vafseo in Japan in the third quarter of 2020. The Company is also entitled to receive up to $175.0 million in commercial milestone payments associated with aggregate sales of all products. In consideration for the exclusive license and other rights contained in the TPC Agreement, TPC made a $20.0 million upfront payment as well as a $20.5 million payment for Phase 2 studies in Japanese patients completed by the Company and reimbursed by TPC. Additionally, the Company is entitled to receive tiered royalty payments ranging from 13% to 20% of annual net sales of Vafseo in the TPC Territory, subject to reduction in certain circumstances.

The Company evaluated the elements of the TPC Agreement in accordance with the provisions of ASC 606 and concluded that the contract counterparty, TPC, is a customer. The Company identified two performance obligations in connection with its material promises under the TPC Agreement as follows: (i) License, Research and Clinical Supply Performance Obligation and (ii) Rights to Future Know-How Performance Obligation.

The transaction price was comprised of: (i) the up-front payment of $20.0 million, (ii) the cost for the Phase 2 studies of $20.5 million, (iii) the cost of all clinical supply provided to TPC for the Phase 3 studies, (iv) $10.0 million in development milestones received, (v) $25.0 million in regulatory milestones received and (vi) $8.7 million in royalties from net sales of Vafseo. The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. As of December 31, 2025, all development milestones and $25.0 million in regulatory milestones have been achieved. No other regulatory milestones or commercial milestones have been assessed as probable and have been fully constrained until the period in which they are achieved.

The Company allocates the transaction price to each performance obligation based on the Company's best estimate of the relative standalone selling price. The Company developed a best estimate of the standalone selling price for the Rights to Future Know-How Performance Obligation primarily based on the likelihood that additional intellectual property covered by the license conveyed will be developed during the term of the arrangement and determined it is immaterial. As such, the Company did not develop a best estimate of standalone selling price for the License, Research and Clinical Supply Performance Obligation and allocated the entire transaction price to this performance obligation.

Revenue for the License, Research and Clinical Supply Performance Obligation for the TPC Agreement is being recognized using a proportional performance method, for which all deliverables have been completed. The Company recognizes any revenue from TPC royalties in the period in which the sales occur. The Company recognized revenue from TPC royalties of $1.8 million, $1.9 million and $2.0 million during the years ended December 31, 2025, 2024 and 2023, respectively. As noted above, in February 2021, the Company entered into the Royalty Agreement, whereby the Company sold its right to receive these royalties and sales milestones under the TPC Agreement, subject to certain caps and other conditions. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for more information. The revenue is classified as collaboration, license and other revenue in the accompanying consolidated statements of operations and comprehensive loss. As of December 31, 2025, there were no accounts receivable, payables or deferred revenue and $0.5 million in contract assets recorded in connection with the TPC Agreement.

Supply of Drug Product to TPC

On July 15, 2020, the Company and TPC entered into a supply agreement, or the TPC Supply Agreement, under which the Company supplies Vafseo drug product to TPC for commercial use in Japan and certain other Asian countries, as contemplated by the TPC Agreement. The term of the TPC Supply Agreement extends throughout the term of the TPC Agreement, and the termination provisions of the TPC Agreement govern termination of the TPC Supply Agreement.

On December 16, 2022, the Company, TPC and Esteve executed an Assignment of Supply Agreement, or the Esteve Assignment Agreement, pursuant to which the rights and obligations of the Company under the Esteve Agreement were transferred to TPC. The Company has no further obligation to take delivery of, or pay for, product delivered by Esteve except as disclosed in Note 10, Commitments and Contingencies.

The Company does not recognize revenue under this arrangement until risk of loss on the drug product passes to TPC and delivery has occurred and TPC has accepted the product. During the years ended December 31, 2025, 2024 and 2023, the Company recognized $1.0 million, $0.7 million and $3.7 million of revenue, respectively, under the TPC Supply Agreement. As of December 31, 2025, there were no accounts receivable, deferred revenue or other current liabilities relating to the TPC Supply Agreement.

JT and Torii Sublicense Agreement

The Company has an Amended and Restated Sublicense Agreement, which was amended in June 2013, with JT and Torii, or the JT and Torii Sublicense Agreement, under which JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate hydrate in Japan. JT and Torii are responsible for the future development and commercialization costs in Japan.

The Company is eligible to receive royalty payments based on a tiered low double-digit percentage of net sales of Riona in Japan inclusive of amounts that the Company must pay to Panion on JT and Torii's net sales of Riona under the Panion License Agreement subject to certain reductions upon expiration or termination of the Amended and Restated License Agreement between the Company and Panion, pursuant to which Company in-licensed the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and commercialization of ferric citrate. The Company is entitled to receive up to an additional $55.0 million upon the achievement of certain annual net sales milestones.

The sublicense under the JT and Torii Sublicense Agreement terminates upon the expiration of all underlying patent rights. Also, JT and Torii may terminate the JT and Torii Sublicense Agreement with or without cause upon at least six months' prior written notice to the Company. Additionally, either party may terminate the JT and Torii Sublicense Agreement for cause upon 60 days’ prior written notice after the breach of any uncured material provision of the JT and Torii Sublicense Agreement, or after certain insolvency events.

The Company evaluated the elements of the JT and Torii Sublicense Agreement in accordance with the provisions of ASC 606 and concluded that the contract counterparty, JT and Torii, is a customer. The Company identified two performance obligations in connection with its obligations under the JT and Torii Sublicense Agreement: (i) License and Supply Performance Obligation and (ii) Rights to Future Know-How Performance Obligation. The Company developed a best estimate of the standalone selling price for the Rights to Future Know-How Performance Obligation primarily based on the likelihood that additional intellectual property covered by the license conveyed will be developed during the term of the arrangement and determined it immaterial. As such, the Company did not develop a best estimate of standalone selling price for the License and Supply Performance Obligation and allocated the entire transaction price to this performance obligation. Additionally, as of the consummation of the Merger, the services associated with the License and Supply Performance Obligation were completed and JT and Torii had secured their own source to manufacture ferric citrate hydrate. As such, any initial license fees as well as any development-based milestones and manufacturing fee revenue were received and recognized prior to the Merger. The Company determined that the remaining consideration that may be payable to the Company under the terms of the sublicense agreement are either quarterly royalties on net sales or payments due upon the achievement of sales-based milestones. In accordance with ASC 606, the Company recognizes sales-based royalties and milestone payments based on the level of sales, when the related sales occur as these amounts have been determined to relate predominantly to the license granted to JT and Torii and therefore are recognized at the later of when the performance obligation is satisfied, or the related sales occur.

During the years ended December 31, 2025, 2024 and 2023, the Company recognized license revenue of $5.7 million, $5.4 million and $5.4 million related to royalties earned on net sales of Riona in Japan, respectively. The Company records the associated mid-single digit percentage of net sales royalty expense due to Panion, the licensor of Riona, in the same period as the royalty revenue from JT and Torii is recorded. As of December 31, 2025, there was $1.5 million in accounts receivables relating to the JT and Torii Sublicense Agreement.

Prior Collaboration and License Agreements

U.S. Collaboration and License Agreement with Otsuka Pharmaceutical Co. Ltd.

On December 18, 2016, the Company entered into a collaboration and license agreement, or Otsuka U.S. Agreement, with Otsuka Pharmaceutical Co. Ltd, or Otsuka. The collaboration was focused on the development and commercialization of Vafseo in the U.S.

On May 12, 2022, the Company received notice from Otsuka that Otsuka had elected to terminate the Otsuka U.S. Agreement and the April 25, 2017 collaboration and license agreement with Otsuka, or Otsuka International Agreement. On June 30, 2022, the Company and Otsuka entered into the Termination and Settlement Agreement, or Otsuka Termination Agreement, pursuant to which, among other things, the Company and Otsuka agreed to terminate the Otsuka U.S. Agreement and the Otsuka International Agreement as of June 30, 2022.

During the year ended December 31, 2023, the Company recognized $2.2 million in collaboration, license and other revenue in connection with the Packaging Validation Transfer Agreement entered into with Otsuka on April 20, 2023. Under the Packaging Validation Transfer Agreement, the parties agreed that responsibility for all remaining packaging validation activities would be transferred from Otsuka to the Company in consideration of payments made by Otsuka to the Company. The Company evaluated the agreement under ASC 606 and concluded it was closely tied to the prior collaboration, license and other revenue agreements and under ASC 606 recognized collaboration, license and other revenue during the year ended December 31, 2023.

13. CAPITAL STOCK

Authorized and Outstanding Capital Stock

As of December 31, 2025, the authorized capital stock of the Company included 350,000,000 shares of common stock, $0.00001 par value per share, of which 265,424,818 and 224,848,992 shares were issued and outstanding at December 31, 2025 and 2024, respectively; and 25,000,000 shares of undesignated preferred stock, $0.00001 par value per share, of which no shares were issued and outstanding at December 31, 2025 and 2024.

At-the-Market Facility

On April 7, 2022, the Company entered into an at-the-market, or the ATM, sales agreement, or the Original Sales Agreement, with Jefferies LLC, or Jefferies, as the Company's sales agent, under which the Company could offer and sell from time to time up to $26.0 million of shares of its common stock at current market prices. During the year ended December 31, 2023, the Company sold 6,189,974 shares of common stock under this program for gross proceeds of $6.8 million ($6.7 million, net of offering expenses). During the year ended December 31, 2024, the Company sold 13,261,311 shares of its common stock under this program with gross proceeds of $19.2 million, ($18.7 million, net of offering expenses).

On September 3, 2024, in connection with the filing of a new shelf registration statement on Form S-3, the Company filed a prospectus related to the Company's amended and restated sales agreement (which amended and restated the Original Sales Agreement), with Jefferies, as the Company’s sales agent, pursuant to which the Company is able to offer and sell up to $75.0 million of its common stock at current market prices from time to time. Since September 12, 2024 (the date the Company’s shelf registration statement on Form S-3 went effective) through December 31, 2024, the Company sold 14,271,631 shares of its common stock under this program with gross proceeds of $24.3 million ($23.8 million, net of offering expenses). During the year ended December 31, 2025, the Company sold 9,437,364 shares of its common stock under this program with gross proceeds of $18.7 million ($18.4 million, net of offering expenses).

Public Offering

On March 19, 2025, the Company entered into an underwriting agreement, or the Underwriting Agreement, with Leerink Partners LLC and Piper Sandler & Co., as representatives of the several underwriters named therein, collectively, the Underwriters, relating to an underwritten public offering, or the Offering, of 25,000,000 shares, or the Shares, of the Company's common stock. The offering price was $2.00 per share, and the Underwriters agreed to purchase the Shares from the Company pursuant to the Underwriting Agreement at a price of $1.88 per share. Under the terms of the Underwriting Agreement, the Company granted the Underwriters a 30-day option to purchase up to 3,750,000 additional shares of common stock, or the Additional Shares, at the public offering price per share, and the Underwriters partially exercised their option and purchased 850,000 Additional Shares on April 22, 2025.

Net proceeds from the Offering were $46.5 million, after deducting underwriting discounts and commissions and offering expenses and net proceeds from the Offering of the Additional Shares were $1.6 million, after deducting underwriting discounts and commissions and offering expenses.

Unregistered Common Stock

In connection with the Vifor License Agreement, CSL Vifor owns 7,571,429 shares of common stock that are unregistered under the Securities Act. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for more information.

Warrants to Purchase Common Stock

In connection with the BlackRock Credit Agreement, described in more detail in Note 7, *Indebtedness*, the Company issued a warrant to purchase 3,076,923 shares of the Company's common stock, at an exercise price per share of $1.30, and upon the borrowing of Tranche C in February 2025, the Company issued additional warrants to purchase 1,153,846 shares of the Company's common stock at an exercise price per share of $1.30. Each warrant is exercisable for eight years from the date of issuance. The warrants and the common stock issuable upon the exercise of such warrants were not registered under the Securities Act. Accordingly, the holder thereof may only sell common stock issued upon exercise of such warrants pursuant to an effective registration statement under the Securities Act covering the resale of those shares, an exemption under Rule 144 under the Securities Act or another applicable exemption under the Securities Act.

On July 21, 2025, the Warrant Holder exercised its option to purchase 2,115,384 shares of the Company's common stock under the Initial Warrant on a cashless basis at an exercise price per share of $1.30. The cashless exercise allowed the Warrant Holder to convert the warrants into shares of the Company's common stock without the need for a cash payment. Instead of paying cash upon exercise, the Warrant Holder received a reduced number of shares based on a predetermined formula. On July 23, 2025, as a result of the cashless exercise, the Company issued 1,408,588 shares of common stock to the Warrant Holder under the Initial Warrant.

14. STOCK-BASED COMPENSATION AND EMPLOYEE RETIREMENT PLANS

Stock-Based Compensation Plans

The Company incurred stock-based compensation expenses of $11.3 million, $7.8 million and $9.3 million for the years ended December 31, 2025, 2024 and 2023, respectively.

Equity Incentive Plans

The following table contains information about the Company's equity incentive plans:

			December 31, 2025		December 31, 2024	
Title of Plan	**Group Eligible**	**Type of Award Granted (or to be Granted)**	**Awards Outstanding**	**Additional Awards Available for Grant**	**Awards Outstanding**	**Additional Awards Available for Grant**
Keryx Equity Plans[1][2]	Employees, directors and consultants	Common stock options and RSUs	148,860	—	163,765	—
Akebia Therapeutics, Inc. 2014 Incentive Plan, as amended [2] [3] (the 2014 Plan) *(replaces 2008 Plan)*	Employees, directors, consultants and advisors	Common stock options, RSUs, SARs and performance awards	8,412,898	—	11,559,708	—
Akebia Therapeutics, Inc. 2023 Stock Incentive Plan, as amended[3] (the 2023 Plan) *(replaces 2014 Plan)*	Employees, officers, directors, consultants and advisors	Common stock options, SARs, restricted stock, unrestricted stock, RSUs, performance awards, other share-based awards and dividend equivalents	15,913,729	24,723,655	10,390,642	11,340,648

(1) The Keryx Equity Plans consist of the Keryx Biopharmaceuticals, Inc. 1999 Share Option Plan, Keryx Biopharmaceuticals, Inc., as amended, the 2004 Long-Term Incentive Plan, as amended, the Keryx Biopharmaceuticals, Inc. 2007 Incentive Plan, the Keryx Biopharmaceuticals Inc. Amended and Restated 2013 Incentive Plan and the Keryx Biopharmaceuticals, Inc. 2018 Equity Incentive Plan.

(2) New awards are no longer being granted under these plans.

(3) This table includes the following inducement awards that are subject to the terms and conditions of the applicable plan but were granted as inducement awards consistent with Nasdaq Listing Rule 5635(c)(4) and not under the applicable plan: 1,050,525 options outstanding under the 2014 Plan and 3,034,085 options outstanding under the 2023 Plan as of December 31, 2025 and 1,151,127 options outstanding under the 2014 Plan and 2,534,775 options outstanding under the 2023 Plan as of December 31, 2024.

(4) On June 10, 2025, the 2023 Plan was amended to increase the number of shares of common stock available for issuance thereunder by 18,900,000 shares.

Common Stock Options and Stock Appreciation Rights

During the year ended December 31, 2025, the Company granted 3,634,300 options to employees and 375,200 options to directors under the 2023 Plan. Options and SARs granted by the Company generally vest over periods of between 12 and 48 months, subject, in each case, to the individual's continued service through the applicable vesting date. Options and SARs generally vest either 100% on the first anniversary of the grant date or in installments of (i) 25% at the one year anniversary and (ii) 12 equal quarterly installments beginning after the one year anniversary of the grant date, subject to the individual's continuous service with the Company. Options and SARs generally expire ten years after the date of grant.

The Company also maintains an inducement award program with a share pool that is separate from the Company's equity plans under which inducement awards may be granted consistent with Nasdaq Listing Rule 5635(c)(4). During the year ended December 31, 2025, the Company granted 1,454,477 options to purchase shares of the Company's common stock to new hires as inducements to such employees entering into employment with the Company, of which 1,152,477 options remained outstanding at December 31, 2025.

The Company grants annual service-based stock options to employees and directors and granted SARs to certain executives under the 2023 Plan and previously granted options under the 2014 Plan. In addition, the Company issues common stock options to directors, new hires and occasionally to other employees not in connection with the annual grant process.

Finally, the Company periodically grants performance-based stock options which generally vest in connection with the achievement of specified commercial, regulatory and corporate milestones. The performance-based stock options also generally feature a time-based vesting component. The expense recognized for these awards is based on the grant date fair value of the Company's common stock multiplied by the number of options granted and recognized over time based on the probability of meeting such commercial, regulatory and corporate milestones.

The combined stock option activity for the year ended December 31, 2025, is as follows:

	Stock Options	Weighted-Average Exercise Price	Weighted-Average Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2024	16,684,325	$ 3.19	7.17 years	$ 6,797
Granted	5,464,077	$ 2.48		
Exercised	(1,205,853)	$ 1.40		
Expired	(1,165,336)	$ 8.67		
Canceled and forfeited	(1,624,955)	$ 1.99		
Outstanding at December 31, 2025	18,152,258	$ 2.85	6.97 years	$ 3,690
Exercisable at December 31, 2025	9,819,097	$ 3.56	5.59 years	$ 2,624
Vested and expected to vest at December 31, 2025	18,152,258	$ 2.85	6.97 years	$ 3,690

The intrinsic value of options exercised during the years ended December 31, 2025 and 2024 was $1.8 million and $0.4 million, respectively. There was immaterial intrinsic value of options exercised during the year ended December 31, 2023, as the value of options exercised in 2023 was immaterial. The fair value of options that vested during the years ended December 31, 2025, 2024 and 2023 was $4.3 million, $3.7 million and $6.4 million, respectively. As of December 31, 2025, there was approximately $11.2 million of unrecognized compensation cost related to common stock options outstanding under the Company's 2023 Plan or the 2014 Plan or made pursuant to the Company's inducement award program, which is expected to be recognized over a weighted average period of 2.64 years.

Restricted Stock Units

Generally, RSUs granted by the Company vest in one of the following ways: (i) 100% of each RSU grant vests on the first anniversary of the grant date, (ii) one third of each RSU grant vests on the first, second and third anniversaries of the grant date, (iii) 50% of each RSU grant vests on the first anniversary and 25% of each RSU grant vests every six months after the one year anniversary of the grant date, or (iv) one third of each RSU grant vests on the first anniversary of the grant date and the remaining two thirds vests in eight substantially equal quarterly installments beginning after the one year anniversary, subject, in each case, to the individual's continued service through the applicable vesting date. The grant-date fair value of the RSUs is recognized as expense on a straight-line basis. The Company determines the fair value of the RSUs based on the closing price of the common stock on the date of the grants.

The Company also periodically grants performance-based restricted stock units, or PSUs, to employees under the 2023 Plan and previously granted PSUs under the 2014 Plan. The PSUs granted by the Company generally vest in connection with the achievement of specified commercial, regulatory and corporate milestones. The PSUs also generally feature a time-based

vesting component. The expense recognized for these awards is based on the grant date fair value of the Company's common stock multiplied by the number of units granted and recognized over time based on the probability of meeting such commercial, regulatory and corporate milestones.

In addition, the Company has granted PSUs to certain employees under the 2023 Plan with a market condition. The PSUs also generally feature a time-based vesting component. The Company uses a Monte Carlo simulation to determine fair value of the award at the grant date. The expense recognized for these awards is based on the calculated fair value multiplied by the number of the target units granted and is amortized over the service period.

RSU and PSU activity is as follows:

	2014 Plan		2023 Plan	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2024	1,321,423	$0.95	4,108,367	$1.59
Granted	—	$0.00	4,492,000	$2.31
Vested	(849,701)	$1.06	(1,636,898)	$1.55
Forfeited and canceled	(141,100)	$0.98	(970,862)	$1.89
Unvested as of December 31, 2025	330,622	$0.63	5,992,607	$2.09

The total fair value of RSUs and PSUs that vested during 2025, 2024 and 2023 (measured on the date of vesting) was $3.4 million, $3.2 million and $8.4 million, respectively. As of December 31, 2025, there was approximately $7.7 million of unrecognized compensation cost related to RSUs and PSUs, which is expected to be recognized over a weighted average period of 1.73 years.

Employee Stock Purchase Plan

On June 6, 2019, the Company's stockholders approved the Amended and Restated 2014 Employee Stock Purchase Plan, or ESPP. Under the ESPP substantially all employees may voluntarily enroll to purchase shares of the Company's common stock through payroll deductions at a price equal to 85% of the lower of the fair market values of the stock as of the beginning or the end of the six-month offering period. An employee's payroll deductions under the ESPP are limited to 15% of the employee's compensation, and an employee may not purchase more than $25,000 worth of stock during any calendar year. In addition, an employee may not purchase more than 1,500 shares in any six-month offering period. As of December 31, 2025 and 2024, a total of 4,260,647 and 4,448,069 shares of the Company's common stock were available for future issuance under the ESPP, respectively. The Company issued 187,422 shares during the year ended December 31, 2025.

Stock-Based Compensation Expense

The Black-Scholes option pricing model is used to estimate the fair value of the common stock options. The weighted-average assumptions used in calculating the fair values of the rights to acquire stock under the 2023 Plan, the 2014 Plan and inducement awards were as follows:

	Years ended December 31,		
Common Stock Options	2025	2024	2023
Risk-free interest rate	3.67% - 4.38%	3.60% - 4.66%	3.54% - 4.81%
Expected volatility	111.61% - 123.58%	109.98% - 119.81%	100.97% - 111.71%
Expected term (years)	5.51 - 6.25	5.51 - 6.25	5.51 - 6.25
Expected dividend yield	—%	—%	—%
Weighted average grant date fair value	$2.14	$1.36	$0.69

The Company has classified stock-based compensation in its consolidated statements of operations and comprehensive loss as follows (in thousands):

	Years ended December 31,		
	2025	2024	2023
Cost of goods sold	$ 683	$ 399	267
Research and development	2,120	1,498	1,964
Selling, general and administrative	8,480	5,840	6,456
Restructuring	—	38	630
Total	$ 11,283	$ 7,775	$ 9,317

Stock-based compensation by type of award was as follows (in thousands):

	Years ended December 31,		
	2025	2024	2023
Stock options	$ 5,356	$ 4,036	$ 5,310
Restricted stock units	5,214	3,655	3,637
Performance RSUs	545	—	297
Employee stock purchase plan	168	84	73
Total	$ 11,283	$ 7,775	$ 9,317

Employee Retirement Plan

In 2008, the Company established a retirement plan, or the Plan, authorized by Section 401(k) of the Internal Revenue Code, or IRC. In accordance with the Plan, all employees who have attained the age of 21 are eligible to participate in the Plan as of the first Entry Date, as defined, following their date of employment. Each employee can contribute a percentage of compensation up to a maximum of the statutory limits per year. Company contributions are discretionary and contributions in the amount of approximately $1.9 million, $1.7 million and $1.7 million were made during the years ended December 31, 2025, 2024 and 2023, respectively.

15. INCOME TAXES

Income before provision for income taxes was as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
United States	$ (3,721)	$ (69,410)	$ (51,925)
Foreign	—	—	—
Income (loss) before taxes	$ (3,721)	$ (69,410)	$ (51,925)

The Company's income tax provision was computed based on the federal statutory rate and the state statutory rates, net of the related federal benefit. The components of provision for income taxes for all periods presented were as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Current:			
Federal	$ —	$ —	$ —
State	1,624	—	—
Foreign	—	—	—
Total current	1,624	—	—
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred	—	—	—
Total income taxes	$ 1,624	$ —	$ —

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes after the adoption of ASU 2023-09 is as follows:

	Year Ended December 31,	
	2025	
	(In thousands)	Percent
U.S. federal statutory tax rate	$ (781)	21.0 %
State and local income taxes, net of federal income tax effect[1]	1,283	(34.5)
Tax credits		
Research and development tax credits	(988)	26.6
Changes in valuation allowances	(533)	14.3
Nontaxable or nondeductible items		
Meals & entertainment	165	(4.4)
Lobbying contributions	294	(7.9)
Stock compensation	680	(18.3)
162(m) compensation limit	731	(19.6)
Pharma fee	105	(2.8)
Warrant liability	651	(17.5)
Other Adjustments		
Other	18	(0.6)
Effective tax rate	$ 1,624	(43.7)%

(1) The states and local jurisdictions that contribute to the majority (greater than 50%) of the tax effect in this category include Tennessee.

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes for years prior to the adoption of ASU 2023-09 is as follows:

	Years Ended December 31,	
	2024	2023
U.S. federal tax at statutory rate	21.0 %	21.0 %
State and local tax at statutory rate	0.6	2.7
Research and development tax credits	1.9	0.3
Change in valuation allowance	(32.5)	(9.1)
Other permanent differences	(1.7)	(2.0)
Stock option cancellations	(1.8)	(3.7)
Stock option shortfalls	—	(1.7)
Effect of rate changes	13.5	(7.7)
Provision to return adjustment	(1.0)	(0.3)
Other	—	0.5
Effective tax rate	— %	— %

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. When realization of the deferred tax asset is more likely than not to occur, the benefit related to the deductible temporary differences attributable to operations is recognized as a reduction of income tax expense. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. The Company cannot be certain that future taxable income will be sufficient to realize its deferred tax assets. Accordingly, the Company has recorded a valuation allowance against the Company's otherwise recognizable net deferred tax assets. The Company continues to maintain the underlying tax benefits to offset future taxable income and to monitor the need for a valuation allowance based on the profitability of its future operations. The valuation allowance decreased by approximately $5.8 million for the year ended December 31, 2025 and increased by $22.5 million and $4.7 million during the years ended December 31, 2024 and 2023, respectively. Significant components of the Company's deferred tax assets and liabilities are as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Accrued expenses and other current liabilities	$ 9,374	$ 1,757
Deferred revenue	15,765	13,222
Sale of royalty	12,251	13,595
R&D credits	7,726	6,152
Capitalized R&D costs	11,873	21,270
Net operating loss carryforward	289,712	291,723
ASC 842 lease liability	832	2,248
Working Capital Fund liability	9,366	10,123
Intangible assets	4,631	2,040
Other	22,021	29,048
Total deferred tax assets	383,551	391,178
Less valuation allowance	(382,001)	(387,803)
Total deferred tax assets, net of valuation allowance	1,550	3,375
Deferred tax liabilities:		
481(a) adjustments	(670)	(1,271)
ROU asset (ASC 842)	(859)	(2,065)
Other	(21)	(39)
Total deferred tax liabilities	(1,550)	(3,375)
Net deferred tax liability	$ —	$ —

As of December 31, 2025, 2024 and 2023, the Company had approximately $1,240.8 million, $1,245.8 million and $1,230.4 million, respectively, of federal net operating losses, or NOLs, carry-forwards which expire through 2037. Included in the $1,240.8 million of federal NOLs are losses of $663.8 million that will carry forward indefinitely as a result of the Tax Cuts and Jobs Act. Additionally, at December 31, 2025, 2024 and 2023, the Company had approximately $562.2 million, $584.3 million

and $590.8 million, respectively, of state NOL carry-forwards, which expire through 2045. The Company also has approximately $5.0 million of federal research and development tax credit carryforwards which expire through 2045 and $3.4 million of state R&D tax credit carryforwards which expire through 2040.

Under the provisions of the IRC, the NOLs and tax credit carry-forwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. NOLs and tax credit carryforwards may become subject to an annual limitation under IRC Sections 382 and 383 if there is more than a 50% change in ownership of the stockholders that own 5% or more of the Company's outstanding stock over a three-year period. The Company completed an evaluation of its ownership changes and concluded that an ownership change did occur on December 12, 2018 for both Akebia and Keryx in connection with the Merger. As a consequence of this ownership change, the Company's NOLs and tax credit carryforwards allocable to the tax periods preceding the ownership change became subject to limitation under Section 382 of the IRC. The Company reduced its associated deferred tax assets by $44.9 million as a result of the limitation. The Company completed an evaluation of its ownership changes as of December 31, 2025 and concluded that an ownership change had not occurred since the previous evaluation done through December 12, 2018. The Company may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside the Company's control. As a result, the Company's ability to utilize these attributes to offset taxable income may be subject to limitations.

The Company has not conducted a full study of its research and development credit carryforwards. A study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts will be presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credit carryforwards and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations at this time, if an adjustment were required.

The Company files income tax returns in the U.S. federal and various state and local jurisdictions. For federal and state income tax purposes, the 2024, 2023 and 2022 tax years remain open for examination under the normal three-year statute of limitations. The statute of limitations for income tax audits in the U.S. will commence upon utilization of NOLs and will expire three years from the filing of the tax return the loss was utilized on.

As of December 31, 2025, the Company's U.S. federal income tax return for the year ended December 31, 2023 is under examination by the Internal Revenue Service. The examination is in its early stages, and no proposed adjustments have been received. The ultimate resolution of this matter is uncertain and could differ from amounts recorded in the consolidated financial statements.

A reconciliation of the beginning and ending amounts of unrecognized tax benefits for the years ending December 31, 2025, 2024 and 2023 are as follows (in thousands):

Balance at December 31, 2022	$	2,697
Reductions based on tax positions of current years		(2,697)
Balance at December 31, 2023		—
Reductions based on tax positions of current years		—
Balance at December 31, 2024		—
Reductions based on tax positions of current years		—
Balance at December 31, 2025	$	—

The Company paid $0.7 million cash for state and local income taxes during the year ended December 31, 2025. The Company did not pay cash for income taxes during the years ended December 31, 2024 and 2023.

16. NET LOSS PER SHARE

Potentially dilutive securities including common stock options, RSUs, SARs and warrants have been excluded from the calculation of diluted net loss per share as their effects would be anti-dilutive. For periods in which the Company reports a net loss, the weighted average number of shares outstanding used to calculate both basic and diluted net loss per share were the same. The shares in the table below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, due to their anti-dilutive effect:

	Years Ended December 31,		
	2025	2024	2023
Warrants	2,115,385	3,076,923	—
Outstanding common stock options	17,516,945	16,049,012	12,690,624
Unvested restricted stock units	6,323,229	5,429,790	3,930,167
Stock appreciation rights	635,313	635,313	635,313
Total	26,590,872	25,191,038	17,256,104

17. SEGMENT INFORMATION

The Company operates as one operating segment focused on developing and commercializing innovative therapeutics primarily in the U.S. The accounting policies of the segment are the same as those described in Note 2, *Summary of Significant Accounting Policies*.

The determination of a single business segment is consistent with the consolidated financial information regularly reviewed by the chief executive officer, who is the Company's CODM, in assessing segment performance and deciding how to allocate resources on a consolidated basis.

The CODM makes decisions on resource allocation, assesses performance of the business, and monitors budget versus actual results using income (loss) from operations. Net income (loss) is also a measure that is considered in monitoring budget versus actual results. The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets.

The following table presents information about reported segment revenues, segment profit and significant segment expenses for the years ended December 31, 2025, 2024 and 2023:

	Years Ended December 31,		
	2025	2024	2023
Revenues	$ 236,196	$ 160,180	$ 194,623
Less:			
Direct cost of product and other revenue	28,136	15,970	26,525
Panion royalty	11,326	9,097	10,048
Excess firm purchase commitment charge	—	2,068	1,533
Amortization of intangible asset	—	36,042	36,042
Research and development	62,359	37,652	63,079
Selling, general and administrative	107,480	106,545	100,233
License	3,396	3,220	3,237
Restructuring	—	58	181
Income (loss) from operations	23,499	(50,472)	(46,256)
Other income (expense)			
Interest expense	(24,179)	(18,185)	(6,032)
Other income	58	94	887
Change in fair value of warrant liability	(3,099)	(330)	—
Loss on extinguishment of debt	—	(517)	—
Loss on termination of lease	—	—	(524)
Net loss before income taxes	(3,721)	(69,410)	(51,925)
Income tax expense	(1,624)	—	—
Net loss	$ (5,345)	$ (69,410)	$ (51,925)

18. SUBSEQUENT EVENTS

The Company has evaluated events and transactions occurring after the balance sheet date through the filing date of this Form 10-K with the Securities and Exchange Commission, to ensure that the audited consolidated financial statements include appropriate disclosure of events both recognized in the accompanying consolidated financial statements as of December 31,

2025, and events which occurred subsequently but were not recognized in the consolidated financial statements. The Company has concluded that no subsequent events have occurred that require disclosure other than the following:

Entry into New Lease Agreement

On January 27, 2026, the Company entered into a lease agreement, or the Waltham Lease, with BP THIRD AVENUE LLC, a Delaware limited liability company, pursuant to which the Company will lease an aggregate of approximately 43,474 square feet, consisting of 28,518 square feet of office space, or the Office Premises, and 14,956 square feet of laboratory space, or Lab Premises, located in Waltham, Massachusetts. The Company intends to relocate its corporate headquarters to the Waltham Lease in September 2026. The Cambridge Lease expires on September 11, 2026.

The Company's annual rent for the Office Premises will start at $0.9 million and will increase at an additional $1.00 per square foot for each successive Rent Year (as defined in the Waltham Lease) until the end of the initial term. The Company's annual rent for the Lab Premises will start at $1.0 million and will increase by approximately 3.0% for each successive Rent Year until the end of the initial term. The Waltham Lease requires a security deposit in the amount of $0.8 million in the form of an irrevocable letter of credit. In addition to rent, the Company is required to pay additional amounts for taxes, insurance, maintenance and other operating expenses.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Management's Evaluation of our Disclosure Controls and Procedures

"Disclosure controls and procedures", as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission, or the SEC, rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in company reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our management, with the participation of our principal executive officer and principal financial officer, carried out an evaluation of our disclosure controls and procedures as of December 31, 2025. Based upon their evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2025, our disclosure controls and procedures were effective at a reasonable assurance level.

Management's Annual Report on Internal Control Over Financial Reporting

Our management, with the participation of our principal executive officer and principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive officer and principal financial officer and effected by our board of directors, management and other personnel to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Our management conducted the assessment of the effectiveness of our internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Based on this assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2025.

Remediation of Previously Identified Material Weakness

As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2024, management identified a material weakness in our internal control over financial reporting relating to our inventory process. Management is committed to maintaining a strong internal control environment. In response to the material weakness identified, management, with the oversight of the Audit Committee of the Board of Directors, took comprehensive actions to remediate the material weakness in internal control over financial reporting relating to our inventory process, including increasing the level of precision of our review controls that support the completeness, accuracy and reasonableness of the sales forecast used to support our inventory evaluations, including the identification and consideration of contrary evidence that could detect a potential error in the sales forecast. The remediation efforts addressed the material weakness and also enhanced our overall financial reporting control environment. As of December 31, 2025, we have determined that our previously reported material weakness has been remediated.

Changes in Internal Control over Financial Reporting

Except for the remediation efforts as noted above, there have been no changes in our internal control over financial reporting during the quarter ended December 31, 2025, as defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations of Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Akebia Therapeutics, Inc.

Opinion on Internal Control Over Financial Reporting

We have audited Akebia Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2025, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Akebia Therapeutics, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2025, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2025 consolidated financial statements of the Company and our report dated February 26, 2026, expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 26, 2026

Item 9B. Other Information

Rule 10b5-1 - Director and Officer Trading Arrangements

From time to time, the Company's directors and officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended, or the Exchange Act), engage in open-market transactions with respect to Company securities, including to satisfy tax withholding obligations when equity awards vest or are exercised, and for diversification or other personal reasons.

Transactions in Company securities by directors and officers are required to be made in accordance with the Company's insider trading policy, which requires that the transactions be in accordance with applicable U.S. federal securities laws that prohibit trading while in possession of material nonpublic information. Rule 10b5-1 under the Exchange Act provides an affirmative defense that enables directors and officers to prearrange transactions in the Company's securities in a manner that avoids concerns about initiating transactions while in possession of material nonpublic information.

None of the Company's directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as each term is defined in Item 408(c) of Regulation S-K) during the quarterly period covered by this report.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Director, Executive Officers and Corporate Governance

The information required by this Item 10 will be included in our Definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation

The information required by this Item 11 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and, other than the information required by Item 402(v) of Regulation S-K, is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item 12 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this Item 13 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 will be included in our Definitive Proxy Statement to be filed with the SEC with respect to our 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) Documents filed as part of this Annual Report on Form 10-K.

(b) Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations and Comprehensive Loss

Consolidated Statements of Stockholders' Equity (Deficit)

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

(2) Schedules

Schedules have been omitted as all required information has been disclosed in the consolidated financial statements and related footnotes.

(3) Exhibits

The Exhibits listed below are filed as part of this Annual Report on Form 10-K.

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filed Date/ Period End Date
2.1**	Agreement and Plan of Merger, dated as of June 28, 2018, by and among Akebia Therapeutics, Inc., Alpha Therapeutics Merger Sub, Inc., and Keryx Biopharmaceuticals, Inc.	8-K	001-36352	2.1	June 28, 2018
2.2	First Amendment to Agreement and Plan of Merger, dated as of October 1, 2018, by and among Akebia Therapeutics, Inc., Alpha Therapeutics Merger Sub, Inc. and Keryx Biopharmaceuticals, Inc.	8-K	001-36352	2.1	October 1, 2018
3.1	Ninth Amended and Restated Certificate of Incorporation	8-K	001-36352	3.1	March 28, 2014
3.2	Certificate of Amendment of Ninth Amended and Restated Certificate of Incorporation of Akebia Therapeutics, Inc.	8-K	001-36352	3.1	June 9, 2020
3.3	Second Amended and Restated Bylaws of Akebia Therapeutics, Inc.	8-K	001-36352	3.1	April 28, 2023
4.1	Form of Common Stock Certificate	S-1/A	333-193969	4.1	March 4, 2014
4.2	Fourth Amended and Restated Investors' Rights Agreement, dated March 5, 2014	10-K	001-36352	4.4	March 4, 2015
4.3#	Amendment No. 1 to Fourth Amended and Restated Investors' Rights Agreement, dated June 28, 2017	10-K	001-36352	4.5	March 12, 2018
4.4#	Investment Agreement between Akebia Therapeutics, Inc. and Vifor (International) Ltd., dated May 12, 2017	10-Q	001-36352	4.1	August 8, 2017
4.5!	Investment Agreement between Akebia Therapeutics, Inc. and Vifor (International) Ltd., dated February 18, 2022	10-K	001-36352	4.5	March 1, 2022
4.6	Description of Registrant's Securities	10-K	001-36352	4.6	February 25, 2021
4.7	Form of Warrant	10-K	001-36352	4.7	March 14, 2024
10.1†	Form of Director and Officer Indemnification Agreement	10-K	001-36352	10.1	March 12, 2018
10.2	Office Lease Agreement Between MA-Riverview/245 First Street, L.L.C. and Akebia Therapeutics, Inc., dated December 3, 2013	S-1	333-193969	10.2	February 14, 2014
10.3	First Amendment to Office Lease Agreement Between Jamestown Premier 245 First, LLC and Akebia Therapeutics, Inc., dated December 15, 2014	10-K	001-36352	10.3	March 4, 2015
10.4	Second Amendment to Office Lease Agreement Between Jamestown Premier 245 First, LLC and Akebia Therapeutics, Inc., dated November 23, 2015	10-K	001-36352	10.4	March 14, 2016

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filed Date/ Period End Date
10.5	Third Amendment to Office Lease Agreement Between Jamestown Premier 245 First, LLC and Akebia Therapeutics, Inc., dated July 25, 2016	10-Q	001-36352	10.1	November 9, 2016
10.6	Fourth Amendment to Office Lease Agreement Between CLPF-Cambridge Science Center, LLC and Akebia Therapeutics, Inc., dated May 1, 2017	10-K	001-36352	10.6	March 12, 2018
10.7	Fifth Amendment to Office Lease Agreement Between CLPF-Cambridge Science Center, LLC and Akebia Therapeutics, Inc. dated April 9, 2018	10-Q	001-36352	10.1	August 8, 2018
10.8	Sixth Amendment to Office Lease Agreement Between CLPF-Cambridge Science Center, LLC and Akebia Therapeutics, Inc. dated November 30, 2020	10-K	001-36352	10.8	February 25, 2021
10.9	Seventh Amendment to Office Lease Agreement Between CLPF-Cambridge Science Center, LLC and Akebia Therapeutics, Inc. dated May 6, 2024.	10-Q	001-36352	10.1	August 8, 2024
10.10*	180 CityPoint Waltham, Massachusetts Lease Agreement Between BP Third Avenue LLC and Akebia Therapeutics, Inc. dated January 27, 2026				
10.11†*	Akebia Therapeutics, Inc. Fifth Amended and Restated Non-Employee Director Compensation Program, effective January 26, 2026				
10.12†	Executive Employment Agreement with John P. Butler, dated September 16, 2013	S-1	333-193969	10.7	February 14, 2014
10.13†	2014 Form of Executive Severance Agreement for Officers	S-1/A	333-193969	10.27	March 4, 2014
10.14†*	Amended and Restated Executive Severance Agreement, dated January 28, 2026, between Akebia Therapeutics, Inc. and John P. Butler				
10.15†	Amended and Restated Executive Severance Agreement, dated January 28, 2026, between Akebia Therapeutics, Inc. and Erik J. Ostrowski	8-K	001-36352	99.2	January 30, 2026
10.16†*	2026 Form of Executive Severance Agreement for Non-CEO C-Level Executives				
10.17†	2014 Incentive Plan	S-1	333-193969	10.29	March 4, 2014
10.18†	Amendment No. 1 to the Akebia Therapeutics, Inc. 2014 Incentive Plan	S-8	333-229366	4.4	January 25, 2019
10.19†	Amended and Restated 2014 Employee Stock Purchase Plan	DEF 14A	001-36352	Appendix A	April 26, 2019
10.20†	Form of Non-Statutory Stock Option Agreement for Officers under 2014 Incentive Plan	S-1/A	333-193969	10.24	March 4, 2014

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filed Date/ Period End Date
10.21†	Form of Non-Statutory Stock Option Agreement for Non-Employee Directors under 2014 Incentive Plan	S-1/A	333-193969	10.25	March 4, 2014
10.22†	Amended and Restated Cash Incentive Plan, effective January 19, 2022	10-K	001-36352	10.28	March 1, 2022
10.23†	Form of Officer Restricted Stock Unit Award Agreement under 2014 Incentive Plan	10-K	001-36352	10.18	March 12, 2018
10.24†	Form of Officer Restricted Stock Unit Award Agreement under 2014 Incentive Plan	10-K	001-36352	10.29	March 26, 2019
10.25†	Form of Officer Inducement Award Non-Statutory Stock Option Agreement	S-8	333-222728	4.4	January 26, 2018
10.26†	Form of Inducement Award Non-Statutory Stock Option Agreement for Non-Officers	S-8	333-222728	4.5	January 26, 2018
10.27†	Form of Officer Performance-Based Stock Option Award, under the Company's 2014 Incentive Plan, as amended	10-Q	001-36352	10.1	November 4, 2021
10.28†	Form of Officer Performance-Based Restricted Stock Unit Award, under the Company's 2014 Incentive Plan, as amended	10-Q	001-36352	10.2	November 4, 2021
10.29†	Form of Officer Restricted Stock Unit Award Agreement under 2014 Incentive Plan (Retention Awards)	10-Q	001-36352	10.6	August 4, 2022
10.30†	Form of Officer Non-Statutory Stock Option Agreement under 2014 Incentive Plan (Retention Awards)	10-Q	001-36352	10.7	August 4, 2022
10.31†	Form of Officer Stock Appreciation Rights Award Agreement under 2014 Incentive Plan	10-Q	001-36352	10.3	May 8, 2023
10.32†	Akebia Therapeutics, Inc. 2023 Stock Incentive Plan, as amended	8-K	001-36352	99.1	June 13, 2025
10.33†	Form of Non-Employee Director Stock Option Agreement under 2023 Stock Incentive Plan	10-Q	001-36352	10.10	August 28, 2023
10.34†	Form of Non-Employee Director Restricted Stock Unit Agreement under 2023 Stock Incentive Plan	10-Q	001-36352	10.12	August 28, 2023
10.35†	Form of Officer Stock Option Agreement under 2023 Stock Incentive Plan	10-Q	001-36352	10.11	August 28, 2023
10.36†	Form of Officer Restricted Stock Unit Agreement under 2023 Stock Incentive Plan	10-Q	001-36352	10.13	August 28, 2023
10.37†	Form of Officer Inducement Award Stock Option Agreement under 2023 Stock Incentive Plan	10-Q	001-36352	10.14	August 28, 2023

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filed Date/ Period End Date
10.38†	Form of Officer Executive Severance Agreement (Reflecting Clawback Policy)	10-K	001-36352	10.43	March 14, 2024
10.39†	Form of Officer Cash Bonus Agreement (Reflecting Clawback Policy)	10-K	001-36352	10.44	March 14, 2024
10.40†	Form of Officer Stock Option Agreement under 2023 Stock Incentive Plan (Reflecting Clawback Policy)	10-K	001-36352	10.45	March 14, 2024
10.41†	Form of Officer Restricted Stock Unit Agreement under 2023 Stock Incentive Plan (Reflecting Clawback Policy)	10-K	001-36352	10.46	March 14, 2024
10.42†*	Form of Officer Restricted Stock Unit Agreement under 2023 Stock Incentive Plan (Reflecting C-Level ESA Terms and Clawback Policy)				
10.43†*	Form of Officer Stock Option Agreement under 2023 Stock Incentive Plan (Reflecting C-Level ESA Terms and Clawback Policy)				
10.44†*	Form of Officer Restricted Stock Agreement under 2023 Stock Incentive Plan (Reflecting C-Level ESA Terms)				
10.45†*	Form of Officer Stock Option Agreement under 2023 Stock Incentive Plan (Reflecting C-Level ESA Terms)				
10.46†	Form of Officer Inducement Award Stock Option Agreement under 2023 Stock Incentive Plan (Reflecting Clawback Policy)	10-K	001-36352	10.47	March 14, 2024
10.47†	Form of Non-Officer Inducement Award Stock Option Agreement under 2023 Stock Incentive Plan	S-8	333-284590	99.2	January 30, 2025
10.48†	Keryx Biopharmaceuticals, Inc. Amended and Restated 2013 Incentive Plan	8-K	000-30929	10.1	May 27, 2016
10.49†	Keryx Biopharmaceuticals, Inc. 2018 Equity Incentive Plan	S-8	333-226005	99.1	June 29, 2018
10.50†	Form of Indemnification Agreement between Keryx Biopharmaceuticals, Inc. and its Directors and Officers	10-Q	000-30929	10.1	November 9, 2016
10.51†	Form of Employee Agreement (Confidentiality, Non-Competition, Non-Solicitation and Development Agreement) applicable to Officers	10-K	001-36352	10.56	March 26, 2019
10.52†	Keryx Biopharmaceuticals, Inc. Fourth Amended and Restated Directors Equity Compensation Plan	8-K	000-30929	10.2	May 27, 2016
10.53†	Keryx Biopharmaceuticals, Inc. Third Amended and Restated Directors Equity Compensation Plan	10-Q	000-30929	10.1	August 7, 2014
10.54†	Keryx Biopharmaceuticals, Inc. Director Non-Statutory Stock Option Award Terms and Conditions under the Third Amended and Restated Directors Equity Compensation Plan	10-K	001-36352	10.59	March 26, 2019

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filed Date/ Period End Date
10.55†	Form of Officer Retention Letter Agreement	10-Q	001-36352	10.6	May 9, 2022
10.56†	Separation Agreement with Ellen Snow, dated March 15, 2024	10-Q	001-36352	10.11	May 9, 2024
10.57!	Collaboration Agreement between Akebia Therapeutics, Inc. and Tanabe Pharma Corporation, formerly Mitsubishi Tanabe Pharma Corporation, dated December 11, 2015	10-K	001-36352	10.49	March 1, 2022
10.58#	Letter Agreement between Akebia Therapeutics, Inc. and Tanabe Pharma Corporation, formerly Mitsubishi Tanabe Pharma Corporation, dated September 26, 2017	10-Q	001-36352	10.1	November 8, 2017
10.59!	Amendment No. 1 to Collaboration Agreement, dated December 2, 2022, by and between Akebia Therapeutics, Inc. and Tanabe Pharma Corporation, formerly Mitsubishi Tanabe Pharma Corporation	10-K	001-36352	10.53	March 10, 2022
10.60!	Second Amended and Restated License Agreement, dated February 18, 2022, by and between Akebia Therapeutics, Inc. and Vifor (International) Ltd.	10-K	001-36352	10.54	March 1, 2022
10.61!	Amendment #1 to Second Amended and Restated License Agreement, dated May 3, 2024, by and between Akebia Therapeutics, Inc. and Vifor (International) Ltd.	10-Q	001-36352	10.3	August 8, 2024
10.62!	Termination and Settlement Agreement, dated July 10, 2024, by and between Akebia Therapeutics, Inc. and Vifor (International) Ltd.	10-Q	001-36352	10.4	August 8, 2024
10.63	Amended and Restated Open Market Sale Agreement, dated September 3, 2024, by and between Akebia Therapeutics, Inc. and Jefferies LLC	S-3	333-281903	1.2	September 3, 2025
10.64!	Second Amended and Restated License Agreement dated April 17, 2019, by and between Akebia Therapeutics, Inc. and Panion & BF Biotech, Inc.	10-Q	001-36352	10.1	August 8, 2019
10.65#	Amended and Restated Sub-License Agreement, dated June 8, 2009, as amended by the First Amendment thereto, dated June 12, 2013, by and between Keryx Biopharmaceuticals, Inc., Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd	10-Q	000-30929	10.1	November 7, 2017
10.66!	Master Manufacturing Services Agreement by and between Keryx Biopharmaceuticals, Inc. and Patheon Manufacturing Services LLC and certain of its affiliates, dated September 27, 2016, and related Product Agreement dated September 27, 2016, and related Product Agreement dated October 12, 2016	10-K	001-36352	10.58	March 1, 2022

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filed Date/ Period End Date
10.67!	Product Agreement, dated August 29, 2017, by and between Keryx Biopharmaceuticals, Inc. and Patheon Inc. (an affiliate of Patheon Manufacturing Services LLC) related to the Master Manufacturing Services Agreement by and between Keryx Biopharmaceuticals, Inc. and Patheon Manufacturing Services LLC and certain of its affiliates dated November 12, 2016	10-K	001-36352	10.78	March 13, 2025
10.68#	Master Manufacturing Services and Supply Agreement, dated December 20, 2017, by and between Keryx Biopharmaceuticals, Inc. and Siegfried Evionnaz SA	10-K	000-30929	10.13	February 21, 2018
10.69	Amendment No. 1 to Master Manufacturing Services and Supply Agreement, dated as of December 21, 2020, by and between Siegfried Evionnaz SA and Keryx Biopharmaceuticals, Inc.	10-K	001-36352	10.57	February 25, 2021
10.70	Amendment No. 2 to Master Manufacturing Services and Supply Agreement, dated as of January 29, 2021, by and between Siegfried Evionnaz SA and Keryx Biopharmaceuticals, Inc.	10-K	001-36352	10.58	February 25, 2021
10.71!	Amendment No. 3 to Master Manufacturing Services and Supply Agreement, dated as of February 11, 2021, by and between Siegfried Evionnaz SA and Keryx Biopharmaceuticals, Inc.	10-K	001-36352	10.59	February 25, 2021
10.72	Amendment No. 4 to Master Manufacturing Services and Supply Agreement, dated as of December 17, 2021, by and between Siegfried Evionnaz SA and Keryx Biopharmaceuticals, Inc.	10-K	001-36352	10.64	March 1, 2022
10.73!	Amendment No. 5 to Master Manufacturing Services and Supply Agreement, dated February 28, 2023, by and between Keryx Biopharmaceuticals, Inc. and Siegfried Evionnaz SA	10-Q	001-36352	10.2	May 8, 2023
10.74#	Exclusive Distribution Agreement between Keryx Biopharmaceuticals, Inc. and Cardinal Health 105, Inc., dated October 16, 2014 and First Amendment to Exclusive Distribution Agreement between Keryx Biopharmaceuticals, Inc. and Cardinal Health 105, Inc., dated April 14, 2015	10-K	001-36352	10.60	March 26, 2019
10.75!	Termination and Settlement Agreement, dated December 22, 2022, by and between Keryx Biopharmaceuticals, Inc. and BioVectra Inc.	10-K	001-36352	10.70	March 10, 2023
10.76!	Loan Agreement, dated November 11, 2019, by and among Akebia Therapeutics, Inc., Keryx Biopharmaceuticals, Inc., Biopharma Credit plc and Biopharma Credit Investments V (Master) LP	10-K	001-36352	10.62	March 12, 2020
10.77!	First Amendment and Waiver, dated February 18, 2022, by and among Akebia Therapeutics, Inc., Biopharma Credit plc, BPCR Limited Partnership and Biopharma Credit Investments V (Master) LP	10-K	001-36352	10.69	March 1, 2022

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filed Date/ Period End Date
10.78!	Second Amendment and Waiver, dated July 15, 2022, by and among Akebia Therapeutics, Inc., Biopharma Credit plc, BPCR Limited Partnership and Biopharma Credit Investments V (Master) LP	10-Q	001-36352	10.9	August 4, 2022
10.79!	Third Amendment to Loan Agreement, dated as of June 30, 2023, by and among Akebia Therapeutics, Inc., Biopharma Credit plc, BPCR Limited Partnership and Biopharma Credit Investments V (Master) LP	10-Q	001-36352	10.2	August 28, 2023
10.80!	Fourth Amendment to Loan Agreement dated as of October 31, 2023, by and among Akebia Therapeutics, Inc., BioPharma Credit PLC, BPCR Limited Partnership, and BioPharma Credit Investments V (Master) LP	10-K	001-36352	10.93	March 14, 2024
10.81!	Guaranty and Security Agreement, dated November 25, 2019, by and between Akebia Therapeutics, Inc., Keryx Biopharmaceuticals, Inc. and Biopharma Credit plc	10-K	001-36352	10.63	March 12, 2022
10.82!	Supply Agreement, dated as of March 11, 2020, by and between Akebia Therapeutics, Inc. and Patheon, Inc.	10-Q	001-36352	10.1	May 5, 2020
10.83!	Supply Agreement, dated as of April 2, 2020, by and between Akebia Therapeutics, Inc. and STA Pharmaceutical Hong Kong Limited	10-Q	001-36352	10.2	August 10, 2020
10.84!	Amendment #1 to Supply Agreement, dated as of April 15, 2021, by and between Akebia Therapeutics, Inc. and STA Pharmaceutical Hong Kong Limited	10-Q	001-36352	10.1	August 5, 2021
10.85!	Amendment #2 to the Supply Agreement, dated as of April 15, 2024, by and between Akebia Therapeutics, Inc. and STA Pharmaceutical Hong Kong Limited	10-Q	001-36352	10.2	August 8, 2024
10.86!	Amendment #3 to the Supply Agreement, dated as of August 15, 2025, by and between Akebia Therapeutics, Inc. and STA Pharmaceutical Hong Kong Limited	10-Q	001-36352	10.1	November 10, 2025
10.87!	Supply Agreement, dated February 10, 2021, by and between Akebia Therapeutics, Inc. and STA Pharmaceutical Hong Kong Limited	10-Q	001-36352	10.4	May 10, 2021
10.88!	Amendment #1 to Supply Agreement, dated October 15, 2024, by and between Akebia Therapeutics, Inc. and STA Pharmaceutical Hong Kong Limited	10-Q	001-36352	10.5	November 7, 2024
10.89!	Royalty Interest Acquisition Agreement, dated February 25, 2021, by and between Akebia Therapeutics, Inc. and HealthCare Royalty Partners IV, L.P.	10-Q	001-36352	10.5	May 10, 2021
10.90!	License Agreement, dated May 24, 2023, by and between Akebia Therapeutics, Inc. and MEDICE Arzneimittel Pütter GmbH & Co. KG	10-Q	001-36352	10.1	August 28, 2023

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filed Date/ Period End Date
10.91!*	Amendment #1 to License Agreement, dated November 12, 2025, by and between Akebia Therapeutics, Inc. and MEDICE Arzneimittel Pütter GmbH & Co. KG				
10.92!	Agreement for the Provision of a Loan Facility dated January 29, 2024 between Akebia Therapeutics, Inc. and Kreos Capital VII (UK) Limited	10-K	001-36352	10.102	March 14, 2024
10.93!	Amendment #1 to Agreement for the Provision of a Loan Facility, dated July 10, 2024, by and between Akebia Therapeutics, Inc. and Kreos Capital VII (UK) Limited	10-Q	001-36352	10.5	August 8, 2024
10.94!	Second Amendment to Agreement for the Provision of a Loan Facility, dated February 3, 2025, by and between Akebia Therapeutics, Inc. and Kreos Capital VII (UK) Limited	10-K	001-36352	10.105	March 13, 2025
10.95	Warrant Agreement dated January 29, 2024 by and between the Company and Kreos Capital VII Aggregator SCSp	10-K	001-36352	10.103	March 14, 2024
10.96!*	Asset Purchase Agreement by and between Akebia Therapeutics, Inc., Q32 Bio Inc. and Q32 Bio Operations Inc. dated November 28, 2025				
10.97!*	License Agreement by and between Cyclerion Therapeutics, Inc. and Akebia Therapeutics, Inc. dated June 3, 2021				
10.98!*	Amendment #1 to License Agreement by and between Cyclerion Therapeutics, Inc. and Akebia Therapeutics, Inc. dated December 13, 2024				
19.1	Akebia Therapeutics, Inc. Insider Trading Compliance Policy	10-K	001-36352	19.1	March 13, 2025
21.1	List of Subsidiaries	10-K	001-36352	21.1	February 25, 2021
23.1*	Consent of Ernst & Young LLP				
31.1*	Certification of Principal Executive Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended				
31.2*	Certification of Principal Financial Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended				
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. 1350				
97.1†	Akebia Therapeutics, Inc. Dodd-Frank Compensation Recovery Policy	10-K	001-36352	97.1	March 14, 2024

Exhibit Number	Description of Exhibit	Incorporated by Reference			
		Schedule/ Form	File No.	Exhibit	Filed Date/ Period End Date
101.INS*	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document)				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

* Filed, or submitted electronically, herewith

† Indicates management contract or compensatory plan

# Indicates portions of the exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment

! Indicates portions of the exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K

** The schedules to the Agreement and Plan of Merger have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish copies of such schedules to the Securities and Exchange Commission upon request by the Commission

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AKEBIA THERAPEUTICS, INC.

Date: February 26, 2026	By:	/s/ John P. Butler
		John P. Butler
		President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report was signed by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Date: February 26, 2026	By:	/s/ John P. Butler John P. Butler *Director, President and Chief Executive Officer (Principal Executive Officer)*
Date: February 26, 2026	By:	/s/ Erik J. Ostrowski Erik J. Ostrowski *Senior Vice President, Chief Financial Officer and Chief Business Officer (Principal Financial Officer)*
Date: February 26, 2026		/s/ Richard C. Malabre Richard C. Malabre *Senior Vice President, Chief Accounting Officer (Principal Accounting Officer)*
Date: February 26, 2026	By:	/s/ Adrian Adams Adrian Adams *Chairperson and Director*
Date: February 26, 2026	By:	/s/ Ron Frieson Ron Frieson *Director*
Date: February 26, 2026	By:	/s/ Steven C. Gilman Steven C. Gilman *Director*
Date: February 26, 2026	By:	/s/ Michael Rogers Michael Rogers *Director*
Date: February 26, 2026	By:	/s/ Cynthia Smith Cynthia Smith *Director*
Date: February 26, 2026	By:	/s/ Myles Wolf Myles Wolf *Director*
Date: February 26, 2026	By:	/s/ LeAnne M. Zumwalt LeAnne M. Zumwalt *Director*

Exhibit 10.10

180 CITYPOINT
WALTHAM, MASSACHUSETTS

Lease Dated January 26, 2026 ("**Execution Date**")

THIS INSTRUMENT IS AN INDENTURE OF LEASE (this "**Lease**") in which the Landlord and the Tenant are the parties hereinafter named, and which relates to space in the building known as 180 CityPoint and having an address at 180 Third Avenue, Waltham, Massachusetts 02451.

The parties to this instrument hereby agree with each other as follows:

ARTICLE I

Reference Data

1.1 Subjects Referred To

Each reference in this Lease to any of the following subjects shall be construed to incorporate the data stated for that subject in this Article:

Landlord:	BP THIRD AVENUE LLC, a Delaware limited liability company
Present Mailing Address of Landlord:	c/o Boston Properties Limited Partnership 800 Boylston Street, Suite 1900 Boston, Massachusetts 02199-8103
Landlord's Construction Representative:	Name/Email: [**]
Tenant:	AKEBIA THERAPEUTICS, INC., a Delaware corporation

Mailing Address of Tenant:	Prior to Phase I Commencement Date: Akebia Therapeutics, Inc. 245 First Street, Suite 1400 Cambridge, MA 02142 Attn: General Counsel Following Phase I Commencement Date: Akebia Therapeutics, Inc. 180 Third Avenue Waltham, MA 02451 Attn: General Counsel In either case, with a copy to: WilmerHale 60 State Street Boston, MA 02109 Attn: Brett M. Jackson
Tenant's Email Address for Information Regarding Billings and Statements:	[**]
Tenant's Email Address for Insurance Matters:	[**]
Tenant's Construction Representative:	Name/Email: [**]
Term or Lease Term:	The period beginning on the Phase I Commencement Date and ending on the last day of the eighty-fourth (84th) calendar month immediately following the Phase I Commencement Date (said period being sometimes called the "**Original Term**"), unless extended or sooner terminated as hereinafter provided.
Extension Option:	One (1) period of five (5) years as provided in and on the terms set forth in Section 3.2 hereof.

Lease Year:	A period of twelve (12) consecutive calendar months, commencing on the first day of January in each year, except that the first Lease Year of the Lease Term hereof shall be the period commencing on the Phase I Commencement Date and ending on the succeeding December 31, and the last Lease Year of the Lease Term hereof shall be the period commencing on January 1 of the calendar year in which the Lease Term ends, and ending with the date on which the Lease Term ends.
Rent Year:	Any twelve (12) month period during the Term of the Lease commencing as of the Phase I Commencement Date, or as of any anniversary of the Phase I Commencement Date, except that if the Phase I Commencement Date does not occur on the first day of a calendar month, then (i) the first Rent Year shall further include the partial calendar month in which the first anniversary of the Phase I Commencement Date occurs, and (ii) the remaining Rent Years shall be the successive twelve-(12)-month periods following the end of such first Rent Year.
Phase I Commencement Date:	The earlier to occur of (i) the date on which Landlord's Office Premises Work has been "substantially completed" and the Office Premises are "ready for occupancy" (as such terms are defined in Exhibit B-1 hereof) or (ii) the date upon which Tenant occupies all or any portion of the Office Premises for its beneficial use. The Phase I Commencement Date is also sometimes referred to herein as the "Commencement Date".
Estimated Phase I Commencement Date:	September 1, 2026
Phase II Commencement Date:	The earlier to occur of (i) the date on which Landlord's Lab Premises Work has been "substantially completed" and the Lab Premises are "ready for occupancy" (as such terms are defined in Exhibit B-1 hereof) or (ii) the date upon which Tenant occupies all or any portion of the Lab Premises for its beneficial use.
Estimated Phase II Commencement Date:	November 1, 2026
Premises:	Prior to the Phase II Commencement Date, the Premises shall consist of the Office Premises only. From and after the Phase II Commencement Date, the Premises shall consist of the Office Premises and the Lab Premises, collectively.

Office Premises:	A portion of the second (2nd) floor of the Building containing 28,518 rentable square feet, in accordance with the floor plan annexed hereto as Exhibit D and incorporated herein by reference.
Lab Premises:	A portion of the third (3rd) floor of the Building containing 14,956 rentable square feet, in accordance with the floor plan annexed hereto as Exhibit D and incorporated herein by reference.
Rentable Floor Area of the Premises:	43,474 rentable square feet.
Number of Parking Privileges:	Subject to the terms and conditions of Article X below, One Hundred Eight (108) parking privileges (i.e., two and one-half (2.5) parking privileges for each 1,000 square feet of the Rentable Floor Area of the Premises, as the same may be expanded pursuant to Section 16.33 below) at no cost to Tenant and for the duration of the Term (as the same may be extended in accordance with this Lease). Such parking privileges shall be on an unreserved basis in the parking structure located beneath the Building.

Exhibit 10.10

Annual Fixed Rent:

(a) During the Original Term of this Lease, Annual Fixed Rent shall be payable by Tenant as set forth below.

Office Premises:

Rent Years
Rate PSF
Annual Rate

Rent Year 1
$31.50
$898,317.00

Rent Year 2
$32.50
$926,835.00

Rent Year 3
$33.50
$955,353.00

Rent Year 4
$34.50
$983,871.00

Rent Year 5
$35.50
$1,012,389.00

Rent Year 6
$36.50
$1,040,907.00

Rent Year 7
$37.50
$1,069,425.00

Lab Premises:

Rent Years
Rate PSF
Annual Rate

Rent Year 1
$70.00
$1,046,920.00

Rent Year 2
$72.10
$1,078,327.60

Rent Year 3
$74.26
$1,110,632.56

Rent Year 4
$76.49
$1,143,984.44

Rent Year 5
$78.79
$1,178,383.24

Rent Year 6
$81.15
$1,213,679.40

Rent Year 7
$83.58
$1,250,022.48

(b) During the Extended Term (if the Extension Option is exercised), as determined pursuant to Section 3.2.

Tenant Electricity:	See Section 5.2.
Additional Rent:	All charges and other sums payable by Tenant as set forth in this Lease, in addition to Annual Fixed Rent.
Total Rentable Floor Area of the Building:	329,195 square feet.
Building:	For the purposes of this Lease, the Building shall mean the building commonly known as 180 CityPoint and numbered 180 Third Avenue, Waltham, Massachusetts, as the same may be altered, expanded, reduced or otherwise changed by Landlord from time to time in accordance with the terms of this Lease.
Property:	The land described on Exhibit A and the Building, together with all common areas, parking areas, garage, and structures, located thereon.
CityPoint Project:	That certain development project known as the CityPoint Project, containing the Property and any other buildings from time to time owned or controlled by Landlord or affiliates of Landlord considered to be part of the CityPoint Project and located on Totten Pond Road, Third Avenue, Fourth Avenue or Fifth Avenue in Waltham, Massachusetts.
180 CityPoint Special Permit:	That certain Special Permit granted by the Waltham City Council by Order Number 33110 dated August 4, 2014 and recorded in Middlesex South Registry of Deeds in Book 64384, Page 443 which governs the development and uses of the Building, as the same may be extended and/or modified from time to time.

Permitted Use:	Office Premises: Subject to Legal Requirements (as such term is defined in Exhibit B-1 hereof), general office use and other ancillary uses related to the foregoing. Lab Premises: Subject to Legal Requirements, research, development and laboratory use together with general office uses related to the same, and other ancillary uses related to the foregoing.
Broker:	Colliers International
Security Deposit:	$810,515.00

1.2 Table of Articles and Sections

1.3 Exhibits

The following Exhibits attached hereto are a part of this Lease, are incorporated herein by reference, and are to be treated as a part of this Lease for all purposes. Undertakings contained in such Exhibits are agreements on the part of Landlord and Tenant, as the case may be, to perform the obligations stated therein to be performed by Landlord and Tenant, as and where stipulated therein.

Exhibit A -- Legal Description of Property

Exhibit B-1 -- Work Agreement

Exhibit B-2 -- Turnkey Office Matrix

Exhibit B-3 -- Turnkey Lab Matrix

Exhibit B-4 -- Office Test Fit Plan

Exhibit B-5 -- Lab Test Fit Plan

Exhibit C-1 -- Landlord's Services

Exhibit C-2 -- Base Building Specifications

Exhibit D -- Floor Plans

Exhibit E -- Form of Declaration Affixing the Commencement Date of Lease

Exhibit F -- Tenant's Monument Signage

Exhibit G -- Intentionally Omitted

Exhibit H -- Broker Determination of Prevailing Market Rent

Exhibit I -- List of Mortgages

Exhibit J -- Form of Letter of Credit

Exhibit K -- Form of Certificate of Insurance

Exhibit L -- Control Area Requirements

Exhibit M -- ROFO Premises

Exhibit N -- Tenant's Chemical Storage Room

ARTICLE II

Premises

2.1 Demise and Lease of Premises

Landlord hereby demises and leases to Tenant, and Tenant hereby leases from Landlord, the Premises in the Building, excluding exterior faces of exterior walls, the common stairways and stairwells, elevators and elevator walls, mechanical rooms, electric and telephone closets, janitor closets, and pipes, ducts, shafts, conduits, wires and appurtenant fixtures serving exclusively or in common other parts of the Building, and if the Premises includes less than the entire rentable

area of any floor, excluding the common corridors, elevator lobbies and restrooms located on such floor. The Rentable Floor Area of the Premises and the Total Rentable Floor Area of the Building are agreed to be the amounts set forth in Section 1.1 above. From and after the Commencement Date and until the end of the Term, Tenant shall have access to the Premises, any freight elevators in the Building (at no additional cost or expense except as provided for in the last sentence of this paragraph) and the Building loading dock twenty-four (24) hours a day, seven (7) days a week, subject to Landlord's reasonable Building security requirements, Legal Requirements, reasonable rules and regulations now or hereafter made by Landlord of which Tenant has been given written notice, the terms of this Lease, and Force Majeure (as defined in Section 16.31). Without limiting the generality of the foregoing, any deliveries to the Building loading dock that are related to Tenant's initial move-in to the Premises or that are anticipated to take more than one (1) hour during normal business hours should be scheduled in advance with Landlord's property manager, but all other Tenant deliveries to the Building loading dock do not need to be scheduled and will be self-managed by Tenant. Landlord's costs associated with the freight elevators and loading dock shall be included in Landlord's Operating Expenses in accordance with Section 7.4 below.

2.2 Appurtenant Rights and Reservations.

(A) Subject to Landlord's right to change or alter any of the following in its discretion as herein provided, Tenant shall have, as appurtenant to the Premises, the non-exclusive right to use in common with others, but not in a manner or extent that would materially interfere with the normal operation and use of the Building as a multi-tenant office/research/laboratory building and subject to reasonable rules of general applicability to tenants of the Building from time to time made by Landlord of which Tenant is given notice: (a) the common lobbies, corridors, stairways, and elevators of the Building, and the pipes, ducts, shafts, conduits, wires and appurtenant meters and equipment serving the Premises in common with others, (b) the loading areas serving the Building and the common walkways and driveways necessary for access to the Building, (c) if the Premises include less than the entire rentable floor area of any floor, the common restrooms, corridors and elevator lobby of such floor and (d) the plazas and other common areas of the Property as Landlord makes the same available to tenants of the Building from time to time; and no other appurtenant rights and easements. As of the date hereof, the following telecommunication providers have been preapproved by Landlord and are permitted access to the Building: Verizon, AT&T, Comcast, CrownCastle and RCN. Tenant shall have the right to contract separately with a telecommunication provider not identified in the preceding sentence and Landlord will not unreasonably withhold consent to any request by Tenant to allow such provider to have access to the Building or to the Premises, provided that Landlord may condition such access, without limitation of the foregoing, on Landlord's reasonable approval of the identity of the service provider, its execution of an access and/or easement agreement reasonably satisfactory to Landlord and, should telecommunications services be furnished by such service provider to both Tenant and other tenants and occupants in the Building, then subject to the payment to Landlord by the service provider of fees assessed by Landlord in its reasonable discretion.

(B) Landlord reserves for its benefit the right from time to time, without material interference with Tenant's use: (a) to install, use, maintain, repair, replace and relocate for service to the Premises and other parts of the Building, or either, pipes, ducts, conduits, wires and appurtenant fixtures, wherever located in the Premises or the Building, and (b) to alter or relocate any other common facility, provided that substitutions are substantially equivalent or better. Installations, replacements and relocations referred to in clause (a) above shall be located so far as practicable in the central core area of the Building, above ceiling surfaces, below floor surfaces or within perimeter walls of the Premises. Except in the case of emergencies or for normal cleaning and maintenance operations, Landlord agrees to give Tenant reasonable advance notice (which notice may be by e-mail) (it being acknowledged that at least 48 hours' advance notice is reasonable) of any of the foregoing activities which require work in the Premises. In all cases, Landlord shall use commercially reasonable efforts to minimize or avoid inconvenience to Tenant in connection with Landlord's exercise of the rights granted herein (consistent with the nature of the rights being exercised).

(C) Landlord reserves and accepts for its benefit all rights of ownership and use in all respects outside the Premises, including without limitation, the Building and all other structures and improvements and plazas and common areas of the Property, except that at all times during the Term of this Lease Tenant shall have a reasonable means of access from a public street to the Premises and the requisite Number of Parking Privileges (subject to the provisions of Section 10.1 below). Without limitation of the foregoing reservation of rights by Landlord, it is understood that in its sole discretion Landlord shall have the right to change and rearrange the plazas and other common areas, to change, relocate and eliminate facilities therein, to erect new buildings thereon, to permit the use of or lease all or part thereof for exhibitions and displays and to sell, lease or dedicate all or part thereof to public use; and further that Landlord shall have the right to make changes in, additions to and eliminations from the Building and other structures and improvements on the Property, the Premises excepted; provided however that Tenant, its employees, agents, clients, customers, and invitees shall at all times, subject to emergencies, Landlord's reasonable Building security requirements, Force Majeure, and the terms and conditions of this Lease, have (i) reasonable access to the Building, the Premises, and the loading dock serving the Premises, and (ii) the requisite Number of Parking Privileges (subject to the provisions of Section 10.1 below). In all cases, Landlord shall use commercially reasonable efforts to minimize or avoid interference with Tenant's use and enjoyment of the Premises in connection with Landlord's exercise of the rights granted herein (consistent with the nature of the rights being exercised).

ARTICLE III

Lease Term and Extension Options

3.1 Term

The Term of this Lease shall be the period specified in Section 1.1 hereof as the "**Lease Term**," unless sooner terminated or extended as herein provided.

As soon as may be convenient after the Phase I Commencement Date and the Phase II Commencement Date have been determined, Landlord and Tenant agree to join with each other

in the execution, in the form of Exhibit E hereto, of a written Declaration Affixing the Commencement Date of Lease in which the Phase I Commencement Date and the Phase II Commencement Date and specified Lease Term of this Lease shall be stated.

3.2 Extension Option

(A) On the conditions (which conditions Landlord may waive by written notice to Tenant) that, both at the time of exercise of the herein described option to extend and as of the commencement of the Extended Term: (i) there exists no "**Event of Default**" (defined in Section 15.1), (ii) this Lease is still in full force and effect, and (iii) Tenant has neither assigned this Lease nor sublet more than fifty percent (50%) of the Rentable Floor Area of the Premises (except for an assignment or subletting permitted without Landlord's consent under Section 12.5 hereof), then Tenant shall have the right (the "**Extension Option**") to extend the Term hereof upon all the same terms, conditions, covenants and agreements herein contained (except for the Annual Fixed Rent which shall be adjusted during the option period as hereinbelow set forth and except that there shall be no further option to extend) for one (1) period of five (5) years as hereinafter set forth. Such option period is sometimes herein referred to as the "**Extended Term**." Notwithstanding any implication to the contrary Landlord has no obligation to make any additional payment to Tenant in respect of any construction allowance or the like or to perform any work to the Premises as a result of the exercise by Tenant of the Extension Option.

(B) If Tenant desires to exercise its Extension Option, then Tenant shall give notice ("**Exercise Notice**") to Landlord, not earlier than twenty (20) months nor later than twelve (12) months prior to the expiration of the Term of this Lease exercising the Extension Option. If Tenant shall not have timely given Tenant's Exercise Notice on or before the date twelve (12) months prior to the expiration of the Term of this Lease, then such Extension Option shall be void and of no further force and effect. Promptly after Landlord's receipt of the Exercise Notice, Landlord shall provide Landlord's quotation to Tenant of a proposed Annual Fixed Rent for the Extended Term ("**Landlord's Rent Quotation**"); provided, however, that in no event shall Landlord be obligated to provide Landlord's Rent Quotation more than twelve (12) months prior to the expiration of the Term of this Lease. If at the expiration of thirty (30) days after Tenant receives Landlord's Rent Quotation (the "**Negotiation Period**"), Landlord and Tenant have not reached agreement on a determination of an Annual Fixed Rent for such Extended Term and executed a written instrument extending the Term of this Lease pursuant to such agreement, then Tenant shall have the right, for thirty (30) days following the expiration of the Negotiation Period, to make a request to Landlord for a broker determination (the "**Broker Determination**") of the Prevailing Market Rent (as defined in Exhibit H) for such Extended Term, which Broker Determination shall be made in the manner set forth in Exhibit H. If Tenant timely shall have requested the Broker Determination, then the Annual Fixed Rent for such Extended Term shall be the Prevailing Market Rent as determined by the Broker Determination. If Tenant does not timely request the Broker Determination, then the Annual Fixed Rent during the Extended Term shall be equal to Landlord's Rent Quotation.

(C) Upon the giving of the Exercise Notice by Tenant to Landlord exercising Tenant's option to extend the Lease Term in accordance with the provisions of Section 3.2 (B) above, then this Lease and the Lease Term hereof shall automatically be deemed extended, for the Extended

Term, without the necessity for the execution of any additional documents, except that Landlord and Tenant agree to enter into an instrument in writing setting forth the Annual Fixed Rent for the Extended Term as determined in the relevant manner set forth in this Section 3.2; and in such event all references herein to the Lease Term or the Term of this Lease shall be construed as referring to the Lease Term, as so extended, unless the context clearly otherwise requires, and except that there shall be no further option to extend the Lease Term.

ARTICLE IV

Condition of Premises; Signage

4.1 Preparation of Premises

The condition of the Premises upon Landlord's delivery along with any work to be performed by either Landlord or Tenant shall be as set forth in the Work Agreement attached hereto as Exhibit B-1 and made a part hereof.

4.2 Signage

A. Building Lobby Directory. Landlord shall provide Tenant with a listing of Tenant's name on any multi-tenant directories in the lobby of the Building. The initial listings of Tenant's name shall be at Landlord's cost and expense. Any changes, replacements or additions by Tenant to such directories shall be at Tenant's sole cost and expense.

B. Elevator Lobby Signage. Tenant shall have the right to list Tenant's name on any multi-tenant directories in the elevator lobbies on the second (2^{nd}) and third (3^{rd}) floors of the Building. The initial listings of Tenant's name shall be at Landlord's cost and expense. Any changes, replacements or additions by Tenant to such directories shall be at Tenant's sole cost and expense.

C. Suite Entry Signage. Tenant may, at its sole cost and expense, install signage containing Tenant's name and/or logo at the entrances of the Office Premises and the Lab Premises ("**Suite Entry Signage**"). The location, size, design, materials, proportions and method of installation of any such Suite Entry Signage shall be subject to the prior approval of Landlord, such approval not to be unreasonably withheld, conditioned, or delayed. Tenant shall maintain such Suite Entry Signage in good condition. The installation, replacement, and removal of such Suite Entry Signage shall be performed at Tenant's sole cost and expense in accordance with the provisions of this Lease applicable to Alterations. Upon the expiration or earlier termination of the Term of this Lease, Tenant shall remove such Suite Entry Signage and repair any damage caused thereby.

D. Monument Signage. Tenant shall have the right, at its sole cost and expense (but with no separate charge by Landlord for the signage rights themselves), to have its name and corporate logo on a sign panel ("**Sign Panel**") on any multi-tenant monument signage on the Property that identifies tenants of the Building (a "**Monument Sign**"). Tenant's right to a Sign Panel on any Monument Sign shall be non-exclusive. The location and placement of Tenant's Sign Panel on the Monument Sign is shown on Exhibit F hereto. The initial

location, design, proportions and color of any Sign Panel shall all be subject to the prior approval of Landlord, which approval shall not be unreasonably withheld, conditioned or delayed. Landlord shall reasonably cooperate with Tenant in obtaining any local approvals required for the Sign Panel, provided that Landlord shall not be obligated to incur any cost or expense in connection therewith. Notwithstanding the foregoing provisions of this Section 4.2(D) to the contrary, upon the first to occur of (x) the expiration of the Term of this Lease, (y) the date on which the Term of this Lease is terminated due to an Event of Default pursuant to the terms and provisions of Section 15.2 below and (z) such time as Tenant has assigned this Lease or subleased more than fifty percent (50%) of the Rentable Floor Area of the Premises (excluding assignments and subleases permitted without Landlord's consent in accordance with Section 12.5 below), then Tenant shall, at its cost and expense, remove the Sign Panel and restore all damage to the Property caused by the installation and/or removal of such Sign Panel. Such removal and restoration shall be performed in accordance with the terms and conditions governing alterations pursuant to Article IX below. The right to the Sign Panel granted pursuant to this Section 4.2(D) is personal to Akebia Therapeutics, Inc. and may not be transferred to any third party (other than to an assignee permitted without Landlord's consent under Section 12.5 below; subject, however, to Landlord's approval of the logo and brand proposed to be displayed on the Sign Panel, which approval shall not be unreasonably withheld).

ARTICLE V

Annual Fixed Rent and Electricity

5.1 Fixed Rent

Tenant agrees to pay to Landlord, (1)(a) commencing on the Phase I Commencement Date with respect to the Office Premises (and commencing on the Phase II Commencement Date with respect to the Lab Premises), and thereafter monthly, in advance, on the first business day of each and every calendar month during the Original Term, a sum equal to one twelfth ($1/12^{th}$) of the Annual Fixed Rent specified in Section 1.1, and (b) commencing on the Phase I Commencement Date with respect to the Office Premises (and commencing on the Phase II Commencement Date with respect to the Lab Premises), and thereafter monthly, in advance, on the first day of each and every calendar month during the Original Term, an amount reasonably estimated by Landlord from time to time to cover Tenant's monthly payments for electricity under Section 5.2 hereinbelow, and (2) on the first day of each and every calendar month during the Extended Term (if exercised), a sum equal to (a) one twelfth ($1/12^{th}$) of the Annual Fixed Rent as determined in Section 3.2 for the Extended Term, plus (b) an amount reasonably estimated by Landlord from time to time to cover Tenant's monthly payments for electricity under Section 5.2 hereinbelow. Until notice of some other designation is given, Annual Fixed Rent and all other charges for which provision is herein made shall be paid by remittance to or for the order of BP Third Avenue LLC by one of the three following methods, chosen by Tenant from time to time in its discretion:

(i) Via VersaPay:

BXP's on-line Tenant Portal, for which an invite will be sent to Tenant from the VersaPay platform from the email address noreply@versapay.com (please contact Landlord at ARDept@bxp.com with any inquiries respecting VersaPay).

(ii) By ACH Transfer:

Bank Name: Bank of America, Dallas, TX
Routing #: 111 000 012
Account #: 3756454460
Account Name: Boston Properties Limited Partnership
Reference: 180 Third Avenue/Tenant Name

(iii) By U.S. Mail:

P.O. Box 3557
Boston, Massachusetts 02241-3557

All remittances received by Landlord, or any agent or designated recipient of Landlord (including, without limitation, Boston Properties Limited Partnership), shall be treated as payment to Landlord. Annual Fixed Rent for any partial month shall be paid by Tenant to Landlord at such rate on a pro rata basis, and, if the Phase I Commencement Date or the Phase II Commencement Date (as the case may be) shall be other than the first day of a calendar month, the first payment of Annual Fixed Rent which Tenant shall make to Landlord shall be a payment equal to a proportionate part of such monthly Annual Fixed Rent for the partial month from the Phase I Commencement Date or the Phase II Commencement Date (as the case may be) to the first day of the succeeding calendar month.

Additional Rent payable by Tenant on a monthly basis, as elsewhere provided in this Lease, likewise shall be prorated, and the first payment on account thereof shall be determined in similar fashion and shall commence on the Phase I Commencement Date with respect to the Office Premises (and the Phase II Commencement Date with respect to the Lab Premises) and other provisions of this Lease calling for monthly payments shall be read as incorporating this undertaking by Tenant.

The Annual Fixed Rent and all other charges for which provision is made in this Lease shall be paid by Tenant to Landlord without setoff, deduction or abatement except as otherwise specifically set forth in this Lease.

5.2 Electric Charges

The parties acknowledge that, as part of Landlord's Work, Landlord, at its sole cost and expense, will be installing a check meter(s) that measures all electricity used in connection with the Premises. Landlord will cause such check meter(s) to be read periodically to determine

electricity consumption measured thereby and the costs thereof. The check meter(s) will be exclusive to the Premises. Commencing on the Phase I Commencement Date with respect to the Office Premises (and the Phase II Commencement Date with respect to the Lab Premises), Tenant shall pay to Landlord, as Additional Rent, all costs associated with Tenant's electricity consumed in connection with the Premises as indicated by such check meter. Tenant shall pay on account of the electrical charges described in the preceding sentence, at the time that monthly installments of Annual Fixed Rent are due and payable, as Additional Rent, an amount equal to 1/12th (prorated for any partial month) of the amount reasonably estimated by Landlord from time to time as the annual cost thereof. Not later than one hundred twenty (120) days after the end of the first calendar year or fraction thereof ending December 31 and of each succeeding calendar year during the Term or fraction thereof at the end of the Term, Landlord shall render Tenant a reasonably detailed accounting showing for the preceding calendar year, or fraction thereof, as the case may be, the actual costs of electricity used by the Premises as measured by the check meter(s) serving the Premises. Said statement to be rendered to Tenant also shall show for the preceding year or fraction thereof, as the case may be, the amount already paid by Tenant on account of electricity, and the amount remaining due from, or overpaid by, Tenant for the year or other period covered by the statement. Any overpayment disclosed by an annual statement shall be credited against the next installment(s) of Annual Fixed Rent due under this Lease, or if the Term has ended, then such overpayment shall be reimbursed to Tenant together with such statement. Any underpayment disclosed by an annual statement shall be paid by Tenant to Landlord within thirty (30) days after receipt of such statement. Further, Landlord may send periodic statements during any calendar year showing, for the preceding billing period(s), the costs of furnishing electricity to the Premises. If such periodic, mid-calendar year statements show that Tenant's actual usage of electricity is greater or less than the preceding calendar year's actual usage upon which Tenant's estimated payments are then being based, then Landlord may reasonably adjust such estimated payments accordingly for the remainder of such calendar year (with the same true-up process set forth above to occur at the end of the applicable calendar year).

ARTICLE VI

Taxes

6.1 Definitions

With reference to the real estate taxes referred to in this Article VI, it is agreed that terms used herein are defined as follows:

(a) "**Tax Year**" means the 12-month period beginning July 1 each year during the Lease Term or if the appropriate Governmental tax fiscal period shall begin on any date other than July 1, such other date.

(b) "**Landlord's Tax Expenses Allocable to the Premises**" means the same proportion of Landlord's Tax Expenses as Rentable Floor Area of Tenant's Premises bears to the sum of the Total Rentable Floor Area of the Building and the rentable floor area of any other buildings on the Property from time to time.

(c) "**Landlord's Tax Expenses**" with respect to any Tax Year means the aggregate "real estate taxes" (hereinafter defined) with respect to that Tax Year reduced by any net abatement receipts with respect to that Tax Year.

(d) "**Real estate taxes**" means all taxes and special assessments of every kind and nature and user fees and other like fees assessed by any Governmental authority (including, but not limited to, any tax, assessment or charge resulting from the creation of a special improvement district) on, or reasonably allocable to the Building or the Property which Landlord shall be obligated to pay for because of or in connection with the ownership, leasing or operation of the Building or the Property (including without limitation, if applicable, the excise prescribed by Massachusetts General Laws (Ter Ed) Chapter 121A, Section 10 and amounts in excess thereof paid to the City of Waltham pursuant to agreement between Landlord and the City), and reasonable expenses of and fees for any formal or informal proceedings for negotiation or abatement of taxes. The amount of special taxes or special assessments to be included shall be limited to the amount of the installment (plus any interest other than penalty interest payable thereon) of such special tax or special assessment required to be paid during the year in respect of which such taxes are being determined. There shall be excluded from such taxes all income, estate, succession, inheritance, transfer, gift, capital stock or any income taxes arising out of or related to ownership and operation of income-producing real estate, or any excise taxes imposed upon Landlord based upon gross or net rentals or other income received by it or any increase in taxes to the extent resulting solely from Landlord's sale of, or otherwise transfer of its interest in, the Property; provided, however, that if at any time during the Lease Term the present system of ad valorem taxation of real property shall be changed so that in lieu of, or in addition to, the whole or any part of the ad valorem tax on real property, there shall be assessed on Landlord a capital levy or other tax on the gross rents received with respect to the Building or the Property, or a Federal, State, County, Municipal, or other local income, franchise, excise or similar tax, assessment, levy or charge (distinct from any now in effect in the jurisdiction in which the Property is located) measured by or based, in whole or in part, upon any such gross rents, then any and all of such taxes, assessments, levies or charges, to the extent so measured or based, shall be deemed to be included within the term "real estate taxes" but only to the extent that the same would be payable if the Building, were the only property of Landlord. Notwithstanding the foregoing, "real estate taxes" shall not include and Tenant shall not be required to pay any portion of any tax or assessment expense or any increase therein (a) levied on Landlord's rental income, unless such tax or assessment is imposed in lieu of real property taxes as set forth above; (b) in excess of the amount which would be payable if such tax or assessment expense were paid in installments over the longest permitted term; or (c) imposed on land and improvements other than the Property.

(e) If during the Lease Term the Tax Year is changed by applicable law to less than a full 12-month period, the Landlord's Tax Expenses and Landlord's Tax Expenses Allocable to the Premises shall each be proportionately reduced.

6.2 Tenant's Share of Real Estate Taxes

Commencing as of the Phase I Commencement Date with respect to the Office Premises (and as of the Phase II Commencement Date with respect to the Lab Premises), Tenant shall pay to Landlord, as Additional Rent, the amount of Landlord's Tax Expenses Allocable to the Premises. Such payments shall be made monthly at the time and in the fashion herein provided for the payment of Annual Fixed Rent. The amount so to be paid to Landlord shall be an amount from time to time reasonably estimated by Landlord to be sufficient to provide Landlord, in the aggregate, a sum equal to Landlord's Tax Expenses Allocable to the Premises, at least ten (10) days before the day on which tax payments by Landlord would become delinquent.

Not later than ninety (90) days after Landlord's Tax Expenses Allocable to the Premises are determinable for the first such Tax Year or fraction thereof and for each succeeding Tax Year or fraction thereof during the Lease Term, Landlord shall render Tenant a statement in reasonable detail certified by a representative of Landlord showing for the preceding year or fraction thereof, as the case may be, real estate taxes allocated to the Building, abatements and refunds, if any, of any such taxes and assessments, reasonable expenditures incurred in obtaining such abatement or refund (recognizing that such expenses may be on a contingency fee basis), the amount of Landlord's Tax Expenses Allocable to the Premises, the amount thereof already paid by Tenant and the amount thereof overpaid by, or remaining due from, Tenant for the period covered by such statement. Within thirty (30) days after the receipt of such statement, Tenant shall pay any sum remaining due. Any balance shown as due to Tenant shall be credited against Annual Fixed Rent next due, or refunded to Tenant within thirty (30) days of the delivery of such statement if the Lease Term has then expired and Tenant has no further monetary or material non-monetary obligation to Landlord (including, without limitation, any obligations with respect to surrender of the Premises). Reasonable expenditures for legal fees and for other expenses incurred in obtaining an abatement or refund may be charged against the abatement or refund before the adjustments are made for the Tax Year (recognizing that such expenses may be on a contingency fee basis). Only Landlord shall have the right to institute tax reduction or other proceedings to reduce real estate taxes or the valuation of the Building and the Property.

To the extent that real estate taxes shall be payable to the taxing authority in installments with respect to periods less than a Tax Year, the statement to be furnished by Landlord shall be rendered and payments made on account of such installments within thirty (30) days after the receipt of an invoice therefor.

ARTICLE VII

Landlord's Repairs and Services and Tenant's Escalation Payments

7.1 Structural Repairs

Except for (a) normal and reasonable wear and use and (b) damage caused by fire or casualty and by eminent domain, Landlord shall, throughout the Lease Term, subject to provisions for reimbursement by Tenant as contained in Section 7.5, keep and maintain, or cause to be kept and maintained, in good order, condition and repair the following portions of the Building: the structural portions of the roof, the exterior and load bearing walls, the foundation, the structural columns and floor slabs and other structural elements of the Building and the parking garage located beneath the Building; provided however, that Tenant shall pay to Landlord, as Additional Rent, the cost of any and all such repairs which may be required as a result of repairs, alterations, or installations made by Tenant or any subtenant, assignee, licensee or concessionaire of Tenant or any agent, servant, employee or contractor of any of them or to the extent of any loss, destruction or damage caused by the omission or negligence of Tenant, any assignee or subtenant or any agent, servant, employee, customer, visitor or contractor of any of them.

7.2 Other Repairs to be Made by Landlord

Except for (a) normal and reasonable wear and use and (b) damage caused by fire or casualty and by eminent domain, and except as otherwise provided in this Lease, and subject to provisions for reimbursement by Tenant as contained in Section 7.5, Landlord agrees to keep and maintain, or cause to be kept and maintained, in good order, condition and repair the common areas and facilities of the Building (and other portions of the Property, including all paved areas and landscaped areas from time to time in existence), including the Base Building (as hereinafter defined in Section 11.4(b)), and all heating, ventilating, air conditioning, plumbing and other Building systems equipment servicing the Premises (including all lines, pipes, wires, conduits and the like, except to the extent serving the Premises exclusively or installed by Tenant or for or on behalf of Tenant by any third party), except that Landlord shall in no event be responsible to Tenant for (a) the condition of glass in and about the Premises (other than for glass in exterior walls for which Landlord shall be responsible unless the damage thereto is attributable to Tenant's negligence or misuse, in which event the responsibility therefor shall be Tenant's), or (b) any condition in the Premises or the Building caused by any act or neglect of Tenant or any agent, employee, contractor, assignee, subtenant, licensee, concessionaire or invitee of Tenant. Without limitation, Landlord shall not be responsible to make any improvements or repairs to the Building or the Premises other than as expressly provided in Section 7.1 or in this Section 7.2, unless expressly otherwise provided in this Lease (including, without limitation, in Exhibit B-1 hereof).

7.3 Services to be Provided by Landlord

In addition, and except as otherwise provided in this Lease and subject to (i) provisions for reimbursement by Tenant as contained in Section 7.5, and (ii) Tenant's responsibilities in regard to electricity as provided in Section 5.2, Landlord agrees to furnish services, utilities, facilities and supplies as set forth in said Exhibit C-1 equal in quality comparable to those customarily

provided by landlords in similar high quality office/research/laboratory buildings in the Central Suburban 128 Market. In addition, Landlord agrees to furnish, at Tenant's expense, reasonable additional Building operation services which are usual and customary in similar quality office/research/laboratory buildings in the Central Suburban 128 Market, and such additional special services as may be mutually agreed upon by Landlord and Tenant, upon reasonable and equitable rates from time to time established by Landlord. Tenant agrees to pay to Landlord, as Additional Rent, the cost of any such additional Building services requested by Tenant and for the cost of any additions, alterations, improvements or other work performed by Landlord in the Premises at the request of Tenant within thirty (30) days after being billed therefor.

Notwithstanding anything contained in this Lease to the contrary, Landlord shall have no obligation to provide Tenant with cleaning, janitorial or trash removal services to any laboratory portion of the Premises (it being understood and agreed that Tenant shall directly obtain such services on its own behalf and at its sole cost and expense in accordance with Section 11.6 below).

Landlord shall provide a dumpster and/or compactor at the Building loading dock for the use by tenants in the Building for the disposal of non-biohazard material. All costs incurred by Landlord in connection with such dumpster and/or compactor shall be included in Landlord's Operating Expenses, but there shall be no additional charge in connection with Tenant's use of such dumpster and/or compactor. In no event may Tenant dispose of any Hazardous Materials with such trash or in such dumpster and/or compactor (it being acknowledged that Tenant shall separately arrange for the transportation and disposal of Hazardous Materials at its own expense in compliance with applicable Environmental Laws).

7.4 Operating Expenses Defined

With reference to the operating expenses referred to in this Article VII, it is agreed that terms used herein are defined as follows:

(a) "**Operating Expenses Allocable to the Premises**" means the same proportion of Landlord's Operating Expenses (as hereinafter defined) as Rentable Floor Area of the Premises bears to the sum of the Total Rentable Floor Area of the Building and any other buildings on the Property from time to time.

(b) "**Landlord's Operating Expenses**" means the cost of operation of the Building and other areas of the Property incurred by Landlord, including, without limitation, those incurred in discharging the obligations under Sections 7.1, 7.2 and 7.3. In addition, such costs shall exclude payments of debt service and any other mortgage or ground lease charges, brokerage commissions, real estate taxes (to the extent paid pursuant to Section 6.2 hereof), and costs of special services rendered to tenants (including Tenant) for which a separate charge is made, but shall include, without limitation, costs for:

i. compensation, wages and all fringe benefits, worker's compensation insurance premiums and payroll taxes paid to, for or with respect to all persons for their

services in the operating, maintaining, managing, insuring or cleaning of the Building or the Property;

ii. payments under service contracts with independent contractors for operating, maintaining or cleaning of the Building or the Property;

iii. steam, water, sewer, gas, oil, electricity and telephone charges (excluding such utility charges separately chargeable to tenants for additional or separate services and electricity charges payable by Tenant in the manner set forth in Section 5.2) and costs of maintaining letters of credit or other security as may be required by utility companies as a condition of providing such services;

iv. cost of maintenance, cleaning and repairs (other than repairs not properly chargeable against income or reimbursed from contractors under guarantees);

v. cost of snow removal and care of landscaping;

vi. cost of building and cleaning supplies and equipment;

vii. premiums for insurance carried with respect to the Building or the Property (including, without limitation, liability insurance, insurance against loss in case of fire or casualty and of monthly installments of Annual Fixed Rent and any Additional Rent which may be due under this Lease and other leases of space in the Building for not more than twelve (12) months in the case of both Annual Fixed Rent and Additional Rent and, if there be any first mortgage on the Building and/or the Property, including such insurance as may be required by the holder of such first mortgage);

viii. management fees at reasonable rates for self-managed buildings in the Central Suburban 128 Market, consistent with the type of occupancy and the services rendered, which such management fees shall not exceed three percent (3%) of the total Gross Rents for the Building ("**Gross Rents for the Building**" for the purposes hereof being defined as all annual fixed rent, Landlord's Operating Expenses, with the exception of the aforesaid management fees, and Landlord's Tax Expenses for the Building for the relevant calendar year;

ix. depreciation for capital improvements made by Landlord during the Lease Term (x) to reduce Landlord's Operating Expenses if Landlord reasonably shall have determined that the annual reduction in Landlord's Operating Expenses shall exceed depreciation therefor or (y) to comply with Legal Requirements that first become applicable to the Building or the Property after the Phase I Commencement Date (the capital expenditures described in subsections (x) and (y) being hereinafter referred to as "**Permitted Capital Expenditures**") plus, in the case of both (x) and (y), an interest factor, reasonably determined by Landlord, as being the interest rate then charged for long term mortgages by institutional lenders on like properties in the Central Suburban 128 Market, and

depreciation in the case of both(x) and (y) shall be determined by dividing the original cost of such capital expenditure by the number of years of useful life of the capital item acquired, which useful life shall be determined reasonably by Landlord in accordance with generally accepted accounting principles and practices in effect at the time of acquisition of the capital item;

x. all reasonable costs of maintaining (but not applying for or obtaining) any certification under the U.S. EPA's Energy Star® rating system, the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED) rating system or a similar "green" system or standard for the Building or the Property;

xi. cost of operating, cleaning and maintaining the parking garage located on the property underneath the Building;

xii. cost of operating, cleaning and maintaining the Amenities (as defined in Section 16.30), but not of constructing new Amenities or relocating existing Amenities, and less any rent or other amounts received by Landlord from any third-party operators of such Amenities; and

xiii. all other reasonable and necessary expenses paid in connection with the operating, cleaning and maintenance of the Building, or the Property or said common areas and facilities and properly chargeable against income.

Notwithstanding the foregoing, the following shall be excluded from Landlord's Operating Expenses:

(i) Nonrecurring costs for the repair or replacement of any structural portion of the Building made necessary as a result of defects in the original design, workmanship or materials;

(ii) All capital expenditures and depreciation, except as otherwise explicitly provided in this Section 7.4;

(iii) Interest on indebtedness, debt amortization, ground rent, and refinancing costs for any mortgage or ground lease of the Building or the Property;

(iv) Legal, auditing, consulting and professional fees and other costs (other than those legal, auditing, consulting and professional fees and other costs incurred in connection with the normal and routine maintenance and operation of the Property), including, without limitation, those: (i) paid or incurred in connection with financings, refinancings or sales of any Landlord's interest in the Building or the Property, (ii) relating to any special reporting required by securities laws, (iii) relating to disputes with tenants or (iv) relating to litigation;

(v) The cost of any item or service to the extent reimbursed or reimbursable to Landlord by insurance required to be maintained under this Lease or by any third party;

(vi) The cost of repairs or replacements incurred by reason of fire or other casualty or condemnation other than costs not in excess of the deductible on any insurance maintained by Landlord which provides a recovery for such repair or replacement;

(vii) Any advertising, promotional or marketing expenses for the Building, including, without limitation, leasing commissions, attorneys' fees, space planning costs and other costs and expenses incurred in connection with the lease, sublease and/or assignment negotiations and transactions with present or prospective tenants or other occupants of the Building;

(viii) The cost of any service or materials provided by any party related to Landlord (other than the management fee, which shall be subject to the terms and provisions of Section 7.4(b)(viii)), to the extent such costs exceed the reasonable cost for such service or materials absent such relationship in buildings similar to the Building in the Central Suburban 128 Market;

(ix) Payments for rented equipment, the cost of which equipment would constitute a capital expenditure if the equipment were purchased to the extent that such payments exceed the amount which could have been included in Landlord's Operating Expenses had Landlord purchased such equipment rather than leasing such equipment;

(x) Penalties, damages, and interest for late payment or violations of any obligations of Landlord, including, without limitation, taxes, insurance, equipment leases and other past due amounts;

(xi) Costs arising from Landlord's political or charitable contributions;

(xii) The cost of testing, remediation or removal of "Hazardous Materials" (as defined herein) in the Building or on the Property required by "Environmental Laws" (as defined herein), provided however, that with respect to the testing, remediation or removal of any material or substance which, as of the Phase I Commencement Date was not considered, as a matter of law, to be a Hazardous Material, but which is subsequently determined to be a Hazardous Material as a matter of law, the costs thereof shall be included in Landlord's Operating Expenses;

(xiii) Wages, salaries, or other compensation paid to any executive employees above the grade of Regional Property Manager;

(xiv) The net (i.e. net of the reasonable costs of collection) amount recovered by Landlord under any warranty or service agreement from any contractor or service provider shall be credited against Landlord's Operating Expenses

(xv) Costs or repair or replacement of any structural portion of the Building made necessary as a result of defects in the original design, workmanship or materials used; and

(xvi) Landlord's general corporate overhead and administrative services (except for property management services related to the operation of the Property, including, without limitation, risk management, accounting, security and energy management services).

Notwithstanding the foregoing, in determining the amount of Landlord's Operating Expenses for any calendar year or portion thereof falling within the Lease Term, if less than ninety-five percent (95%) of the sum of the Total Rentable Floor Area of the Building and the rentable floor area of any other buildings on the Property from time to time shall have been occupied by tenants at any time during the period in question, then, at Landlord's election, those components of Landlord's Operating Expenses that vary based on occupancy for such period shall be adjusted to equal the amount such components of Landlord's Operating Expenses would have been for such period had occupancy been ninety-five percent (95%) throughout such period; provided that in no event shall the portion of Landlord's Operating Expenses attributable to the operation of the Amenities at the Building be subject to such gross-up.

7.5 Tenant's Share of Operating Expenses

(A) Commencing as of the Phase I Commencement Date with respect to the Office Premises (and as of the Phase II Commencement Date with respect to the Lab Premises), and continuing thereafter throughout the remainder of the Lease Term, Tenant shall pay to Landlord, as Additional Rent, with respect to any full calendar year or fraction of a calendar year falling within the Lease Term, Operating Expenses Allocable to the Premises.

(B) Payments by Tenant on account of the Operating Expenses Allocable to the Premises shall be made monthly at the time and in the fashion herein provided for the payment of Annual Fixed Rent. The monthly amount so to be paid to Landlord shall be an amount from time to time reasonably estimated by Landlord to be sufficient to cover, in the aggregate, a sum equal to the Operating Expenses Allocable to the Premises for each calendar year during the Lease Term.

(C) No later than one hundred twenty (120) days after the end of the first calendar year or fraction thereof ending December 31 and of each succeeding calendar year during the Lease Term or fraction thereof at the end of the Lease Term, Landlord shall render Tenant a statement in reasonable detail and according to generally accepted accounting practices certified by a representative of Landlord, showing for the preceding calendar year or fraction thereof, as the case may be, Landlord's Operating Expenses and Operating Expenses Allocable to the Premises. Said statement to be rendered to Tenant also shall show for the preceding year or fraction thereof, as the case may be, the amounts already paid by Tenant on account of Operating Expenses Allocable to the Premises and the amount of Operating Expenses Allocable to the

Premises remaining due from, or overpaid by, Tenant for the year or other period covered by the statement.

If such statement shows a balance remaining due to Landlord, Tenant shall pay same to Landlord on or before the thirtieth (30th) day following receipt by Tenant of said statement. Any balance shown as due to Tenant shall be credited against Annual Fixed Rent next due, or refunded to Tenant within thirty (30) days of the delivery of such statement if the Lease Term has then expired and Tenant has no further monetary or material non-monetary obligation to Landlord (including, without limitation, any obligations with respect to surrender of the Premises).

Any payment by Tenant for the Operating Expenses Allocable to the Premises shall not be deemed to waive any rights of Tenant to claim that the amount thereof was not determined in accordance with the provisions of this Lease.

(D) Subject to the provisions of this paragraph and provided no uncured monetary or material non-monetary Event of Default exists, Tenant shall have the right, at Tenant's cost and expense, to examine all documentation and calculations prepared in the determination of the Landlord's Tax Expenses Allocable to the Premises, Operating Expenses Allocable to the Premises and Tenant's payment on account of electricity under Section 5.2 above ("**Electricity Expenses**"):

(i) Such documentation and calculations shall be made available to Tenant at the offices where Landlord keeps such records during normal business hours within a reasonable time after Landlord receives a written request from Tenant to make such examination.

(ii) Tenant shall have the right to make such examination no more than once in respect of any period for which Landlord has given Tenant a statement of the actual amount of Landlord's Tax Expenses, Landlord's Operating Expenses or the Electricity Expenses, as applicable.

(iii) Except as provided by the last sentence of this Section 7.5(D), any request for examination in respect of any Tax Year or calendar year, as applicable, may be made no more than one hundred eighty (180) days after Landlord advises Tenant in writing of the actual amount of Landlord's Tax Expenses, Landlord's Operating Expenses or the Electricity Expenses, as applicable in respect of such period and provides to Tenant the appropriate year-end statement required under Section 5.2, Section 6.2 or this Section 7.5, as applicable (provided, however, that if after any audit is performed hereunder, it is finally determined that Tenant has been overcharged on account of Landlord's Tax Expenses Allocable to the Premises, Operating Expenses Allocable to the Premises and/or the Electricity Expenses by more than three percent (3%) for the Tax Year or calendar year in question, Tenant may request to examine the documentation and calculations for the overcharged item for the immediately preceding Tax Year or calendar year, as applicable).

(iv) In no event shall Tenant utilize the services of any examiner who is being paid by Tenant on a contingent fee basis.

(v) As a condition to performing any such examination, Tenant and its examiners shall be required to execute and deliver to Landlord an agreement, in form reasonably acceptable to Landlord, agreeing to keep confidential any information which it discovers about Landlord or the Building in connection with such examination, provided however, that Tenant shall be permitted to share such information with each of its permitted subtenants so long as such subtenants execute and deliver to Landlord similar confidentiality agreements.

(vi) If, after the audit by Tenant of Landlord's books and records pursuant to this Section 7.5 with respect to any Tax Year or calendar year, it is finally determined that: (i) Tenant has made an overpayment on account of Landlord's Tax Expenses Allocable to the Premises, Operating Expenses Allocable to the Premises and/or the Electricity Expenses, as applicable, Landlord shall credit any such overpayment against the next installment(s) of Annual Fixed Rent thereafter payable by Tenant, except that if such overpayment is determined after the termination or expiration of the term of this Lease, Landlord shall promptly refund to Tenant the amount of any such overpayment less any amounts then due from Tenant to Landlord; and (ii) Tenant has made an underpayment on account of Landlord's Tax Expenses Allocable to the Premises, Operating Expenses Allocable to the Premises and/or the Electricity Expenses, as applicable, Tenant shall, within thirty (30) days of such determination, pay any such underpayment to Landlord.

(vii) If, after any such audit is performed, it is finally determined that Tenant has been overcharged on account of Landlord's Tax Expenses Allocable to the Premises, Operating Expenses Allocable to the Premises and/or the Electricity Expenses by more than three percent (3%) for the Tax Year or calendar year in question, Landlord shall reimburse Tenant for the reasonable third-party costs incurred by Tenant in performing such audit.

(viii) Tenant hereby acknowledges and agrees that Tenant's sole right to contest the statements supporting Landlord's determination of the Landlord's Tax Expenses Allocable to the Premises, Operating Expenses Allocable to the Premises and Electricity Expenses shall be as expressly set forth in this Section. If Tenant shall fail to timely exercise Tenant's right to inspect Landlord's books and records as provided in this Section, with respect to any calendar year or Tax Year, as applicable, Landlord's statement of Landlord's Tax Expenses, Landlord's Operating Expenses or the Electricity Expenses shall be conclusive and binding on Tenant (subject to the proviso set forth at the end of clause (iii) above regarding Tenant's ability to request examinations for the immediately preceding year).

Except where Landlord's need to make any such correction is caused by any correction, change and/or charge from any public entity or utility company (provided that Landlord's negligent acts or omissions are not a contributing factor to such correction, change and/or charge), Landlord shall have no right to correct any year end statement with respect to any Tax Year or calendar year after the date one (1) year after the end of the period in question. Notwithstanding any provision hereof to the contrary, if Landlord provides Tenant with any such corrected statement, then Tenant shall have one hundred eighty (180) days from the receipt of any such corrected statement to request an examination as set forth above in this Section 7.5 (subject to the proviso set forth at the end of clause (iii) above regarding Tenant's ability to request examinations for the immediately preceding year).

7.6 No Damage

(A) Except as may be expressly otherwise provided in this Lease, Landlord shall not be liable to Tenant for any compensation or reduction of rent by reason of inconvenience or annoyance or for loss of business arising from the necessity of Landlord or its agents entering the Premises for any purposes in this Lease authorized, or for repairing the Premises or any portion of the Building or the Property however the necessity may occur. In case Landlord is prevented or delayed from making any repairs, alterations or improvements, or furnishing any services or performing any other covenant or duty to be performed on Landlord's part, by reason of any cause reasonably beyond Landlord's control, including, without limitation, by reason of Force Majeure (as defined in Section 16.31 hereof) or for any cause due to any act or neglect of Tenant or Tenant's servants, agents, employees, licensees or any person claiming by, through or under Tenant, Landlord shall not be liable to Tenant therefor, nor, except as expressly otherwise provided in this Lease, shall Tenant be entitled to any abatement or reduction of rent by reason thereof, or right to terminate this Lease, nor shall the same give rise to a claim in Tenant's favor that such failure constitutes actual or constructive, total or partial, eviction from the Premises, but Landlord shall nonetheless use commercially reasonably efforts to mitigate the adverse impact of any such event on Tenant's use and enjoyment of the Premises to the extent it is within Landlord's reasonable ability to do so under the circumstances and where such efforts are reasonably likely to actually mitigate the adverse impact aforesaid.

(B) Landlord reserves the right to stop any service or utility system, when necessary by reason of accident or emergency, or until necessary repairs have been completed; provided, however, that in each instance of stoppage, Landlord shall exercise reasonable diligence to eliminate the cause thereof. Except in case of emergency repairs, Landlord will give Tenant reasonable advance notice of any contemplated stoppage and will use reasonable efforts to avoid unnecessary inconvenience to Tenant by reason thereof.

(C) Notwithstanding anything to the contrary in this Lease contained, if due to (i) any repairs, alterations, replacements, or improvements made by Landlord, (ii) Landlord's failure to make any repairs, alterations, or improvements required to be made by Landlord hereunder, or to provide any service required to be provided by Landlord hereunder (which for purpose of this
Section 7.6 shall expressly exclude the lack of availability of any common amenities (including
the Amenities) that are temporarily shut down or provided at a limited capacity or scope to

the extent due to any Force Majeure event), or (iii) any failure of any electric service required to be provided by Landlord hereunder, any portion of the Premises becomes untenantable so that for the Premises Untenantability Cure Period, as hereinafter defined, the continued operation in the ordinary course of Tenant's business is materially adversely affected, then, provided that Tenant ceases to use the affected portion of the Premises during the entirety of the Premises Untenantability Cure Period by reason of such untenantability, and that such untenantability and Landlord's inability to cure such condition is not caused by (x) the fault or neglect of Tenant or Tenant's agents, employees or contractors, or (y) the failure or inability of the applicable utility company to provide electrical, water, or sewer service to the point of connection for the Building (other than due to Landlord's failure to maintain the corresponding building systems or applicable permits in accordance with applicable laws), Annual Fixed Rent, Landlord's Tax Expenses Allocable to the Premises and Operating Expenses Allocable to the Premises shall thereafter be abated in proportion to such untenantability and its impact on the continued operation in the ordinary course of Tenant's business until the day such condition no longer has the material adverse effect referred to above. Notwithstanding the foregoing to the contrary, in the event any such untenantability is due to the failure or inability of the applicable utility company to provide electrical, water, or sewer service to the point of connection for the Building and Landlord receives payment for such shut down from Landlord's insurance carrier providing loss of rents insurance, Landlord shall provide Tenant with an abatement in accordance with the immediately preceding sentence (subject to the conditions set forth therein) in an amount equal to the payment actually received by Landlord (but only allocable to and on account of the Premises) for such shut down of service to the Premises from Landlord's insurance carrier less the amount of any deductible contained in such loss of rents insurance coverage and less any amount received by Tenant for such interruption from business interruption insurance it maintains. For the purposes hereof, the "**Premises Untenantability Cure Period**" shall be defined as five (5) consecutive business days after Landlord's receipt of written notice from Tenant of the condition causing untenantability in the Premises, provided however, that the Premises Untenantability Cure Period shall be ten (10) consecutive business days after Landlord's receipt of written notice from Tenant of such condition causing untenantability in the Premises if either the condition was caused by causes beyond Landlord's control or Landlord is unable to cure such condition as the result of causes beyond Landlord's control.

In addition, if due to (i) any repairs, alterations, replacements, or improvements made by Landlord, (ii) Landlord's failure to make any repairs, alterations, or improvements required to be made by Landlord hereunder, or to provide any service required to be provided by Landlord hereunder (which for purpose of this Section 7.6 shall expressly exclude the lack of availability
of any common amenities (including the Amenities) that are temporarily shut down or
provided at a limited capacity or scope to the extent due to any Force Majeure event), or (iii) any failure of any electric service required to be provided by Landlord hereunder, the operation of Tenant's business in the Premises in the normal course is materially adversely affected for a period of five (5) consecutive months after Landlord's receipt of written notice of such condition from Tenant, then, provided that Tenant ceases to use the affected portion of the Premises for the period of such untenantability and such untenantability and Landlord's inability to cure such condition is not caused by (x) the fault or neglect of Tenant or Tenant's agents, employees or contractors, or (y) the failure or inability of the applicable utility company to provide electrical, water, or sewer service to the point of connection for the Building (other than due to Landlord's

failure to maintain the corresponding building systems or applicable permits in accordance with applicable laws), then Tenant may terminate this Lease by giving Landlord written notice as follows:

(i) Said notice shall be given after said five (5) month period.

(ii) Said notice shall set forth an effective date which is not earlier than thirty (30) days after Landlord receives said notice.

(iii) If said condition is remedied on or before the date thirty (30) days after the receipt of such notice, said notice shall have no further force and effect.

(iv) If said condition is not remedied on or before the date thirty (30) days after the receipt of such notice for any reason other than Tenant's fault, as aforesaid, the Lease shall terminate as of said effective date, and the Annual Fixed Rent and Additional Rent due under the Lease shall be apportioned as of said effective date.

The remedies set forth in this Section 7.6 shall be Tenant's sole remedies for the events described herein. The provisions of this subsection (C) shall not apply in the event of untenantability caused by fire or other casualty, or taking (which shall be subject to the terms and conditions of Article XIV below).

ARTICLE VIII

Tenant’s Repairs

8.1 Tenant’s Repairs and Maintenance

Tenant covenants and agrees that, from and after the date that possession of the Premises is delivered to Tenant and until the end of the Lease Term, Tenant will keep neat and clean and maintain in good order, condition and repair the Premises and every part thereof (together with any equipment or systems (i) located within the Premises and installed by Tenant or for or on behalf of Tenant by any third party, or (ii) exclusively serving the Premises whether located in or outside of the Premises), excepting only for those maintenance and repairs for which Landlord is responsible under the terms of Article VII of this Lease and damage by fire or casualty and as a consequence of the exercise of the power of eminent domain. Tenant shall not permit or commit any waste, and Tenant shall be responsible for the cost of repairs which may be made necessary by reason of damages to common areas in the Building or the Property caused by Tenant, Tenant’s agents, employees, contractors, sublessees, licensees, concessionaires or invitees. Tenant shall maintain all its equipment, furniture and furnishings in good order and repair.

If repairs are required to be made by Tenant pursuant to the terms hereof, Landlord may demand that Tenant make the same forthwith, and if Tenant refuses or neglects to commence such repairs and complete the same with reasonable dispatch after such demand, Landlord may (but shall not be required to do so) make or cause such repairs to be made pursuant to the provisions of Section 16.17 below.

ARTICLE IX

Alterations

9.1 Landlord's Approval

Tenant covenants and agrees not to make alterations, additions or improvements to the Premises, whether before or during the Lease Term, except in accordance with plans and specifications therefor first approved by Landlord in writing, which approval shall not be unreasonably withheld or delayed. However, Landlord's determination of matters relating to aesthetic issues relating to alterations, additions or improvements which are visible outside the Premises shall be in Landlord's sole discretion. Without limiting such standard, Landlord shall not be deemed unreasonable:

(a) for withholding approval of any alterations, additions or improvements which (i) in Landlord's opinion would reasonably be expected to adversely affect any structural or exterior element of the Building, any area or element outside of the Premises or any facility or base building mechanical system serving any area of the Building outside of the Premises, or (ii) involve or affect the exterior design, size, height or other exterior dimensions of the Building, or (iii) enlarge the Rentable Floor Area of the Premises, or (iv) are inconsistent in any material respect, in Landlord's reasonable judgment, with alterations satisfying Landlord's standards for new alterations in the Building, or (v) will require unusual expense to readapt the Premises to normal office and/or lab use (as applicable) on Lease termination or expiration (including, without limitation, rooftop HVAC units, generators, specialty equipment, ventilation shafts for Tenant's equipment, halon systems, etc.) or increase the cost of construction or of insurance or taxes on the Building or of the services provided by Landlord herein pursuant to Section 7.3 unless Tenant first gives assurance acceptable to Landlord for payment of such increased cost and that such readaptation will be made prior to such termination without expense to Landlord (alterations, additions or improvements described in subclauses (i) through (v) being sometimes collectively referred to as "**Special Improvements**"); or

(b) for making its approval conditional on Tenant's agreement to restore the Premises to its condition prior to such alteration, addition, or improvement at the expiration or earlier termination of the Lease Term, reasonable wear and tear and casualty expected.

Landlord's review and approval of any such plans and specifications or under Exhibit B-1 and consent to perform work described therein shall not be deemed an agreement by Landlord that such plans, specifications and work conform with applicable Legal Requirements and requirements of insurers of the Building and the other requirements of the Lease with respect to Tenant's insurance obligations (herein called "**Insurance Requirements**") nor deemed a waiver of Tenant's obligations under this Lease with respect to applicable Legal Requirements and Insurance Requirements nor impose any liability or obligation upon Landlord with respect to the

completeness, design sufficiency or compliance of such plans, specifications and work with applicable Legal Requirements and Insurance Requirements. Further, Tenant acknowledges that Tenant is acting for its own benefit and account, and that Tenant shall not be acting as Landlord's agent in performing any work in the Premises, accordingly, no contractor, subcontractor or supplier shall have a right to lien Landlord's interest in the Property in connection with any such work. Within 30 days after receipt of an invoice from Landlord (together with reasonable supporting back-up documentation), Tenant shall pay to Landlord, as a fee for Landlord's review of any plans or work (excluding any review respecting initial improvements performed pursuant to Exhibit B-1 but including any review of plans or work relating to any assignment or subletting), as Additional Rent, an amount equal to the sum of : (i) $150/hour for time spent by senior level in-house personnel and $100/hour for time spent by junior level in-house personnel, plus (ii) reasonable third party expenses incurred by Landlord to review Tenant's plans and Tenant's work.

9.2 Conformity of Work

Tenant covenants and agrees that any alterations, additions, improvements or installations made by it to or upon the Premises shall be done in a good and workmanlike manner and in compliance with all applicable Legal Requirements and Insurance Requirements now or hereafter in force, that materials of good quality (but in no event of lesser quality than reasonably appropriate for the maintenance of a consistently high quality building) shall be employed therein and that the structure of the Building shall not be endangered or impaired thereby.

9.3 Performance of Work, Governmental Permits and Insurance

All of Tenant's alterations and additions and installation of furnishings shall be coordinated with any work being performed by or for Landlord and in such manner as to maintain harmonious labor relations and not to damage the Building or the Property or interfere with Building construction or operation and, except for installation of furnishings, shall be performed by Landlord's general contractor or by contractors or workers first approved by Landlord in its reasonable discretion. Except for work by Landlord's general contractor, Tenant shall procure all necessary governmental permits before making any repairs, alterations, other improvements or installations. Tenant agrees to save harmless and indemnify Landlord from any and all injury, loss, claims or damage to any person or property occasioned by or arising out of the doing of any such work whether the same be performed prior to or during the Term of this Lease. At Landlord's reasonable election, taking into account the scope and cost of the proposed alteration, Tenant shall cause its contractor to maintain a payment and performance bond in such amount and with such companies as Landlord shall reasonably approve. In addition, Tenant shall cause each contractor to carry insurance in accordance with Section 13.14 hereof and to deliver to Landlord certificates of all such insurance. Tenant shall also prepare and submit to Landlord a set of as-built plans, in both print and electronic forms, showing such work performed by Tenant to the Premises promptly after any such alterations, improvements or installations are substantially complete and promptly after any wiring or cabling for Tenant's computer, telephone and other communications systems is installed by Tenant or Tenant's contractor. Without limiting any of Tenant's obligations hereunder, Tenant shall be responsible, as Additional Rent, for the costs of any alterations, additions or improvements in or to the Building that are required in order to

comply with Legal Requirements as a result of any work performed by Tenant. Landlord shall have the right to provide rules and regulations (which shall be applied in a non-discriminatory manner) relative to the performance of any alterations, additions, improvements and installations by Tenant hereunder and Tenant shall abide by all such reasonable rules and regulations and shall cause all of its contractors to so abide including, without limitation, payment for the costs of using Building services. Tenant acknowledges and agrees that Landlord shall be the owner of any additions, alterations and improvements in the Premises or the Building to the extent paid for by Landlord.

9.4 Liens

Tenant covenants and agrees to pay promptly when due the entire cost of any work done on the Premises by Tenant, its agents, employees or contractors, and not to cause or permit any liens for labor or materials performed or furnished in connection therewith to attach to the Premises or the Building or the Property and promptly to discharge (whether by bonding or otherwise) any such liens which may so attach.

9.5 Nature of Alterations

All work, construction, repairs, alterations, other improvements or installations made to or upon the Premises (including, but not limited to, all components of Landlord's Work), shall become part of the Premises and shall become the property of Landlord and remain upon and be surrendered with the Premises as a part thereof upon the expiration or earlier termination of the Lease Term, except as follows:

(a) All furniture, equipment, other personal property, and trade fixtures whether by law deemed to be a part of the realty or not, installed at any time or times by Tenant or any person claiming under Tenant shall remain the property of Tenant or persons claiming under Tenant and may be removed by Tenant or any person claiming under Tenant at any time or times during the Lease Term or any occupancy by Tenant thereafter and shall be removed by Tenant at the expiration or earlier termination of the Lease Term if so requested by Landlord. Tenant shall repair any damage to the Premises occasioned by the removal by Tenant or any person claiming under Tenant of any such property from the Premises.

(b) At the expiration or earlier termination of the Lease Term, Tenant shall remove: (i) any wiring, cables or other installations appurtenant thereto for Tenant's computer, telephone and other communication systems and equipment whether located in the Premises or in any other portion of the Building, including all risers (collectively, "**Cable**"), unless Landlord notifies Tenant in writing that such Cable shall remain in the Premises, and (ii) any alterations, additions and improvements made with Landlord's consent during the Lease Term for which such removal was made a condition of such consent under Section 9.1(b). Upon such removal Tenant shall restore the Premises to their condition prior to such alterations, additions and improvements and repair any damage occasioned by such removal and restoration.

(c) If Tenant shall make any alterations, additions or improvements to the Premises for which Landlord's approval is required under Section 9.1 (after giving effect to the provisions of Section 9.7), without obtaining such approval, then at Landlord's request at any time during the Lease Term, and at any event at the expiration or earlier termination of the Lease Term, Tenant shall remove such alterations, additions and improvements and restore the Premises to their condition prior to the same (reasonable wear and tear and casualty excepted) and repair any damage occasioned by such removal and restoration. Nothing herein shall be deemed to be a consent to Tenant to make any such alterations, additions or improvements, the provisions of Section 9.1 and Section 9.7 being applicable to any such work.

9.6 Increases in Taxes

Tenant shall pay, as Additional Rent, one hundred percent (100%) of the portion of any increase in real estate taxes on the Building which shall, at any time after the Phase I Commencement Date (with respect to the Office Premises) or after the Phase II Commencement Date (with respect to the Lab Premises), result from alterations, additions or improvements to the Premises made by Tenant if the taxing authority specifically determines such portion of any increase results from such alterations, additions or improvements made by Tenant.

9.7 Alterations Permitted Without Landlord's Consent

Notwithstanding the terms of Section 9.1, Tenant shall have the right, without obtaining the prior consent of Landlord but upon notice to Landlord given ten (10) days prior to the commencement of any work (which notice shall specify the nature of the work in reasonable detail), to make alterations, additions or improvements to the Premises where:

(a) the same are within the interior of the Premises within the Building, and do not affect the exterior of the Premises and the Building, and are not visible from the exterior of the Premises or the Building (including no signs on windows);

(b) the same do not affect the roof, any structural element of the Building, the mechanical, electrical, plumbing, heating, ventilating, air-conditioning and fire protection systems of the Building;

(c) with the exception of painting and carpeting (which shall not be subject to the dollar limits set forth in this subsection (c)), the cost of any individual alteration, addition or improvement shall not exceed $350,000.00 and the aggregate cost of said alterations, additions or improvements made by Tenant during any applicable Rent Year shall not exceed $1,000,000.00 in cost; and

(d) Tenant shall comply with the provisions of this Lease and if such work increases the cost of insurance or taxes or of services, Tenant shall pay for any such increase in cost;

provided, however, that Tenant shall, within thirty (30) days after the making of such changes, send to Landlord plans and specifications describing the same in reasonable detail and provided further that Landlord, by notice to Tenant given at least thirty (30) days prior to the expiration or earlier termination of the Lease Term, may, if any such alterations, addition or improvement constitutes a Special Improvement, require Tenant to restore the Premises to its condition prior to construction of such Special Improvement (reasonable wear and tear and casualty excepted) at the expiration or earlier termination of the Lease Term.

ARTICLE X

Parking

10.1 Parking Privileges

Landlord shall provide to Tenant the Number of Parking Privileges specified in Section 1.1 for the parking of automobiles, in common with use by other tenants from time to time of the Property, and on a first-come, first-served basis, with overnight parking permitted, at no cost to Tenant and for the duration of the Term (as the same may be extended in accordance with this Lease). Such parking privileges shall be on an unreserved basis in the parking structure located beneath the Building. Tenant covenants and agrees that it and all persons claiming by, through and under it, shall at all times abide by all reasonable rules and regulations promulgated by Landlord with respect to the use of the parking areas on the Property. The parking privileges granted herein are non-transferable except to a permitted assignee or subtenant as provided in Article XII below. Further, Landlord assumes no responsibility whatsoever for loss or damage due to fire, theft or otherwise to any automobile(s) parked on the Property or to any personal property therein, however caused, and Tenant covenants and agrees, upon request from Landlord from time to time, to notify its officers, employees, agents and invitees of such limitation of liability. Tenant acknowledges and agrees that a license only is hereby granted, and no bailment is intended or shall be created. In the event that the Rentable Floor Area of the Premises decreases at any time during the Lease Term, the Number of Parking Privileges provided to Tenant hereunder shall be reduced proportionately in accordance with the parking ratio set forth in Section 1.1.

ARTICLE XI

Certain Tenant Covenants

11.1 Rent. Tenant covenants and agrees to the following during the Lease Term and for such further time as Tenant occupies any part of the Premises to pay when due all Annual Fixed Rent and Additional Rent and all charges for utility services rendered to the Premises and service inspections therefor (except as otherwise provided in Exhibit C-1) and, as further Additional Rent, all charges for additional and special services rendered pursuant to Section 7.3. In the event Tenant pays any utilities for the Premises directly to the utility company or provider, Tenant

shall, upon written request from Landlord from time to time, provide Landlord with a copy of recent utility bills relating to the Premises.

11.2 Use. Tenant covenants and agrees to the following during the Lease Term and for such further time as Tenant occupies any part of the Premises to use and occupy the Premises for the Permitted Use only, and not to injure or deface the Premises or the Building or the Property and not to permit in the Premises any auction sale, vending machine (other than vending machines for use by Tenant's employees and business invitees) or nuisance, or the emission from the Premises of any objectionable noise or odor, nor to permit in the Premises anything which would in any way result in the leakage of fluid or the growth of mold, and not to use or devote the Premises or any part thereof for any purpose other than the Permitted Use, nor any use thereof which is inconsistent with the maintenance of the Building as an office/research/laboratory building of the first-class in the quality of its maintenance, use and occupancy, or which is improper, offensive, contrary to law or ordinance or liable to invalidate or increase the premiums for any insurance on the Building or its contents or liable to render necessary any alteration or addition to the Building.

11.3 Hazardous Materials.

Notwithstanding anything to the contrary contained herein, Tenant shall not keep, maintain, use or store any Hazardous Materials in any portions of the Premises other than the Lab Premises and in accordance with the provisions of this Section 11.3 (except that, with respect to the Office Premises, Tenant may use standard office supplies; provided that Tenant uses, stores and disposes such substances in proper containers and in compliance with all Environmental Laws, and Tenant obtains and complies with all permits required by Environmental Laws prior to the use or presence of any such substances in the Office Premises). As a material inducement to Landlord to allow Tenant to use Hazardous Materials in the Lab Premises in connection with its business, Tenant shall not, without the prior written consent of Landlord (not to be unreasonably withheld, conditioned, or delayed), bring or permit to be brought or kept in or on the Lab Premises or elsewhere in the Building or the Property (i) any inflammable, combustible or explosive fluid, material, chemical or substance (except for standard office supplies stored in proper containers); and (ii) any Hazardous Material (hereinafter defined), other than Tenant's Hazardous Materials (as hereinafter defined), provided that the same shall at all times be brought upon, kept or used in so-called 'control areas' (the number and size of which shall be reasonably determined by Landlord) and in accordance with all applicable Environmental Laws (hereinafter defined) and prudent environmental practice and (with respect to medical waste and so-called "biohazard" materials) good scientific and medical practice. Tenant agrees to deliver to Landlord, at least sixty (60) days prior to the Phase II Commencement Date, a list identifying the types and quantities of Hazardous Materials that Tenant proposes to keep, maintain, use or store at the Premises ("**Tenant's Hazardous Materials**"), which initial list of Tenant's Hazardous Materials shall be subject to Landlord's reasonable review and approval. Without limiting the foregoing or any of the other requirements or conditions set forth in this Section 11.3, Tenant shall be required to operate any control areas within the Lab Premises in accordance with the parameters set forth on Exhibit L attached hereto. Tenant shall be responsible for assuring that all laboratory uses are adequately and properly vented. On or before each anniversary of the Phase II Commencement Date, and on any earlier date during the 12-month period on which

Tenant intends to add a new Hazardous Material or materially increase the quantity of any Hazardous Material to the list of Tenant's Hazardous Materials, Tenant shall submit to Landlord an updated list of Tenant's Hazardous Materials for Landlord's review and approval, which approval shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, with respect to any of Tenant's Hazardous Materials which Tenant does not properly handle, store or dispose of in compliance with all applicable Environmental Laws, prudent environmental practice and (with respect to medical waste and so-called "biohazard materials") good scientific and medical practice, Tenant shall, upon written notice from Landlord, no longer have the right to bring such material into the Building or the Property until Tenant has demonstrated, to Landlord's reasonable satisfaction, that Tenant has implemented programs to thereafter properly handle, store or dispose of such material. In order to induce Landlord to waive its otherwise applicable requirement that Tenant maintain insurance in favor of Landlord against liability arising from the presence of radioactive materials in the Lab Premises, and without limiting the foregoing, Tenant hereby represents and warrants to Landlord that at no time during the Term will Tenant bring upon, or permit to be brought upon, the Lab Premises any radioactive materials whatsoever (except for those contained, in accordance with Legal Requirements, in Tenant's equipment, such as its imaging devices).

(a) Environmental Laws Defined. For purposes hereof, "**Environmental Laws**" shall mean all laws, statutes, ordinances, rules and regulations of any local, state or federal governmental authority having jurisdiction concerning environmental, health and safety matters, including but not limited to any discharge by any of the Tenant Parties of any Hazardous Material (hereinafter defined) into the air, surface water, sewers, soil or groundwater whether within or outside the Premises, including, without limitation (a) the Federal Water Pollution Control Act, 33 U.S.C. Section 1251 et seq., (b) the Federal Resource Conservation and Recovery Act, 42 U.S.C. Section 6901 et seq., (c) the Comprehensive Environmental Response, Compensation and Liability Act, 42 U.S.C. Section 9601 et seq., (d) the Toxic Substances Control Act of 1976, 15 U.S.C. Section 2601 et seq., and (e) Chapter 21E of the General Laws of Massachusetts. Tenant, at its sole cost and expense, shall comply with (i) Environmental Laws, and (ii) any rules, requirements and safety procedures of the Massachusetts Department of Environmental Protection and/or the City of Waltham with respect to Tenant's use, storage and disposal of any Hazardous Materials. In addition, Tenant will not use or permit the Premises to be used for any purpose or in any manner that would void Tenant's or Landlord's insurance, increase the insurance risk, or cause the disallowance of any sprinkler or other credits.

(b) Hazardous Material Defined. As used herein, the term "**Hazardous Material**" means asbestos, oil or any hazardous, radioactive or toxic substance, material or waste or petroleum derivative which is or becomes regulated by any Environmental Law, including without limitation live organisms, viruses and fungi, medical waste and any so-called "biohazard" materials. The term "**Hazardous Material**" includes, without limitation, oil and/or any material or substance which is (i) designated as a "hazardous substance," "hazardous material," "oil," "hazardous waste" or toxic substance under any Environmental Law.

(c) Chemical Safety Program. Tenant shall establish and maintain a chemical safety program administered by a licensed, qualified individual in accordance with the requirements of any applicable governmental authority. Tenant shall be solely responsible for all costs incurred in connection with such chemical safety program, and Tenant shall provide Landlord with such documentation as Landlord may reasonably require evidencing Tenant's compliance with the requirements of (a) any applicable governmental authority with respect to such chemical safety program and (b) this Section 11.3(c). Tenant shall obtain and maintain during the Term any permit required by any such applicable governmental authority related to such chemical safety program.

(d) Testing. At any time, and from time to time, Landlord shall have the right to conduct appropriate tests of the Building or the Property or any portion thereof (other than the Premises) to determine whether there has been any release of Hazardous Materials as a result of the acts or omissions of any of the Tenant Parties (as defined in Section 13.1) in violation of this Lease. Further, Landlord shall have the right, from time to time (not to exceed more than once per calendar year unless required more frequently by any mortgagee or governmental authority) to inspect the Premises and conduct appropriate tests to determine (i) whether there has been any release of Hazardous Materials as a result of the acts or omissions of any of the Tenant Parties in violation of this Lease and/or (ii) compliance with the terms of this Section 11.3. Tenant shall execute affidavits, certifications and the like, as may be reasonably requested by Landlord from time to time concerning Tenant's best knowledge and belief concerning the presence of Hazardous Materials in or on the Premises, the Building or the Property. In addition to the foregoing, if Landlord reasonably believes that any Hazardous Materials have been released on the Premises in violation of this Lease or any Legal Requirement, Landlord shall have the right to conduct appropriate tests of the Premises or any portion thereof to demonstrate that Hazardous Materials are present or that contamination has occurred due to the acts or omissions of any of the Tenant Parties in violation of this Lease. Tenant shall pay all reasonable costs of any such tests conducted pursuant to this Section 11.3(d) if such tests reveal that Hazardous Materials exist at the Building, the Property, or the Premises in violation of this Lease or any Legal Requirement. Further, Landlord shall have the right to cause a third party consultant retained by Landlord to review, but not more than once in any calendar year, Tenant's lab operations, procedures and permits to ascertain whether or not Tenant is complying with law and adhering to prudent industry standards (the cost of which shall be included in Landlord's Operating Expenses, provided that Tenant shall not be required to pay more than $4,000 on account of such costs in any one calendar year). Tenant shall have the right to approve such third-party consultant (such approval not to be unreasonably withheld, conditioned or delayed), with Tenant hereby pre-approving Safety Partners, Inc. and any other reputable vendor which regularly performs similar consulting services in similar quality office/research/laboratory buildings in the Central Suburban 128 Market. Tenant agrees to cooperate in good faith with any such review and to provide to such consultant any information requested by such consultant and reasonably required in order for such consultant to perform such review, but nothing contained herein shall require Tenant to provide proprietary or confidential information to such consultant. Any testing or review carried out by Landlord or its consultants pursuant to this Section 11.3 shall only be done after

reasonable notice to Tenant of at least 48 hours, at reasonable times, in the presence of a Tenant representative, and subject to Tenant's reasonable confidentiality and security policies.

(e) Indemnity; Remediation. Without limitation of the provisions of Section 13.1 below, Tenant hereby covenants and agrees to indemnify, defend and hold the Landlord Parties harmless from and against any and all claims against any of the Landlord Parties arising out of contamination of any part of the Building or the Property or other adjacent property, which contamination arises as a result of: (i) the presence of Hazardous Material in the Premises, the presence of which is caused by any act or omission of any of the Tenant Parties (i.e., Tenant bringing such Hazardous Material into the Premises), or (ii) from a breach by Tenant of its obligations under this Section 11.3. This indemnification of the Landlord Parties by Tenant includes, without limitation, reasonable costs incurred in connection with any investigation of site conditions or any cleanup, remedial, removal or restoration work or any other response actions required by any federal, state or local governmental agency or political subdivision because of Hazardous Material present in the soil, soil vapor or ground water on or under or any indoor air in the Building based upon the circumstances identified in the first sentence of this subsection. The indemnification and hold harmless obligations of Tenant under this subsection shall survive the expiration or any earlier termination of this Lease.

Without limiting the obligations set forth above, if any Hazardous Material is in, on, under, at or about the Building or the Property as a result of the acts or omissions of any of the Tenant Parties and results in any contamination of any part of the Property or any adjacent property that is in violation of any applicable Environmental Law or that requires the performance of any response action pursuant to any Environmental Law, Tenant shall promptly take all actions at Tenant's sole cost and expense as are reasonably necessary to reduce such Hazardous Material to amounts below any applicable reportable quantity, any applicable reportable concentration and any other applicable standard set forth in any Environmental Law such that no further response actions are required; provided that Tenant shall first obtain Landlord's written approval of such actions, which approval shall not be unreasonably withheld, conditioned or delayed so long as such actions would not be reasonably expected to have a material adverse effect on the market value or utility of the Building or the Property for the Permitted Uses, and in any event, Landlord shall not withhold its approval of any proposed actions which are required by applicable Environmental Laws (such approved actions, "**Tenant's Remediation**"). In the event that Tenant fails to complete Tenant's Remediation prior to the end of the Term, then:

(i) until the completion of Tenant's Remediation (as evidenced by the certification of Tenant's Licensed Site Professional (as such term is defined by applicable Environmental Laws), who shall be reasonably acceptable to Landlord) (the "**Remediation Completion Date**"), Tenant shall pay to Landlord, with respect to the portion of the Premises which reasonably cannot be occupied by a new tenant until completion of Tenant's Remediation, (A) Additional Rent on account of Operating Expenses and Real Estate Taxes and (B) Annual Fixed Rent in an

amount equal to the greater of (1) the fair market rental value of such portion of the Premises (determined by Landlord in its reasonable discretion), and (2) Annual Fixed Rent attributable to such portion of the Premises in effect immediately prior to the end of the Term; and

(ii) Tenant shall maintain responsibility for Tenant's Remediation and Tenant shall complete Tenant's Remediation as soon as reasonably practicable in accordance with Environmental Laws. If Tenant does not diligently pursue completion of Tenant's Remediation, Landlord shall have the right to either (A) assume control for overseeing Tenant's Remediation, in which event Tenant shall pay all reasonable costs and expenses of Tenant's Remediation (it being understood and agreed that all costs and expenses of Tenant's Remediation incurred pursuant to contracts entered into, by Tenant shall be deemed reasonable) within thirty (30) days of demand therefor (which demand shall be made no more often than monthly), and Landlord shall be substituted as the party identified on any governmental filings as the party responsible for the performance of such Tenant's Remediation or (B) require Tenant to maintain responsibility for Tenant's Remediation, in which event Tenant shall complete Tenant's Remediation as soon as reasonably practicable in accordance with Environmental Laws, it being understood that Tenant's Remediation shall not contain any requirement that Tenant remediate any contamination to levels or standards more stringent than those associated with the Property's current office, research and development and laboratory uses. The provisions of this Section shall survive the expiration or earlier termination of this Lease.

(f) Disclosures. Prior to bringing any Hazardous Material into any part of the Property, Tenant shall deliver to Landlord the following information with respect thereto: (a) a description of handling, storage, use and disposal procedures; (b) all plans or disclosures and/or emergency response plans which Tenant has prepared, including without limitation for a spill of Hazardous Materials, and all plans which Tenant is required to supply to any governmental agency or authority pursuant to any Environmental Laws; (c) copies of all Required Permits relating thereto; and (d) other information reasonably requested by Landlord.

(g) Removal. Tenant shall be responsible, at its sole cost and expense, for Hazardous Material and other biohazard disposal services for the Premises. Such services shall be performed by contractors reasonably acceptable to Landlord and on a sufficient basis to ensure that the Premises are at all times kept neat, clean and free of Hazardous Materials and biohazards except in accordance with prudent industry standards.

(h) End of Term Obligations. Prior to the expiration of this Lease (or within thirty (30) days after any earlier termination), Tenant shall clean and otherwise decommission all interior surfaces (including floors, walls, ceilings, and counters), piping, supply lines, waste lines, acid neutralization systems and plumbing in and/or exclusively serving the Premises, and all exhaust or other ductwork in and/or exclusively serving the Premises, in each case which has carried or released or been contacted by any Hazardous Materials or other

chemical or biological materials used in the operation of the Premises, and shall otherwise clean the Premises so as to satisfy the Surrender Plan (defined below).

(i) Surrender Plan. At least thirty (30) days prior to the expiration of the Term (or, if applicable, within five (5) business days after any earlier termination of this Lease), Tenant shall deliver to Landlord a reasonably detailed narrative description of the actions proposed (or required by any Legal Requirements) to be taken by Tenant in order to render the Premises (including any alterations, additions or improvements permitted or required by Landlord to remain therein) free of Hazardous Materials and otherwise released for unrestricted use and occupancy including without limitation causing the Premises to be decommissioned in accordance with the regulations of the U.S. Nuclear Regulatory Commission and/or the Massachusetts Department of Public health (the "**MDPH**") for the control of radiation, and cause the Premises to be released for unrestricted use by the Radiation Control Program of the MDPH (the "**Surrender Plan**"). The Surrender Plan (i) shall be accompanied by a current list of (A) all Required Permits held by or on behalf of any Tenant Party with respect to Hazardous Materials in, on, under, at or about the Premises, and (B) Tenant's Hazardous Materials, and (ii) shall be subject to the review and approval of Landlord's environmental consultant. In connection with review and approval of the Surrender Plan, upon request of Landlord, Tenant shall deliver to Landlord or its consultant such additional non-proprietary information concerning the use of and operations within the Premises as Landlord shall reasonably request. On or before the expiration of the Term (or, if applicable, the date that is thirty (30) days after any earlier termination of this Lease), Tenant shall (i) perform or cause to be performed all actions described in the approved Surrender Plan, and (ii) deliver to Landlord a certification from a third party certified industrial hygienist reasonably acceptable to Landlord certifying that the Premises do not contain any Hazardous Materials and evidence that the approved Surrender Plan shall have been satisfactorily completed by a contractor acceptable to Landlord, and Landlord shall have the right, subject to reimbursement at Tenant's expense as set forth below, to cause Landlord's environmental consultant to inspect the Premises and perform such additional procedures as may be deemed reasonably necessary to confirm that the Premises are, as of the expiration of the Term (or, if applicable, the date which is thirty (30) days after any earlier termination of this Lease), free of Hazardous Materials and otherwise available for unrestricted use and occupancy as aforesaid. Landlord shall have the unrestricted right to deliver the Surrender Plan and any report by Landlord's environmental consultant with respect to the surrender of the Premises to third parties. Such third parties and the Landlord Parties shall be entitled to rely on the Surrender Plan. If Tenant shall fail to prepare or submit a Surrender Plan approved by Landlord, or if Tenant shall fail to complete the approved Surrender Plan, or if such Surrender Plan, whether or not approved by Landlord, shall fail to adequately address the use of Hazardous Materials by any of the Tenant Parties in, on, at, under or about the Premises, Landlord shall have the right to take any such actions as Landlord may deem reasonable or appropriate to assure that the Premises and the Property are surrendered in the condition required hereunder, the reasonable cost of which actions shall be reimbursed by Tenant as Additional Rent upon demand. Tenant's obligations under this Section shall survive the expiration or earlier termination of the Term.

(j) Exceptions to Liability. Notwithstanding any provision of this Lease to the contrary, Tenant shall in no event have any liability (by way of indemnification or otherwise) for, nor shall Tenant be responsible for the clean-up, removal or remediation of, any Hazardous Materials from the Premises or the Property or for any related loss or damage, to the extent that such Hazardous Materials: (i) existed in, on or under the Premises or the Property, as the case may be, on the Phase I Commencement Date (with respect to the Office Premises) or the Phase II Commencement Date (with respect to the Lab Premises), or (ii) were placed or released in, on or under the Premises or the Property other than by the act or omission of Tenant or any Tenant Party, except to the extent (if any) Tenant or any Tenant Party exacerbates the same.

(k) Landlord Representation. Landlord represents to Tenant that, to the best of Landlord's actual knowledge as of the substantial completion of Landlord's Work, there will be no Hazardous Materials in the Premises which are required to be removed or otherwise abated in accordance with applicable Environmental Laws. Subject to the limitations of Section 16.24 hereof, Landlord agrees to indemnify and save Tenant and all Tenant Parties harmless from liability, loss and damage to persons or property and from any claims, actions, proceedings and expenses in connection therewith resulting from (x) Hazardous Materials that are present in the Building or the Property as the result of the actions of Landlord and any Landlord Party, and (y) Hazardous Materials that existed in, at or on the Building or the Property as of the Phase I Commencement Date (with respect to the Office Premises) and the Phase II Commencement Date (with respect to the Lab Premises); provided, however, that in no event shall the foregoing indemnity render Landlord liable for any loss or damage to Tenant's Property and Landlord shall in no event be liable for indirect or consequential damages. Landlord hereby agrees to use reasonable efforts to enforce the terms of its leases with other tenants of the Building in the event of a violation of Environmental Laws resulting from the action or inaction of any tenant or occupant of the Building or any employee, agent or contractor thereof; provided, however, in no event shall Landlord be liable to Tenant for any violation of Environmental Laws by any tenant or occupant of the Building.

(l) Chemical Storage Room. During the Term, Tenant shall have the right to use the area on the P-5 parking level of the Building's garage shown as "Tenant's Chemical Storage Room" on Exhibit N attached hereto ("**Tenant's Chemical Storage Room**") solely for storage of Hazardous Materials subject to and in accordance with the terms and conditions of this Lease. Usage or dispensing of such Hazardous Materials in Tenant's Chemical Storage Room is forbidden. To the extent any Legal Requirements set a maximum quantity of any Hazardous Materials which may be stored, used or brought into the Building without additional licensing, permitting or authorizations therefor, Tenant shall not be permitted to use, store or bring into the Building (including Tenant's Chemical Storage Room) more than Tenant is allowed in each so-called "control zone" within the Premises (as more particularly set forth on Exhibit L attached hereto). Notwithstanding anything in this Lease to the contrary, Landlord shall not have and expressly disclaims any liability (unless arising from the gross negligence or willful misconduct of Landlord or Landlord's employees, agents, consultants, or contractors) related to Tenant's use or storage of Hazardous Materials within Tenant's Chemical Storage Room, it being acknowledged by Tenant that Tenant is best suited to evaluate the safety and efficacy of its Hazardous Materials usage and procedures in

the Premises and in Tenant's Chemical Storage Room. Tenant shall have the same insurance and indemnification obligations respecting Tenant's Chemical Storage Room as Tenant has under this Lease with respect to the Premises, but Tenant shall not pay Annual Fixed Rent or Additional Rent with respect to Tenant's Chemical Storage Room. All costs incurred by Landlord in connection with Tenant's Chemical Storage Room shall be included in Landlord's Operating Expenses.

11.4 Miscellaneous Covenants. Tenant covenants and agrees to the following during the Lease Term and for such further time as Tenant occupies any part of the Premises

(a) Not to obstruct in any manner any portion of the Building not hereby leased or any portion thereof or of the Property used by Tenant in common with others; not without prior consent of Landlord to permit the painting or placing of any signs, curtains, blinds, shades, awnings, aerials or flagpoles, or the like, visible from outside the Premises; and to comply with all reasonable rules and regulations or the requirements of any tenant handbook applicable to all similarly-situated tenants of the building and now or hereafter implemented, of which Tenant has been given notice, for the care and use of the Building and the Property and their facilities and approaches, but Landlord shall not be liable to Tenant for the failure of other occupants of the Building to conform to such rules and regulations. Landlord shall not enforce such rules and regulations other than in a non-discriminatory manner. If and to the extent there is any conflict between the provisions of this Lease and any rules and regulations or customer handbook for the Building, the provisions of this Lease shall control.

(b) To comply with all applicable Legal Requirements now or hereafter in force regarding the operation of Tenant's business and the use, condition, configuration and occupancy of the Premises, including without limitation, all applicable standards and regulations of the Federal Occupational Safety and Health Administration ("**OSHA Requirements**"), which obligation shall include ensuring that all contractors (including sub-contractors) that Tenant utilizes to perform work in the Premises comply with OSHA Requirements and that all required training is provided for such work. In addition, Tenant shall, at its sole cost and expense, promptly comply with any Legal Requirements that relate to the Base Building (as hereinafter defined), but only to the extent such obligations are triggered solely by Tenant's specific use of the Premises (it being understood that such "specific use" shall be deemed to include, without limitation, Tenant's laboratory, research and development, and manufacturing operations) or alterations, additions or improvements in the Premises performed or requested by Tenant. "**Base Building**" shall include the structural portions of the Building, the public restrooms and the Building mechanical, electrical and plumbing systems and equipment located in the internal core of the Building on the floor or floors on which the Premises are located. Tenant shall promptly pay all fines, penalties and damages that may arise out of or be imposed because of its failure to comply with the provisions of this Section 11.4. Without limiting the foregoing, Tenant shall, at Tenant's sole cost and expense, apply for, seek and obtain prior to the date on which Tenant commences occupancy of all or any portion of the Premises all necessary state and local licenses, permits and approvals needed for the operation of Tenant's business in the Premises, including any necessary permits and

approvals directly or indirectly relating or incident to the conduct of its activities on the Premises, its scientific experimentation, transportation, storage, handling, use and disposal of any Hazardous Materials or animals or laboratory specimens (collectively, the "**Required Permits**"). Tenant shall thereafter maintain all Required Permits. Tenant, at Tenant's expense, shall at all times comply with the terms and conditions of each Required Permit. Within ten (10) business days of request by Landlord from time to time (but no more than once per calendar year), Tenant shall furnish Landlord with copies of all Required Permits that Tenant has obtained together with a certificate certifying that such permits are all of the permits that Tenant has obtained with respect to the Premises.

(c) To keep the Premises equipped with all safety appliances required by law or ordinance or any other regulation of any public authority because of any use made by Tenant other than normal office/research/lab use, and to procure all licenses and permits so required because of any use made by Tenant other than normal office/lab use, and, if requested by Landlord, to do any work so required because of such use, it being understood that the foregoing provisions shall not be construed to broaden in any way Tenant's Permitted Use.

(d) Not to place a load upon any floor in the Premises exceeding an average rate of 100 pounds of live load (including 20 pounds allocated for partitions) per square foot of floor area; and not to move any safe, vault or other heavy equipment in, about or out of the Premises except in such manner and at such time as Landlord shall in each instance authorize (acting reasonably). Tenant's business machines and mechanical equipment shall be placed and maintained by Tenant at Tenant's expense in settings sufficient to absorb and prevent vibration or noise that may be transmitted to the Building structure or to any other space in the Building.

(e) To pay promptly when due all taxes which may be imposed upon personal property (including, without limitation, fixtures and equipment) in the Premises to whomever assessed.

(f) To pay, as Additional Rent, all reasonable out-of-pocket costs, counsel and other fees incurred by Landlord in connection with the successful enforcement by Landlord of any obligations of Tenant under this Lease or in connection with any bankruptcy case involving Tenant.

(g) Not to do or permit anything to be done in or upon the Premises, or bring in anything or keep anything therein, which shall increase the rate of insurance on the Premises or on the Building above the standard rate applicable to premises being occupied for the use to which Tenant has agreed to devote the Premises; and Tenant further agrees that, in the event that Tenant shall do any of the foregoing, Tenant will promptly pay to Landlord, on demand, any such increase resulting therefrom, which shall be due and payable as Additional Rent hereunder.

(h) To comply with all applicable Legal Requirements now or hereafter in force which shall impose a duty on Landlord or Tenant relating to or as a result of the use or occupancy of

the Premises; provided that Tenant shall not be required (i) to make any alterations or additions to the base building systems or to the structure, roof, exterior and load bearing walls, foundation, structural floor slabs and other structural elements of the Building or (ii) to perform or satisfy any other obligation of Landlord under this Lease, unless the same are required by such Legal Requirements as a result of or in connection with Tenant's use or occupancy of the Premises, other than for general office/research/laboratory use. Tenant shall promptly pay all fines, penalties and damages that may arise out of or be imposed because of its failure to comply with the provisions of this Section 11.4.

(i) Landlord encourages (but does not require or obligate) all employers at the Building to become members of the 128 Business Council and to participate in programs offered by the Massachusetts Bay Transit Authority or other entities designed to encourage the use of mass transit. Landlord encourages (but does not require or obligate) all tenants in the Building to provide subsidies for the purchase by their employees of monthly transit passes and to inform their employees of the benefits of using monthly transit passes.

(j) Any vendors engaged by Tenant to perform services in or to the Premises including, without limitation, janitorial contractors and moving contractors shall be coordinated with any work being performed by or for Landlord and in such manner as to maintain harmonious labor relations and not to damage the Building or the Property or unreasonably interfere with construction within or operation of the Building or the Property and shall be performed by vendors first approved by Landlord, which approval shall not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, the following vendors do not require Landlord's approval: brokerage, accounting, legal, employment staffing and contingent labor, office and other supplies, furniture providers (but not installers), construction consultants not performing any physical work in the Building (but not architects), and food catering.

11.5 OFAC

A. As an inducement to Landlord to enter into this Lease, Tenant hereby represents and warrants that, to Tenant's knowledge: (i) Tenant is not, nor is fifty percent (50%) or more of Tenant owned or controlled directly or indirectly by, any person, group, entity or nation named on the Specially Designated Nationals and Blocked Persons List maintained by the Office of Foreign Assets Control of the United States Treasury ("**OFAC**") (any such person, group, entity or nation being hereinafter referred to as a "**Prohibited Person**"); (ii) Tenant is not (nor is fifty percent (50%) or more of Tenant owned or controlled, directly or indirectly, by any person, group, entity or nation which is) acting directly or indirectly for or on behalf of any Prohibited Person; and (iii) Tenant (and any person, group, or entity which Tenant controls, directly or indirectly) has not knowingly conducted nor will knowingly conduct business nor has knowingly engaged nor will knowingly engage in any transaction or dealing with any Prohibited Person that either may cause or causes Landlord to be in violation of any OFAC rule or regulation, including without limitation any assignment of this Lease or any subletting of all or any portion of the Premises. In connection with the foregoing, it is expressly understood and

agreed that (x) any breach by Tenant of the foregoing representations and warranties shall be deemed a default by Tenant under Section 15.1(d) of this Lease and shall be covered by the indemnity provisions of Section 13.1 below, and (y) the representations and warranties contained in this subsection shall be continuing in nature and shall survive the expiration or earlier termination of this Lease. Notwithstanding anything contained herein to the contrary, for the purposes of this subsection (A) the phrase "owned or controlled directly or indirectly by any person, group, entity or nation" and all similar such phrases shall not include any holder of a direct or indirect interest in a publicly traded company whose shares are listed and traded on a United States national stock exchange.

B. As an inducement to Tenant to enter into this Lease, Landlord hereby represents and warrants that, to Landlord's knowledge: (i) Landlord is not, nor is fifty percent (50%) or more of Landlord owned or controlled directly or indirectly by, any Prohibited Person; (ii) Landlord is not (nor is fifty percent (50%) or more of Landlord owned or controlled, directly or indirectly, by any person, group, entity or nation which is) acting directly or indirectly for or on behalf of any Prohibited Person; and (iii) Landlord (and any person, group, or entity which Landlord controls, directly or indirectly) has not knowingly conducted nor will knowingly conduct business nor has knowingly engaged nor will knowingly engage in any transaction or dealing with any Prohibited Person that either may cause or causes Tenant to be in violation of any OFAC rule or regulation. In connection with the foregoing, it is expressly understood and agreed that the representations and warranties contained in this subsection shall be continuing in nature and shall survive the expiration or earlier termination of this Lease. Notwithstanding anything contained herein to the contrary, for the purposes of this subsection (B) the phrase "owned or controlled directly or indirectly by any person, group, entity or nation" and all similar such phrases shall not include (x) any shareholder of Boston Properties, Inc., (y) any holder of a direct or indirect interest in a publicly traded company whose shares are listed and traded on a United States national stock exchange or (z) any limited partner, unit holder or shareholder owning an interest of five percent (5%) or less in Boston Properties Limited Partnership or the holder of any direct or indirect interest in Boston Properties Limited Partnership.

11.6 Cleaning of Lab Premises.

Tenant shall be responsible, at its sole cost and expense, for janitorial and trash removal services, and other biohazard disposal services for the Lab Premises (with Landlord providing janitorial services to the Office Premises pursuant to Exhibit C-1). Such services shall be performed by licensed (where required by law or governmental regulation), insured and qualified contractors approved in advance, in writing, by Landlord (which approval shall not be unreasonably withheld, delayed or conditioned) and on a sufficient basis to ensure that such areas are at all times kept neat and clean.

11.7 Pest Control.

Tenant, at Tenant's sole cost and expense, shall cause the Premises to be inspected on a reasonably regular basis (but no more than once per month) or as needed, and shall cause all portions of the Premises used for the storage, preparation, service or consumption of food or beverages to be cleaned daily in a reasonable manner, and to be treated against infestation by insects, rodents and other vermin and pests whenever there is evidence of any infestation. Tenant shall not permit any person to enter the Premises for the purpose of providing such inspection and/or extermination services, unless such persons have been approved by Landlord, which approval shall not be unreasonably withheld, delayed, or conditioned. If requested by Landlord, Tenant shall, at Tenant's sole cost and expense, store any refuse generated in the Premises by the consumption of food or beverages in a cold box or similar facility.

11.8 Energy Conservation.

Landlord may institute upon written notice to Tenant such policies, programs and measures as may be necessary, required, or expedient for the conservation and/or preservation of energy or energy services (which shall be non-discriminatory with respect to tenants in similar circumstances) (collectively, the "**Conservation Program**"), provided however, that the Conservation Program does not, by reason of such policies, programs and measures, reduce the level of energy or energy services being provided to the Premises below the level of energy or energy services (i) then being provided in comparable combination laboratory, research and development and office buildings in the vicinity of the Premises, provided the same shall not come at a material cost to Tenant, or materially adversely affect Tenant's use of the Premises for any of the Permitted Uses, or (ii) as may be necessary or required to comply with Legal Requirements or the other provisions of this Lease. Upon receipt of such notice, Tenant shall use commercially reasonable efforts to comply with the Conservation Program.

11.9 Recycling.

Upon written notice, Landlord may establish commercially reasonable policies, programs and measures for the recycling of paper, products, plastic, tin and other materials (a "**Recycling Program**"). Upon receipt of such notice, Tenant will use commercially reasonable efforts to comply with the Recycling Program at Tenant's sole cost and expense.

11.10 pH System.

Subject to the terms and conditions of this Section 11.10, during the Term of this Lease, Tenant shall have the right, in common with others, to connect to and use the PH neutralization system for the Building (the "**pH Neutralization System**"). Landlord has obtained or will obtain a wastewater treatment operator permit (a "**MWRA pH Permit**") from the Massachusetts Water Resources Authority ("**MWRA**") for the operation of the pH Neutralization System. The type, size, location, and manner of all connections and discharges by Tenant to the pH Neutralization System shall be subject to the approval of Landlord in each instance prior to connecting to the pH Neutralization System. Tenant's use of the pH Neutralization System shall be subject to the following conditions:

(1) Tenant's use of the pH Neutralization System shall be at Tenant's sole risk to the extent permitted pursuant to applicable laws (Landlord making no representation or warranty regarding the sufficiency of the pH Neutralization System for Tenant's use).

(2) Tenant shall pay for its proportionate share of all ongoing operational costs of the pH Neutralization System as part of Landlord's Operating Expenses. During the Term, Landlord shall maintain, repair and/or replace the pH Neutralization System for the Building to ensure the same remains in good working condition and available for Tenant's use.

(3) Tenant's use of the pH Neutralization System shall be undertaken by Tenant in compliance with all applicable laws, including, but not limited to the MWRA pH Permit, required in connection with such use by Tenant.

(4) The pH Neutralization System may be relocated by Landlord (not more than once during the Term), at Landlord's sole cost and expense, to another area in the Building, provided that (i) such relocated pH Neutralization System shall provide comparable functionality and utility to the pH Neutralization System in its existing location, and (ii) such relocated pH Neutralization System shall be operational and available for Tenant's use prior to the decommissioning of the existing pH Neutralization System so as to ensure that Tenant has no interruption in service in connection with such relocation.

(5) The use of the pH Neutralization System shall be subject to the rules and regulations for the Building.

(6) Tenant shall not introduce any substances or materials into the pH Neutralization System which (x) are in violation of the terms of the MWRA pH Permit, (y) are in violation of applicable laws, or (z) would materially interfere with the proper functioning of the pH Neutralization System.

The scope of the Surrender Plan (as defined in Section 11.3(i)) shall include all actions proposed by Tenant for the proper decommissioning of its use of the pH Neutralization System, and all requirements under this Lease for the surrender of the Premises shall also apply to Tenant's decommissioning and cessation of use of such pH Neutralization System.

11.11 No Vivarium

Notwithstanding any other provision of this Lease, Tenant shall not use the Premises, or any part thereof, or suffer or permit the use of the Premises or any part thereof by any of the Tenant Parties, as a vivarium.

11.12 Building Generator

The parties acknowledge that Landlord has installed a 400 kW back-up generator for use by certain tenants of the Building (the "**Building Generator**"). Subject to the provisions of this

Section 11.12, Tenant shall be entitled to utilize up to 2.2424 watts per square foot of the Premises from the Building Generator. As part of Landlord's Operating Expenses, Tenant shall be obligated to pay Tenant's Generator Share (as hereinafter defined) of any costs incurred by Landlord in connection with maintaining, repairing, replacing and/or insuring the Building Generator ("**Generator Costs**"). "**Tenant's Generator Share**" shall mean 25.00%. Notwithstanding the foregoing, the parties acknowledge that the Generator Connections (as hereinafter defined) serve the Premises exclusively, and therefore agree that Tenant's Generator Share shall be 100% with respect to any Generator Costs attributable to such Generator Connections. Tenant shall pay, at the time that monthly installments of Annual Fixed Rent are due and payable, as Additional Rent, an amount equal to 1/12th of the amount reasonably estimated by Landlord from time to time as Tenant's Generator Share of the annual Generator Costs. Promptly after the end of each calendar year during the Term, Landlord shall render Tenant a reasonably detailed accounting showing the actual Generator Costs for the preceding calendar year. Said statement shall show for the preceding year the amount already paid by Tenant on account of Generator Costs, and the amount remaining due from, or overpaid by, Tenant for the year covered by the statement. Any overpayment disclosed by an annual statement shall be credited against the next installment(s) of Annual Fixed Rent due under this Lease, or if the Term has ended, then such overpayment shall be reimbursed to Tenant together with such statement. Any underpayment disclosed by an annual statement shall be paid by Tenant to Landlord within thirty (30) days after receipt of such statement. Landlord expressly disclaims any warranties with regard to the Building Generator or the installation thereof, including any warranty of merchantability or fitness for a particular purpose. Notwithstanding the foregoing, Landlord shall maintain the following in good working order throughout the Term: (i) the Building Generator (including, without limitation, any equipment connecting the Building Generator up to and including the distribution panel located within the electrical closet on the first (1st) floor of the Building), and (ii) any connections or other distribution infrastructure related to Tenant's utilization of the Building Generator that extend beyond such distribution panel (the items described in this subclause (ii) being collectively referred to herein as the "**Generator Connections**"); provided, however, that Landlord shall not be liable for any failure to make any repairs or to perform any maintenance of the Building Generator that is an obligation of Landlord unless and except to the extent that Landlord fails to make such repairs or perform such maintenance and such failure persists for an unreasonable time after Tenant provides Landlord with written notice (which notice may be sent by e-mail) of the need for such repairs or maintenance.

ARTICLE XII

Assignment and Subletting

12.1 Restrictions on Transfer

Except as otherwise expressly provided herein, Tenant covenants and agrees that it shall not assign, mortgage, pledge, hypothecate or otherwise transfer this Lease and/or Tenant's interest in this Lease or sublet (which term, without limitation, shall include granting of concessions, licenses or the like) the whole or any part of the Premises. If and so long as Tenant is a private

corporation with fewer than five hundred (500) shareholders or a limited liability company or a partnership, an assignment, within the meaning of this Article XII, shall be deemed to include one or more sales or transfers of stock or membership or partnership interests, by operation of law or otherwise, or the issuance of new stock or membership or partnership interests, by which an aggregate of more than fifty percent (50%) of Tenant's stock or membership or partnership interests shall be vested in a party or parties who are not stockholders or members or partners as of the date hereof (a "**Majority Interest Transfer**"). For the avoidance of doubt, and notwithstanding anything in this Article XII to the contrary, any public offering of shares in Tenant or the exchange of shares in Tenant on a nationally recognized stock exchange shall not be deemed an assignment within the meaning of this Article XII. For the purpose of this Section 12.1, ownership of stock or membership or partnership interests shall be determined in accordance with the principles set forth in Section 544 of the Internal Revenue Code of 1986, as amended from time to time, or the corresponding provisions of any subsequent law. In addition, the following shall be deemed an assignment within the meaning of this Article XII: (a) the merger or consolidation of Tenant into or with any other entity, or the sale of all or substantially all of its assets, and (b) the establishment by the Tenant or a permitted successor or assign of one or more series of (1) members, managers, limited liability company interests or assets, which may have separate rights, powers or duties with respect to specified property or obligations of the Tenant (or such successor or assignee) or profits or losses associated with specified property or obligations of the Tenant (or such successor or assignee), pursuant to §18-215 of the Delaware Limited Liability Company Act, as amended, or similar laws of other states or otherwise, or (2) limited partners, general partners, partnership interests or assets, which may have separate rights, powers or duties with respect to specified property or obligations of the Tenant (or such successor or assignee) or profits or losses associated with specified property or obligations of the Tenant (or such successor or assignee) pursuant to §17-218 of the Delaware Revised Uniform Limited Partnership Act, as amended, or similar laws of other states or otherwise (a "**Series Reorganization**"). Any assignment, mortgage, pledge, hypothecation, transfer or subletting not expressly permitted in or consented to by Landlord under this Article XII shall, at Landlord's election, be void, of no force and effect, and confer no rights on or in favor of third parties. In addition, Landlord shall be entitled to seek specific performance of or other equitable relief with respect to the provisions hereof.

12.2 Tenant's Notice

Notwithstanding the provisions of Section 12.1 above, in the event Tenant desires to assign this Lease or to sublet the whole or any part of the Premises (partial subletting being permitted subject to the provisions of Section 12.7(G) below), Tenant shall give Landlord notice (the "**Proposed Transfer Notice**") of any proposed sublease or assignment, and said notice shall specify the provisions of the proposed assignment or subletting, including (a) the name and address of the proposed assignee or subtenant, (b) in the case of a proposed assignment or subletting pursuant to Section 12.4 below, such information as to the proposed assignee's or proposed subtenant's net worth and financial capability and standing as may reasonably be required for Landlord to make the determination referred to in said Section 12.4 (provided, however, that Landlord shall hold such information confidential having the right to release same to its officers, accountants, attorneys and mortgage lenders on a confidential basis), (c) all of the terms and provisions upon which the proposed assignment or subletting is to be made (including

in the case of a proposed subletting, the area proposed to be sublet and the proposed sublease term), (d) in the case of a proposed assignment or subletting pursuant to Section 12.4 below, all other information necessary to make the determination referred to in said Section 12.4 and (e) in the case of a proposed assignment or subletting pursuant to Section 12.5 below, such information as may be reasonably required by Landlord to determine that such proposed assignment or subletting complies with the requirements of said Section 12.5.

12.3 Landlord's Termination Right

Notwithstanding the provisions of Section 12.2 above, in the event Tenant desires to (i) assign this Lease or (ii) sublet any portion of the Premises that (together with any such portions already sublet by Tenant) comprises more than fifty percent (50%) of the Rentable Floor Area of the Premises for a term equal to all or substantially all of the remaining Lease Term hereof, then Tenant shall notify Landlord thereof in writing, which notice shall identify the affected portion of the Premises (the "**Recapture Premises**"). Landlord shall have the right at its sole option, to be exercised within twenty (20) days after receipt of Tenant's Proposed Transfer Notice (the "**Acceptance Period**"), to terminate this Lease solely with respect to the Recapture Premises as of a date specified in a notice to Tenant, which date shall not be earlier than sixty (60) days nor later than one hundred and twenty (120) days after Landlord's notice to Tenant; provided, however, that upon the termination date as set forth in Landlord's notice, all obligations relating to the period after such termination date (but not those relating to the period before such termination date) shall cease and promptly upon being billed therefor by Landlord, Tenant shall make final payment of all Annual Fixed Rent and Additional Rent due from Tenant through the termination date. In the event that Landlord shall not exercise its termination rights as aforesaid, or shall fail to give any or timely notice pursuant to this Section, the provisions of Sections 12.4, 12.6 and 12.7 shall be applicable. This Section 12.3 shall not be applicable to an assignment or sublease pursuant to Section 12.5. From and after the termination date the Rentable Floor Area of the Premises shall be reduced to the rentable floor area of the remainder of the Premises and the definition of Rentable Floor Area of the Premises shall be so amended, and after such termination all references in this Lease to the "Premises" or the "Rentable Floor Area of the Premises" shall be deemed to be references to the remainder of the Premises and, accordingly, Tenant's payments for Annual Fixed Rent, operating costs, real estate taxes and electricity shall be reduced on a pro rata basis to reflect the size of the remainder of the Premises.

In the case of a partial subletting where Landlord has exercised its termination right pursuant to this Section 12.3, Landlord shall be responsible, at its sole cost and expense, for all work necessary to separately physically demise that portion of the Premises which are being terminated from the remainder of the Premises.

12.4 Consent of Landlord

Notwithstanding the provisions of Section 12.1 above, but subject to the provisions of this Section 12.4 and the provisions of Sections 12.6 and 12.7 below, in the event that Landlord shall not have exercised the termination right as set forth in Section 12.3, or shall have failed to give any or timely notice under Section 12.3, then for a period of one hundred and eighty (180) days (i) after the receipt of Landlord's notice stating that Landlord does not elect the termination right,

or (ii) after the expiration of the Acceptance Period, in the event Landlord shall not give any or timely notice under Section 12.3 as the case may be, Tenant shall have the right to assign this Lease or sublet the whole (or any part) of the Premises in accordance with the Proposed Transfer Notice; provided that, in each instance, Tenant first obtains the express prior written consent of Landlord, which consent shall not be unreasonably withheld, conditioned, or delayed, Landlord hereby agreeing to grant (or withhold) such consent within ten (10) business days following the expiration of the Acceptance Period.

Without limiting the foregoing standard, Landlord shall not be deemed to be unreasonably withholding its consent to such a proposed assignment or subleasing if:

(a) the proposed assignee or subtenant is an occupant of the Building or is (or within the previous thirty (30) days has been) in active negotiation with Landlord for premises in the Building and Landlord has existing space that satisfies such party's needs, or

(b) the proposed assignee or subtenant is not of a character consistent with the operation of a first class office/research/laboratory building (by way of example Landlord shall not be deemed to be unreasonably withholding its consent to an assignment or subleasing to any governmental or quasi-governmental agency), or

(c) giving appropriate weight, if applicable, to the fact that Tenant will nevertheless remain liable under this Lease, the proposed assignee or subtenant does not possess adequate financial capability to perform the Tenant obligations as and when due or required, or

(d) the assignee or subtenant proposes to use the Premises (or part thereof) for a purpose other than the purpose for which the Premises may be used as stated in Section 1.1 hereof, or

(e) the character of the business to be conducted or the proposed use of the Premises by the proposed subtenant or assignee shall (i) be likely to materially increase Landlord's Operating Expenses beyond that which Landlord now incurs for use by Tenant; (ii) be likely to materially increase the burden on elevators or other Building systems or equipment over the burden prior to such proposed subletting or assignment; or (iii) materially violate or be likely to materially violate any provisions or restrictions contained herein relating to the use or occupancy of the Premises, or

(f) there shall be existing a monetary or material non-monetary Event of Default (defined in Section 15.1), or

(g) any part of the rent payable under the proposed assignment or sublease shall be based in whole or in part on the income or profits derived from the Premises or if any proposed assignment or sublease shall potentially

have any adverse effect on the real estate investment trust qualification requirements applicable to Landlord and its affiliates, or

(h) the holder of any mortgage or ground lease on property which includes the Premises does not approve of the proposed assignment or sublease, where such mortgage holder or ground lessor has approval rights with respect to such proposed assignment or subletting pursuant to the terms of its mortgage or ground lease, or

(i) due to the identity or business of a proposed assignee or subtenant, such approval would cause Landlord to be in violation of any covenant or restriction contained in another lease or other agreement affecting space in the Building.

If Landlord shall consent to the proposed assignment or subletting, as the case may be, then, in such event, Tenant may thereafter sublease (the whole or any part of the Premises) or assign pursuant to Tenant's notice, as given hereunder; provided, however, that if such assignment or sublease shall not be executed and delivered to Landlord within one hundred eighty (180) days after the date of Landlord's consent, the consent shall be deemed null and void and the provisions of Section 12.2 shall be applicable.

12.5 Exceptions

Notwithstanding the provisions of Sections 12.1, 12.3 and 12.4 above, but subject to the provisions of Section 12.2 above and Section 12.7 below, Tenant shall have the right, without the prior written consent of Landlord:

(x) to assign this Lease or to sublet the Premises (in whole or in part) to any other entity (the "**Successor Entity**") (i) which controls or is controlled by Tenant or Tenant's parent corporation or which is under common control with Tenant, provided that such transfer or transaction is for a legitimate regular business purpose of Tenant other than a transfer of Tenant's interest in this Lease, or (ii) which purchases all or substantially all of the assets of Tenant, or (iii) which purchases all or substantially all of the stock of (or other ownership or membership interests in) Tenant or (iv) which merges with, consolidates into, or combines with Tenant, or into which Tenant may be converted, or

(y) to effect a Series Reorganization, or

(z) to engage in a Majority Interest Transfer,

provided that in any of the foregoing events as described in clauses (y) or (z) above the transaction is for a legitimate business purpose of Tenant other than the limitation or segregation of the liabilities of Tenant, and provided further that in any of the foregoing events as described in clauses (x), (y) and (z), the entity to which this Lease is so assigned or which so sublets the Premises or the series established by the Series Reorganization has a credit worthiness (e.g. net

assets on a pro forma basis using generally accepted accounting principles consistently applied and using the most recent financial statements) which is the same or better than the Tenant as of the date of this Lease (the foregoing transferees referred to, individually or collectively, as a "**Permitted Transferee**"). Tenant shall give Landlord notice of any planned sublease or assignment pursuant to this Section 12.5 at least ten (10) days prior to the effective date of such planned sublease or assignment, along with such information as may be reasonably requested by Landlord to determine that such planned assignment or subletting complies with the requirements of this Section 12.5; provided that, if prior notice of such planned sublease or assignment cannot be given due to confidentiality requirements imposed on Tenant by a contractual obligation or applicable regulatory requirements, then Tenant instead shall be required to give notice to Landlord of the occurrence of such assignment or sublease as soon as it is legally permitted, but no later than ten (10) business days following the effective date of such assignment or sublease.

Except in cases of statutory merger or a Series Reorganization, in which case the surviving entity in the merger or the series to which this Lease has been designated shall be liable as the Tenant under this Lease, Tenant shall continue to remain fully liable under this Lease, on a joint and several basis with the Permitted Transferee. If any parent, affiliate or subsidiary of Tenant to which this Lease is assigned or the Premises sublet (in whole or in part) shall cease to be such a parent, affiliate or subsidiary, and if such cessation was contemplated at the time of the assignment or subletting, such cessation shall be considered an assignment or subletting requiring Landlord's consent.

12.6 Profit on Subleasing or Assignment

In the case of any assignment or subleasing as to which Landlord may consent (other than an assignment or subletting permitted under Section 12.5 above) such consent shall be upon the express and further condition, covenant and agreement, and Tenant hereby covenants and agrees that, in addition to the Annual Fixed Rent, Additional Rent and other charges to be paid pursuant to this Lease, fifty percent (50%) of the "Assignment/Sublease Profits" (hereinafter defined), if any, shall be paid to Landlord. The "**Assignment/Sublease Profits**" shall be the excess, if any, of (a) the "Assignment/Sublease Net Revenues" as hereinafter defined over (b) the Annual Fixed Rent and Additional Rent and other charges provided in this Lease (provided, however, that for the purpose of calculating the Assignment/Sublease Profits in the case of a sublease, appropriate proportions in the applicable Annual Fixed Rent, Additional Rent and other charges under this Lease shall be made based on the percentage of the Premises subleased and on the terms of the sublease). The "**Assignment/Sublease Net Revenues**" shall be the fixed rent, additional rent and all other charges and sums payable either initially or over the term of the sublease or assignment less the reasonable costs of Tenant incurred in such subleasing or assignment (the definition of which shall be limited to brokerage commissions, advertising and marketing costs, rent concessions, attorneys' fees, architect and construction management fees, and alteration allowances, in each case actually paid and expressly excluding the amount of any construction or other allowance provided by Landlord to Tenant), as set forth in a statement certified by an appropriate officer of Tenant and delivered to Landlord within thirty (30) days of the full execution of the sublease or assignment document, amortized over the term of the sublease or assignment.

All payments of the Assignment/Sublease Profits due Landlord shall be made within ten (10) days of receipt of same by Tenant.

12.7 Additional Conditions

(A) It shall be a condition of the validity of any assignment or subletting consented to under Section 12.4 above, or any assignment or subletting of right under Section 12.5 above, that both Tenant and the assignee or sublessee enter into a separate written instrument directly with Landlord in a form and containing terms and provisions reasonably required by Landlord, including, without limitation, the agreement of the assignee or sublessee to be bound directly to Landlord for all the obligations of the Tenant hereunder, including, without limitation, the obligation (a) to pay the rent and other amounts provided for under this Lease (but in the case of a partial subletting pursuant to Section 12.5, such subtenant shall agree on a pro rata basis to be so bound) and (b) to comply with the provisions of Article XII hereof and (c) to indemnify the "Landlord Parties" (as defined in Section 13.13) as provided in Section 13.1 hereof. Such assignment or subletting shall not relieve the Tenant named herein of any of the obligations of the Tenant hereunder and Tenant shall remain fully and primarily liable therefor and the liability of Tenant and such assignee (or subtenant, as the case may be) shall be joint and several. Further, and notwithstanding the foregoing, the provisions hereof shall not constitute a recognition of the sublease or the subtenant thereunder, as the case may be, and at Landlord's option, upon the termination or expiration of the Lease (whether such termination is based upon a cause beyond Tenant's control, a default of Tenant, the agreement of Tenant and Landlord or any other reason), the sublease shall be terminated.

(B) As Additional Rent, Tenant shall pay to Landlord as a fee for Landlord's review of any proposed assignment or sublease requested by Tenant and the preparation of any associated documentation in connection therewith, within thirty (30) days after receipt of an invoice from Landlord, an amount equal to the reasonable out of pocket legal fees or other expenses incurred by Landlord in connection with such request (such amount not to exceed $3,000).

(C) If this Lease be assigned, or if the Premises or any part thereof be sublet or occupied by anyone other than Tenant, Landlord may upon prior notice to Tenant, at any time and from time to time, collect rent and other charges from the assignee, sublessee or occupant and apply the net amount collected to the rent and other charges herein reserved, but no such assignment, subletting, occupancy or collection shall be deemed a waiver of this covenant, or a waiver of the provisions of Article XII hereof, or the acceptance of the assignee, sublessee or occupant as a tenant or a release of Tenant from the further performance by Tenant of covenants on the part of Tenant herein contained, the Tenant herein named to remain primarily liable under this Lease.

(D) The consent by Landlord to an assignment or subletting under Section 12.4 above, or the consummation of an assignment or subletting of right under Section 12.5 above, shall in no way be construed to relieve Tenant from obtaining the express consent in writing of Landlord to any further assignment or subletting.

(E) Landlord shall be entitled to one hundred percent (100%) of any Assignment/Sublease Profits reasonably allocable (in Landlord's reasonable determination consistent with Section 12.6) to any calendar month of the Term during which there is or was subsisting, at any time during said calendar month, a monetary or material non-monetary Event of Default (as defined in Section 15.1).

(F) Without limiting Tenant's obligations under Article IX, Tenant shall be responsible, at Tenant's sole cost and expense, for performing all work necessary to comply with Legal Requirements and Insurance Requirements in connection with any assignment or subletting hereunder including, without limitation, any work in connection with such assignment or subletting.

(G) In addition to the other requirements set forth in this Lease and notwithstanding any other provisions of this Lease, partial sublettings of the Premises shall only be permitted under the following terms and conditions: (i) the layout of both the subleased premises and the remainder of the Premises must comply with applicable laws, ordinances, rules and/or regulations, and must be reasonably approved by Landlord, including, without limitation, all requirements concerning access and egress; (ii) in the event the subleased premises are separately physically leased from the remainder of the Premises, except as provided in Section 12.3, Tenant shall pay all costs of separately physically demising the subleased premises; and (iii) there shall be no more than three (3) subleases in effect in the Premises at any given time.

ARTICLE XIII

Indemnity and Insurance

13.1 Tenant's Indemnity

(a) Indemnity. To the fullest extent permitted by law, but subject to the limitations in Section 16.24 hereof, Tenant waives any right to contribution against the Landlord Parties (as hereinafter defined) and agrees to indemnify and save harmless the Landlord Parties from and against all claims of whatever nature by a third party to the extent arising from or claimed to have arisen from (i) any act, omission or negligence of any of the Tenant Parties (as hereinafter defined) occurring in or about the Premises, the Building, or the Property; (ii) any accident, injury or damage whatsoever caused to any person, or to the property of any person, occurring in or about the Premises from the earlier of (A) the date on which any Tenant Party first enters the Premises for any reason or (B) the Commencement Date, and thereafter throughout and until the end of the Lease Term, and after the end of the Lease Term for so long after the end of the Lease Term as any of Tenant's Property (as defined in Section 13.4) remains on the Premises, or Tenant or anyone acting by, through or under Tenant may use, be in occupancy of any part of, or have access to the Premises or any portion thereof; (iii) any accident, injury or damage whatsoever occurring outside the Premises but within the Building or elsewhere at the Property, where such accident, injury or damage results, or is claimed to have resulted, from any act, omission or negligence on the part of any of the Tenant Parties; or (iv) any breach of this Lease by Tenant. Tenant shall pay such indemnified amounts as they are incurred by the Landlord Parties. This indemnification shall not be construed to deny or reduce any other rights or obligations of indemnity that any of the Landlord Parties may have under this Lease. The indemnification rights

of Landlord Parties provided in this Lease are their exclusive indemnification rights with respect to this Lease. Landlord Parties waive any additional rights to indemnification they may have against Tenant Parties with respect to this Lease under common law. Notwithstanding anything contained herein to the contrary, Tenant shall not be obligated to indemnify a Landlord Party for any claims to the extent that such Landlord Party's damages result from matters included in Landlord's indemnity in Section 13.1.1 of this Article.

(b) Breach. In the event that Tenant breaches any of its indemnity obligations hereunder: (i) Tenant shall pay to the Landlord Parties all liabilities, loss, cost, or expense (including reasonable attorneys' fees) incurred as a result of said breach; and (ii) the Landlord Parties may deduct and offset from any amounts due to Tenant under this Lease any amounts owed by Tenant pursuant to this Section 13.1(b).

(c) No limitation. The indemnification obligations under this Section 13.1 shall not be limited in any way by any limitation on the amount or type of damages, compensation or benefits payable by or for Tenant or any subtenant or other occupant of the Premises under workers' compensation acts, disability benefit acts, or other employee benefit acts. Tenant waives any immunity from or limitation on its indemnity or contribution liability to the Landlord Parties based upon such acts.

(d) Subtenants and other occupants. Tenant shall require its subtenants and other occupants of the Premises to provide similar indemnities to the Landlord Parties in a form reasonably acceptable to Landlord.

(e) Survival. The terms of this Section 13.1 shall survive any termination or expiration of this Lease.

(f) Costs. The foregoing indemnity and hold harmless agreement shall include indemnity for all reasonable costs, expenses and liabilities (including, without limitation, reasonable attorneys' fees and disbursements) incurred by the Landlord Parties in connection with any such claim or any action or proceeding brought thereon, and the defense thereof. In addition, in the event that any action or proceeding shall be brought against one or more Landlord Parties by reason of any such claim, Tenant, upon request from the Landlord Party, shall resist and defend such action or proceeding on behalf of the Landlord Party by counsel appointed by Tenant's insurer (if such claim is covered by insurance without reservation) or otherwise by counsel reasonably satisfactory to the Landlord Party. The Landlord Parties shall not be bound by any compromise or settlement of any such claim, action or proceeding without the prior written consent of such Landlord Parties.

(g) Landlord Parties and Tenant Parties. The term "**Landlord Party**" or "**Landlord Parties**" shall mean Landlord, any affiliate of Landlord, Landlord's managing agents for the Building, each mortgagee (if any), each ground lessor (if any)**,** and each of their respective direct or indirect partners, officers, shareholders, directors, members, trustees, beneficiaries, servants, employees, principals, contractors, licensees, agents or representatives. For the purposes of this Lease, the term "**Tenant Party**" or "**Tenant Parties**" shall mean Tenant, any affiliate of Tenant, any permitted subtenant or any other permitted occupant of the Premises, and each of their

respective direct or indirect partners, officers, shareholders, directors, members, trustees, beneficiaries, servants, employees, principals, contractors, licensees, agents, invitees or representatives.

13.1.1 Landlord's Indemnity. To the fullest extent permitted by law, but subject to the limitations in Section 16.24 and in Section 13.2 and Section 13.13 of this Article, and to the extent not resulting from any act, omission, fault, negligence or willful misconduct of Tenant or its contractors, licensees, invitees, agents, servants or employees, Landlord waives its right to contribution and agrees to indemnify and save harmless Tenant from and against any claim by a third party arising from any injury to any person occurring in the Premises or in the Property after the date that possession of the Premises is first delivered to Tenant and until the expiration or earlier termination of the Lease Term, to the extent such injury results from the negligence or willful misconduct of Landlord or any Landlord Party, or from any breach or default by Landlord in the performance or observance of its covenants or obligations under this Lease; provided, however, that in no event shall the aforesaid indemnity render Landlord responsible or liable for any loss or damage to fixtures, personal property or other property of Tenant, and Landlord shall in no event be liable for any indirect or consequential damages. Tenant shall provide notice of any such third party claim to Landlord as soon as practicable. Landlord shall have the right, but not the duty, to defend the claim. The provisions of this Section shall not be applicable to (i) the holder of any mortgage now or hereafter on the Property or Building (whether or not such holder shall be a mortgagee in possession of or shall have exercised any rights under a conditional, collateral or other assignment of leases and/or rents respecting the Property or Building), or (ii) any person acquiring title as a result of, or subsequent to, a foreclosure of any such mortgage or a deed in lieu of foreclosure, except to the extent of liability insurance maintained by either of the foregoing. The indemnification rights of Tenant provided in this Lease are its exclusive indemnification rights with respect to this Lease. Tenant waives any additional rights to indemnification it may have against Landlord Parties with respect to this Lease under common law. The terms of this Section 13.1.1 shall survive any termination or expiration of this Lease.

13.2 Tenant's Risk

Tenant agrees to use and occupy the Premises, and to use such other portions of the Building and the Property as Tenant is given the right to use by this Lease at Tenant's own risk. The Landlord Parties shall not be liable to the Tenant Parties for any damage, injury, loss, compensation, or claim (including, but not limited to, claims for the interruption of or loss to a Tenant Party's business) based on, arising out of or resulting from any cause whatsoever, including, but not limited to, repairs to any portion of the Premises or the Building or the Property, any fire, robbery, theft, mysterious disappearance, or any other crime or casualty, any cyber attack affecting the Building, systems or any computer systems in the Premises, the actions of any other tenants of the Building or of any other person or persons, or any leakage in any part or portion of the Premises or the Building or the Property, or from water, rain or snow that may leak into, or

flow from any part of the Premises or the Building or the Property, or from drains, pipes or plumbing fixtures in the Building or the Property. Any goods, property or personal effects stored or placed in or about the Premises shall be at the sole risk of the Tenant Party, and neither the Landlord Parties nor their insurers shall in any manner be held responsible therefor. The Landlord Parties shall not be responsible or liable to a Tenant Party, or to those claiming by, through or under a Tenant Party, for any loss or damage that may be occasioned by or through the acts or omissions of persons occupying adjoining premises or any part of the premises adjacent to or connecting with the Premises or any part of the Building or otherwise. The provisions of this section shall be applicable to the fullest extent permitted by law, and until the expiration or earlier termination of the Lease Term, and during such further period as any of Tenant's Property remains on the Premises, or Tenant or anyone acting by, through or under Tenant may use, be in occupancy of any part of, or have access to the Premises or of the Building.

13.3 Tenant's Commercial General Liability Insurance

Tenant agrees to maintain in full force on or before the earlier of (i) the date on which Tenant or any Tenant Party first accesses the Premises in connection with the work contemplated in Section 1.1(B)(4) of the Work Agreement attached as Exhibit B-1 hereto, or (ii) the Commencement Date, and thereafter throughout and until the end of the Lease Term, and after the end of the Lease Term for so long as any of Tenant's Property remains on the Premises, or Tenant or anyone acting by, through or under Tenant may use, be in occupancy of any part of, or have access to the Premises or any portion thereafter, a policy of commercial general liability insurance, on an occurrence basis, issued on a form at least as broad as Insurance Services Office ("**ISO**") Commercial General Liability Coverage "occurrence" form CG 00 01 10 01 or another Commercial General Liability "occurrence" form providing equivalent coverage. Such insurance shall include contractual liability coverage, specifically covering but not limited to the indemnification obligations undertaken by Tenant in this Lease. The minimum limits of liability of such insurance shall be $5,000,000.00 per occurrence, which may be satisfied through a combination of primary and excess/umbrella insurance. In addition, in the event Tenant hosts a function in the Premises, in the Building or on the Property, Tenant agrees to obtain, and cause any persons or parties providing services for such function to obtain, the appropriate insurance coverages as reasonably determined by Landlord (including liquor liability coverage, if applicable) and provide Landlord with evidence of the same upon request.

13.4 Tenant's Property Insurance

Tenant shall maintain at all times during the Term of this Lease, and during such earlier or later time as Tenant may be performing work in or to the Premises or have property, fixtures, furniture, equipment, machinery, goods, supplies, wares or merchandise on the Premises, and continuing thereafter so long as any of Tenant's Property, remains on the Premises, or Tenant or anyone acting by, through or under Tenant may use, be in occupancy of or have access to, any part of the Premises, business interruption insurance and insurance against loss or damage covered by the so-called "all risk" or equivalent type insurance coverage with respect to (i) Tenant's property, fixtures, furniture, equipment, machinery, goods, supplies, wares and merchandise, and other property of Tenant located at the Premises, (ii) all additions, alterations

and improvements made by or on behalf of the Tenant in the Premises (except to the extent paid for by Landlord in connection with this Lease) or existing in the Premises as of the date of this Lease ("**Leasehold Improvements**"), and (iii) any property of third parties, including but not limited to leased or rented property, in the Premises in Tenant's care, custody, use or control, provided that such insurance in the case of (iii) may be maintained by such third parties (collectively, "**Tenant's Property**"). At the request of Landlord (provided that Landlord may not make such request more than once in any 24 month period), Tenant shall provide to Landlord a reasonably detailed description of the Leasehold Improvements made by or on behalf of Tenant and the approximate cost thereof. The business interruption insurance required by this section shall be in minimum amounts typically carried by prudent tenants engaged in similar operations, but in no event shall be in an amount less than $3,000,000. The "all risk" or equivalent insurance required by this section shall be in an amount at least equal to the full replacement cost of Tenant's Property. In addition, during such time as Tenant is performing work in or to the Premises, Tenant, at Tenant's expense, shall also maintain, or shall cause its contractor(s) to maintain, builder's risk insurance for the full insurable value of such work. Landlord and such additional persons or entities as Landlord may reasonably request shall be named as loss payees, as their interests may appear, on the policy or policies required by this section for Leasehold Improvements. In the event of loss or damage covered by the "all risk" or equivalent insurance required by this Lease, the responsibilities for repairing or restoring the loss or damage shall be determined in accordance with Article XIV. To the extent that Landlord is obligated to pay for the repair or restoration of the loss or damage covered by the policy, Landlord shall be paid the proceeds of the "all risk" or equivalent insurance covering the loss or damage. To the extent Tenant is obligated to pay for the repair or restoration of the loss or damage, covered by the policy, Tenant shall be paid the proceeds of the "all risk" or equivalent insurance covering the loss or damage. If both Landlord and Tenant are obligated to pay for the repair or restoration of the loss or damage covered by the policy, the insurance proceeds shall be paid to each of them in the pro rata proportion of their obligations to repair or restore the loss or damage. If the loss or damage is not repaired or restored (for example, if the Lease is terminated pursuant to Article XIV), the insurance proceeds shall be paid to Landlord and Tenant in the pro rata proportion of their relative contributions to the cost of the leasehold improvements covered by the policy.

13.5 Tenant's Other Insurance

Tenant agrees to maintain in full force on or before the earlier of (i) the date on which any Tenant Party first enters the Premises for any reason or (ii) the Commencement Date, and thereafter throughout the end of the Term, and after the end of the Term for so long after the end of the Term any of Tenant's Property remains on the Premises or as Tenant or anyone acting by, through or under Tenant may use, be in occupancy of, or have access to the Premises or any portion thereafter, (1) automobile liability insurance (covering any automobiles owned or operated by Tenant at the Property); (2) worker's compensation insurance as required by law; (3) employer's liability insurance. Such automobile liability insurance shall be in an amount not less than One Million Dollars ($1,000,000) for each accident. Such employer's liability insurance shall be in an amount not less than One Million Dollars ($1,000,000) for each accident, One Million Dollars ($1,000,000) disease-policy limit, and One Million Dollars ($1,000,000) disease-each employee; and (4) pollution/environmental liability insurance covering the environmental risks of Tenant's business with limits of not less than Two Million Dollars ($2,000,000) per

occurrence and not less than Three Million Dollars ($3,000,000) in the aggregate, with respect to environmental contamination and pollution of the Property caused by Tenant.

13.6 Requirements for Tenant's Insurance

All insurance required to be maintained by Tenant pursuant to this Lease shall be maintained with responsible companies that are admitted to do business, and are in good standing in the Commonwealth of Massachusetts and that have a rating of at least "A" and are within a financial size category of not less than "Class X" in the most current Best's Key Rating Guide or such similar rating as may be reasonably selected by Landlord. All such insurance shall: (1) be acceptable in form and content to Landlord; and (2) contain a clause requiring the insurer to provide Landlord thirty (30) days' prior written notice of cancellation or failure to renew. All commercial general liability and excess/umbrella liability insurance policies shall be primary and noncontributory. No such policy shall contain any self-insured retention greater than $100,000.00 for property insurance and $25,000.00 for commercial general liability insurance. Any deductibles and such self-insured retentions shall be deemed to be "insurance" for purposes of the waiver in Section 13.13 below. Landlord reserves the right from time to time (but no more than once during any three (3) year period during the Term) to require Tenant to obtain higher minimum amounts of insurance based on such limits as are customarily carried with respect to similar properties in the area in which the Premises are located. The minimum amounts of insurance required by this Lease shall not be reduced by the payment of claims or for any other reason. In the event Tenant shall fail to obtain or maintain any insurance meeting the requirements of this Article, or to deliver such policies or certificates as required by this Article, Landlord may, at its option, on five (5) days notice to Tenant, procure such policies for the account of Tenant, and the cost thereof shall be paid to Landlord within ten (10) business days after delivery to Tenant of bills therefor. Landlord reserves the right to use a third-party provider to administer the collection of Tenant's insurance certificates and compliance with the insurance requirements hereunder. In the event Landlord chooses to do so, Landlord's service provider will contact Tenant using Tenant's Email Address for Insurance Matters listed in Section 1.1 to provide further information.

13.7 Additional Insureds

To the fullest extent permitted by law, the commercial general liability and auto insurance carried by Tenant pursuant to this Lease, and any additional liability insurance carried by Tenant pursuant to Section 13.5 of this Lease or any other provision of this Lease, shall name Landlord, Landlord's managing agent, and such other persons as Landlord may reasonably request from time to time as additional insureds with respect to liability arising out of or related to this Lease or the operations of Tenant (collectively "**Additional Insureds**"). Such insurance shall provide primary coverage without contribution from any other insurance carried by or for the benefit of Landlord, Landlord's managing agent, or other Additional Insureds. Such insurance shall also waive any right of subrogation against each Additional Insured. For the avoidance of doubt, each primary policy and each excess/umbrella policy through which Tenant satisfies its obligations under this Section 13.7 must provide coverage to the Additional Insureds that is primary and non-contributory.

13.8 Certificates of Insurance

On or before the earlier of (i) the date on which any Tenant Party first enters the Premises for any reason or (ii) the Commencement Date, Tenant shall furnish Landlord with certificates evidencing the insurance coverage required by this Lease, and renewal certificates shall be furnished to Landlord at least annually thereafter, and prior to the expiration date of each policy for which a certificate was furnished (acceptable forms of such certificates for liability and property insurance, respectively, as of the date hereof, are attached as Exhibit K, however, other forms of certificates may satisfy the requirements of this Section 13.8). Failure by the Tenant to provide the certificates or letters required by this Section 13.8 shall not be deemed to be a waiver of the requirements in this Section 13.8. Upon request by Landlord, a true and complete copy of any insurance policy required by this Lease shall be delivered to Landlord within ten (10) days following Landlord's request.

13.9 Subtenants and Other Occupants

Tenant shall require its subtenants and other occupants of the Premises to provide written documentation evidencing the obligation of such subtenant or other occupant to indemnify the Landlord Parties to the same extent that Tenant is required to indemnify the Landlord Parties pursuant to Section 13.1 above, and to maintain insurance that meets the requirements of this Article, and otherwise to comply with the requirements of this Article, provided that the terms of this Section 13.9 shall not relieve Tenant of any of its obligations to comply with the requirements of this Article. Tenant shall require all such subtenants and occupants to supply certificates of insurance evidencing that the insurance requirements of this Article have been met and shall forward such certificates to Landlord on or before the earlier of (i) the date on which the subtenant first enters the Premises or (ii) the commencement of the sublease. Tenant shall be responsible for identifying and remedying any deficiencies in such certificates or policy provisions.

13.10 No Violation of Building Policies

Tenant shall not commit or permit any violation of the policies of fire, boiler, sprinkler, water damage or other insurance covering the Property and/or the fixtures, equipment and property therein carried by Landlord, or do or permit anything to be done, or keep or permit anything to be kept, in the Premises, which in case of any of the foregoing (i) would result in termination of any such policies, (ii) would adversely affect Landlord's right of recovery under any of such policies, or (iii) would result in reputable and independent insurance companies refusing to insure the Property or the property of Landlord in amounts reasonably satisfactory to Landlord.

13.11 Tenant to Pay Premium Increases

To the extent that, because of anything done, caused or permitted to be done, or omitted by Tenant (or its subtenant or other occupants of the Premises), the rates for liability, fire, boiler, sprinkler, water damage or other insurance on the Property and equipment of Landlord or any other tenant or subtenant in the Building shall be higher than they otherwise would be, Tenant shall reimburse Landlord and/or the other tenants and subtenants in the Building for the additional insurance premiums thereafter paid by Landlord or by any of the other tenants and

subtenants in the Building which shall have been charged because of the aforesaid reasons, such reimbursement to be made from time to time on Landlord's demand.

13.12 Landlord's Insurance

(a) Required insurance. Landlord shall maintain insurance against loss or damage with respect to the Building on an "all risk" or equivalent type insurance form, with customary exceptions, subject to such deductibles and self-insured retentions as Landlord may reasonably determine, in an amount equal to at least the replacement value of the Building. Landlord shall also maintain such insurance with respect to any improvements, alterations, and fixtures of Tenant located at the Premises to the extent paid for by Landlord. The cost of such insurance shall be treated as a part of Landlord's Operating Expenses. Payment for losses thereunder shall be made solely to Landlord.

(b) Optional insurance. Landlord may maintain such additional insurance with respect to the Building and the Property, including, without limitation, earthquake insurance, terrorism insurance, flood insurance, liability insurance and/or rent insurance, as Landlord may in its sole discretion elect. Landlord may also maintain such other insurance as may from time to time be required by the holder of any mortgage on the Building or Property. The cost of all such additional insurance shall also be part of Landlord's Operating Expenses.

(c) Blanket and self-insurance. Any or all of Landlord's insurance may be provided by blanket coverage maintained by Landlord or any affiliate of Landlord under its insurance program for its portfolio of properties, or by Landlord or any affiliate of Landlord under a program of self-insurance, and in such event Landlord's Operating Expenses shall include the portion of the reasonable cost of blanket insurance or self-insurance that is allocated to the Building.

(d) No obligation. Landlord shall not be obligated to insure, and shall not assume any liability of risk of loss for, Tenant's Property, including any such property or work of Tenant's subtenants or occupants. Landlord will also have no obligation to carry insurance against, nor be responsible for, any loss suffered by Tenant, subtenants or other occupants due to interruption of Tenant's or any subtenant's or occupant's business.

13.13 Waiver of Subrogation

To the fullest extent permitted by law, and notwithstanding any term or provision of this Lease to the contrary, the parties hereto waive and release any and all rights of recovery against the other, and agree not to seek to recover from the other or to make any claim against the other, and in the case of Landlord, against all Tenant Parties, and in the case of Tenant, against all Landlord Parties, for any loss or damage incurred by the waiving/releasing party to the extent such loss or damage is insured under any insurance policy required by this Lease or which would have been so insured had the party carried the insurance it was required to carry hereunder. Tenant shall obtain from its subtenants and other occupants of the Premises a similar waiver and release of claims against any or all of Tenant or Landlord. In addition, the parties hereto (and in the case of Tenant, its subtenants and other occupants of the Premises) shall procure an appropriate clause

in, or endorsement on, any insurance policy required by this Lease pursuant to which the insurance company waives subrogation. The insurance policies required by this Lease shall contain no provision that would invalidate or restrict the parties' waiver and release of the rights of recovery in this section. The parties hereto covenant that no insurer shall hold any right of subrogation against the parties hereto by virtue of such insurance policy.

13.14 Tenant's Work

During such times as Tenant is performing work or having work or services performed in or to the Premises, Tenant shall require its contractors, and their subcontractors of all tiers, to obtain and maintain commercial general liability, automobile, workers compensation, employer's liability, builder's risk, and equipment/property insurance in such amounts and on such terms as are customarily required of such contractors and subcontractors on similar projects. The amounts and terms of all such insurance are subject to Landlord's written approval, which approval shall not be unreasonably withheld. The commercial general liability and auto insurance carried by Tenant's contractors and their subcontractors of all tiers pursuant to this Section 13.14 shall name the Additional Insureds as additional insureds with respect to liability arising out of or related to their work or services. Such insurance shall provide primary coverage without contribution from any other insurance carried by or for the benefit of Landlord, Landlord's managing agent, or other Additional Insureds. Such insurance shall also waive any right of subrogation against each Additional Insured. Tenant shall obtain and submit to Landlord, prior to the earlier of (i) the entry onto the Premises by such contractors or subcontractors or (ii) commencement of the work or services, certificates of insurance evidencing compliance with the requirements of this Section 13.14.

ARTICLE XIV

Fire, Casualty and Taking

14.1 Damage Resulting from Casualty

In case the Building is damaged by fire or casualty, Landlord shall promptly notify Tenant in writing of Landlord's reasonable estimate of the length of time necessary to repair or restore the damage from such fire or casualty from the time that repair work would commence ("**Landlord's Restoration Estimate**"). If Landlord's Restoration Estimate indicates a repair period of more than three hundred (300) days from the date that repair work would commence, Landlord may, at its election, terminate this Lease by notice given to Tenant within sixty (60) days after the date of such fire or other casualty, specifying the effective date of termination. The effective date of termination specified by Landlord shall not be less than thirty (30) days nor more than forty-five (45) days after the date of notice of such termination. Unless terminated pursuant to the foregoing provisions, this Lease shall remain in full force and effect following any such damage subject, however, to the following provisions.

If the Premises shall be damaged by fire or casualty and Landlord's Restoration Estimate indicates a repair period of more than three hundred (300) days from the time that repair work would commence, then Tenant shall have the right, by giving notice to Landlord not later than

thirty (30) days after receipt of Landlord's Restoration Estimate, to terminate this Lease, whereupon this Lease shall terminate as of the date of such notice with the same force and effect as if such date were the date originally established as the expiration date hereof. If during the last eighteen (18) months of the Lease Term as it may have been extended, the Premises shall be damaged by fire or casualty and Landlord's Restoration Estimate indicates a repair period of more than one hundred fifty (150) days from the date of such casualty, then Tenant shall have the right, by giving notice to Landlord not later than thirty (30) days after receipt of Landlord's Restoration Estimate, to terminate this Lease, whereupon this Lease shall terminate as of the date of such notice with the same force and effect as if such date were the date originally established as the expiration date hereof.

If the Building or any part thereof is damaged by fire or casualty and this Lease is not so terminated, or Landlord has no right to terminate this Lease, and in either such case the holder of any mortgage which includes the Building as a part of the mortgaged premises or any ground lessor of any ground lease which includes the Building as part of the demised premises allows the net insurance proceeds to be applied to the restoration of the Building, Landlord, promptly after such damage and the determination of the net amount of insurance proceeds available shall use due diligence to restore the Premises and the Building in the event of damage thereto (excluding Tenant's Property (as defined in Section 13.4 hereof), except as expressly provided in the immediately following paragraph of this Section 14.1) into proper condition for use and occupation and a just proportion of the Annual Fixed Rent, Landlord's Tax Expenses Allocable to the Premises and Operating Expenses Allocable to the Premises according to the nature and extent of the injury to the Premises shall be abated from the date of casualty until the Premises shall have been put by Landlord substantially into such condition and are made available for occupancy by Tenant. If such net insurance proceeds are not allowed by such mortgagee or ground lessor to be applied to, or are otherwise insufficient for, the restoration of the Building and if Landlord does not otherwise elect to spend the additional funds necessary to fully restore the Building, then Landlord shall give notice ("**Landlord's Insufficient Insurance Proceeds Notice**") to Tenant that Landlord does not elect to fund the amount of the insufficiency and Tenant shall thereafter have the right to terminate this Lease by providing Landlord with a notice of termination within thirty (30) days after Tenant's receipt of Landlord's Insufficient Insurance Proceeds Notice (the effective date of which termination shall not be less than sixty (60) days after the date of such notice of such termination).

Notwithstanding the foregoing, if Landlord is proceeding with the restoration of the Building and the Premises in accordance with the previous paragraph, Landlord shall also restore any alterations, additions or improvements within the Premises that are part of Tenant's Property (x) which have previously been approved by Landlord in accordance with the terms and provisions of this Lease or which have been performed in accordance with the provisions of Section 9.7 (including the requirement that Landlord be notified thereof) or which are existing in the Premises as of the date of this Lease, and (y) with respect to which Tenant has carried "all risk" or other equivalent insurance covering the loss or damage in accordance with Section 13.4 above and pays the proceeds of such insurance (or an amount equivalent thereto) to Landlord within five (5) business days following Landlord's written request); provided, however, that in no event shall Landlord be required to fund any insufficiency in the insurance proceeds (or equivalent

amount) provided by Tenant with respect to such loss or damage (or to fund any of the costs of restoration in the absence of any payment by Tenant).

Where Landlord is obligated or otherwise elects to effect restoration of the Premises, unless such restoration is completed on or before the later of (i) one (1) year from the date of the casualty or (ii) the last day of the estimated restoration period set forth in Landlord's Restoration Estimate, such periods set forth in clauses (i) and (ii) to be subject, however, to extension where the delay in completion of such work is due to Force Majeure, as defined in Section 16.31 below (but in no event beyond eighteen (18) months from the date of the casualty or taking), Tenant, as its sole and exclusive remedy, shall have the right to terminate this Lease at any time after the expiration of such later period (as extended) until the restoration is substantially completed, such termination to take effect as of the thirtieth (30^{th}) day after the date of receipt by Landlord of Tenant's notice, with the same force and effect as if such date were the date originally established as the expiration date hereof unless, within such thirty (30) day period such restoration is substantially completed, in which case Tenant's notice of termination shall be of no force and effect and this Lease and the Lease Term shall continue in full force and effect.

14.2 Uninsured Casualty

Notwithstanding anything to the contrary contained in this Lease, if the Building or the Premises shall be substantially damaged by fire or casualty as the result of a risk not covered by the forms of casualty insurance at the time required to be maintained by Landlord pursuant to this Lease, and such fire or casualty damage cannot, in the ordinary course, reasonably be expected to be repaired within one hundred fifty (150) days from the time that repair work would commence, Landlord may, at its election, terminate the Term of this Lease by notice to Tenant given within thirty (30) days after such loss. If Landlord shall give such notice, then this Lease shall terminate as of the date of such notice with the same force and effect as if such date were the date originally established as the expiration date hereof.

14.3 Rights of Termination for Taking

If the Building, or such portion thereof as to render the balance (if reconstructed to the maximum extent practicable in the circumstances) unsuitable for Tenant's purposes, shall be taken by condemnation or right of eminent domain, Landlord or Tenant shall have the right to terminate this Lease by notice to the other of its desire to do so, provided that such notice is given not later than thirty (30) days after Tenant has been deprived of possession. If either party shall give such notice, then this Lease shall terminate as of the date of such notice with the same force and effect as if such date were the date originally established as the expiration date hereof.

Further, if so much of the Building or the Property shall be so taken that continued operation of the Building would be uneconomic as determined by Landlord in its reasonable discretion, Landlord shall have the right to terminate this Lease by giving notice to Tenant of Landlord's desire to do so not later than thirty (30) days after Tenant has been deprived of possession of the Premises (or such portion thereof as may be taken). Landlord agrees not to exercise such termination right in a discriminatory manner insofar as any election Landlord makes, or refrains from making, pursuant to any termination right Landlord may have with respect to other tenants

of the Building whose premises are similarly affected. If Landlord shall give such notice, then this Lease shall terminate as of the date of such notice with the same force and effect as if such date were the date originally established as the expiration date hereof.

Should any part of the Premises be so taken or condemned during the Lease Term hereof, and should this Lease not be terminated in accordance with the foregoing provisions, and the holder of any mortgage which includes the Premises as part of the mortgaged premises or any ground lessor of any ground lease which includes the Premises as part of the demised premises allows the net condemnation proceeds to be applied to the restoration of the Building, Landlord agrees that after the determination of the net amount of condemnation proceeds available to Landlord, Landlord shall use due diligence to put what may remain of the Premises into proper condition for use and occupation as nearly like the condition of the Premises prior to such taking as shall be practicable (excluding Tenant's Property). If such net condemnation proceeds are not allowed by such mortgagee or ground lessor to be applied to, or are otherwise insufficient for, the restoration of the Building (and/or the Property) and if Landlord does not otherwise elect to spend the additional funds necessary to fully restore the Building (and/or the Property), then Landlord shall give notice ("**Landlord's Insufficient Condemnation Proceeds Notice**") to Tenant that Landlord does not elect to fund the amount of the insufficiency and Tenant shall thereafter have the right to terminate this Lease by providing Landlord with a notice of termination within thirty (30) days after Tenant's receipt of Landlord's Insufficient Condemnation Proceeds Notice (the effective date of which termination shall not be less than sixty (60) days after the date of such notice of such termination).

If the Premises shall be affected by any exercise of the power of eminent domain and neither Landlord nor Tenant shall terminate this Lease as provided above, then the Annual Fixed Rent, and Landlord's Tax Expenses Allocable to the Premises and Operating Expenses Allocable to the Premises shall be justly and equitably abated and reduced according to the nature and extent of the loss of use thereof suffered by Tenant; and in case of a taking which permanently reduces the Rentable Floor Area of the Premises, a just proportion of the Annual Fixed Rent, Landlord's Tax Expenses Allocable to the Premises, and Operating Expenses Allocable to the Premises shall be abated for the remainder of the Lease Term.

14.4 Award

Except as otherwise provided in this Section 14.4, Landlord shall have and hereby reserves and excepts, and Tenant hereby grants and assigns to Landlord, all rights to recover for damages to the Building, the Property and the leasehold interest hereby created, and compensation accrued or hereafter to accrue by reason of such taking, damage or destruction, as aforesaid, and by way of confirming the foregoing, Tenant hereby grants and assigns, and covenants with Landlord to grant and assign to Landlord, all rights to such damages or compensation.

However, nothing contained herein shall be construed to prevent Tenant from prosecuting in any such proceedings a claim for its trade fixtures so taken or relocation, moving and other dislocation expenses.

ARTICLE XV

Default

15.1 Tenant's Default

This Lease and the term of this Lease are subject to the limitation that Tenant shall be in default if, at any time during the Lease Term, any one or more of the following events (herein called an "**Event of Default**" or a "**Default of Tenant**" or similar reference) shall occur and not be cured prior to the expiration of the notice and cure period (if any) herein provided, as follows:

(a) Tenant shall fail to pay any installment of the Annual Fixed Rent, or any Additional Rent or any other monetary amount due under this Lease on or before the date on which the same becomes due and payable, and such failure continues for five (5) days after written notice from Landlord thereof; or

(b) Landlord having rightfully given the notice specified in (a) above to Tenant twice in any consecutive twelve (12) month period, Tenant shall fail thereafter to pay the Annual Fixed Rent, Additional Rent or any other monetary amount due under this Lease on or before the date on which the same becomes due and payable; or

(c) Tenant shall assign its interest in this Lease or sublet any portion of the Premises in violation of the requirements of Article XII of this Lease; or

(d) Tenant shall fail to perform or observe some term or condition of this Lease which, because of its character, would immediately and materially jeopardize Landlord's interest (such as, but without limitation, failure to maintain general liability insurance, or the employment of labor and contractors within the Premises which interfere with Landlord's work, in violation of Sections 9.3, 11.4 or 11.10 or Exhibit B-1, or a failure to observe the requirements of Section 11.2), and such failure continues for three (3) business days after notice from Landlord to Tenant thereof; or

(e) Tenant shall fail to perform or observe any other requirement, term, covenant or condition of this Lease (not hereinabove in this Section 15.1 specifically referred to) on the part of Tenant to be performed or observed and such failure shall continue for thirty (30) days after written notice thereof from Landlord to Tenant, or if said default shall reasonably require longer than thirty (30) days to cure, if Tenant shall fail to commence to cure said default within thirty (30) days after written notice thereof and/or fail to continuously prosecute the curing of the same to completion with due diligence; or

(f) The estate hereby created shall be taken on execution or by other process of law; or

(g) Tenant shall make an assignment or trust mortgage arrangement, so-called, for the benefit of its creditors; or

(h) Tenant shall judicially be declared bankrupt or insolvent according to law; or

(i) a receiver, guardian, conservator, trustee in involuntary bankruptcy or other similar officer is appointed to take charge of all or any substantial part of Tenant's property by a court of competent jurisdiction; or

(j) any petition shall be filed against Tenant in any court, whether or not pursuant to any statute of the United States or of any State, in any bankruptcy, reorganization, composition, extension, arrangement or insolvency proceeding, and such proceedings shall not be fully and finally dismissed within sixty (60) days after the institution of the same; or

(k) Tenant shall file any petition in any court, whether or not pursuant to any statute of the United States or any State, in any bankruptcy, reorganization, composition, extension, arrangement or insolvency proceeding; or

(l) Tenant abandons the Premises. Tenant shall not be deemed to have abandoned the Premises if Tenant provides Landlord with reasonable advance notice prior to vacating and, at the time of vacating the Premises, (i) Tenant has made reasonable arrangements to Landlord's satisfaction for (a) the security of the Premises for the balance of the Term and (b) the removal of any Hazardous Materials from the Premises and/or decommissioning of any laboratory facilities within the Premises, and (ii) Tenant continues during the balance of the Term to satisfy and perform all of Tenant's obligations under this Lease as they come due. Temporary non-use of the Premises, as appropriate, for repair, restoration, remodeling, change from research to development or another phase of Tenant's business that complies with the Permitted Use shall not in and of itself be deemed to be abandonment.

15.2 Termination; Re-Entry

Upon the happening of any one or more of the aforementioned Events of Default (notwithstanding any license of a former breach of covenant or waiver of the benefit hereof or consent in a former instance), Landlord or Landlord's agents or servants may give to Tenant a notice (hereinafter called "**Notice of Termination**") terminating this Lease on a date specified in such Notice of Termination (which shall be not less than five (5) days after the date of the mailing of such Notice of Termination), and this Lease and the Lease Term, as well as any and all of the right, title and interest of the Tenant hereunder, shall wholly cease and expire on the date set forth in such Notice of Termination (Tenant hereby waiving any rights of redemption) in the same manner and with the same force and effect as if such date were the date originally specified herein for the expiration of the Lease Term, and Tenant shall then quit and surrender the Premises to Landlord.

In addition or as an alternative to the giving of such Notice of Termination, Landlord or Landlord's agents or servants may, by any suitable action or proceeding at law, immediately or at any time thereafter re-enter the Premises and remove therefrom Tenant, its agents, employees, servants, licensees, and any subtenants and other persons, and all or any of its or their property therefrom, and repossess and enjoy the Premises, together with all additions, alterations and improvements thereto; but, in any event under this Section 15.2, Tenant shall remain liable as hereinafter provided.

The words "re-enter" and "re-entry" as used throughout this Article XV are not restricted to their technical legal meanings.

15.3 Continued Liability; Re-Letting

(A) If this Lease is terminated or if Landlord shall re-enter the Premises as aforesaid, or in the event of the termination of this Lease, or of re- entry, by or under any proceeding or action or any provision of law by reason of an Event of Default hereunder on the part of Tenant, Tenant covenants and agrees forthwith to pay and be liable for, on the days originally fixed herein for the payment thereof, amounts equal to the several installments of Annual Fixed Rent, all Additional Rent and other charges reserved as they would, under the terms of this Lease, become due if this Lease had not been terminated or if Landlord had not entered or re-entered, as aforesaid, and whether the Premises be relet or remain vacant, in whole or in part, or for a period less than the remainder of the Lease Term, or for the whole thereof, but, in the event the Premises be relet by Landlord, Tenant shall be entitled to a credit in the net amount of rent and other charges received by Landlord in reletting, after deduction of all reasonable expenses incurred in reletting the Premises (including, without limitation, remodeling costs, brokerage fees and the like), and in collecting the rent in connection therewith, in the following manner:

Amounts received by Landlord after reletting shall first be applied against such Landlord's reasonable expenses, until the same are recovered, and until such recovery, Tenant shall pay, as of each day when a payment would fall due under this Lease, the amount which Tenant is obligated to pay under the terms of this Lease (Tenant's liability prior to any such reletting and such recovery not in any way to be diminished as a result of the fact that such reletting might be for a rent higher than the rent provided for in this Lease); when and if such expenses have been completely recovered, the amounts received from reletting by Landlord as have not previously been applied shall be credited against Tenant's obligations as of each day when a payment would fall due under this Lease, and only the net amount thereof shall be payable by Tenant. Further, Tenant shall not be entitled to any credit of any kind for any period after the date when the term of this Lease is scheduled to expire according to its terms.

(B) Landlord agrees to use reasonable efforts to relet the Premises after Tenant vacates the same in the event this Lease is terminated based upon an Event of Default by Tenant hereunder. The marketing of the Premises in a manner similar to the manner in which Landlord markets other premises within Landlord's control within the Building shall be deemed to have satisfied Landlord's obligation to use "reasonable efforts" hereunder. In

no event shall Landlord be required to (i) solicit or entertain negotiations with any other prospective tenant for the Premises until Landlord obtains full and complete possession of the Premises (including, without limitation, the final and unappealable legal right to relet the Premises free of any claim of Tenant), (ii) relet the Premises before leasing other vacant space in the Building, or (iii) lease the Premises for a rental less than the current fair market rent then prevailing for similar office/research/laboratory space in the Building.

(C) In the alternative, Landlord may elect, which election may be made by notice given to Tenant at any time after the termination of this Lease under Section 15.2, above, and whether or not Landlord shall have collected any damages as hereinbefore provided in this Article XV, but as final damages and in lieu of all other such damages beyond the date of such notice, to require Tenant to pay such a sum as at the time of such notice represents the amount of the excess, if any, of (a) the discounted present value, at a discount rate of 6%, of the Annual Fixed Rent, Additional Rent and other charges which would have been payable by Tenant under this Lease for the remainder of the Lease Term if the Lease terms had been fully complied with by Tenant, over and above (b) the discounted present value, at a discount rate of 6%, of the Annual Fixed Rent, Additional Rent and other charges that would be received by Landlord if the Premises were re-leased at the time of such notice for the remainder of the Lease Term at the fair market value (including provisions regarding periodic increases in Annual Fixed Rent if such are applicable) prevailing at the time of such notice as reasonably determined by Landlord.

For the purposes of this Article, if Landlord elects to require Tenant to pay damages in accordance with this Section 15.3(C), the total rent shall be computed by assuming Landlord's Tax Expenses Allocable to the Premises under Section 6.2 and the Operating Expenses Allocable to the Premises under Section 7.5 to be the same as were payable for the twelve (12) calendar months (or if less than twelve (12) calendar months of the Term have elapsed since the date hereof, the partial year) immediately preceding such termination of re-entry.

(D) Nothing contained in this Lease shall limit or prejudice the right of Landlord to prove for and obtain in proceedings for bankruptcy or insolvency by reason of the termination of this Lease, an amount equal to the maximum allowed by any statute or rule of law in effect at the time when, and governing the proceeds in which, the damages are to be proved, whether or not the amount be greater, equal to, or less than the amount of the loss or damages referred to above.

15.4 Liquidated Damages

In lieu of any other damages or indemnity and in lieu of the recovery by Landlord of all sums payable under all the foregoing provisions of this Article XV, Landlord may elect to collect from Tenant, by notice to Tenant, given to Tenant at the time of termination, and Tenant shall thereupon pay, as liquidated damages, an amount equal to the sum of (a) the Annual Fixed Rent and all Additional Rent payable for the lesser of (i) the twelve (12) months ended next prior to such termination and (ii) the number of full plus any partial months remaining in the Lease Term,

plus (b) the amount of Annual Fixed Rent and Additional Rent of any kind accrued and unpaid at the time of such termination, plus (c) any and all expenses which the Landlord may have incurred for and with respect to the collection of any such rent. Notwithstanding the foregoing, Landlord shall not be entitled to collect liquidated damages under the provisions of this paragraph if such liquidated damages would exceed the damages to which Landlord would have been entitled had it elected to collect liquidated damages under the provisions of Section 15.3(C).

15.5 Waiver of Redemption

Tenant, for itself and any and all persons claiming through or under Tenant, including its creditors, upon the termination of this Lease and of the term of this Lease in accordance with the terms hereof, or in the event of entry of judgment for the recovery of the possession of the Premises in any action or proceeding, or if Landlord shall enter the Premises by process of law or otherwise, hereby waives any right of redemption provided or permitted by any statute, law or decision now or hereafter in force, and does hereby waive, surrender and give up all rights or privileges which it or they may or might have under and by reason of any present or future law or decision, to redeem the Premises or for a continuation of this Lease for the term of this Lease hereby demised after having been dispossessed or ejected therefrom by process of law, or otherwise.

15.6 Landlord's Default

Landlord shall in no event be in default in the performance of any of Landlord's obligations hereunder unless and until Landlord shall have failed to perform such obligations within thirty (30) days, or such additional time as is reasonably required to correct any such default, after notice by Tenant to Landlord properly specifying wherein Landlord has failed to perform any such obligation.

Tenant shall not assert any right to deduct the cost of repairs or any monetary claim against the Landlord from rent thereafter due and payable, but shall look solely to the Landlord for satisfaction of such claim.

ARTICLE XVI

Miscellaneous Provisions

16.1 Waiver

Failure on the part of Landlord or Tenant to complain of any action or non-action on the part of the other, no matter how long the same may continue, shall never be a waiver by Tenant or Landlord, respectively, of any of its rights hereunder.

Further, no waiver by Landlord of any condition of this Lease, nor any failure by Tenant to deliver any security deposit, letter of credit, pre-paid rent, financial information, or other item required upon the execution and delivery of this Lease, shall be construed as excusing satisfaction of any such condition or the delivery of any such item by Tenant, and Landlord reserves the right to declare the failure of Tenant to satisfy any such condition or deliver any

such item an Event of Default under this Lease (subject to any applicable notice and cure period set forth in Section 15.1). Further, no waiver at any time of any of the provisions hereof by Landlord or Tenant shall be construed as a waiver of any of the other provisions hereof, and a waiver at any time of any of the provisions hereof shall not be construed as a waiver at any subsequent time of the same provisions. The consent or approval of Landlord or Tenant to or of any action by the other requiring such consent or approval shall not be construed to waive or render unnecessary Landlord's or Tenant's consent or approval to or of any subsequent similar act by the other.

No payment by Tenant, or acceptance by Landlord, of a lesser amount than shall be due from Tenant to Landlord shall be treated otherwise than as a payment on account. The acceptance by Landlord of a check for a lesser amount with an endorsement or statement thereon, or upon any letter accompanying such check, that such lesser amount is payment in full, shall be given no effect, and Landlord may accept such check without prejudice to any other rights or remedies which Landlord may have against Tenant. Further, the acceptance by Landlord of Annual Fixed Rent, Additional Rent or any other charges paid by Tenant under this Lease shall not be or be deemed to be a waiver by Landlord of any default by Tenant, whether or not Landlord knows of such default, except for such defaults as to which such payment relates.

16.2 Cumulative Remedies

Except as expressly provided in this Lease, the specific remedies to which Landlord and Tenant may resort under the terms of this Lease are cumulative and are not intended to be exclusive of any other remedies or means of redress which they may be lawfully entitled to seek in case of any breach or threatened breach of any provisions of this Lease. In addition to the other remedies provided in this Lease, Landlord shall be entitled to the restraint by injunction of the violation or attempted or threatened violation of any of the covenants, conditions or provisions of this Lease or to seek specific performance of any such covenants, conditions or provisions, provided, however, that the foregoing shall not be construed as a confession of judgment by Tenant.

16.3 Quiet Enjoyment

This Lease is subject and subordinate to all matters of record. Landlord agrees that, upon Tenant's paying the Annual Fixed Rent, Additional Rent and other charges herein reserved, and performing and observing the covenants, conditions and agreements hereof upon the part of Tenant to be performed and observed, Tenant shall and may peaceably hold and enjoy the Premises during the term of this Lease (exclusive of any period during which Tenant is holding over after the expiration or termination of this Lease without the consent of Landlord), without interruption or disturbance from Landlord or persons claiming through or under Landlord, subject, however, to the terms of this Lease. This covenant shall be construed as running with the land to and against subsequent owners and successors in interest, and is not, nor shall it operate or be construed as, a personal covenant of Landlord, except to the extent of the Landlord's interest in the Premises, and this covenant and any and all other covenants of Landlord contained in this Lease shall be binding upon Landlord and upon such subsequent owners or successors in interest of Landlord's interest under this Lease, including ground or master lessees, to the extent

of their respective interests, as and when they shall acquire same and then only for so long as they shall retain such interest.

16.4 Surrender

(A) No act or thing done by Landlord during the Lease Term shall be deemed an acceptance of a surrender of the Premises, and no agreement to accept such surrender shall be valid, unless in writing signed by Landlord. No employee of Landlord or of Landlord's agents shall have any power to accept the keys of the Premises as an acceptance of a surrender of the Premises prior to the termination of this Lease; provided, however, that the foregoing shall not apply to the delivery of keys to Landlord or its agents in its (or their) capacity as managing agent or for purpose of emergency access. In any event, however, the delivery of keys to any employee of Landlord or of Landlord's agents shall not operate as a termination of the Lease or a surrender of the Premises.

(B) Upon the expiration or earlier termination of the Lease Term, Tenant shall surrender the Premises to Landlord in the condition as required by Sections 8.1 and 9.5, first removing all goods and effects of Tenant and completing such other removals as may be permitted or required pursuant to Section 9.5.

16.5 Brokerage

(A) Tenant warrants and represents that Tenant has not dealt with any broker in connection with the consummation of this Lease other than the Broker designated in Section 1.1 hereof; and in the event any claim is made against the Landlord relative to dealings with brokers other than the Broker designated in Section 1.1 hereof, Tenant shall defend the claim against Landlord with counsel of Tenant's selection first reasonably approved by Landlord and save harmless and indemnify Landlord on account of loss, cost or damage which may arise by reason of such claim.

(B) Landlord warrants and represents that Landlord has not dealt with any broker in connection with the consummation of this Lease other than the Broker designated in Section 1.1 hereof; and in the event any claim is made against the Tenant relative to dealings by Landlord with brokers other than the Broker designated in Section 1.1 hereof, Landlord shall defend the claim against Tenant with counsel of Landlord's selection first reasonably approved by Tenant and save harmless and indemnify Tenant on account of loss, cost or damage which may arise by reason of such claim. Landlord agrees that it shall be solely responsible for the payment of brokerage commissions to the Broker designated in Section 1.1 hereof in connection with the Original Term.

16.6 Invalidity of Particular Provisions

If any term or provision of this Lease, including but not limited to any waiver of contribution or claims, indemnity, obligation, or limitation of liability or of damages, or the application thereof to any person or circumstance shall, to any extent, be invalid or unenforceable, the remainder of this Lease, or the application of such term or provision to persons or circumstances other than

those as to which it is held invalid or unenforceable, shall not be affected thereby, and each term and provision of this Lease shall be valid and be enforced to the fullest extent permitted by law.

16.7 Provisions Binding, Etc.

The obligations of this Lease shall run with the land, and except as herein otherwise provided, the terms hereof shall be binding upon and shall inure to the benefit of the successors and assigns, respectively, of Landlord and Tenant and, if Tenant shall be an individual, upon and to his heirs, executors, administrators, successors and assigns. Each term and each provision of this Lease to be performed by Tenant shall be construed to be both a covenant and a condition. The reference contained to successors and assigns of Tenant is not intended to constitute a consent to assignment by Tenant, but has reference only to those instances in which Landlord may have later given consent to a particular assignment as required by the provisions of Article XII hereof.

16.8 Recording; Confidentiality

Each of Landlord and Tenant agree not to record the within Lease, but each party hereto agrees, on the request of the other, to execute a so-called Notice of Lease or short form lease in form recordable and complying with applicable law and reasonably satisfactory to Landlord's and Tenant's attorneys. In no event shall such document set forth the rent or other charges payable by Tenant under this Lease; and any such document shall expressly state that it is executed pursuant to the provisions contained in this Lease, and is not intended to vary the terms and conditions of this Lease.

Tenant agrees that this Lease and the terms contained herein will be treated as strictly confidential and except as required by law (or except with the written consent of Landlord) Tenant shall not disclose the same to any third party except for Tenant's advisors, brokers, partners, lenders, accountants and attorneys who have been advised of the confidentiality provisions contained herein and agree to be bound by the same; provided that Tenant shall be permitted at any time, upon reasonable prior written notice to Landlord, to disclose the terms of this Lease publicly to the extent required by law in connection with any filing made by Tenant with the United States Securities and Exchange Commission ("**SEC**"), which disclosure may require attaching a copy of this Lease to such filing; provided, however that Tenant shall redact from such disclosed copy of this Lease any sensitive or confidential information if and to the extent permitted under applicable SEC rules and regulations). In the event Tenant is required by law (other than in connection with any filing made by Tenant with the SEC as aforesaid) to provide this Lease or disclose any of its terms, Tenant shall give Landlord prompt notice of such requirement prior to making disclosure so that Landlord may seek an appropriate protective order. If failing the entry of a protective order Tenant is compelled to make disclosure, Tenant shall only disclose portions of the Lease which Tenant is required to disclose and will exercise reasonable efforts to obtain assurance that confidential treatment will be accorded to the information so disclosed.

16.9 Notices and Time for Action

Whenever, by the terms of this Lease, notice shall or may be given either to Landlord or to Tenant, such notices shall be in writing and shall be sent by hand, registered or certified mail, or overnight or other commercial courier, postage or delivery charges, as the case may be, prepaid as follows:

If intended for Landlord, addressed to Landlord at the address set forth in Article I of this Lease (or to such other address or addresses as may from time to time hereafter be designated by Landlord by like notice) with a copy to Landlord at the same address, Attention: Regional General Counsel.

If intended for Tenant, addressed to Tenant at the address set forth in Article I of this Lease except that from and after the Commencement Date the address of Tenant shall be the Premises (or to such other address or addresses as may from time to time hereafter be designated by Tenant by like notice).

Except as otherwise provided herein, all such notices shall be effective when received; provided, that (i) if receipt is refused, notice shall be effective upon the first occasion that such receipt is refused, (ii) if the notice is unable to be delivered due to a change of address of which no notice was given, notice shall be effective upon the date such delivery was attempted, (iii) if the notice address is a post office box number, notice shall be effective the day after such notice is sent as provided hereinabove or (iv) if the notice is to a foreign address, notice shall be effective two (2) days after such notice is sent as provided hereinabove.

Where provision is made for the attention of an individual or department, the notice shall be effective only if the wrapper in which such notice is sent is addressed to the attention of such individual or department. Any notice given by an attorney on behalf of Landlord or by Landlord's managing agent shall be considered as given by Landlord and shall be fully effective. Any notice given by an attorney on behalf of Tenant shall be considered as given by Tenant and shall be fully effective.

In the event Tenant's mailing address for notices or any email address for Tenant contained in Article I should change during the Term, Tenant shall promptly notify Landlord of the same.

Time is of the essence with respect to any and all notices and periods for giving of notice or taking any action thereto under this Lease.

16.10 When Lease Becomes Binding and Authority

Employees or agents of Landlord have no authority to make or agree to make a lease or any other agreement or undertaking in connection herewith. The submission of this document for examination and negotiation does not constitute an offer to lease, or a reservation of, or option for, the Premises, and this document shall become effective and binding only upon the execution and delivery hereof by both Landlord and Tenant. All negotiations, considerations, representations and understandings between Landlord and Tenant are incorporated herein and

may be modified or altered only by written agreement between Landlord and Tenant, and no act or omission of any employee or agent of Landlord shall alter, change or modify any of the provisions hereof. Landlord and Tenant hereby represent and warrant to the other that all necessary action has been taken to enter this Lease and that the person signing this Lease on behalf of Landlord and Tenant has been duly authorized to do so.

16.11 Paragraph Headings

The paragraph headings throughout this instrument are for convenience and reference only, and the words contained therein shall in no way be held to explain, modify, amplify or aid in the interpretation, construction or meaning of the provisions of this Lease.

16.12 Rights of Mortgagee

This Lease shall be subject and subordinate to any mortgage now or hereafter on the Building (or the Property or both or any part thereof), and to all renewals, modifications, consolidations, replacements and extensions thereof and all substitutions therefor, provided that in the case of a future mortgage the holder of such mortgage agrees to recognize the right of Tenant to use and occupy the Premises upon the payment of rent and other charges payable by Tenant under this Lease and the performance by Tenant of Tenant's obligations hereunder. In confirmation of such subordination and recognition, Tenant shall execute and deliver promptly such instruments of subordination as such mortgagee may reasonably request, subject to receipt of such instruments of recognition from such mortgagee as Tenant may reasonably request (Tenant hereby agreeing to pay any reasonable legal or other fees charged by the mortgagee in connection with providing the same). In the event that any mortgagee or its respective successor in title shall succeed to the interest of Landlord, then this Lease shall nevertheless continue in full force and effect and Tenant shall and does hereby agree to attorn to such mortgagee or successor and to recognize such mortgagee or successor as its landlord. If any holder of a mortgage which includes the Premises, executed and recorded prior to the Date of this Lease, shall so elect, this Lease, and the rights of Tenant hereunder, shall be superior in right to the rights of such holder, with the same force and effect as if this Lease had been executed, delivered and recorded, or a statutory notice hereof recorded, prior to the execution, delivery and recording of any such mortgage. The election of any such holder shall become effective upon either notice from such holder to Tenant in the same fashion as notices from Landlord to Tenant are to be given hereunder or by the recording in the appropriate registry or recorder's office of an instrument in which such holder subordinates its rights under such mortgage to this Lease.

If in connection with obtaining financing a bank, insurance company, pension trust or other institutional lender shall request reasonable modifications in this Lease as a condition to such financing, Tenant will not unreasonably withhold, delay or condition its consent thereto, provided that (i) such modifications do not increase the monetary obligations of Tenant hereunder or materially adversely affect the leasehold interest hereby created or Tenant's rights hereunder and (ii) Landlord shall be responsible for the payment of all reasonable costs incurred by Tenant in complying with such request such as, for example, attorneys' fees.

Landlord agrees to use commercially reasonable efforts to cause the holder of any mortgage encumbering the Property to enter into a subordination, non-disturbance and attornment agreement (an "**SNDA**") with Tenant, which SNDA shall be on such holder's standard form (with such modifications thereto requested by Tenant that such mortgage holder may reasonably approve), and that provides, among other things, that so long as Tenant is not in an Event of Default under this Lease, foreclosure or other enforcement of such mortgage shall not terminate Tenant's right to possession of the Premises and that Tenant's rights under this Lease shall be recognized by the holder of such mortgage to the extent and subject to the limitations in the SNDA. Landlord shall not be obligated to pay any fee or reimburse any costs of such holder. If such holder conditions its agreement to enter into such SNDA upon any such payment or reimbursement, any such costs associated with changes requested to such holder's standard form shall be the sole responsibility of Tenant. Landlord represents and warrants that no mortgage encumbers the Property as of the date of this Lease.

16.13 Rights of Ground Lessor

If Landlord's interest in property (whether land only or land and buildings) which includes the Premises is acquired by another party and simultaneously leased back to Landlord herein, then unless such ground lease provides by its terms that it is subordinate to this Lease, Landlord shall cause the holder of the ground lessor's interest in such lease to enter into a recognition agreement with Tenant simultaneously with the sale and leaseback, wherein the ground lessor will agree to recognize the right of Tenant to use and occupy the Premises upon the payment of Annual Fixed Rent, Additional Rent and other charges payable by Tenant under this Lease and the performance by Tenant of Tenant's obligations hereunder, and wherein Tenant shall agree to attorn to such ground lessor as its Landlord and to perform and observe all of the tenant obligations hereunder, in the event such ground lessor succeeds to the interest of Landlord hereunder under such ground lease.

16.14 Notice to Mortgagee and Ground Lessor

After receiving notice from any person, firm or other entity that it holds a mortgage which includes the Premises as part of the mortgaged premises, or that it is the ground lessor under a lease with Landlord as ground lessee, which includes the Premises as a part of the leased premises, no notice from Tenant to Landlord shall be effective unless and until a copy of the same is given to such holder or ground lessor at the address as specified in said notice (as it may from time to time be changed), and the curing of any of Landlord's defaults by such holder or ground lessor within a reasonable time after such notice (including a reasonable time to obtain possession of the premises if the mortgagee or ground lessor elects to do so) shall be treated as performance by Landlord. For the purposes of this Section 16.14, the term "mortgage" includes a mortgage on a leasehold interest of Landlord (but not one on Tenant's leasehold interest). If any mortgage is listed on Exhibit I then the same shall constitute notice from the holder of such mortgage for the purposes of this Section 16.14.

16.15 Assignment of Rents

With reference to any assignment by Landlord of Landlord's interest in this Lease, or the rents payable hereunder, conditional in nature or otherwise, which assignment is made to the holder of a mortgage or ground lease on property which includes the Premises, Tenant agrees:

(a) That the execution thereof by Landlord, and the acceptance thereof by the holder of such mortgage, or the ground lessor, shall never be treated as an assumption by such holder or ground lessor of any of the obligations of Landlord hereunder, unless such holder, or ground lessor, shall, by notice sent to Tenant or under a SNDA, specifically otherwise elect or agree; and

(b) That, except as aforesaid, such holder or ground lessor shall be treated as having assumed Landlord's obligations hereunder only upon foreclosure of such holder's mortgage and the taking of possession of the Premises, or, in the case of a ground lessor, the assumption of Landlord's position hereunder by such ground lessor. In no event shall the acquisition of title to the Building and the land on which the same is located by a purchaser which, simultaneously therewith, leases the entire Building or such land back to the seller thereof be treated as an assumption, by operation of law or otherwise, of Landlord's obligations hereunder, but Tenant shall look solely to such seller-lessee, and its successors from time to time in title, for performance of Landlord's obligations hereunder. In any such event, this Lease shall be subject and subordinate to the lease to such purchaser provided that such purchaser-lessor agrees to recognize the right of Tenant to use and occupy the Premises upon the payment of rent and all other charges payable by Tenant under this Lease and the performance by Tenant of Tenant's obligations under this Lease. For all purposes, such seller-lessee, and its successors in title, shall be the landlord hereunder unless and until Landlord's position shall have been assumed by such purchaser-lessor.

16.16 Status Report and Financial Statements

Recognizing that the parties hereto may find it necessary to establish to third parties, such as accountants, banks**,** potential or existing mortgagees**,** potential purchasers or the like, the then current status of performance hereunder, each party (the "**Non-Requesting Party**") on the request of the other party (the "**Requesting Party**") made from time to time, will promptly (and in any event within ten (10) business days) furnish to the Requesting Party, addressed to any existing or potential holder of any mortgage encumbering the Premises, the Building or the Property, or any potential purchaser of the Premises, the Building, or the Property (each an "**Interested Party**") a statement of the status of any reasonable matter pertaining to this Lease, including, without limitation, acknowledgments that (or the extent to which) each party is in compliance with its obligations under the terms of this Lease; provided, however, that in the event that either party is requested to provide more than one (1) such statement in any twelve (12) month period, the Requesting Party shall be responsible for the payment of all reasonable costs incurred by the Non-Requesting Party in providing such statements, including, without limitation, attorneys' fees.

In addition, unless and for so long as Tenant is not a publicly-traded entity with financial statements that are freely available to the public which are certified to the governmental regulatory authorities, Tenant shall deliver to Landlord, or any Interested Party designated by Landlord, financial statements of Tenant, as reasonably requested by Landlord including, but not limited to, financial statements for the past three (3) years.

Any such status statement and non-publicly available financial statement, which shall be certified by Tenant's executives to the same extent as publicly-available financial statements of publicly-traded entities, which are delivered by Tenant pursuant to this Section 16.16 may be relied upon by any Interested Party.

16.17 Self-Help

If Tenant shall at any time fail to make any payment or perform any act which Tenant is obligated to make or perform under this Lease and (except in the case of emergency) if the same continues unpaid or unperformed beyond applicable grace periods, then Landlord may, but shall not be obligated so to do, after ten (10) business days' written notice to and demand upon Tenant, or without notice to or demand upon Tenant in the case of any emergency, and without waiving, or releasing Tenant from, any obligations of Tenant in this Lease contained, make such payment or perform such act which Tenant is obligated to perform under this Lease in such manner and to such extent as may be reasonably necessary, and, in exercising any such rights, pay any costs and expenses, employ counsel and incur and pay reasonable attorneys' fees. All sums so paid by Landlord and all reasonable and necessary costs and expenses of Landlord incidental thereto, together with interest thereon at the annual rate equal to the sum of (a) the Base Rate from time to time announced by Bank of America, N.A. or its successor as its Base Rate and (b) two percent (2%) (but in no event greater than the maximum rate permitted by applicable law), from the date of the making of such expenditures by Landlord, shall be deemed to be Additional Rent and, except as otherwise in this Lease expressly provided, shall be payable to the Landlord on demand, and if not promptly paid shall be added to any rent then due or thereafter becoming due under this Lease, and Tenant covenants to pay any such sum or sums with interest as aforesaid, and Landlord shall have (in addition to any other right or remedy of Landlord) the same rights and remedies in the event of the non-payment thereof by Tenant as in the case of default by Tenant in the payment of Annual Fixed Rent.

16.18 Holding Over

Any holding over by Tenant after the expiration or earlier termination of the term of this Lease shall be treated as a tenancy at sufferance and shall be on the terms and conditions as set forth in this Lease, as far as applicable except that Tenant shall pay as a use and occupancy charge an amount equal to the greater of (x) 200% of the Annual Fixed Rent and Additional Rent calculated (on a daily basis) at the rate payable under the terms of this Lease immediately prior to the commencement of such holding over, or (y) the fair market rental value of the Premises, in each case for the period measured from the day on which Tenant's hold-over commences and terminating on the day on which Tenant vacates the Premises. Notwithstanding the foregoing, for the first sixty (60) days of any holding over, the percentage figure set forth above shall instead be

150%. In addition, Tenant shall save Landlord, its agents and employees harmless and will exonerate, defend and indemnify Landlord, its agents and employees from and against any and all damages which Landlord may suffer on account of Tenant's hold-over in the Premises after the expiration or prior termination of the term of this Lease. Notwithstanding the foregoing, however, Tenant shall not be liable for indirect or consequential damages incurred by Landlord during the first thirty (30) days of any holding over by Tenant.

Nothing in the foregoing nor any other term or provision of this Lease shall be deemed to permit Tenant to retain possession of the Premises or hold over in the Premises after the expiration or earlier termination of the Lease Term. All property which remains in the Building or the Premises after the expiration or termination of this Lease shall be conclusively deemed to be abandoned and may either be retained by Landlord as its property or sold or otherwise disposed of in such manner as Landlord may see fit. If any part thereof shall be sold, then Landlord may receive the proceeds of such sale and apply the same, at its option against the expenses of the sale, the cost of moving and storage, any arrears of rent or other charges payable hereunder by Tenant to Landlord and any damages to which Landlord may be entitled under this Lease and at law and in equity.

16.19 Entry by Landlord

Landlord, and its duly authorized representatives, shall, upon reasonable prior notice (except in the case of emergency), have the right to enter the Premises (i) at all reasonable times (except at any time in the case of emergency) for the purposes of inspecting the condition of same and making such repairs, alterations, additions or improvements thereto as may be necessary if Tenant fails to do so as required hereunder (but the Landlord shall have no duty whatsoever to make any such inspections, repairs, alterations, additions or improvements except as otherwise provided in Sections 4.1, 7.1, and 7.2, and Exhibit B-1), (ii) to show and market the Premises to prospective tenants from and after such time as Tenant's extension option has lapsed unexercised during the Original Term, or during the final twelve (12) months of the Extended Term, as applicable, and (iii) at any reasonable time during the Lease Term to show the Premises to prospective purchasers and mortgagees. In addition, to the extent that it is necessary to enter the Premises in order to access any area that serves any portion of the Building outside the Premises, then Tenant shall, upon as much advance notice as is practical under the circumstances, and in any event at least forty-eight (48) hours' prior written notice (except that no notice shall be required in emergency situations), permit contractors engaged by Landlord or by other occupants of the Building to pass through the Premises in order to access such areas but only if accompanied at all times by a representative of Landlord. The parties agree and acknowledge that, despite reasonable and customary precautions (which Landlord agrees it shall exercise), any property or equipment in the Premises of a delicate, fragile or vulnerable nature may nevertheless be damaged in the course of performing Landlord's obligations. Accordingly, Tenant shall take reasonable protective precautions with unusually fragile, vulnerable or sensitive property and equipment. Notwithstanding anything to the contrary contained herein, Tenant shall be entitled to have a representative present for any access by Landlord or any Landlord Parties in exercising its rights under this Section 16.19.

In the event Tenant sends a notice alleging the existence of a dangerous or unsafe condition, any requirements for prior notice or limitations on Landlord's access to the Premises contained in this Lease shall be deemed waived by Tenant so that Landlord may immediately exercise its rights under this Section 16.19 and Section 16.17 in such manner as Landlord deems necessary in its sole but reasonable discretion to remedy such dangerous or unsafe condition.

16.20 Tenant's Payments

Each and every payment and expenditure, other than Annual Fixed Rent, shall be deemed to be Additional Rent hereunder, whether or not the provisions requiring payment of such amounts specifically so state, and shall be payable, unless otherwise provided in this Lease, within thirty (30) days after written demand by Landlord, and in the case of the non-payment of any such amount, Landlord shall have, in addition to all of its other rights and remedies, all the rights and remedies available to Landlord hereunder or by law in the case of non-payment of Annual Fixed Rent. Unless expressly otherwise provided in this Lease, the performance and observance by Tenant of all the terms, covenants and conditions of this Lease to be performed and observed by Tenant shall be at Tenant's sole cost and expense. Except as otherwise expressly provided herein, if Tenant has not objected to any statement of Additional Rent which is rendered by Landlord to Tenant within one hundred twenty (120) days after Landlord has rendered the same to Tenant, then the same shall be deemed to be a final account between Landlord and Tenant not subject to any further dispute. In the event that Tenant shall seek Landlord's consent or approval under this Lease, then Tenant shall reimburse Landlord, upon demand (accompanied by reasonable supporting documentation), as Additional Rent, for all reasonable costs and expenses, including legal and architectural costs and expenses, incurred by Landlord in processing such request, whether or not such consent or approval shall be given. Notwithstanding anything in this Lease to the contrary, if Landlord or any affiliate of Landlord has elected to qualify as a real estate investment trust ("**REIT**"), any service required or permitted to be performed by Landlord pursuant to this Lease, the charge or cost of which may be treated as impermissible tenant service income under the laws governing a REIT, may be performed by a taxable REIT subsidiary that is affiliated with either Landlord or Landlord's property manager, an independent contractor of Landlord or Landlord's property manager (the "**Service Provider**"). If Tenant is subject to a charge under this Lease for any such service, then, at Landlord's written direction, Tenant will pay such charge either to Landlord for further payment to the Service Provider or directly to the Service Provider, and, in either case, (i) Landlord will credit such payment against Additional Rent due from Tenant under this Lease for such service, and (ii) such payment to the Service Provider will not relieve Landlord from any obligation under the Lease concerning the provisions of such service.

16.21 Late Payment

If Landlord shall not have received any payment or installment of Annual Fixed Rent or Additional Rent (the "**Outstanding Amount**") on or before the date on which the same first becomes payable under this Lease (the "**Due Date**"), the amount of such payment or installment shall incur a late charge equal to the sum of: (a) five percent (5%) of the Outstanding Amount for administration and bookkeeping costs associated with the late payment and (b) interest on the Outstanding Amount from the Due Date through and including the date such payment or

installment is received by Landlord, at a rate equal to the lesser of (i) the rate announced by Bank of America, N.A. (or its successor) from time to time as its prime or base rate (or if such rate is no longer available, a comparable rate reasonably selected by Landlord), plus two percent (2%), or (ii) the maximum applicable legal rate, if any. Such interest shall be deemed Additional Rent and shall be paid by Tenant to Landlord upon demand. However, not more than once per calendar year, the aforesaid late charge will not be imposed until five (5) days after written notice of such delinquency is given to Tenant, in which case the aforesaid late charge shall be due only if such delinquency fails to be cured within such five (5) day period. Additionally, in the case where Tenant is entitled to such additional five (5) day cure period after notice, as provided above, interest on the Outstanding Amount shall not begin to accrue until the day following such five (5) day grace period. The aforesaid late charge and interest accrued upon any Outstanding Amount shall be deemed Additional Rent and shall be paid by Tenant to Landlord upon demand.

16.22 Counterparts

This Lease may be executed in several counterparts, each of which shall be deemed an original, and such counterparts shall constitute but one and the same instrument.

16.23 Entire Agreement

This Lease constitutes the entire agreement between the parties hereto, Landlord's managing agent and their respective affiliates with respect to the subject matter hereof and thereof and supersedes all prior dealings between them with respect to such subject matter, and there are no verbal or collateral understandings, agreements, representations or warranties not expressly set forth in this Lease. No subsequent alteration, amendment, change or addition to this Lease shall be binding upon Landlord or Tenant, unless reduced to writing and signed by the party or parties to be charged therewith.

16.24 Landlord Liability

Tenant shall neither assert nor seek to enforce any claim for breach of this Lease against any of Landlord's assets other than Landlord's interest in the Building and the Property (and the proceeds of any insurance claim or eminent domain proceeding in connection therewith), and Tenant agrees to look solely to such interest for the satisfaction of any liability of Landlord under this Lease, it being specifically agreed that neither Landlord, nor any successor holder of Landlord's interest hereunder, nor any beneficiary of any trust of which any person from time to time holding Landlord's interest is trustee, nor any such trustee, nor any member, manager, partner, director or stockholder nor Landlord's managing agent shall ever be personally liable for any such liability. This paragraph shall not limit any right that Tenant might otherwise have to obtain injunctive relief against Landlord or Landlord's successors-in-interest, or to take any other action which shall not involve the personal liability of Landlord, or of any successor holder of Landlord's interest hereunder, or of any beneficiary of any trust of which any person from time to time holding Landlord's interest is trustee, or of any such trustee, or of any manager, member, partner, director or stockholder of Landlord or of Landlord's managing agent, to respond in monetary damages from Landlord's assets other than Landlord's interest in said Building and the Property (and the proceeds of any insurance claim or eminent domain proceeding in connection

therewith), as aforesaid, but in no event shall Tenant have the right to terminate or cancel this Lease or to withhold rent or to set-off any claim or damages against rent as a result of any default by Landlord or breach by Landlord of its covenants or any warranties or promises hereunder, except in the case of a wrongful eviction of Tenant from the Premises (constructive or actual) by Landlord continuing after notice to Landlord thereof and a reasonable opportunity for Landlord to cure the same.

In no event shall either party hereto ever be liable for any indirect or consequential damages or loss of profits or the like, provided that the foregoing shall not limit or alter any procedural right or remedy of Landlord under this Lease nor shall the same apply to the obligations of Tenant with respect to any holdover by Tenant after the expiration or earlier termination of this Lease (except as other limited by Section 16.18) or the obligations under this Lease with respect to Hazardous Materials.

16.25 No Partnership

The relationship of the parties hereto is that of landlord and tenant and no partnership, joint venture or participation is hereby created.

16.26 Security Deposit

(A) Concurrently with the execution of this Lease, Tenant shall pay to Landlord a security deposit in the amount of $810,515.00 and Landlord shall hold the same, throughout the Term of this Lease (including the Extended Term, if applicable), unless sooner returned to Tenant as provided in this Section 16.26, as security for the performance by Tenant of all obligations on the part of Tenant to be performed under this Lease. Such deposit shall be in the form of an irrevocable, unconditional, negotiable letter of credit (the "**Letter of Credit**"). The Letter of Credit shall (i) be issued by and drawn on a bank reasonably approved by Landlord and at a minimum having a long term issuer credit rating from S&P Global Ratings of A- or a comparable rating from Moody's Investors Service, Inc., (ii) be substantially in the form attached hereto as Exhibit J (or such other form as approved by Landlord, which approval shall not be unreasonably withheld, conditioned or delayed) , (iii) permit one or more draws thereunder to be made accompanied only by certification by Landlord or Landlord's managing agent that pursuant to the terms of this Lease, Landlord is entitled to draw upon such Letter of Credit, (iv) permit transfers at any time without charge, (v) permit presentment in Boston, Massachusetts and (vi) provide that any notices to Landlord be sent to the notice address provided for Landlord in this Lease. If the credit rating for the issuer of such Letter of Credit falls below the standard set forth in (i) above or if the financial condition of such issuer changes in any other material adverse way or if any trustee, receiver or liquidator shall be appointed for the issuer, Landlord shall have the right to require that Tenant provide a substitute letter of credit that complies in all respects with the requirements of this Section, and Tenant's failure to provide the same within thirty (30) days following Landlord's written demand therefor shall entitle Landlord to immediately draw upon the Letter of Credit. Any such Letter of Credit shall be for a term of two (2) years (or for one (1) year if the issuer thereof regularly and customarily only issues letters of credit for a maximum term of one (1) year) and shall in either case provide for automatic renewals through the date which is sixty (60) days subsequent to the scheduled expiration of this Lease (as the same may be

extended) or if the issuer will not grant automatic renewals, the Letter of Credit shall be renewed by Tenant each year and each such renewal shall be delivered to and received by Landlord not later than forty-five (45) days before the expiration of the then current Letter of Credit (herein called a "**Renewal Presentation Date**"). In the event of a failure to so deliver any such renewal Letter of Credit on or before the applicable Renewal Presentation Date (including, without limitation, in the event of a notice of non-renewal from the issuer), Landlord shall be entitled to present the then existing Letter of Credit for payment and to receive the proceeds thereof, which proceeds shall be held as Tenant's security deposit, subject to the terms of this Section 16.26. Any failure or refusal of the issuer to honor the Letter of Credit shall be at Tenant's sole risk and shall not relieve Tenant of its obligations hereunder with regard to the security deposit. Upon the occurrence of any default of Tenant that continues beyond notice (the delivery of which shall not be required for purposes of this Section 16.26 if Landlord is prevented or prohibited from delivering the same under applicable law, including, but not limited to, all applicable bankruptcy and insolvency law) and the expiration of any applicable cure periods, Landlord shall have the right from time to time without prejudice to any other remedy Landlord may have on account thereof, to draw on all or any portion of such deposit held as a Letter of Credit and to apply the proceeds of such Letter of Credit or any cash held as such deposit, or any part thereof, to Landlord's damages arising from such default on the part of Tenant under the terms of this Lease. If Landlord so applies all or any portion of such deposit, Tenant shall within seven (7) days after notice from Landlord deposit cash with Landlord in an amount sufficient to restore such deposit to the full amount stated in this Section 16.26. While Landlord holds any cash deposit Landlord shall have no obligation to pay interest on the same and shall have the right to commingle the same with Landlord's other funds. Neither the holder of a mortgage nor the lessor in a ground lease on property which includes the Premises shall ever be responsible to Tenant for the return or application of any such deposit, whether or not it succeeds to the position of Landlord hereunder, unless such deposit shall have been received in hand by such holder or ground lessor.

There not then being an outstanding Event of Default and Tenant having performed all of its obligations under this Lease, including the payment of all outstanding Annual Fixed Rent and Additional Rent, Landlord shall promptly return the deposit, or so much thereof as shall not have theretofore been applied in accordance with the terms of this Section 16.26, to Tenant on the expiration or earlier termination of the term of this Lease (as the same may have been extended) and surrender possession of the Premises by Tenant to Landlord in the condition required in the Lease at such time.

(B) Landlord shall return a One Hundred Sixty-Two Thousand One Hundred Three and 00/100 Dollars ($162,103.00) portion (the "**Reduction Amount**") of the security deposit to Tenant so that the remainder of such Security Deposit (the "**Remaining Amount**") shall be Six Hundred Forty-Eight Thousand Four Hundred Twelve and 00/100 Dollars ($648,412.00) (or if such security deposit is in the form of a Letter of Credit, Landlord shall return the original Letter of Credit promptly after Tenant delivers a new Letter of Credit which reduces the amount secured by the Letter of Credit by the Reduction Amount and otherwise in strict conformity with the requirements herein) at the beginning of the thirty-sixth (36th) full calendar month immediately following the Phase I Commencement Date (the "**Scheduled Reduction Date**") if (i) Tenant is not then in default under the terms of this Lease without the benefit of notice or

grace, (ii) Landlord has not applied such Security Deposit or any portion thereof to Landlord's damages arising from any default on the part of Tenant, whether or not Tenant has restored the amount so applied by Landlord, (iii) there have not been more than three (3) monetary or material non-monetary Events of Default that occurred during the Term, even if later cured, (iv) Tenant has not declared bankruptcy at any point during the Term and (v) Tenant's annual revenues for its most recently completed fiscal year are at least $175,000,000.00 (as determined by Landlord based on its review of the quarterly financial statements included in Tenant's then-most recent Form 10-Q filed with the SEC (or, if Tenant is not publicly traded, based on Landlord's review of Tenant's most recent consolidated financial statements prepared in accordance with generally accepted accounting principles). In the event that Tenant does not meet all of the foregoing conditions set forth in clauses (i) through (v) of the immediately preceding sentence at the beginning of the thirty-sixth (36th) full calendar month immediately following the Phase I Commencement Date, then the Scheduled Reduction Date shall be deferred until such date as Tenant has met such conditions.

(C) If Tenant believes that it has satisfied all the conditions precedent to a reduction in the amount of the Security Deposit, then it shall request such reduction in writing to Landlord, which request shall certify to Landlord that all such conditions have been satisfied. If Landlord agrees, in its reasonable and prompt determination, that all of the aforesaid conditions are met, the Security Deposit shall be so reduced in accordance with this Section 16.26. If Tenant is prevented from receiving such reduction based upon a default by Tenant hereunder, Tenant shall have the right to resubmit such request so long as Tenant cures such default before the expiration of any applicable notice and cure period. No Letter of Credit shall automatically reduce, but any reduction in the amount thereof shall require Landlord's prior written notice to the issuer of the Letter of Credit of the reduced amount. Promptly after Landlord's receipt of Tenant's request for a reduction as described above, Landlord shall determine whether such a reduction is permitted in accordance with this Section 16.26, and if it is, Landlord shall notify the issuer of the Letter of Credit of the amount to which the Letter of Credit shall be reduced.

16.27 Governing Law

This Lease shall be governed exclusively by the provisions hereof and by the law of The Commonwealth of Massachusetts, as the same may from time to time exist.

16.28 Waiver of Trial by Jury

To induce Landlord to enter into this Lease, the Tenant hereby waives any right to trial by jury in any action, proceeding or counterclaim brought by either Landlord or Tenant on any matters whatsoever arising out of or any way connected with this Lease, the relationship of the Landlord and the Tenant, the Tenant's use or occupancy of the Premises and/or any claim of injury or damage, including but not limited to, any summary process eviction action.

16.29 Electronic Signatures

The parties acknowledge and agree that this Lease may be executed by electronic signature, which shall be considered as an original signature for all purposes and shall have the same force

and effect as an original signature. Without limitation, "electronic signature" shall include faxed versions of an original signature or electronically scanned and transmitted versions (e.g., via pdf) of an original signature.

16.30 Building Amenities

The Building currently contains a conference center, outdoor terrace, shared collaboration space, grab-and-go caféteria/food hall, and a fitness center that includes (i) a basketball court that converts to an auditorium for company gatherings and (ii) unisex individual locker and shower pods (each an "**Amenity**" and collectively the "**Amenities**"), and Tenant shall have the right to use such Amenities, without payment of an additional fee or charge, in common with other tenants and occupants of the Building entitled to use thereof throughout the Term hereof. For so long as Landlord shall elect to operate any of the Amenities in the Building, Landlord shall repair, maintain, insure and clean the same in a manner consistent with the level of repair, maintenance, insurance and cleaning of similar amenities in other comparable properties in the Route 128/Mass Pike Market Area. Landlord shall be permitted to grant access and use rights to the Amenities to tenants and occupants of buildings owned or operated by Landlord or any of its affiliates in the CityPoint Project (provided such other tenants and occupants pay a fair and equitable amount for the use of the Amenities to reduce Operating Expenses as reasonably determined by Landlord). The cost of maintaining, repairing and operating the Amenities shall be included in Landlord's Operating Expenses pursuant to Section 7.4.

16.31 Force Majeure

In the event Landlord or Tenant is in any way delayed, impeded, interrupted, stopped or prevented from performing any of its obligations under this Lease (except, with respect to Tenant, its obligations to give notice with respect to any option explicitly set forth in this Lease, to take any actions required by specific dates or within specific time periods under Exhibit B-1 attached hereto, to surrender the Premises as and when required by this Lease and to maintain insurance as required by this Lease) due to fire, casualty, act of God, epidemic, pandemic, breach of cyber security, strike, lockout, labor dispute or disruption, disruption in the supply chain or other inability by the exercise of reasonable diligence to obtain materials or parts, act of war, terrorism, breakdown, accident, civil commotion, laws, regulations, restrictions, orders, quarantines, construction moratoria or other action or inaction by any local, state or federal governmental or health authority (including, without limitation, any shelter-in-place orders, stay at home orders, occupancy restrictions or limitations or any restriction on travel related to the forgoing that preclude or restrict Landlord or Tenant or their agents, contractors or employees from accessing or using the Premises), or any other cause or event to the extent beyond such party's reasonable control regardless of whether such cause or event is (i) related to the specifically enumerated causes or events in this paragraph or (ii) foreseeable or unforeseeable (each, an event of "**Force Majeure**"), such cause or event of Force Majeure shall excuse the performance of the obligation of such party under this Lease for a period equal to such delay, impediment, interruption, stoppage or prevention, including the time reasonably necessary to repair any damage caused by the Force Majeure event, if any. Notwithstanding anything to the contrary contained in this Lease and for avoidance of doubt, in no event will (i) any party be entitled to claim Force Majeure due to any act or inaction within its reasonable control, (ii)

financial hardship constitute an event of Force Majeure nor (iii) any event of Force Majeure in any way affect, excuse, suspend, reduce or abate the obligation of Tenant to timely pay all rent and other charges payable by Tenant pursuant to the terms of this Lease, except as expressly provided in Article XIV or entitle either party to terminate this Lease, except as explicitly provided in Article XIV. A party invoking the benefit of the Force Majeure provisions shall notify the other party to the existence of the Force Majeure event within five (5) business days after becoming aware of the circumstances giving rise to such party invoking the benefit of the Force Majeure provisions. In all events, a party claiming the benefit of the Force Majeure provisions shall use commercially reasonable efforts to mitigate the impact of such Force Majeure event on the non-claiming party.

16.32 Shuttle Service

Landlord currently provides or otherwise arranges for Shuttle Service (defined below) to and from the Building on weekdays (subject to weather conditions that adversely impact travel, holidays and Force Majeure), and Tenant's employees shall, subject to seating availability, have the right to use such Shuttle Service at all times that such Shuttle Service is in operation and available for use by tenants of the Building. "**Shuttle Service**" shall mean express shuttle bus service that is provided or contracted for by Landlord between the Building, the Alewife MBTA station, and additional commuting locations in the Waltham/Cambridge/Boston area as reasonably determined by Landlord from time to time. Landlord shall have the right to adjust the schedule, frequency, and route(s) of the Shuttle Service as it reasonably determines based on demand. No fee shall be charged to any passenger that utilizes the Shuttle Service provided by Landlord; provided that all costs of providing such Shuttle Service shall be included as part of Landlord's Operating Expenses, subject to the provisions of Section 7.4. Tenant's use of the Shuttle Service shall be at Tenant's sole risk, and Tenant hereby acknowledges that Landlord shall have no liability with respect thereto. Without limiting the foregoing, Landlord reserves the right to temporarily suspend the Shuttle Service if Landlord reasonably determines that such Shuttle Service is not being adequately utilized by tenants of the Building and/or the CityPoint Project. Further, Landlord may elect to permanently eliminate the Shuttle Service following a temporary suspension if Landlord reasonably believes that such Shuttle Service is not desired by, or would not be adequately utilized by, tenants of the Building and/or the CityPoint Project.

16.33 Right of First Offer

A. ROFO Conditions. On the conditions ("**ROFO Conditions**") (which conditions Landlord may waive by written notice to Tenant) that both at the time that Landlord is required to give Landlord's ROFO Notice, as hereinafter defined, and as of the ROFO Premises Commencement Date, as hereinafter defined, (i) there exists no Event of Default, (ii) this Lease is still in full force and effect, (iii) Tenant has not assigned this Lease or sublet more than fifty percent (50%) of the Premises (excluding any assignment or subletting permitted without Landlord's consent under Section 12.5 hereof), and (iv) Tenant, itself, is occupying at least fifty (50%) of the Premises, Tenant shall have the following recurring right ("Right of First Offer") to lease the ROFO Premises, as hereinafter defined, when such ROFO Premises becomes Available for Lease to Tenant, as hereinafter defined.

B. Definition of ROFO Premises. "**ROFO Premises**" shall be defined as the portion of the third (3rd) floor of the Building shown on Exhibit M attached hereto, when such area(s) become Available for Lease, as hereinafter defined, during the Term of this Lease. For the purposes of this Section 16.33, the ROFO Premises shall be deemed to be "**Available for Lease**" when Landlord determines, in its reasonable judgment, that such area will become available for leasing to Tenant (i.e., when Landlord determines, in its reasonable judgment, that the then-current occupant of such ROFO Premises will vacate such ROFO Premises, and when Landlord intends to offer such ROFO Premises for lease).

C. Exercise of Right to Lease ROFO Premises. Landlord shall give Tenant written notice ("**Landlord's ROFO Notice**") at the time that Landlord determines, as aforesaid, that the ROFO Premises will become Available for Lease to Tenant. Landlord's ROFO Notice shall set forth Landlord's quotation of a proposed annual fixed rent applicable to the ROFO Premises, the Permitted Uses applicable to the ROFO Premises, and the anticipated ROFO Premises Commencement Date. Tenant may lease such ROFO Premises in its entirety only, by delivering written notice of exercise to Landlord ("**Tenant's ROFO Exercise Notice**") within ten (10) business days after the date of Landlord's ROFO Notice. If Tenant disagrees with Landlord's proposed annual fixed rent applicable to the ROFO Premises, Tenant shall so state in Tenant's ROFO Exercise Notice, and the matter shall be submitted for a broker determination of the Prevailing Market Rent applicable to the ROFO Premises in accordance with the provisions of Exhibit H hereof. Notwithstanding the foregoing, Tenant shall have no right to exercise its Right of First Offer if less than twelve (12) months would remain in the Term as of the ROFO Premises Commencement Date. In any case where Tenant has no right to exercise its Right of First Offer (that is, during the last twelve (12) months of the Term of the Lease, or if the ROFO Conditions are not met), Landlord shall not be obligated to deliver Landlord's ROFO Notice to Tenant. If Tenant fails to timely give Tenant's ROFO Exercise Notice, Tenant shall have no further right to lease the ROFO Premises in question until such ROFO Premises have been leased to a third party and thereafter again become "Available for Lease", time being of the essence of this Section 16.33.

D. Lease Provisions Applying to ROFO Premises. The leasing to Tenant of such ROFO Premises shall be upon all of the same terms and conditions of the Lease (subject to application of the Prevailing Market Rent as aforesaid), except as follows:

(i) The "**ROFO Premises Commencement Date**" shall be the date that Landlord delivers such ROFO Premises to Tenant.
(ii) The "**ROFO Premises Rent Commencement Date**" shall be as set forth in Landlord's ROFO Notice.
(iii) The Permitted Use with respect to such ROFO Premises shall be as designated by Landlord in Landlord's ROFO Notice.

(iv) Tenant shall take such ROFO Premises "as-is" in its then (i.e., as of the date of delivery) state of construction, finish, and decoration, without any obligation on

the part of Landlord to construct or prepare any ROFO Premises for Tenant's occupancy.

(v) The expiration date in respect of the ROFO Premises shall be the expiration date of the Term of the Lease (as the same may be extended pursuant to the terms hereof).

E. Execution of Lease Amendments. Notwithstanding the fact that Tenant's exercise of the above-described option to lease the ROFO Premises shall be self-executing, as aforesaid, the parties hereby agree promptly to execute a lease amendment reflecting the addition of the ROFO Premises. The execution of such lease amendment shall not be deemed to waive any of the conditions to Tenant's exercise of the herein option to lease the ROFO Premises, unless otherwise specifically provided in such lease amendment.

F. Prior Rights. Notwithstanding anything herein to the contrary, Tenant's right of first offer in this Section 16.33 is subject and subordinate to (i) the expansion rights (whether such rights are designated as a right of first offer, right of first refusal, expansion option or otherwise) of any tenant of the Building existing on the date hereof and (ii) the right of Landlord to extend the term of the lease of any then-existing tenant of the ROFO Premises (whether or not pursuant to rights under such tenant's lease) or execute a new lease with the then-occupant of the ROFO Premises prior to the ROFO Premises becoming Available for Lease, which rights shall be deemed prior to the rights of Tenant under this Section 16.33.

G. Hold-Over Premium. If Tenant shall timely exercise its rights under this Section 16.33 with respect to the ROFO Premises designated in Landlord's ROFO Notice and if, thereafter, the then occupant of the ROFO Premises with respect to which Tenant shall have so exercised such right wrongfully fails to deliver possession of such premises at the time when its tenancy is scheduled to expire, Landlord shall use reasonable efforts and due diligence (which shall be limited to the commencement within sixty (60) days after the date on which the hold-over commences and prosecution of an eviction proceeding, but shall not require the taking of any appeal) to evict such occupant from such ROFO Premises and to recover from such occupant any Hold-Over Premium (as defined below) payable by such occupant. In such event, the ROFO Premises Commencement Date and the ROFO Premises Rent Commencement Date shall, in the event of such holding over by such occupant, be deferred until possession of the additional space is delivered to Tenant. The failure of the then occupant of such premises to so vacate shall not constitute a default or breach by Landlord (subject to Landlord's obligations as set forth above to the timely commencement and prosecution of an eviction proceeding) and shall not give Tenant any right to terminate this Lease or to deduct from, offset against or withhold Annual Fixed Rent or Additional Rent (or any portions thereof); provided, however, that Tenant shall have the right to require Landlord to pay to Tenant fifty percent (50%) of the net (i.e. net of the costs and expenses, including attorneys' fees, incurred by Landlord in obtaining such Hold-Over Premium) amount of any Hold-Over Premium received by Landlord from such hold-over occupant relative to periods from and after the thirty-first (31st) day of any hold-over, when and if Landlord receives any such payment. For the purposes hereof, the term "**Hold-Over Premium**" shall be defined as the amount (if any) which a hold-over occupant of any portion of the Available ROFO Space

is required to pay to Landlord in respect of its hold-over in the premises (whether characterized as rent, damages, or use and occupation) in excess of the amount of fixed rent and other charges which the tenant under whom such occupant claims would have been required to pay to Landlord had the term of such tenant's lease been extended throughout the period of such hold-over at the same rental rate as such tenant was required to pay during the last month of its tenancy.

[*Signatures on Following Page*]

EXECUTED in two or more counterparts by persons or officers hereunto duly authorized on the Date set forth in Section 1.1 above.

LANDLORD:

BP THIRD AVENUE LLC,
a Delaware limited liability company

By: BOSTON PROPERTIES LIMITED PARTNERSHIP, a Delaware limited partnership, its sole member

By: BXP, INC., a Delaware corporation, its General Partner

By: /s/ Patrick Mulvihill
Name: Patrick Mulvihill
Title: SVP

TENANT:

AKEBIA THERAPEUTICS, INC.,
a Delaware corporation

By: /s/ Erik J. Ostrowski

Name: Erik J. Ostrowski

Title: CFO & CBO

Exhibit 10.11

AKEBIA THERAPEUTICS, INC.
FIFTH AMENDED AND RESTATED NON-EMPLOYEE
DIRECTOR COMPENSATION PROGRAM

Effective January 26, 2026

Non-employee members of the Board of Directors (the "***Board***") of Akebia Therapeutics, Inc. (the "***Company***") shall be eligible to receive cash and equity compensation as set forth in this Fifth Amended and Restated Non-Employee Director Compensation Program (this "***Program***"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who is eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program shall be reviewed by the Board periodically and may be amended, modified or terminated by the Board at any time in its sole discretion and nothing herein should be construed as a guarantee to any Non-Employee Director of any particular level of cash or equity compensation. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. This Program shall become effective on the date set forth above (the "***Effective Date***").

1. Cash Compensation.

(a) Annual Retainers. Each Non-Employee Director shall be eligible to receive an annual retainer of $50,000 for service on the Board.

(b) Additional Annual Retainers. In addition to the annual retainer payable pursuant to Section 1(a) above, a Non-Employee Director shall be eligible to receive the following annual retainers:

(i) Chairperson of the Board. A Non-Employee Director serving as Chairperson of the Board shall be eligible to receive an additional annual retainer of $40,000 for such service; provided, that, in the event that a Non-Employee Director is one of two concurrently serving Chairpersons of the Board, the additional annual retainer payable to such Non-Employee Director pursuant to this Section 1(b)(i) shall be $20,000.

(ii) Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee of the Board (the "***Audit Committee***") shall be eligible to receive an additional annual retainer of $20,000 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson of the Audit Committee) shall be eligible to receive an additional annual retainer of $10,000 for such service.

(iii) Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee of the Board (the "***Compensation Committee***") shall be eligible to receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson of the Compensation Committee) shall be eligible to receive an additional annual retainer of $7,500 for such service.

(iv) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee of the Board (the "***NCG Committee***") shall be eligible to receive an additional annual retainer of $10,000 for such service. A Non-Employee Director serving as a member of the NCG Committee (other than the Chairperson of the NCG Committee) shall be eligible to receive an additional annual retainer of $5,000 for such service.

(v) Research and Development Committee. A Non-Employee Director serving as Chairperson of the Research and Development Committee of the Board (the "***R&D Committee***") shall be eligible to receive an additional annual retainer of $10,000 for such service. A Non-Employee Director serving as a member of the R&D Committee (other than the Chairperson of the R&D Committee) shall be eligible to receive an additional annual retainer of $5,000 for such service.

(c) Payment of Retainers. The annual retainers described in Sections 1(a) and 1(b) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section 1(b), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

2. Equity Compensation. Non-Employee Directors shall be granted the equity awards described below. Each award described below shall be granted under and shall be subject to the terms and provisions of the Company's 2023 Stock Incentive Plan, as amended, or any other successor Company equity incentive plan under which awards are permitted to be made to Non-Employee Directors (the "***Equity Plan***") and (i) for option awards, a non-qualified stock option award agreement, including attached exhibits, in substantially the form of award agreement applicable to Non-Employee Directors most recently approved by the Board and/or the Compensation Committee, as applicable, and (ii) for restricted stock unit awards, a restricted stock unit award agreement, including attached exhibits, in substantially the form of award agreement applicable to Non-Employee Directors most recently approved by the Board and/or the Compensation Committee, as applicable. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein. For the avoidance of doubt, if there is any conflict between the terms of the Equity Plan (including the applicable award agreements thereunder) and this Program, the Equity Plan (including the applicable award agreements thereunder) shall control.

(a) Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall be eligible to receive, on the date of such initial election or appointment, an option to purchase 214,400 shares of the Company's common stock (subject to adjustment as provided in the Equity Plan). The awards described in this Section 2(a) shall be referred to as "***Initial Awards***." No Non-Employee Director shall be granted more than one Initial Award.

(b) Subsequent Awards. A Non-Employee Director who (i) has been serving on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted, on the date of such annual meeting, an option to purchase 53,600 shares of the Company's common stock (subject to adjustment as provided in the Equity Plan) and 35,700 restricted stock units of the Company. The option awards described in this Section 2(b) shall be referred to as "***Subsequent Options***", the restricted stock unit awards described in this Section 2(b) shall be referred to as "***Subsequent RSUs***", and the Subsequent Options and Subsequent RSUs shall together be referred to as the "***Subsequent Awards***." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Awards on the date of such meeting as well.

(c) Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section 2(a) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section 2(b) above.

(d) Terms of Awards Granted to Non-Employee Directors.

(i) Purchase Price. The per share exercise price of each option granted to a Non-Employee Director shall equal the fair market value (as determined pursuant to the Equity Plan) of a share of the Company's common stock on the date the option is granted.

(ii) Vesting. Each Initial Award shall vest and become exercisable in accordance with the following schedule, subject to the Non-Employee Director remaining in continuous employment or other service relationship with the Company ("***Service***") through each such vesting date: 33 1/3% of the Initial Award shall vest on the one-year anniversary of the date of grant and 66 2/3% shall vest ratably on the first day of each calendar quarter between the one-year anniversary of the date of grant and the third anniversary of the date of grant. Each Subsequent Option shall vest and become exercisable in full on the first anniversary of the date of grant (or, if earlier, immediately prior to the first annual meeting of the Company's stockholders occurring after the date of grant), subject to the Non-Employee Director remaining in continuous Service through such vesting date. Each Subsequent RSU shall vest in full on the first anniversary of the date of grant (or, if earlier, immediately prior to the first annual meeting

of the Company's stockholders occurring after the date of grant), subject to the Non-Employee Director remaining in continuous Service through such vesting date. Each Initial Award and Subsequent Award that is then-outstanding shall vest and become exercisable in full upon a change in control of the Company or termination of the Non-Employee Director's Service due to the Non-Employee Director's death or Disability. For purposes of the Program, "***Disability***" means Executive's inability by reason of physical or mental impairment to perform his/her job duties for a period exceeding twelve (12) consecutive weeks.

(iii) Term. The term of each option granted to a Non-Employee Director shall be ten (10) years from the date the option is granted.

3. Non-Employee Director Compensation Limit. Notwithstanding anything herein to the contrary, the cash compensation and equity compensation that each Non-Employee Director is entitled to receive under this Program shall be subject to any limits set forth in the applicable Equity Plan with respect to limits on awards to Non-Employee Directors.

4. Reimbursements. The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of such Non-Employee Director's duties to the Company in accordance with the Company's applicable expense reimbursement policies and procedures, as in effect from time to time. To the extent that any reimbursement under this Program provides for a deferral of compensation under Section 409A of the Internal Revenue Code of 1986, as amended: (a) the amount eligible for reimbursement in one calendar year may not affect the amount eligible for reimbursement in any other calendar year; (b) the right to reimbursement is not subject to liquidation or exchange for another benefit; and (c) any such reimbursement of an expense must be made on or before the last day of the calendar year following the calendar year in which the expense was incurred.

AMENDED AND RESTATED EXECUTIVE SEVERANCE AGREEMENT

This **AMENDED AND RESTATED EXECUTIVE SEVERANCE AGREEMENT** (the "***Agreement***") is entered into as of the 28th day of January, 2026 (the "***Effective Date***"), by and between **Akebia Therapeutics, Inc.,** a Delaware corporation ("***Akebia***" or the "***Company***"), and John P. Butler, a resident of the Commonwealth of Virginia (the "***Executive***").

WHEREAS, Executive is a valued employee of the Company;

WHEREAS, Executive and the Company are party to an Executive Severance Agreement dated as of the 3rd day of March, 2014 (the "***Original Executive Severance Agreement***"); and

WHEREAS, Executive and the Company desire to amend and restate the Original Executive Severance Agreement in its entirety to provide certain severance benefits to Executive according to, and contingent upon, the terms and conditions stated herein (the "***Severance Benefits***").

NOW, THEREFORE, in consideration of the foregoing and the mutual promises contained herein, and of other good and valuable consideration, including the compensation to be received by Executive from the Company from time to time, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending legally to be bound, hereby agree as follows:

1. Definitions.

(a) Cause. For purposes of this Agreement, and in each case as determined by the Compensation Committee of the Company's Board of Directors (the "***Compensation Committee***") in its sole and reasonable discretion, the following will constitute "***Cause***":

(i) indictment or conviction for either any felony offense or any other crime involving dishonesty;

(ii) participation in any fraud, theft, embezzlement or other misconduct or act of dishonesty involving the Company or any of its subsidiaries;

(iii) intentional damage to any property of the Company or any of its subsidiaries;

(iv) breach of the holder's duties of good faith and fair dealing that are owed to the Company or any of its subsidiaries;

(v) breach or violation of any agreement between Executive and the Company or any of its subsidiaries, including, without limitation, any employment, confidentiality, non-competition, non-solicitation or assignment of inventions agreement;

(vi) conduct which in the good faith and reasonable determination of the Board of Directors demonstrates gross unfitness to serve;

(vii) failure to comply with the code of conduct of the Company or any of its subsidiaries or any other policies of the Company that have been approved by the Board of Directors or its authorized delegate,

(viii) insubordination or failure to follow the directions of the Board of Directors or of the Chief Executive Officer or President of the Company; or

(ix) any other conduct by Executive that could be expected to be harmful to the business, interests or reputation of the Company or any of its subsidiaries.

Executive shall have thirty (30) days after notice from the Company to cure the deficiency leading to the Cause determination (except with respect to Sections 1(a)(i) and 1(a)(ii) above, for which no notice is required) if, in the sole and reasonable discretion of the Compensation Committee, such deficiency is curable.

(b) Good Reason. For purposes of this Agreement the following will constitute "***Good Reason***" for Executive to terminate his employment with the Company. For the avoidance of doubt, Executive shall not be considered to have terminated his employment for Good Reason unless Executive has (A) reasonably determined in good faith that a Good Reason condition has occurred; (B) not consented to the occurrence that he alleges constitutes Good Reason; (C) given the Company written Notice of Termination for Good Reason not more than sixty (60) days after the initial existence of the alleged condition giving rise to Good Reason; (D) given the Company at least thirty (30) days after receipt of such notice to cure the alleged deficiency; and (E) terminated his employment within sixty (60) days following the Company's receipt of such notice.

(i) a material reduction in the nature or status of Executive's responsibilities, authority, position or duties (unless arising directly or indirectly in connection with a documented and significant performance issue in Executive's then-current position, as determined by the Compensation Committee in its sole and reasonable discretion). Notwithstanding the foregoing, neither of the following shall constitute Good Reason: (A) a reassignment of Executive to a position within the Company of substantially equivalent level or status with respect to Executive's responsibilities and duties existing immediately prior to such reassignment, or (B) a change in reporting structure;

(ii) a material adverse reduction in the amount of aggregate cash compensation provided to Executive or failure by the Company to pay such compensation, except where such reduction occurs contemporaneously with the implementation of a firm-wide cost-reduction program affecting comparable executives (a "***Reduction Program***");

(iii) the failure by the Company to continue in effect any incentive compensation plan in which Executive participates, unless an equitable alternative compensation arrangement has been provided, except that to the extent that participation in such plans has been reduced or eliminated for all other eligible executives, in which case the failure to continue Executive in any such plan shall not constitute Good Reason; or

(iv) establishment of the Company's primary operations in any place beyond a fifty (50) mile radius of Cambridge, Massachusetts; provided, that Executive primarily provides services in Cambridge at the time of such establishment.

In all respects, the definition of Good Reason shall be interpreted to comply with Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***"), and any successor statute, regulation and guidance thereto ("***Section 409A***").

(c) Change in Control. For purposes of this Agreement, a "***Change in Control***" means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company's securities:

(i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities;

(ii) a change in the composition of the Board of Directors occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors. "***Incumbent Directors***" will mean directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board of Directors with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company);

(iii) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or

(iv) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets.

Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (a) its sole purpose is to change the domicile of the Company's incorporation; or (b) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A.

(d) Notice of Termination. For purposes of this Agreement, a "***Notice of Termination***" means a notice which, if applicable, sets forth the specific "cause" or "good reason" provision of this Section 2 and sets forth the effective date of termination.

(e) Disability. For purposes of this Agreement, "***Disability***" means Executive's inability by reason of physical or mental impairment to perform his job duties for a period exceeding twelve (12) consecutive weeks.

2. Termination of Agreement. This Agreement will terminate automatically upon (a) Executive's termination for Cause; (b) mutual agreement between the Company and Executive; (c) Executive's death, or (d) Executive's Disability. Upon termination of this Agreement, Executive or his heirs or estate (as applicable) only will be entitled to payments required by law or agreement and benefits afforded under the Company's employee benefit plans existing at the time of termination and in which the Executive participates.

3. Severance Benefits Upon Termination of Executive's Employment. If Executive's employment is terminated, then he may be entitled to certain monetary and non-monetary compensation and benefits as set forth below (the "***Severance Benefits***"):

(a) Termination by the Company for Cause; Executive's Death or Disability. If Executive's employment is terminated by the Company for Cause or on account of the Executive's Disability, or if Executive's employment is terminated due to the Executive's death, then the Company shall pay Executive all amounts earned or accrued but not paid as of the effective date of such termination, including (i) Executive's then-current base salary; (ii) legitimate business expenses incurred by Executive in the performance of his duties to the Company in accordance with the Company's normal policies and practices; (iii) vacation pay in accordance with applicable law and the Company's normal policies and practices; and (iv) any earned or accrued bonus or incentive compensation with respect to the calendar year ended prior to the year in which the termination became effective (collectively, "***Accrued Compensation***").

(b) Termination by Executive without Good Reason. If Executive terminates his employment without Good Reason, then the Company will pay Executive all Accrued Compensation earned through the date of such resignation. Nothing herein shall prohibit the Company, in its discretion, from effectuating Executive's resignation sooner than the date set forth in Executive's Notice of Termination.

(c) Termination by the Company without Cause or by Executive for Good Reason (No Change in Control). If Executive's employment is terminated by the Company without Cause or by the Executive for Good Reason where there has not been a Change in Control, and provided that the Executive has satisfied all conditions precedent as set forth herein, then the Company shall:

(i) pay Executive all Accrued Compensation;

(ii) continue paying Executive's then-base salary for a period of twelve (12) months payable in accordance with the normal payroll practices of the Company for its executives generally, with the first such payment to be made on the first payroll date that occurs after the day that is sixty (60) days after the date of termination, retroactive to the date of Executive's termination, or such other method of payment as determined by the Company;

(iii) pay Executive an amount equal to one hundred percent (100%) of his annual target bonus for the year in which the termination occurs, such amount to be payable in a lump-sum on the first payroll date that occurs after the day that is sixty (60) days after the date of termination; and

(iv) provided that Executive appropriately and timely completes all required elections, the Company shall pay the premiums for health and dental insurance continuation (for Executive and all Executive's eligible dependents) under the Consolidated Omnibus Budget Reconciliation Act ("***COBRA***") at the same amount and to the same extent it would if Executive still was employed by the Company until the earliest of (A) the last day of the month which falls twelve (12) months from the date of Executive's termination (or such other period as required by applicable law); (B) the date that Executive and eligible dependents are no

longer eligible to receive continuation coverage under COBRA; or (C) the date Executive becomes eligible to receive health or dental care coverage pursuant to the health or dental care plan of a new employer.

In the event that the Company terminates Executive's employment without Cause as set forth in this Section 3(c), but the Company determines within one (1) year of such termination that the Company had the right to terminate Executive's employment for Cause pursuant to Sections 1(a) and 3(a) above, the Company may terminate the payment of any amounts still owed to Executive pursuant to this Section 3(c).

(d) Termination by the Company without Cause or by Executive for Good Reason (Change in Control). If Executive's employment is terminated by the Company without Cause or by Executive for Good Reason, in either case on or within twelve (12) months after the occurrence of a Change in Control, then the Company shall:

(i) pay Executive all Accrued Compensation;

(ii) continue paying Executive's then-base salary for a period of twenty four (24) months payable in accordance with the normal payroll practices of the Company for its executives generally, with the first such payment to be made on the first payroll date that occurs after the day that is sixty (60) days after the date of termination, retroactive to the date of Executive's termination, or such other method of payment as determined by the Company;

(iii) pay Executive an amount equal to two hundred percent (200%) of his annual target bonus for the year in which the termination occurs, such amount to be payable in a lump-sum on the first payroll date that occurs after the day that is sixty (60) days after the date of termination; and

(iv) provided that Executive appropriately and timely completes all required elections, the Company shall pay the premiums for health and dental insurance continuation (for Executive and all Executive's eligible dependents) under COBRA at the same amount and to the same extent it would if Executive still was employed by the Company until the earliest of (A) the last day of the month which falls twenty-four (24) months from the date of Executive's termination; (B) the date that Executive and eligible dependents are no longer eligible to receive continuation coverage under COBRA; or (C) the date Executive becomes eligible to receive health or dental care coverage pursuant to the health or dental care plan of a new employer. Notwithstanding the foregoing, if Executive and his eligible dependents are no longer eligible to receive continuation coverage under COBRA solely because, under applicable law, they are ineligible to receive continuation coverage under COBRA after the eighteenth (18^{th}) month following the date of Executive's termination, the Company will instead pay to the Executive, at the time such continuation coverage under COBRA ends, a taxable lump sum payment equal to six (6) months' worth of the premiums the Company would have paid had coverage extended to twenty-four (24) months.

In the event that the Company terminates Executive's employment without Cause as set forth in this Section 3(d), but the Company determines within one (1) year of such termination that the Company had the right to terminate Executive's employment for Cause pursuant to Sections 1(a) and 3(a) above, the Company may terminate the payment of any amounts still owed to Executive pursuant to this Section 3(d).

(e) Notice of Termination Required. Any purported termination by the Company or by Executive must be communicated by a written Notice of Termination to the other party. For purposes of this Agreement, no purported termination of employment will be effective without a Notice of Termination.

(f) Timing of Payments. The Accrued Compensation payable to Executive as provided in this Section 3 will be paid pursuant to applicable state law or within ten (10) business days after the effective date of Executive's employment termination, whichever period is shorter. Any other compensation provided for in this Section 3 will be paid as set forth above, subject to Section 9 below.

(g) Payroll Taxes and Withholdings. All Severance Benefits provided for in this Section 3 shall, to the extent required, be subject to ordinary and required payroll taxes, deductions and income tax withholding.

(h) Reemployment. If Executive becomes reemployed by the Company prior to the end of the period in which Executive is entitled to receive Severance Benefits, Executive will no longer be entitled to receive such Severance Benefits (except for any Accrued Compensation) as of the effective date of such reemployment.

(i) Benefit Plans. Executive's entitlement to any other compensation or benefits upon termination of his employment shall be determined in accordance with the Company's employee benefit plans and other applicable programs and practices then in effect.

4. Conditions Precedent to Receipt of Severance Benefits. Executive shall not be entitled to receive (or continue to receive) any Severance Benefits, except for Accrued Compensation, and shall not be entitled to any continued vesting of outstanding equity awards pursuant to Section 5(b) below unless:

(a) Executive executes (prior to the deadline established by the Company), does not revoke and complies with a general release of all claims against the Company and its officers, directors and employees upon terms and in a form reasonably acceptable to the Company;

(b) Executive executes (and does not rescind such acceptance within seven (7) business days after such execution) and complies fully with a new agreement to be entered into between Executive and the Company containing post-termination restrictive covenants (including, without limitation, covenants of non-disclosure, non-solicitation and non-competition, and covenants regarding the assignment of intellectual property) with the same scope, duration and conditions as any post-termination restrictive covenants previously agreed to between Executive and the Company at any time during Executive's employment with the Company; and

(c) Executive complies fully with Sections 6 and 7 hereof.

5. Treatment of Equity.

(a) Upon a Change in Control – Awards granted before Effective Date. One hundred percent (100%) of Executive's then outstanding unvested options, restricted shares, restricted stock units or other equity-based awards granted on or prior to the Effective Date shall immediately vest upon a Change in Control. The exercisability of stock options (or other awards requiring exercise) shall be extended, to the extent feasible and to the extent consistent with applicable law and the terms of the Company's equity plans or programs (each, as in effect from time to time, a "***Company Equity Plan***" and, together, the "***Company Equity Plans***") and the

award agreements issued thereunder, beyond any lockup or similar restrictive period set forth in any documents executed in connection with a Change in Control. The Compensation Committee may determine in its reasonable discretion whether it is advisable or feasible to amend a Company Equity Plan or Plans and/or any equity agreements issued thereunder between the Company and Executive in order to effect the extended period of exercise contemplated by this Section 5(a). For the avoidance of doubt, no amendment shall be made by the Compensation Committee in furtherance of this Section 5(a) other than in accordance with Section 409A.

(b) Upon Termination by the Company without Cause or by Executive for Good Reason (No Change in Control). Executive's then outstanding unvested options, restricted shares, restricted stock units and other equity-based awards shall remain outstanding and continue to vest in accordance with the terms of the applicable equity agreement(s) for the period of time during which Executive continues to receive Severance Benefits, as if he or she remained employed during such time, in accordance with Section 3(c)(ii) hereof. The Compensation Committee may determine in its reasonable discretion whether it is advisable or feasible to amend a Company Equity Plan or Plans and/or any equity agreements issued thereunder existing between the Company and Executive in order to effect the extended period of vesting contemplated by this Section 5(b). For the avoidance of doubt, no amendment shall be made by the Compensation Committee in furtherance of this Section 5(b) other than in accordance with Section 409A.

(c) Upon Termination by the Company without Cause or by Executive for Good Reason (Change in Control) – Awards granted after Effective Date. If Executive's employment is terminated by the Company without Cause or by Executive for Good Reason, in either case on or within twelve (12) months after the occurrence of a Change in Control, then one hundred percent (100%) of Executive's then outstanding unvested options, restricted shares, restricted stock units and other equity-based awards granted after the Effective Date shall immediately vest upon such termination. The exercisability of stock options (or other awards requiring exercise) shall be extended, to the extent feasible and to the extent consistent with applicable law and the terms of the Company Equity Plans and the award agreements issued thereunder, beyond any lockup or similar restrictive period set forth in any documents executed in connection with the Change in Control. The Compensation Committee may determine in its reasonable discretion whether it is advisable or feasible to amend a Company Equity Plan or Plans and/or any equity agreements issued thereunder between the Company and Executive in order to effect the extended period of exercise contemplated by this Section 5(c). For the avoidance of doubt, no amendment shall be made by the Compensation Committee in further of this Section 5(a), nor shall any acceleration of vesting or settlement occur, other than in accordance with Section 409A.

6. Cooperation. During employment and after the termination of Executive's employment for any reason, Executive agrees to cooperate with, and at the request of, the Company in the defense or prosecution of any legal matter or claim in which the Company, any of its affiliates, or any of their past or present employees, agents, officers, directors, attorneys, successors or assigns, may be or become involved and which arises or arose during Executive's employment, to the extent such cooperation does not unreasonably interfere with Executive's personal or professional schedule. Executive will be reimbursed for any reasonable out-of-pocket expenses incurred thereby.

7. Non-Disparagement; Permitted Disclosures.

(a) Except for permitted disclosures described in Section 7(b) below, Executive agrees that during his employment and for the greater of (A) one (1) year following the termination of his employment (regardless of the reason for termination) or (B) the period during which Executive receives Severance Benefits hereunder, Executive will not make any

statements that are disparaging about or adverse to the business interests of the Company or which are intended to harm the reputation of the Company including, but not limited to, any statements that disparage any product, service, finances, employees, officers, directors, capabilities or any other aspect of the Company's business, products or services.

(b) Nothing in this Agreement, including Section 7(a) above, or elsewhere prohibits or restricts Executive from communicating with, or voluntarily providing information Executive believes indicates possible or actual violations of the law to, local, state or federal government agencies, any legislative body, law enforcement, or any self-regulatory organization (including but not limited to the Securities and Exchange Commission). Executive is not required to notify the Company of any such communications or disclosures.

8. Successors and Assigns.

(a) Assignment by Company. The Company may, without the consent of Executive, assign this Agreement or delegate its obligations hereunder to any firm, entity, company or person (collectively, a "***Person***") in the event that the Company shall hereafter effect a reorganization, consolidate with, or merge into, such Person or transfer all or substantially all of its properties or assets to such Person.

(b) Assignment by Executive. Neither this Agreement nor any right or interest hereunder will be assignable or transferable by Executive, his beneficiaries or legal representatives, except by will or by the laws of descent and distribution. All payments under this Agreement will inure to the benefit of and be enforceable by Executive's legal personal representative(s).

9. Tax Consequences.

(a) The Company does not guarantee the tax treatment or tax consequences associated with Severance Benefits or vesting continuation or acceleration received by Executive hereunder.

(b) Parachute Payments. To the extent consistent with applicable law, the payment of any amounts or the provision of any benefits under this Agreement including, without limitation, the payment of Severance Benefits pursuant to Section 3 above or the accelerated vesting of equity pursuant to Section 5 above, will be reduced or adjusted to avoid triggering the excise tax imposed by Section 4999 of the Code, if such adjustment would result in the provision of a greater total benefit, on a net after-tax basis (after taking into account taking any applicable federal, state and local income taxes and the excise tax imposed by Section 4999), to Executive.

(c) Section 409A. The provisions of this Agreement are intended to comply with the requirements of Section 409A or with the conditions for an exemption from such requirements, and shall be construed accordingly. Notwithstanding any provision of this Agreement to the contrary, if at the time of Executive's separation from service (as defined below) Executive is a specified employee (as defined below), as determined by the Company, any and all amounts payable in connection with such separation from service that constitute deferred compensation subject to Section 409A, as determined by the Company, and that would otherwise be payable within six (6) months following such separation from service, shall instead be paid on the date that follows the date of such separation from service by six (6) months (or, if earlier, as soon as practicable following the Executive's death) to the extent permitted or required by Section 409A. For purposes of this Agreement, all references to "termination of employment" and correlative phrases shall be construed to require a "separation from service" (as defined in Section 1.409A-1(h) of the Treasury regulations after giving effect to the presumptions contained

therein), and the term "specified employee" means an individual determined by the Company to be a specified employee under Treasury regulation Section 1.409A-1(i).

Each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments.

Any reimbursement for expenses that would constitute nonqualified deferred compensation subject to Section 409A shall be subject to the following additional rules: (i) no reimbursement of any such expense shall affect Executive's right to reimbursement of any such expense in any other taxable year; (ii) reimbursement of the expense shall be made, if at all, promptly, but not later than the end of the calendar year following the calendar year in which the expense was incurred; and (iii) the right to reimbursement shall not be subject to liquidation or exchange for any other benefit.

10. Notices. All notices, requests, demands, and other communications called for hereunder will be in writing and will be deemed given (a) on the date of delivery if delivered personally, (b) one (1) day after being sent overnight by a well-established commercial overnight service, or (c) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing:

If to the Company:

Akebia Therapeutics, Inc.
Attention: General Counsel
245 First Street, Suite 1400
Cambridge, Massachusetts 02142

If to Executive:

at the last residential address known by the Company

11. Non-Exclusivity of Rights. Nothing in this Agreement will prevent or limit Executive's continuing or future participation in any benefit, bonus, incentive or other plan or program provided by the Company or any of its subsidiaries and for which Executive may qualify, nor will anything herein limit or reduce such rights as Executive may have under any other agreements with the Company or any of its subsidiaries. Amounts which are vested benefits or which Executive is otherwise entitled to receive under any plan or program of the Company or any of its subsidiaries will be payable in accordance with such plan or program, except as explicitly modified by this Agreement.

12. Amendments. No provision of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing and signed by Executive and a member of the Board of Directors of the Company.

13. No Waiver. No waiver by either party hereto at any time of any breach by the other party hereto of, or compliance with, any condition or provision of this Agreement to be performed by such other party will be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time.

14. **Governing Law.** This Agreement will be governed by and construed and enforced in accordance with the laws of the State of Delaware, without giving effect to the conflict of law principles thereof.

15. **Dispute Resolution/Jurisdiction/Venue.** Any dispute concerning this Agreement shall be heard by a court of competent jurisdiction within Massachusetts. The parties hereby acknowledge that they are subject to the personal jurisdiction of the Massachusetts courts in any county where the Company has operations or facilities and/or Executive resides.

16. **Expenses.** To the extent Executive elects to have independent legal counsel review and or negotiate the terms of this Agreement or any release required by this Agreement, Executive shall be solely responsible for all associated costs and fees, including but not limited to attorneys' fees.

17. **Severability.** The provisions of this Agreement will be deemed severable and the invalidity or unenforceability of any provision will not affect the validity or enforceability of the other provisions hereof.

18. **Effect on Other Agreements.** The terms of this Agreement replace and supersede the terms in all other and prior agreements between Executive and the Company, including, without limitation, the Original Executive Severance Agreement, that relate to (i) post-separation severance and other post-separation benefits and (ii) equity acceleration in connection with a change of control, whether written or oral or express or implied, and no representations, promises, assurances or agreements have been made regarding the subject matter of this Agreement, except such as has been stated in this Agreement. For the avoidance of doubt, (a) the terms of any existing employment agreement or other agreement between Executive and the Company regarding assignment of intellectual property, confidentiality and non-disclosure, non-competition and non-solicitation between Executive and the Company shall remain in full force and effect and (b) all other terms in offer letters, employment agreements or any other agreements between Executive and the Company that do not relate to (1) post-separation severance or other post-separation benefits or (2) equity acceleration in connection with a change of control, will remain in full force and effect.

THE COMPANY AND EXECUTIVE ACKNOWLEDGE THAT (A) EACH HAS CAREFULLY READ THIS AGREEMENT, (B) EACH UNDERSTANDS ITS TERMS, (C) ALL UNDERSTANDINGS AND AGREEMENTS BETWEEN THE COMPANY AND EXECUTIVE RELATING TO THE SUBJECTS COVERED IN THIS AGREEMENT ARE CONTAINED IN IT, AND (D) EACH HAS ENTERED INTO THIS AGREEMENT VOLUNTARILY AND NOT IN RELIANCE ON ANY PROMISES OR REPRESENTATIONS BY THE OTHER, OTHER THAN THOSE CONTAINED IN THIS AGREEMENT ITSELF.

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized person and Executive has executed this Agreement effective as of the day and year first above written.

EXECUTIVE

By: /s/ John P. Butler
John P. Butler
President and Chief Executive Officer

AKEBIA THERAPEUTICS, INC.

By: /s/ Erik J. Ostrowski
Erik J. Ostrowski
SVP, Chief Financial Officer and Chief Business Officer

Exhibit 10.16

EXECUTIVE SEVERANCE AGREEMENT

This **EXECUTIVE SEVERANCE AGREEMENT** (the "***Agreement***") is entered into by and between **Akebia Therapeutics, Inc.**, a Delaware corporation ("***Akebia***" or the "***Company***"), and _____, a resident of _____ (the "***Executive***"), and is effective as of _____ (the "***Effective Date***").

WHEREAS, Executive is a valued employee of the Company; and

WHEREAS, the Company desires to provide certain severance benefits to Executive according to, and contingent upon, the terms and conditions stated herein (the "***Severance Benefits***").

NOW, THEREFORE, in consideration of the foregoing and the mutual promises contained herein, and of other good and valuable consideration, including the compensation to be received by Executive from the Company from time to time, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending legally to be bound, hereby agree as follows:

1. Definitions.

(a) Cause. For purposes of this Agreement, and in each case as determined by the Compensation Committee of the Company's Board of Directors (the "***Compensation Committee***") in its sole and reasonable discretion, the following will constitute "***Cause***":

(i) indictment or conviction for either any felony offense or any other crime involving dishonesty;

(ii) participation in any fraud, theft, embezzlement or other misconduct or act of dishonesty involving the Company or any of its subsidiaries;

(iii) intentional damage to any property of the Company or any of its subsidiaries;

(iv) breach of the holder's duties of good faith and fair dealing that are owed to the Company or any of its subsidiaries;

(v) breach or violation of any agreement between Executive and the Company or any of its subsidiaries, including, without limitation, any employment, confidentiality, non-competition, non-solicitation or assignment of inventions agreement;

(vi) conduct which in the good faith and reasonable determination of the Board of Directors demonstrates gross unfitness to serve;

(vii) failure to comply with the code of conduct of the Company or any of its subsidiaries or any other policies of the Company that have been approved by the Board of Directors or its authorized delegate,

(viii) insubordination or failure to follow the directions of the Board of Directors or of the Chief Executive Officer or President of the Company; or

(ix) any other conduct by Executive that could be expected to be harmful to the business, interests or reputation of the Company or any of its subsidiaries.

Executive shall have thirty (30) days after notice from the Company to cure the deficiency leading to the Cause determination (except with respect to Sections 1(a)(i) and 1(a)(ii) above, for which no notice is required) if, in the sole and reasonable discretion of the Compensation Committee, such deficiency is curable.

(b) Good Reason. For purposes of this Agreement the following will constitute "***Good Reason***" for Executive to terminate his/her employment with the Company. For the avoidance of doubt, Executive shall not be considered to have terminated his/her employment for Good Reason unless Executive has (A) reasonably determined in good faith that a Good Reason condition has occurred; (B) not consented to the occurrence that s/he alleges constitutes Good Reason; (C) given the Company written Notice of Termination for Good Reason not more than sixty (60) days after the initial existence of the alleged condition giving rise to Good Reason; (D) given the Company at least thirty (30) days after receipt of such notice to cure the alleged deficiency; and (E) terminated his/her employment within sixty (60) days following the Company's receipt of such notice:

(i) a material reduction in the nature or status of Executive's responsibilities, authority, position or duties (unless arising directly or indirectly in connection with a documented and significant performance issue in Executive's then-current position, as determined by the Compensation Committee in its sole and reasonable discretion). Notwithstanding the foregoing, neither of the following shall constitute Good Reason: (A) a reassignment of Executive to a position within the Company of substantially equivalent level or status with respect to Executive's responsibilities and duties existing immediately prior to such reassignment, or (B) a change in reporting structure;

(ii) a material adverse reduction in the amount of aggregate cash compensation provided to Executive or failure by the Company to pay such compensation, except where such reduction occurs contemporaneously with the implementation of a firm-wide cost-reduction program affecting comparable executives (a "***Reduction Program***");

(iii) the failure by the Company to continue in effect any incentive compensation plan in which Executive participates, unless an equitable alternative compensation arrangement has been provided, except that to the extent that participation in such plans has been reduced or eliminated for all other eligible executives, in which case the failure to continue Executive in any such plan shall not constitute Good Reason; or

(iv) establishment of the Company's primary operations in any place beyond a fifty (50) mile radius of Cambridge, Massachusetts; provided, that Executive primarily provides services in Cambridge at the time of such establishment.

In all respects, the definition of Good Reason shall be interpreted to comply with Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***"), and any successor statute, regulation and guidance thereto ("***Section 409A***").

(c) Change in Control. For purposes of this Agreement, a "***Change in Control***" means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company's securities:

(i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities;

(ii) a change in the composition of the Board of Directors occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors. "Incumbent Directors" will mean directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board of Directors with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company);

(iii) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or

(iv) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets.

Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (a) its sole purpose is to change the domicile of the Company's incorporation; or (b) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction.

In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A.

(d) Notice of Termination. For purposes of this Agreement, a "***Notice of Termination***" means a notice which, if applicable, sets forth the specific "cause" or "good reason" provision of this Section 1 and sets forth the effective date of termination.

(e) Disability. For purposes of this Agreement, "***Disability***" means Executive's inability by reason of physical or mental impairment to perform his/her job duties for a period exceeding twelve (12) consecutive weeks.

2. Termination of Agreement. This Agreement will terminate automatically upon (a) Executive's termination for Cause; (b) mutual agreement between the Company and Executive; (c) Executive's death, or (d) Executive's Disability. Upon termination of this Agreement, Executive or his/her heirs or estate (as applicable) only will be entitled to payments required by law or agreement and benefits afforded under the Company's employee benefit plans existing at the time of termination and in which the Executive participates.

3. Severance Benefits Upon Termination of Executive's Employment. If Executive's employment is terminated, then s/he may be entitled to certain monetary and non-monetary compensation and benefits as set forth below (the "***Severance Benefits***"):

(a) Termination by the Company for Cause; Executive's Death or Disability. If Executive's employment is terminated by the Company for Cause or on account of the Executive's Disability, or if Executive's employment is terminated due to the Executive's death, then the Company shall pay Executive all amounts earned or accrued but not paid as of the effective date of such termination, including (i) Executive's then-current base salary; (ii) legitimate business expenses incurred by Executive in the performance of his/her duties to the Company in accordance with the Company's normal policies and practices; (iii) vacation pay in accordance with applicable law and the Company's normal policies and practices; and (iv) any earned or accrued bonus or incentive compensation with respect to the calendar year ended prior to the year in which the termination became effective (collectively, "***Accrued Compensation***").

(b) Termination by Executive without Good Reason. If Executive terminates his/her employment without Good Reason, then the Company will pay Executive all Accrued Compensation earned through the date of such resignation. Nothing herein shall prohibit the Company, in its discretion, from effectuating Executive's resignation sooner than the date set forth in Executive's Notice of Termination.

(c) Termination by the Company without Cause or by Executive for Good Reason (No Change in Control). If Executive's employment is terminated by the Company without Cause or by the Executive for Good Reason where there has not been a Change in Control, and provided that the Executive has satisfied all conditions precedent as set forth herein, then the Company shall:

(i) pay Executive all Accrued Compensation;

(ii) continue paying Executive's then-base salary for a period of twelve (12) months payable in accordance with the normal payroll practices of the Company for its executives generally, with the first such payment to be made on the first payroll date that occurs after the day that is sixty (60) days after the date of termination, retroactive to the date of Executive's termination, or such other method of payment as determined by the Company; and

(iii) provided that Executive appropriately and timely completes all required elections, the Company shall pay the premiums for health and dental insurance continuation (for Executive and all Executive's eligible dependents) under the Consolidated Omnibus Budget Reconciliation Act ("***COBRA***") at the same amount and to the same extent it would if Executive still was employed by the Company until the earliest of (A) the last day of the month which falls twelve (12) months from the date of Executive's termination (or such other period as required by applicable law); (B) the date that Executive and eligible dependents are no longer eligible to receive continuation coverage under COBRA; or (C) the date Executive becomes eligible to receive health or dental care coverage pursuant to the health or dental care plan of a new employer.

In the event that the Company terminates Executive's employment without Cause as set forth in this Section 3(c), but the Company determines within one (1) year of such termination that the Company had the right to terminate Executive's employment for Cause pursuant to Sections 1(a) and 3(a) above, the Company may terminate the payment of any amounts still owed to Executive pursuant to this Section 3(c).

(d) Termination by the Company without Cause or by Executive for Good Reason (Change in Control). If Executive's employment is terminated by the Company without Cause or by Executive for Good Reason, in either case on or within twelve (12) months after the occurrence of a Change in Control; then the Company shall:

(i) pay Executive all Accrued Compensation;

(ii) continue paying Executive's then-base salary for a period of twelve (12) months payable in accordance with the normal payroll practices of the Company for its executives generally, with the first such payment to be made on the first payroll date that occurs after the day that is sixty (60) days after the date of termination, retroactive to the date of Executive's termination, or such other method of payment as determined by the Company;

(iii) pay Executive an amount equal to one hundred percent (100%) of his/her annual target bonus for the year in which the termination occurs, such amount to be payable in a lump-sum on the first payroll date that occurs after the day that is sixty (60) days after the date of termination; and

(iv) provided that Executive appropriately and timely completes all required elections, the Company shall pay the premiums for health and dental insurance continuation (for Executive and all Executive's eligible dependents) under COBRA at the same amount and to the same extent it would if Executive still was employed by the Company until the earliest of (A) the last day of the month which falls twelve (12) months from the date of Executive's termination (or such other period as required by applicable law); (B) the date that Executive and eligible dependents are no longer eligible to receive continuation coverage under COBRA; or (C) the date Executive becomes eligible to receive health or dental care coverage pursuant to the health or dental care plan of a new employer.

In the event that the Company terminates Executive's employment without Cause as set forth in this Section 3(d), but the Company determines within one (1) year of such termination that the Company had the right to terminate Executive's employment for Cause pursuant to Sections 1(a) and 3(a) above, the Company may terminate the payment of any amounts still owed to Executive pursuant to this Section 3(d).

(e) Notice of Termination Required. Any purported termination by the Company or by Executive must be communicated by a written Notice of Termination to the other party. For purposes of this Agreement, no purported termination of employment will be effective without a Notice of Termination.

(f) Timing of Payments. The Accrued Compensation payable to Executive as provided in this Section 3 will be paid pursuant to applicable state law or within ten (10) business days after the effective date of Executive's employment termination, whichever period is shorter. Any other compensation provided for in this Section 3 will be paid as set forth above, subject to Section 9 below.

(g) Payroll Taxes and Withholdings. All Severance Benefits provided for in this Section 3 shall, to the extent required, be subject to ordinary and required payroll taxes, deductions and income tax withholding.

(h) Reemployment. If Executive becomes reemployed by the Company prior to the end of the period in which Executive is entitled to receive Severance Benefits, Executive will no longer be

entitled to receive such Severance Benefits (except for any Accrued Compensation) as of the effective date of such reemployment.

(i) Benefit Plans. Executive's entitlement to any other compensation or benefits upon termination of his/her employment shall be determined in accordance with the Company's employee benefit plans and other applicable programs and practices then in effect.

4. Conditions Precedent to Receipt of Severance Benefits. Executive shall not be entitled to receive (or continue to receive) any Severance Benefits, except for Accrued Compensation, and shall not be entitled to any continued vesting of outstanding equity awards pursuant to Section 5(b) below unless:

(a) Executive executes (prior to the deadline established by the Company), does not revoke and complies with a general release of all claims against the Company and its officers, directors and employees upon terms and in a form reasonably acceptable to the Company;

(b) Executive executes (and does not rescind such acceptance within seven (7) business days after such execution) and complies fully with a new agreement to be entered into between Executive and the Company containing post-termination restrictive covenants (including, without limitation, covenants of non-disclosure, non-solicitation and non-competition, and covenants regarding the assignment of intellectual property) with the same scope, duration and conditions as any post-termination restrictive covenants previously agreed to between Executive and the Company at any time during Executive's employment with the Company; and

(c) Executive complies fully with Sections 6 and 7 hereof.

5. Treatment of Equity.

(a) Upon a Termination by the Company without Cause or by Executive for Good Reason (Change in Control). If Executive's employment is terminated by the Company without Cause or by Executive for Good Reason, in either case on or within twelve (12) months after the occurrence of a Change in Control, then one hundred percent (100%) of Executive's then outstanding unvested options, restricted shares, restricted stock units and other equity-based awards shall immediately vest upon such termination. The exercisability of stock options (or other awards requiring exercise) shall be extended, to the extent feasible and to the extent consistent with applicable law and the terms of the Company's equity plans or programs (each, as in effect from time to time, a "***Company Equity Plan***" and, together, the "***Company Equity Plans***") and the award agreements issued thereunder, beyond any lockup or similar restrictive period set forth in any documents executed in connection with a Change in Control. The Compensation Committee may determine in its reasonable discretion whether it is advisable or feasible to amend a Company Equity Plan or Plans and/or any equity agreements issued thereunder between the Company and Executive in order to effect the extended period of exercise contemplated by this Section 5(a). For the avoidance of doubt, no amendment shall be made by the Compensation Committee in furtherance of this Section 5(a), nor shall any acceleration of vesting or settlement occur, other than in accordance with Section 409A.

(b) Upon Termination by the Company without Cause or by Executive for Good Reason (No Change in Control). Executive's then outstanding unvested options, restricted shares, restricted stock units and other equity-based awards shall remain outstanding and continue to vest in accordance with the terms of the applicable equity agreement(s) for the period of time during which Executive continues to receive Severance Benefits, as if he or she remained employed during such time, in accordance with Section 3(c)(ii) hereof. The Compensation Committee may determine in its reasonable discretion whether

it is advisable or feasible to amend a Company Equity Plan or Plans and/or any equity agreements issued thereunder existing between the Company and Executive in order to effect the extended period of vesting contemplated by this Section 5(b). For the avoidance of doubt, (i) no amendment shall be made by the Compensation Committee in furtherance of this Section 5(b) other than in accordance with Section 409A and (ii) in the event the termination giving rise to the payment of Severance Benefits occurs following a Change in Control, the acceleration provisions of Section 5(a) above, rather than those of this Section 5(b), shall apply to Executive's outstanding unvested options, restricted shares, restricted stock units and other equity-based awards.

6. Cooperation. During employment and after the termination of Executive's employment for any reason, Executive agrees to cooperate with, and at the request of, the Company in the defense or prosecution of any legal matter or claim in which the Company, any of its affiliates, or any of their past or present employees, agents, officers, directors, attorneys, successors or assigns, may be or become involved and which arises or arose during Executive's employment, to the extent such cooperation does not unreasonably interfere with Executive's personal or professional schedule. Executive will be reimbursed for any reasonable out-of-pocket expenses incurred thereby.

7. Non-Disparagement; Permitted Disclosures.

(a) Except for permitted disclosures described in Section 7(b) below, Executive agrees that during his/her employment and for the greater of (A) one (1) year following the termination of his/her employment (regardless of the reason for termination) or (B) the period during which Executive receives Severance Benefits hereunder, Executive will not make any statements that are disparaging about or adverse to the business interests of the Company or which are intended to harm the reputation of the Company including, but not limited to, any statements that disparage any product, service, finances, employees, officers, directors, capabilities or any other aspect of the Company's business, products or services.

(b) Nothing in this Agreement, including Section 7(a) above, or elsewhere prohibits or restricts Executive from communicating with, or voluntarily providing information Executive believes indicates possible or actual violations of the law to, local, state or federal government agencies, any legislative body, law enforcement, or any self-regulatory organization (including but not limited to the Securities and Exchange Commission). Executive is not required to notify the Company of any such communications or disclosures.

8. Successors and Assigns.

(a) Assignment by Company. The Company may, without the consent of Executive, assign this Agreement or delegate its obligations hereunder to any firm, entity, company or person (collectively, a "***Person***") in the event that the Company shall hereafter effect a reorganization, consolidate with, or merge into, such Person or transfer all or substantially all of its properties or assets to such Person.

(b) Assignment by Executive. Neither this Agreement nor any right or interest hereunder will be assignable or transferable by Executive, his/her beneficiaries or legal representatives, except by will or by the laws of descent and distribution. All payments under this Agreement will inure to the benefit of and be enforceable by Executive's legal personal representative(s).

9. Tax Consequences.

(a) The Company does not guarantee the tax treatment or tax consequences associated with Severance Benefits or vesting continuation or acceleration received by Executive hereunder.

(b) Parachute Payments. To the extent consistent with applicable law, the payment of any amounts or the provision of any benefits under this Agreement including, without limitation, the payment of Severance Benefits pursuant to Section 3 above or the accelerated vesting of equity pursuant to Section 5 above, will be reduced or adjusted to avoid triggering the excise tax imposed by Section 4999 of the Code, if such adjustment would result in the provision of a greater total benefit, on a net after-tax basis (after taking into account taking any applicable federal, state and local income taxes and the excise tax imposed by Section 4999), to Executive.

(c) Section 409A. The provisions of this Agreement are intended to comply with the requirements of Section 409A or with the conditions for an exemption from such requirements, and shall be construed accordingly. Notwithstanding any provision of this Agreement to the contrary, if at the time of Executive's separation from service (as defined below) Executive is a specified employee (as defined below), as determined by the Company, any and all amounts payable in connection with such separation from service that constitute deferred compensation subject to Section 409A, as determined by the Company, and that would otherwise be payable within six (6) months following such separation from service, shall instead be paid on the date that follows the date of such separation from service by six (6) months (or, if earlier, as soon as practicable following the Executive's death) to the extent permitted or required by Section 409A. For purposes of this Agreement, all references to "termination of employment" and correlative phrases shall be construed to require a "separation from service" (as defined in Section 1.409A-1(h) of the Treasury regulations after giving effect to the presumptions contained therein), and the term "specified employee" means an individual determined by the Company to be a specified employee under Treasury regulation Section 1.409A-1(i).

Each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments.

Any reimbursement for expenses that would constitute nonqualified deferred compensation subject to Section 409A shall be subject to the following additional rules: (i) no reimbursement of any such expense shall affect Executive's right to reimbursement of any such expense in any other taxable year; (ii) reimbursement of the expense shall be made, if at all, promptly, but not later than the end of the calendar year following the calendar year in which the expense was incurred; and (iii) the right to reimbursement shall not be subject to liquidation or exchange for any other benefit.

10. Notices. All notices, requests, demands, and other communications called for hereunder will be in writing and will be deemed given (a) on the date of delivery if delivered personally, (b) one (1) day after being sent overnight by a well-established commercial overnight service, or (c) four (4) days after being mailed by registered or certified mail, return receipt requested, prepaid and addressed to the parties or their successors at the following addresses, or at such other addresses as the parties may later designate in writing:

If to the Company:

Akebia Therapeutics, Inc.
Attention: General Counsel
245 First Street, Suite 1400
Cambridge, Massachusetts 02142

If to Executive:

at the last residential address known by the Company

11. **Non-Exclusivity of Rights**. Nothing in this Agreement will prevent or limit Executive's continuing or future participation in any benefit, bonus, incentive or other plan or program provided by the Company or any of its subsidiaries and for which Executive may qualify, nor will anything herein limit or reduce such rights as Executive may have under any other agreements with the Company or any of its subsidiaries. Amounts which are vested benefits or which Executive is otherwise entitled to receive under any plan or program of the Company or any of its subsidiaries will be payable in accordance with such plan or program, except as explicitly modified by this Agreement.

12. **Amendments**. No provision of this Agreement may be modified, waived or discharged unless such waiver, modification or discharge is agreed to in writing and signed by Executive and the Chief Executive Officer of the Company.

13. **No Waiver**. No waiver by either party hereto at any time of any breach by the other party hereto of, or compliance with, any condition or provision of this Agreement to be performed by such other party will be deemed a waiver of similar or dissimilar provisions or conditions at the same or at any prior or subsequent time.

14. **Governing Law**. This Agreement will be governed by and construed and enforced in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the conflict of law principles thereof.

15. **Dispute Resolution/Jurisdiction/Venue**. Any dispute concerning this Agreement shall be heard by a court of competent jurisdiction within Massachusetts. The parties hereby acknowledge that they are subject to the personal jurisdiction of the Massachusetts courts in any county where the Company has operations or facilities and/or Executive resides.

16. **Expenses**. To the extent Executive elects to have independent legal counsel review and or negotiate the terms of this Agreement or any release required by this Agreement, Executive shall be solely responsible for all associated costs and fees, including but not limited to attorneys' fees.

17. **Severability**. The provisions of this Agreement will be deemed severable and the invalidity or unenforceability of any provision will not affect the validity or enforceability of the other provisions hereof.

18. **Effect on Other Agreements**. The terms of this Agreement replace and supersede the terms in all other and prior agreements between Executive and the Company that relate to (i) post-separation severance and other post-separation benefits and (ii) equity acceleration in connection with a change of control, whether written or oral or express or implied, and no representations, promises, assurances or agreements have been made regarding the subject matter of this Agreement, except such as has been stated in this Agreement. For the avoidance of doubt, (a) the terms of any existing employment agreement or other agreement between Executive and the Company regarding assignment of intellectual property, confidentiality and non-disclosure, non-competition and non-solicitation between Executive and the Company shall remain in full force and effect and (b) all other terms in offer letters, employment agreements or any other agreements between Executive and the Company that do not relate to (1) post-separation severance or other post-separation benefits or (2) equity acceleration in connection with a change of control, will remain in full force and effect.

THE COMPANY AND EXECUTIVE ACKNOWLEDGE THAT (A) EACH HAS CAREFULLY READ THIS AGREEMENT, (B) EACH UNDERSTANDS ITS TERMS, (C) ALL UNDERSTANDINGS AND AGREEMENTS BETWEEN THE COMPANY AND EXECUTIVE RELATING TO THE SUBJECTS COVERED IN THIS AGREEMENT ARE CONTAINED IN IT, AND (D) EACH HAS ENTERED INTO THIS AGREEMENT VOLUNTARILY AND NOT IN RELIANCE ON ANY PROMISES OR REPRESENTATIONS BY THE OTHER, OTHER THAN THOSE CONTAINED IN THIS AGREEMENT ITSELF.

IN WITNESS WHEREOF, the Company has caused this Agreement to be executed by its duly authorized person and Executive has executed this Agreement effective as of the day and year first above written.

EXECUTIVE AKEBIA THERAPEUTICS, INC.

By:_____ By: _____

[NAME] John P. Butler

President and Chief Executive Officer

Exhibit 10.42

AKEBIA THERAPEUTICS, INC.

RESTRICTED STOCK UNIT AGREEMENT FOR OFFICERS
2023 STOCK INCENTIVE PLAN

Akebia Therapeutics, Inc. (the "Company") hereby grants the following restricted stock units pursuant to its 2023 Stock Incentive Plan, as amended (the "Plan"). The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of recipient (the "Participant"):	
Grant Date:	
Number of restricted stock units ("RSUs") granted:	
Vesting Start Date:	

This grant of RSUs satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

Vesting Schedule:

Vesting Date:	Number of RSUs that Vest:
All vesting is dependent on the Participant remaining an Eligible Participant, as provided herein.	

This grant of RSUs satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

Akebia Therapeutics, Inc.

_____
Signature of Participant

_____
Street Address

_____
City/State/Zip Code

By: _____
Name of Officer
Title:

Akebia Therapeutics, Inc.

Restricted Stock Unit Agreement for Officers
Incorporated Terms and Conditions

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Award of Restricted Stock Units.

The Company has granted to the Participant, subject to the terms and conditions set forth in this Restricted Stock Unit Agreement (this "Agreement") and in the Company's 2023 Stock Incentive Plan, as amended (the "Plan"), an award with respect to the number of RSUs set forth in the Notice of Grant that forms part of this Agreement (the "Notice of Grant"). Each RSU represents the right to receive one share of common stock, $0.00001 par value per share, of the Company (the "Common Stock") upon vesting of the RSU, subject to the terms and conditions set forth herein.

2. Vesting; Delivery.

(a) General. The RSUs shall vest in accordance with the Vesting Schedule set forth in the Notice of Grant (the "Vesting Schedule"), subject to the terms of any Executive Severance Agreement or other written agreement between the Participant and the Company. Any fractional shares resulting from the application of any percentages used in the Vesting Schedule shall be rounded down to the nearest whole number of RSUs.

(b) Change in Control.

i. Treatment of RSUs in a Change in Control. Following the occurrence of a Change in Control, the RSUs will become fully vested in the event that the Participant is terminated without Cause or terminates his or her status as an Eligible Participant for Good Reason. Such vesting acceleration will take place automatically and immediately on the date of such termination of status as an Eligible Participant without Cause or for Good Reason, as the case may be, so that the RSUs will be fully vested upon such termination.

ii. Definitions.

(A) "Cause" means, if the Participant is subject to an Executive Severance Agreement or other written agreement with the Company, in any case which agreement contains a definition of "cause" for termination

of service, the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any fiduciary duty or of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

(B) "Change in Control" means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company's securities: (A) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; (B) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (C) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (D) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (I) its sole purpose is to change the domicile of the Company's incorporation; or (II) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.

(C) "Good Reason" means a material diminishment of the Participant's job responsibilities or duties, or base compensation or, if the Participant is a party to an Executive Severance Agreement or other written agreement with the Company, is defined under the Participant's Executive Severance Agreement or other agreement.

(D) "Incumbent Directors" means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or

nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).

(c) Delivery. Upon the vesting of the RSU, the Company will deliver to the Participant, for each RSU that becomes vested, one share of Common Stock, subject to the payment of any taxes pursuant to Section 7. The Common Stock will be delivered to the Participant as soon as practicable following each vesting date, but in any event within 30 days of such date.

3. Forfeiture of Unvested RSUs Upon Cessation of Service.

In the event that the Participant ceases to be an employee, officer, or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive awards under the Plan (an "Eligible Participant") for any reason or no reason, with or without cause, all of the RSUs that are unvested as of the time of such cessation shall be forfeited immediately and automatically to the Company, without the payment of any consideration to the Participant, effective as of such cessation. The Participant shall have no further rights with respect to the unvested RSUs or any Common Stock that may have been issuable with respect thereto. If the Participant provides services to a subsidiary of the Company, any references in this Agreement to provision of services to the Company shall instead be deemed to refer to service with such subsidiary.

Notwithstanding the foregoing, to the extent the Participant is a party to an Executive Severance Agreement or other written employment agreement with the Company that provides for the RSUs to remain outstanding and continue to vest during a specified period of time following Participant's cessation of status as an Eligible Participant (such period, the "Severance Period"), the RSUs will remain outstanding and will continue to vest, and the Shares will be delivered upon such vesting, in accordance with the terms of this Agreement during the Severance Period as if the Participant had continued to be an Eligible Participant during such period, subject to any conditions on the vesting and delivery as may be contained in such Executive Severance Agreement or other written agreement. For the avoidance of doubt, any portion of the RSUs that fails to vest during the Severance Period will immediately be forfeited on the last day of such period.

4. Restrictions on Transfer.

The Participant shall not sell, assign, transfer, pledge, hypothecate, encumber or otherwise dispose of, by operation of law or otherwise (collectively "transfer") any RSUs, or any interest therein. The Company shall not be required to treat as the owner of any RSUs or issue any Common Stock to any transferee to whom such RSUs have been transferred in violation of any of the provisions of this Agreement.

5. Rights as a Stockholder.

The Participant shall have no rights as a stockholder of the Company with respect to any shares of Common Stock that may be issuable with respect to the RSUs until the issuance of the shares of Common Stock to the Participant following the vesting of the RSUs.

6. Provisions of the Plan.

This Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Agreement.

7. Tax Matters.

(a) Acknowledgments; No Section 83(b) Election. The Participant acknowledges that he or she is responsible for obtaining the advice of the Participant's own tax advisors with respect to the award of RSUs and the Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating to the RSUs. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's tax liability that may arise in connection with the acquisition, vesting and/or disposition of the RSUs. The Participant acknowledges that no election under Section 83(b) of the Internal Revenue Code of 1986, as amended (the "Code"), is available with respect to RSUs.

(b) Withholding. The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state, local or other taxes of any kind required by law to be withheld with respect to the vesting of the RSUs. At such time as the Participant is not aware of any material nonpublic information about the Company or the Common Stock and is not prohibited from doing so by the Company's insider trading policy or otherwise, the Participant shall execute the instructions set forth in Schedule A attached hereto (the "Durable Automatic Sell-to-Cover Instruction") as the means of satisfying such tax obligation unless the Participant has already executed such instruction, as determined by the Company. If the Participant does not execute the Durable Automatic Sell-to-Cover Instruction prior to an applicable vesting date, then the Participant agrees that if under applicable law the Participant will owe taxes at such vesting date on the portion of the award then vested the Company shall be entitled to immediate payment from the Participant of the amount of any tax required to be withheld by the Company. The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

8. Miscellaneous.

(a) No Right to Continued Service. The Participant acknowledges and agrees that, notwithstanding the fact that the vesting of the RSUs is contingent upon his or her continued service to the Company, this Agreement does not constitute an express or implied promise of

continued service relationship with the Participant or confer upon the Participant any rights with respect to a continued service relationship with the Company or any affiliate of the Company.

(b) Section 409A. The RSUs awarded pursuant to this Agreement are intended to be exempt from or comply with the requirements of Section 409A of the Code and the Treasury Regulations issued thereunder ("Section 409A"). The delivery of shares of Common Stock on the vesting of the RSUs may not be accelerated or deferred unless permitted or required by Section 409A.

(c) Participant's Acknowledgments. The Participant acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; (iv) is agreeing, in accepting this award, to be bound by any clawback policy that the Company has in place or may adopt in the future; and (v) is fully aware of the legal and binding effect of this Agreement.

(d) Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflicts of laws provisions.

9. Clawback Policy.

In accepting this award, the Participant agrees and acknowledges that the Participant is subject to, and bound by, the terms of any clawback policy that the Company has in place or may adopt in the future, including without limitation Akebia Therapeutic Inc.'s Compensation Recovery Policy adopted in accordance with stock exchange listing requirements. The Participant agrees that in the event it is determined in accordance with any such policy that any compensation or compensatory award granted, earned or paid to the Participant including this award or pursuant to any other compensation arrangement must be forfeited or reimbursed to the Company, the Participant will promptly take any action necessary to effectuate such forfeiture and/or reimbursement as determined by the Company.

Schedule A

Durable Automatic Sell-to-Cover Instruction

This Durable Automatic Sell-to-Cover Instruction (this "Instruction"), which is being delivered to Akebia Therapeutics, Inc. (the "Company") by the undersigned on the date set forth below (the "Adoption Date"), relates to the Covered RSUs (as defined following my signature below). This Instruction provides for "eligible sell-to-cover transactions" (as described in Rule 10b5-1(c)(1)(ii)(D)(3) under the Securities Exchange Act of 1934 (the "Exchange Act")) and is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c)(1) under the Exchange Act.

I acknowledge that upon vesting and settlement of any Covered RSUs in accordance with the applicable RSU's terms, whether vesting is based on the passage of time or the achievement of performance goals, I will have compensation income equal to the fair market value of the shares of the Company's common stock subject to the RSUs that are settled on such settlement date and that the Company is required to withhold income and employment taxes in respect of that compensation income.

I desire to establish a plan and process to satisfy such withholding obligation in respect of all Covered RSUs through an automatic sale of a portion of the shares of the Company's common stock that would otherwise be issuable to me on each applicable settlement date, such portion to be in an amount sufficient to satisfy such withholding obligation, with the proceeds of such sale delivered to the Company in satisfaction of such withholding obligation.

I understand that the Company has arranged for the administration and execution of its equity incentive programs and the sale of securities by participants thereunder pursuant to a platform administered by a third party (the "Administrator") and the Administrator's designated brokerage partner.

Upon the settlement of any of my Covered RSUs after the 30th day following the Adoption Date (or if I am an officer of the Company on the Adoption Date, after the 120th day following the Adoption Date), I hereby appoint the Administrator (or any successor administrator) to automatically sell such number of shares of the Company's common stock issuable with respect to such RSUs that vested and settled as is sufficient to generate net proceeds sufficient to satisfy the Company's minimum statutory withholding obligations with respect to the income recognized by me in connection with the vesting and settlement of such RSUs (based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes, that are applicable to such income), and the Company shall receive such net proceeds in satisfaction of such tax withholding obligation.

I hereby appoint the Chief Executive Officer, Chief Financial Officer, General Counsel and Secretary of the Company to serve as my attorneys in fact to arrange for the sale of shares of the Company's common stock in accordance with this Instruction. I agree to execute and deliver such documents, instruments and certificates as may reasonably be required in connection with the sale of the shares of common stock pursuant to this Instruction.

Unless the last box in the definition of Covered RSUs below is checked, if I have previously adopted an automatic sale or sell-to-cover instruction relating to Covered RSUs, this Instruction shall be void *ab initio*.

I hereby certify that, as of the Adoption Date:

(i) I am not prohibited from entering into this Instruction by the Company's insider trading policy or otherwise;

(ii) I am not aware of any material nonpublic information about the Company or its common stock; and

(iii) I am adopting this Instruction in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5 under the Exchange Act.

Exhibit 10.43

AKEBIA THERAPEUTICS, INC.
STOCK OPTION AGREEMENT FOR OFFICERS
2023 STOCK INCENTIVE PLAN

Akebia Therapeutics, Inc. (the "Company") hereby grants the following stock option pursuant to its 2023 Stock Incentive Plan, as amended (the "Plan"). The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of optionee (the "Participant"):	
Grant Date:	
Incentive Stock Option or Nonstatutory Stock Option:	
Number of shares of the Company's Common Stock subject to this option ("Shares"):	
Option exercise price per Share:[1]	
Number, if any, of Shares that vest immediately on the grant date:	
Shares that are subject to vesting schedule:	
Vesting Start Date:	
Final Exercise Date: [2]	

Vesting Schedule:

Vesting Date:	Number of Options that Vest:
All vesting is dependent on the Participant remaining an Eligible Participant, as provided herein.	

This option satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

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[1] This must be at least 100% of the Grant Date Fair Market Value (as defined in the Plan) of the Common Stock on the date of grant (110% in the case of a Participant that owns more than 10% of the total combined voting power of all classes of stock of the Company or its parent or subsidiary (a "10% Shareholder") when the option is intended to qualify as an incentive stock option (an "ISO") under Section 422 of the Internal Revenue Code).

[2] The Final Exercise Date must be no more than 10 years (5 years in the case of a 10% Shareholder for an option intended to qualify as an ISO) from the date of grant. The correct approach to calculate the final exercise date is to use the day immediately prior to the date ten years out from the date of the stock option award grant (or 5 years, as applicable).

Akebia Therapeutics, Inc.

_____
Signature of Participant

_____
Street Address

_____
City/State/Zip Code

By: _____
Name of Officer
Title:

Akebia Therapeutics, Inc.

Stock Option Agreement for Officers
Incorporated Terms and Conditions

1. Grant of Option.

This agreement evidences the grant by the Company, on the grant date (the "Grant Date") set forth in the Notice of Grant that forms part of this agreement (the "Notice of Grant"), to the Participant of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2023 Stock Incentive Plan, as amended (the "Plan"), the number of Shares set forth in the Notice of Grant of common stock, $0.00001 par value per share, of the Company ("Common Stock"), at the exercise price per Share set forth in the Notice of Grant. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the Final Exercise Date set forth in the Notice of Grant (the "Final Exercise Date").

The option evidenced by this agreement is intended to be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code") to the maximum extent permitted by law, solely to the extent designated as an incentive stock option in the Notice of Grant. Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

(a) General. Subject to this Agreement and the terms of any Executive Severance Agreement or other written agreement between the Participant and the Company, this option will become exercisable ("vest") in accordance with the vesting schedule set forth in the Notice of Grant.

(b) Change in Control.

(i) Treatment of Option in a Change in Control. Following the occurrence of a Change in Control, the option shall become fully vested and exercisable in the event that the Participant is terminated without Cause or terminates his or her status as an Eligible Participant for Good Reason. Such vesting acceleration shall take place automatically and immediately on the date of such termination of status as an Eligible Participant without Cause or for Good Reason, as the case may be, so that the option shall be fully vested and exercisable upon such termination.

(ii) Definitions.

(i) "Change in Control" means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company's securities: (A) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of

securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; (B) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (C) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (D) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (I) its sole purpose is to change the domicile of the Company's incorporation; or (II) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.

(ii) "Good Reason" means a material diminishment of the Participant's job responsibilities or duties, or base compensation or, if the Participant is a party to an Executive Severance Agreement or other written agreement with the Company, is defined under the Participant's Executive Severance Agreement or other agreement.

(iii) "Incumbent Directors" means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).

(c) Exercisability. The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, in the form of the Stock Option Exercise Notice attached as Annex A, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, or in such other form (which may be electronic) as is approved by the Company, together with payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share or for fewer than ten whole shares.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee, officer, or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in this paragraph or in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation; and, provided, further, that to the extent the Participant is a party to an Executive Severance Agreement or other written agreement with the Company that provides for the option to remain outstanding and continue to vest during a specified period of time following the Participant's cessation of status as an Eligible Participant (such period, the "Severance Period"), the option shall remain outstanding and shall continue to vest in accordance with the terms of this Agreement during the Severance Period as if the Participant had remained an Eligible Participant during such period, subject to any conditions on continued vesting as may be contained in such Executive Severance Agreement or other written agreement. Any portion of this option that vests during such Severance Period will remain exercisable until the earlier of (A) the date that is three (3) months following the date that is the last day of such Severance Period, or (B) the Final Exercise Date, and except to the extent previously exercised as permitted by this Section 3(c) will thereupon immediately terminate. For the avoidance of doubt, any portion of the option that fails to vest during the Severance Period will immediately be forfeited on the last day of such period. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the restrictive covenants (including, without limitation, the non-competition, non-solicitation, or confidentiality provisions) of any employment contract, any non-competition, non-solicitation, confidentiality or assignment agreement to which the Participant is a party, or any other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death. If the Participant dies prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death of the Participant, by an authorized transferee of the Participant, provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment, consulting, director or advisor relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination. If, prior to the Final Exercise Date, the Participant is given notice by the Company of the termination of his or her service by the Company for Cause, and the effective date of such termination is subsequent to the date of delivery of such notice, the right to exercise this option shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's service shall not be terminated for Cause as provided in such notice or (ii) the effective date of such termination (in which case the right to exercise this option shall, pursuant to the preceding sentence, terminate upon the effective date of such termination). If the Participant is a party to an Executive Severance Agreement or other written agreement with the Company, in any case which agreement contains a definition of "cause" for termination of service, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise,

"Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any fiduciary duty or of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

4. Tax Matters.

(a) (a) Withholding. No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

(b) Disqualifying Disposition. If this option is an incentive stock option and the Participant disposes of Shares acquired upon exercise of this option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this option, the Participant shall notify the Company in writing of such disposition.

5. Transfer Restrictions; Clawback.

(a) This option may not be sold, assigned, transferred, pledged, encumbered or otherwise disposed of by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

(b) In accepting this option, the Participant agrees to be bound by any clawback policy that the Company has in place or may adopt in the future.

6. Provisions of the Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is furnished to the Participant with this option. Notwithstanding the foregoing, to the extent the Participant has entered into an Executive Severance Agreement with the Company, for so long as such Executive Severance Agreement remains in effect, the terms of such Executive Severance Agreement as they relate to the option shall control in the event of a conflict with this Agreement or the Plan.

7. Clawback Policy.

In accepting this option, the Participant agrees and acknowledges that the Participant is subject to, and bound by, the terms of any clawback policy that the Company has in place or may adopt in the future, including without limitation Akebia Therapeutic Inc.'s Compensation Recovery Policy adopted in accordance with stock exchange listing requirements. The Participant agrees that in the event it is determined in accordance with any such policy that any compensation or compensatory award granted, earned or paid to the Participant including this option or pursuant to any other compensation arrangement must be forfeited or reimbursed to the

Company, the Participant will promptly take any action necessary to effectuate such forfeiture and/or reimbursement as determined by the Company.

ANNEX A

Akebia Therapeutics, Inc.

Stock Option Exercise Notice

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142

Dear Sir or Madam:

I, _____(the "Participant"), hereby irrevocably exercise the right to purchase ____ shares of the Common Stock, $0.00001 par value per share (the "Shares"), of Akebia Therapeutics, Inc. (the "Company") at $___per share pursuant to the Company's 2023 Stock Incentive Plan, as amended, and a stock option agreement with the Company dated ____ (the "Option Agreement"). Enclosed herewith is a payment of $____, the aggregate purchase price for the Shares. The Shares should be registered in my name as it appears below or, if so indicated below, jointly in my name and the name of the person designated below, with right of survivorship.

Dated: _____

_____
Signature
Print Name:

Address:
_____
_____

Name and address of persons in whose name the Shares are to be jointly registered (if applicable):

_____

Exhibit 10.44

AKEBIA THERAPEUTICS, INC.
RESTRICTED STOCK UNIT AGREEMENT FOR OFFICERS
2023 STOCK INCENTIVE PLAN

Akebia Therapeutics, Inc. (the "Company") hereby grants the following restricted stock units pursuant to its 2023 Stock Incentive Plan, as amended (the "Plan"). The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of recipient (the "Participant"):	
Grant Date:	
Number of restricted stock units ("RSUs") granted:	
Vesting Start Date:	

This grant of RSUs satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

Vesting Schedule:

Vesting Date:	Number of RSUs that Vest:
All vesting is dependent on the Participant remaining an Eligible Participant, as provided herein.	

This grant of RSUs satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

Akebia Therapeutics, Inc.

_____
Signature of Participant

_____
Street Address

_____
City/State/Zip Code

By: _____
Name of Officer
Title:

Akebia Therapeutics, Inc.

Restricted Stock Unit Agreement for Officers
Incorporated Terms and Conditions

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Award of Restricted Stock Units.

The Company has granted to the Participant, subject to the terms and conditions set forth in this Restricted Stock Unit Agreement (this "Agreement") and in the Company's 2023 Stock Incentive Plan, as amended (the "Plan"), an award with respect to the number of RSUs set forth in the Notice of Grant that forms part of this Agreement (the "Notice of Grant"). Each RSU represents the right to receive one share of common stock, $0.00001 par value per share, of the Company (the "Common Stock") upon vesting of the RSU, subject to the terms and conditions set forth herein.

2. Vesting; Delivery.

(a) General. The RSUs shall vest in accordance with the Vesting Schedule set forth in the Notice of Grant (the "Vesting Schedule"), subject to the terms of any Executive Severance Agreement or other written agreement between the Participant and the Company. Any fractional shares resulting from the application of any percentages used in the Vesting Schedule shall be rounded down to the nearest whole number of RSUs.

(b) Change in Control.

i. Treatment of RSUs in a Change in Control. Following the occurrence of a Change in Control, the RSUs will become fully vested in the event that the Participant is terminated without Cause or terminates his or her status as an Eligible Participant for Good Reason. Such vesting acceleration will take place automatically and immediately on the date of such termination of status as an Eligible Participant without Cause or for Good Reason, as the case may be, so that the RSUs will be fully vested upon such termination.

ii. Definitions.

(A) "Cause" means, if the Participant is subject to an Executive Severance Agreement or other written agreement with the Company, in

any case which agreement contains a definition of "cause" for termination of service, the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any fiduciary duty or of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

(B) "Change in Control" means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company's securities: (A) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; (B) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (C) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (D) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (I) its sole purpose is to change the domicile of the Company's incorporation; or (II) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.

(C) "Good Reason" means a material diminishment of the Participant's job responsibilities or duties, or base compensation or, if the Participant is a party to an Executive Severance Agreement or other written agreement with the Company, is defined under the Participant's Executive Severance Agreement or other agreement.

(D) "Incumbent Directors" means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election

or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).

(c) Delivery. Upon the vesting of the RSU, the Company will deliver to the Participant, for each RSU that becomes vested, one share of Common Stock, subject to the payment of any taxes pursuant to Section 7. The Common Stock will be delivered to the Participant as soon as practicable following each vesting date, but in any event within 30 days of such date.

3. Forfeiture of Unvested RSUs Upon Cessation of Service.

In the event that the Participant ceases to be an employee, officer, or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive awards under the Plan (an "Eligible Participant") for any reason or no reason, with or without cause, all of the RSUs that are unvested as of the time of such cessation shall be forfeited immediately and automatically to the Company, without the payment of any consideration to the Participant, effective as of such cessation. The Participant shall have no further rights with respect to the unvested RSUs or any Common Stock that may have been issuable with respect thereto. If the Participant provides services to a subsidiary of the Company, any references in this Agreement to provision of services to the Company shall instead be deemed to refer to service with such subsidiary.

Notwithstanding the foregoing, to the extent the Participant is a party to an Executive Severance Agreement or other written employment agreement with the Company that provides for the RSUs to remain outstanding and continue to vest during a specified period of time following Participant's cessation of status as an Eligible Participant (such period, the "Severance Period"), the RSUs will remain outstanding and will continue to vest, and the Shares will be delivered upon such vesting, in accordance with the terms of this Agreement during the Severance Period as if the Participant had continued to be an Eligible Participant during such period, subject to any conditions on the vesting and delivery as may be contained in such Executive Severance Agreement or other written agreement. For the avoidance of doubt, any portion of the RSUs that fails to vest during the Severance Period will immediately be forfeited on the last day of such period.

4. Restrictions on Transfer.

The Participant shall not sell, assign, transfer, pledge, hypothecate, encumber or otherwise dispose of, by operation of law or otherwise (collectively "transfer") any RSUs, or any interest therein. The Company shall not be required to treat as the owner of any RSUs or issue any Common Stock to any transferee to whom such RSUs have been transferred in violation of any of the provisions of this Agreement.

5. Rights as a Stockholder.

The Participant shall have no rights as a stockholder of the Company with respect to any shares of Common Stock that may be issuable with respect to the RSUs until the issuance of the shares of Common Stock to the Participant following the vesting of the RSUs.

6. Provisions of the Plan.

This Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Agreement.

7. Tax Matters.

(a) Acknowledgments; No Section 83(b) Election. The Participant acknowledges that he or she is responsible for obtaining the advice of the Participant's own tax advisors with respect to the award of RSUs and the Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating to the RSUs. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's tax liability that may arise in connection with the acquisition, vesting and/or disposition of the RSUs. The Participant acknowledges that no election under Section 83(b) of the Internal Revenue Code of 1986, as amended (the "Code"), is available with respect to RSUs.

(b) Withholding. The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state, local or other taxes of any kind required by law to be withheld with respect to the vesting of the RSUs. At such time as the Participant is not aware of any material nonpublic information about the Company or the Common Stock and is not prohibited from doing so by the Company's insider trading policy or otherwise, the Participant shall execute the instructions set forth in Schedule A attached hereto (the "Durable Automatic Sell-to-Cover Instruction") as the means of satisfying such tax obligation unless the Participant has already executed such instruction, as determined by the Company. If the Participant does not execute the Durable Automatic Sell-to-Cover Instruction prior to an applicable vesting date, then the Participant agrees that if under applicable law the Participant will owe taxes at such vesting date on the portion of the award then vested the Company shall be entitled to immediate payment from the Participant of the amount of any tax required to be withheld by the Company. The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

8. Miscellaneous.

(a) No Right to Continued Service. The Participant acknowledges and agrees that, notwithstanding the fact that the vesting of the RSUs is contingent upon his or her continued service to the Company, this Agreement does not constitute an express or implied promise of

continued service relationship with the Participant or confer upon the Participant any rights with respect to a continued service relationship with the Company or any affiliate of the Company.

(b) Section 409A. The RSUs awarded pursuant to this Agreement are intended to be exempt from or comply with the requirements of Section 409A of the Code and the Treasury Regulations issued thereunder ("Section 409A"). The delivery of shares of Common Stock on the vesting of the RSUs may not be accelerated or deferred unless permitted or required by Section 409A.

(c) Participant's Acknowledgments. The Participant acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; (iv) is agreeing, in accepting this award, to be bound by any clawback policy that the Company has in place or may adopt in the future; and (v) is fully aware of the legal and binding effect of this Agreement.

(d) Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflicts of laws provisions.

Schedule A

Durable Automatic Sell-to-Cover Instruction

This Durable Automatic Sell-to-Cover Instruction (this "Instruction"), which is being delivered to Akebia Therapeutics, Inc. (the "Company") by the undersigned on the date set forth below (the "Adoption Date"), relates to the Covered RSUs (as defined following my signature below). This Instruction provides for "eligible sell-to-cover transactions" (as described in Rule 10b5-1(c)(1)(ii)(D)(3) under the Securities Exchange Act of 1934 (the "Exchange Act")) and is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c)(1) under the Exchange Act.

I acknowledge that upon vesting and settlement of any Covered RSUs in accordance with the applicable RSU's terms, whether vesting is based on the passage of time or the achievement of performance goals, I will have compensation income equal to the fair market value of the shares of the Company's common stock subject to the RSUs that are settled on such settlement date and that the Company is required to withhold income and employment taxes in respect of that compensation income.

I desire to establish a plan and process to satisfy such withholding obligation in respect of all Covered RSUs through an automatic sale of a portion of the shares of the Company's common stock that would otherwise be issuable to me on each applicable settlement date, such portion to be in an amount sufficient to satisfy such withholding obligation, with the proceeds of such sale delivered to the Company in satisfaction of such withholding obligation.

I understand that the Company has arranged for the administration and execution of its equity incentive programs and the sale of securities by participants thereunder pursuant to a platform administered by a third party (the "Administrator") and the Administrator's designated brokerage partner.

Upon the settlement of any of my Covered RSUs after the 30th day following the Adoption Date (or if I am an officer of the Company on the Adoption Date, after the 120th day following the Adoption Date), I hereby appoint the Administrator (or any successor administrator) to automatically sell such number of shares of the Company's common stock issuable with respect to such RSUs that vested and settled as is sufficient to generate net proceeds sufficient to satisfy the Company's minimum statutory withholding obligations with respect to the income recognized by me in connection with the vesting and settlement of such RSUs (based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes, that are applicable to such income), and the Company shall receive such net proceeds in satisfaction of such tax withholding obligation.

I hereby appoint the Chief Executive Officer, Chief Financial Officer, General Counsel and Secretary of the Company to serve as my attorneys in fact to arrange for the sale of shares of the Company's common stock in accordance with this Instruction. I agree to execute and deliver such documents, instruments and certificates as may reasonably be required in connection with the sale of the shares of common stock pursuant to this Instruction.

Unless the last box in the definition of Covered RSUs below is checked, if I have previously adopted an automatic sale or sell-to-cover instruction relating to Covered RSUs, this Instruction shall be void *ab initio*.

I hereby certify that, as of the Adoption Date:

(i) I am not prohibited from entering into this Instruction by the Company's insider trading policy or otherwise;

(ii) I am not aware of any material nonpublic information about the Company or its common stock; and

(iii) I am adopting this Instruction in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5 under the Exchange Act.

Exhibit 10.45

AKEBIA THERAPEUTICS, INC.
STOCK OPTION AGREEMENT FOR OFFICERS
2023 STOCK INCENTIVE PLAN

Akebia Therapeutics, Inc. (the "Company") hereby grants the following stock option pursuant to its 2023 Stock Incentive Plan, as amended (the "Plan"). The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of optionee (the "Participant"):	
Grant Date:	
Incentive Stock Option or Nonstatutory Stock Option:	
Number of shares of the Company's Common Stock subject to this option ("Shares"):	
Option exercise price per Share:[1]	
Number, if any, of Shares that vest immediately on the grant date:	
Shares that are subject to vesting schedule:	
Vesting Start Date:	
Final Exercise Date: [2]	

Vesting Schedule:

Vesting Date:	Number of Options that Vest:
All vesting is dependent on the Participant remaining an Eligible Participant, as provided herein.	

This option satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

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[1] This must be at least 100% of the Grant Date Fair Market Value (as defined in the Plan) of the Common Stock on the date of grant (110% in the case of a Participant that owns more than 10% of the total combined voting power of all classes of stock of the Company or its parent or subsidiary (a "10% Shareholder") when the option is intended to qualify as an incentive stock option (an "ISO") under Section 422 of the Internal Revenue Code).

[2] The Final Exercise Date must be no more than 10 years (5 years in the case of a 10% Shareholder for an option intended to qualify as an ISO) from the date of grant. The correct approach to calculate the final exercise date is to use the day immediately prior to the date ten years out from the date of the stock option award grant (or 5 years, as applicable).

Akebia Therapeutics, Inc.

_____
Signature of Participant

_____
Street Address

_____
City/State/Zip Code

By: _____
Name of Officer
Title:

Akebia Therapeutics, Inc.

Stock Option Agreement for Officers
Incorporated Terms and Conditions

1. Grant of Option.

This agreement evidences the grant by the Company, on the grant date (the "Grant Date") set forth in the Notice of Grant that forms part of this agreement (the "Notice of Grant"), to the Participant of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2023 Stock Incentive Plan, as amended (the "Plan"), the number of Shares set forth in the Notice of Grant of common stock, $0.00001 par value per share, of the Company ("Common Stock"), at the exercise price per Share set forth in the Notice of Grant. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the Final Exercise Date set forth in the Notice of Grant (the "Final Exercise Date").

The option evidenced by this agreement is intended to be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code") to the maximum extent permitted by law, solely to the extent designated as an incentive stock option in the Notice of Grant. Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

(a) General. Subject to this Agreement and the terms of any Executive Severance Agreement or other written agreement between the Participant and the Company, this option will become exercisable ("vest") in accordance with the vesting schedule set forth in the Notice of Grant.

(b) Change in Control.

(i) Treatment of Option in a Change in Control. Following the occurrence of a Change in Control, the option shall become fully vested and exercisable in the event that the Participant is terminated without Cause or terminates his or her status as an Eligible Participant for Good Reason. Such vesting acceleration shall take place automatically and immediately on the date of such termination of status as an Eligible Participant without Cause or for Good Reason, as the case may be, so that the option shall be fully vested and exercisable upon such termination.

(ii) Definitions.

(i) "Change in Control" means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company's securities: (A) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of

securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; (B) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (C) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (D) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (I) its sole purpose is to change the domicile of the Company's incorporation; or (II) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.

(ii) "Good Reason" means a material diminishment of the Participant's job responsibilities or duties, or base compensation or, if the Participant is a party to an Executive Severance Agreement or other written agreement with the Company, is defined under the Participant's Executive Severance Agreement or other agreement.

(iii) "Incumbent Directors" means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).

(c) Exercisability. The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, in the form of the Stock Option Exercise Notice attached as Annex A, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, or in such other form (which may be electronic) as is approved by the Company, together with payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share or for fewer than ten whole shares.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee, officer, or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in this paragraph or in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation; and, provided, further, that to the extent the Participant is a party to an Executive Severance Agreement or other written agreement with the Company that provides for the option to remain outstanding and continue to vest during a specified period of time following the Participant's cessation of status as an Eligible Participant (such period, the "Severance Period"), the option shall remain outstanding and shall continue to vest in accordance with the terms of this Agreement during the Severance Period as if the Participant had remained an Eligible Participant during such period, subject to any conditions on continued vesting as may be contained in such Executive Severance Agreement or other written agreement. Any portion of this option that vests during such Severance Period will remain exercisable until the earlier of (A) the date that is three (3) months following the date that is the last day of such Severance Period, or (B) the Final Exercise Date, and except to the extent previously exercised as permitted by this Section 3(c) will thereupon immediately terminate. For the avoidance of doubt, any portion of the option that fails to vest during the Severance Period will immediately be forfeited on the last day of such period. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the restrictive covenants (including, without limitation, the non-competition, non-solicitation, or confidentiality provisions) of any employment contract, any non-competition, non-solicitation, confidentiality or assignment agreement to which the Participant is a party, or any other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death. If the Participant dies prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death of the Participant, by an authorized transferee of the Participant, provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment, consulting, director or advisor relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination. If, prior to the Final Exercise Date, the Participant is given notice by the Company of the termination of his or her service by the Company for Cause, and the effective date of such termination is subsequent to the date of delivery of such notice, the right to exercise this option shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's service shall not be terminated for Cause as provided in such notice or (ii) the effective date of such termination (in which case the right to exercise this option shall, pursuant to the preceding sentence, terminate upon the effective date of such termination). If the Participant is a party to an Executive Severance Agreement or other written agreement with the Company, in any case which agreement contains a definition of "cause" for termination of service, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise,

"Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any fiduciary duty or of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

4. Tax Matters.

(a) (a) Withholding. No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

(b) Disqualifying Disposition. If this option is an incentive stock option and the Participant disposes of Shares acquired upon exercise of this option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this option, the Participant shall notify the Company in writing of such disposition.

5. Transfer Restrictions; Clawback.

(a) This option may not be sold, assigned, transferred, pledged, encumbered or otherwise disposed of by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

(b) In accepting this option, the Participant agrees to be bound by any clawback policy that the Company has in place or may adopt in the future.

6. Provisions of the Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is furnished to the Participant with this option. Notwithstanding the foregoing, to the extent the Participant has entered into an Executive Severance Agreement with the Company, for so long as such Executive Severance Agreement remains in effect, the terms of such Executive Severance Agreement as they relate to the option shall control in the event of a conflict with this Agreement or the Plan.

ANNEX A

Akebia Therapeutics, Inc.

Stock Option Exercise Notice

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142

Dear Sir or Madam:

I, _____(the "Participant"), hereby irrevocably exercise the right to purchase ____ shares of the Common Stock, $0.00001 par value per share (the "Shares"), of Akebia Therapeutics, Inc. (the "Company") at $___per share pursuant to the Company's 2023 Stock Incentive Plan, as amended, and a stock option agreement with the Company dated ____ (the "Option Agreement"). Enclosed herewith is a payment of $____, the aggregate purchase price for the Shares. The Shares should be registered in my name as it appears below or, if so indicated below, jointly in my name and the name of the person designated below, with right of survivorship.

Dated: _____

_____
Signature
Print Name:

Address:
_____
_____

Name and address of persons in whose name the Shares are to be jointly registered (if applicable):

_____

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

AMENDMENT #1 TO LICENSE AGREEMENT

This **AMENDMENT #1 TO LICENSE AGREEMENT** (this "**Amendment #1**"), by and between **Akebia Therapeutics, Inc.,** a corporation organized and existing under the laws of the state of Delaware with its principal offices at 245 First Street, Cambridge, MA 02142 ("**Akebia**"), and **MEDICE Arzneimittel Pütter GmbH & Co. KG**, a limited partnership organized under the laws of Germany, with corporate domicile at Kuhloweg 37, 58638 Iserlohn, Germany, registered at local court Iserlohn, HRA 1037 ("**Licensee**"), represented by its general partner Medice Verwaltungs-GmbH, a private liability company with identical corporate domicile, registered at local court Iserlohn, HRB 200, represented by Dr. Richard Ammer, is effective as of **November 10, 2025** (the "**Amendment Effective Date**"). Akebia and Licensee may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, reference is made to that certain License Agreement, dated May 24, 2023, by and between Akebia and Licensee (the "**License Agreement**"), and reference is made to that certain Supply Agreement, dated concurrently with this Amendment #1, by and between Akebia and Licensee (the "**Drug Substance Supply Agreement,**" as more fully defined below);

WHEREAS, pursuant to the Drug Substance Supply Agreement, Akebia shall supply (or have supplied) Drug Substance (as defined below) to Licensee and Licensee will use such Drug Substance to Manufacture Licensed Products; and

WHEREAS, in connection with the supply of such Drug Substance to Licensee pursuant to the Drug Substance Supply Agreement, the Parties hereby desire to amend certain terms of the License Agreement, which is hereby amended as set forth below.

NOW, THEREFORE the Parties agree as follows:

1. Amendments. As of the Amendment Effective Date, the following amendments are made to the License Agreement:

a. The following definitions are added to the License Agreement, and the numbering for all ensuing definitions shall be deemed accordingly adjusted for all purposes of the License Agreement:

1.15 "**Arising DP Technology**" has the meaning set forth in Section 8.1.5 (Arising DP Technology).

1.31 "**Drug Substance**" means the active pharmaceutical ingredient (API) for vadadustat, which is also commonly referred to as drug substance.

1.32 "**Drug Substance Supply Agreement**" has the meaning set forth in the recitals for Amendment #1.

1.80 "**Manufacture of Drug Product**" means to Manufacture Licensed Drug Product using Drug Substance supplied to Licensee by or on behalf of Akebia under the Drug Substance Supply Agreement.

b. The following definitions in the License Agreement are hereby deleted in their entirety and replaced with the following (the section numbering for which has been adjusted to account for the new definitions added in clause (a) hereof):

1.7 "**Akebia Know-How**" means all Know-How (excluding Joint Know-How but including any Akebia Improvements) that (a) is Controlled as of the Effective Date or during the Term by Akebia or any of its Affiliates; and (b) is necessary for the Development (solely as set forth in this Agreement), Manufacture of Drug Product, Packaging, or Commercialization of the Licensed Product in the Field in the Territory.

1.8 "**Akebia Patent Rights**" means all Patent Rights (excluding Joint Patent Rights, but including patent rights that cover Akebia Improvements) that (a) are Controlled as of the Effective Date or during the Term by Akebia or any of its Affiliates in the Territory, and (b) are necessary (or, with respect to patent applications, would be necessary if such patent applications were to issue) for the Territory-Specific Development, Manufacture of Drug Product, Packaging, or Commercialization of the Licensed Product in the Field in the Territory. All Akebia Patent Rights as of the Effective Date are set forth on Schedule 1.8.

1.59 "**Joint Know-How**" means any Improvement that is made during the Term in the performance of any activities under this Agreement (including under the licenses granted hereunder) jointly by at least one Representative of Akebia and at least one Representative of Licensee, but expressly excluding any Know-How included in the Arising DP Technology.

c. Section 8.1 of the License Agreement is hereby deleted in its entirety and replaced with the following:

8.1 Supply and Purchase Obligations.

8.1.1 Supply by Akebia. Subject to the terms and conditions of this Agreement and the Supply Agreement, Akebia will use Commercially Reasonable Efforts to Manufacture or have Manufactured and supply to Licensee the Licensed Product in Tablet Formulation (in bulk form) for commercial supply and Territory-Specific Development in the Territory. In addition, subject to the terms and conditions of this Agreement and in accordance with the terms of the Drug

Substance Supply Agreement, (a) Akebia will Manufacture or have Manufactured and supply to Licensee Drug Substance for commercial supply and Territory-Specific Development in the Territory and (b) Licensee will purchase from Akebia all of Licensee's requirements of the Drug Substance for Territory-Specific Development and commercial use in the Territory in accordance with Section 2.3 of the Drug Substance Supply Agreement.

8.1.2 **Packaging and Labeling**. Licensee will be responsible, at its sole cost and expense, for all packaging and labeling, and other related activities required to convert the Licensed Product supplied by Akebia or Manufactured by Licensee into Finished Form (such activities, collectively, "**Packaging**"), including all packaging and labeling of such Licensed Product for use in the Field in the Territory and for all costs associated therewith. As of the Effective Date of this Agreement, Licensee shall assume responsibility for all costs associated with Packaging activities. Upon Licensee's request, Akebia will, at Akebia's reasonable discretion, provide reasonable cooperation and technical assistance in order to support the tech transfer to Licensee's representatives of Akebia Know-How necessary to support Licensee's analytical methods and stability testing of the Licensed Product in furtherance of Licensee's Packaging activities; *provided that* Licensee will provide to Akebia any information, data, and reports relating to Licensee's analytical methods and stability testing of the Licensed Product. In the event such technology transfer requires more resources of Akebia than that which would be considered reasonable and standard in the industry, upon Akebia's request, prior to Akebia providing further assistance, the Parties shall agree to the terms upon which Licensee will reimburse Akebia for all out-of-pocket costs incurred by or on behalf of Akebia in connection with such technology transfer going forward.

8.1.3 **Manufacture of Drug Product Using Drug Substance**. Licensee has the right and responsibility, at its sole cost and expense, to Manufacture Drug Product using the Drug Substance supplied to Licensee by or on behalf of Akebia under the Drug Substance Supply Agreement and solely in the Field in the Territory during the Term. Notwithstanding any provision to the contrary set forth in Section 2.2 (Rights or Licensee to Grant Sublicenses), Licensee may not sublicense (including to contract manufacturers) its rights to Manufacture Drug Product without the express written consent of Akebia. The Parties will conduct Technology Transfer (as defined in the Drug Substance Supply Agreement) with respect to the Manufacture of Drug Product in accordance with the applicable provisions of the Drug Substance Supply Agreement, including Section 5.4 (Technology Transfer).

8.1.4 **Future Supply Agreement**. Upon Akebia's request, the Parties will discuss in good faith the terms of a supply agreement pursuant to which Licensee would

supply such Licensed Product to Akebia on commercially reasonable to be negotiated by the Parties in good faith. Under any such supply agreement pursuant to which Licensee would supply Licensed Product to Akebia, the transfer price will not exceed [**].

8.1.5 Arising DP Technology. Notwithstanding the terms of Section 10.3 or any provision to the contrary set forth in the Drug Substance Supply Agreement, Akebia will solely own all rights, title, and interests in and to any (a) Know-How (including any Improvement) that is developed or invented during the Term in the Manufacture of Drug Product or the conduct of the Technology Transfer (as defined in the Drug Substance Supply Agreement), in each case, whether solely by a Party or its Representatives or joint by at least one Representative of Akebia and at least one Representative of Licensee and (b) any Patent Rights that Cover any such Know-How (all such Know-How and Patent Rights, collectively, the "**Arising DP Technology**"). All Know-How included in the Arising DP Technology will be included in the Akebia Know-How and all such Patent Rights included in the Arising DP Technology will be included in the Akebia Patent Rights. Licensee will and hereby does assign to Akebia, and Akebia hereby accepts, all of Licensee's rights, title, and interests in, to and under any Arising DP Technology. To the extent Licensee is unable to assign any Arising DP Technology to Akebia as aforesaid due to restrictions under Applicable Law, Licensee will, and hereby does, grant to Akebia and its Affiliates an irrevocable, perpetual, fully-paid-up, royalty-free, exclusive license under such Arising DP Technology for use in all fields worldwide and without further obligation or liability to Licensee. Licensee, at Licensee's sole cost and expense, will provide Akebia with all reasonably requested assistance to effect the foregoing assignment and will execute any and all documents necessary to perfect such assignment. In addition, Licensee will promptly disclose to Akebia any information, invention, data, or discovery (regardless of whether patentable or copyrightable), innovation, communication, or report, that is developed or invented by or on behalf of Licensee in the Manufacture of Drug Product.

d. Section 8.3 of the License Agreement is hereby amended by deleting the first sentence and replacing it with the following:

8.3 Quality Agreement. Prior to delivery of any Licensed Product or Drug Substance under the Supply Agreement or Drug Substance Supply Agreement, respectively, the Parties will also enter into one or more quality technical agreements (each a "**Quality Agreement**") containing reasonable and customary terms and conditions regarding quality assurance and quality control and compliance with GMP and GCP (as applicable).

e. Section 17.5 of the Agreement is hereby deleted in its entirety and replaced with the following:

17.5 Entire Agreement; Amendment. This Agreement, together with all exhibits and schedules attached hereto, the Supply Agreement, the Drug Substance Supply Agreement, any Quality Agreement, and any Pharmacovigilance Agreement constitutes the entire agreement between the Parties with respect to the subject matter hereof (including that certain Confidential Disclosure Agreement between the Parties dated [**] ("**Confidential Disclosure Agreement**")); *provided that* all information shared by the Parties pursuant to the Confidential Disclosure Agreement will be Confidential Information under this Agreement, and the use and disclosure thereof will be governed by Article XIII**.** (Confidentiality). This Agreement will not be modified, or amended, except by another agreement in writing executed by the Parties.

2. Capitalized Terms. All capitalized terms used but not defined herein shall have meaning set forth in the License Agreement, except where noted otherwise.

3. No Other Changes. Except as otherwise provided herein, all provisions of the Agreement, as amended shall remain in full force and effect.

4. Governing Law. This Amendment #1, and the rights of the Parties hereunder, will be construed under and governed by the laws of England and Wales, exclusive of its conflicts of laws principles.

5. Counterparts. This Amendment #1 may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Each Party may execute this Amendment #1 in Adobe™ Portable Document Format (PDF) or other electronic signature sent by electronic mail, including DocuSign®. PDF signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Parties have executed this Amendment #1 to the License Agreement effective as of the Amendment Effective Date written above.

AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

MEDICE Arzneimittel Pütter GmbH & Co. KG

By: /s/ Andreas Kellermann

Name: Andreas Kellermann

Title: Head Corporate Legal

By: /s/ Hansjörg Jakubetz

Name: Hansjörg Jakubetz, PhD

Title: Head Alliance Management

[Signature page to Amendment #1 to License Agreement]

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

ASSET PURCHASE AGREEMENT

between

Q32 Bio Inc.

and

Q32 Bio Operations Inc.

and

Akebia Therapeutics, Inc.

Dated as of November 28, 2025

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ASSET PURCHASE AGREEMENT

This **ASSET PURCHASE AGREEMENT**, dated as of November 28, 2025 (this "**Agreement**"), is made by and between Akebia Therapeutics, Inc., a Delaware corporation ("**Buyer**"), on the one hand, and Q32 Bio Inc., a Delaware corporation, and Q32 Bio Operations Inc., a Delaware corporation (together, the "**Seller**"), on the other hand. Buyer and Seller are each referred to as a "**Party**," and, together, the "**Parties**." Capitalized terms used herein shall have the meanings assigned to such terms in the text of this Agreement or in Section 7.1 (*Certain Terms*).

R E C I T A L S:

WHEREAS, Seller, directly and indirectly through certain of its Affiliates, owns, licenses or otherwise holds certain rights to research, develop, manufacture, and commercialize Products (as defined below) in the Territory in the Field and to the Acquired Program (such business in the Territory, the "**Business**"); and

WHEREAS, Seller desires to sell (or cause to be sold), and Buyer desires to purchase or cause certain of its Affiliates to purchase, certain of its assets related to the Business and Buyer is willing to assume or cause certain of its Affiliates to assume certain liabilities related to the Business, in each case, upon the terms and subject to the conditions set forth herein.

NOW, THEREFORE, the Parties agree as follows:

ARTICLE 1

SALE AND PURCHASE OF ASSETS, ASSUMPTION OF LIABILITIES

Section 1.1 Sale and Purchase.

(a) Purchase and Sale of Transferred Assets. Subject to the terms and conditions hereof, at the Closing, Seller will, and will cause the Selling Affiliates to, sell, convey, assign, and transfer to Buyer, and Buyer will purchase, acquire, and accept from Seller all rights, title, and interests in and to the Transferred Assets, in each case free and clear of all Liens other than Permitted Liens. Notwithstanding the foregoing or anything to the contrary in this Agreement, but subject to the obligations set forth in Section 4.2 (*Confidentiality*), Buyer acknowledges and agrees that Seller may retain such copies of all or any part of the documentation that is included in the Transferred Assets, as may be reasonably necessary for archival purposes and for purposes of complying with applicable Law and Seller's document retention policy.

(b) Excluded Assets. Notwithstanding any provision to the contrary set forth in this Agreement, Buyer will not acquire, pursuant to this Agreement or any of the transactions contemplated hereby, any rights, title or interests in any Excluded Asset.

(c) Assumed Liabilities. Subject to the terms and conditions hereof, at the Closing, Buyer shall assume or cause certain of its Affiliates to assume the Assumed Liabilities and shall satisfy and discharge the Assumed Liabilities as and when they become due. After the Closing, Buyer shall pay or cause certain of its Affiliates to pay all Assumed Liabilities as and when such Assumed Liabilities become due.

(d) Excluded Liabilities. Neither Buyer nor any of its Affiliates shall assume or be obligated to pay, perform or otherwise discharge any Excluded Liability. Seller and/or the Selling Affiliates, as the case may be, will remain liable to pay, perform and discharge all Excluded Liabilities as and when such Excluded Liabilities become due.

(e) Business Transfer Documents. To the extent required under applicable Law or as reasonably deemed necessary by either of the Parties hereto, to effect the transactions contemplated hereunder, the Parties shall execute and deliver, or cause their respective Affiliates to execute and deliver, such asset and/or business transfer agreements, bills of sale, deeds, assignments, assumptions and other documents and instruments of sale, conveyance, assignment, novation, transfer and assumption (the "**Business Transfer Documents**") as are necessary to effect any transfer of the Transferred Assets at the Closing or such other time for transfer as contemplated by Section 1.1(g) (*Transferred Assets Subject to Third-Party Consent*), Section 4.4 (*Shared Contracts*), or Section 4.17 (*Transferred Materials*) or any assumption of the Assumed Liabilities at the Closing. The Business Transfer Documents shall be in form and substance reasonably agreed to by the Parties and as is usual and customary in the applicable jurisdiction; provided that the Parties agree and acknowledge that the Business Transfer Documents are intended solely to formalize the terms and conditions of this Agreement in order to comply with any applicable Law and shall be, in all respects, consistent with the terms and conditions set forth in this Agreement. In the event of any inconsistency between this Agreement and a Business Transfer Document, this Agreement shall control. For the avoidance of doubt, Business Transfer Documents shall include confirmatory assignments, declarations, and related paperwork necessary to perfect Buyer's title in the Transferred IP (including all inventions claimed or disclosed in any Transferred Patent Right).

(f) Designation of Affiliates; Performance of Obligations by Affiliates. To the extent that any of the Transferred Assets are under the control of any of the Selling Affiliates, Seller shall cause such Selling Affiliates to promptly take such legal action as may be necessary to consummate the transfer to Buyer of such Transferred Assets under terms and conditions which are consistent with and subject to the terms of this Agreement. Any obligation of Seller under or pursuant to this Agreement may be satisfied, met or fulfilled, in whole or in part, at Seller's sole and exclusive option, either by Seller directly, or by any Selling Affiliate that Seller causes to satisfy, meet or fulfill such obligation, in whole or in part. Notwithstanding the foregoing, this Section 1.1(f) (*Designation of Affiliates; Performance of Obligations by Affiliates*) shall not be construed to relieve Seller from any of its obligations under this Agreement.

(g) Transferred Assets Subject to Third-Party Consent.

(i) To the extent that the sale, conveyance, assignment or transfer or attempted sale, conveyance, assignment or transfer to Buyer of any Transferred Asset or Assumed Liability would require any governmental or Third Party consent, authorization, approval or waiver (each, a "**Transfer Approval**" and such Transferred Asset or Assumed Liability subject to such Transfer Approval, the "**Unassigned Right**") and such Transfer Approval shall not have been obtained prior to the Closing, this Agreement shall not constitute a sale, conveyance, assignment or transfer thereof. With respect to any such Transferred Contract, during the period commencing on the Closing Date and continuing until the earlier of (A) the [**] of the later of (1) the Closing Date or (2) the Contract Expiration Date, the Parties shall use commercially reasonable efforts and cooperate with each other to obtain promptly such Transfer Approvals with respect to such Unassigned Right; provided that neither Seller nor the Selling Affiliates shall be required to pay any consideration, or to commence, defend, or participate in any Litigation or offer or grant any financial or other accommodation to any Third Party in connection with the foregoing; provided that providing administrative assistance to effectuate a Transfer

Approval (*e.g.*, administrative actions of either Party to enter into a new agreement to account for Buyer's purchase of the Unassigned Rights in the applicable Transferred Contract) will not be deemed an accommodation to any Third Party. Notwithstanding the foregoing, and for the avoidance of doubt, if any such Transfer Approval is obtained following the Closing Date with respect to any Transferred Asset, Seller or the Selling Affiliates, as applicable, shall promptly assign, convey and transfer any such Transferred Asset to Buyer at no additional cost.

(ii) Unless otherwise provided in any Ancillary Agreement, from the Closing Date until the earlier of (x) the Contract Expiration Date, if applicable, or (y) the date a Transfer Approval with respect to an Unassigned Right is obtained, Seller shall, and shall cause the Selling Affiliates to, use commercially reasonable efforts to (A) maintain the effectiveness of, and to the extent required by the terms of the applicable Transferred Asset, operate or act in respect of such Transferred Asset in all material respects in the ordinary course of business consistent with past practice and taking into account the transactions contemplated by this Agreement and (B) enforce, at Buyer's written request, or allow Buyer and its Affiliates to enforce, in each case at Buyer's cost, any rights of the Seller or Selling Affiliates under or in respect of any such Transferred Asset against the other Party or parties thereto. In addition, Seller and Buyer shall, and shall cause their respective Affiliates to, cooperate in an arrangement, reasonable and lawful as to Seller and Buyer, designed to provide Buyer and its Affiliates the benefits arising under or resulting from such Transferred Asset, which arrangement shall include Seller consulting with Buyer as to the operation of or actions to be taken in respect of such Transferred Asset, except as prohibited by Law. Seller shall, and shall cause the Selling Affiliates to, without further consideration therefor, pay and remit to Buyer promptly all monies, rights and other consideration in respect of such performance as promptly as practicable after receipt thereof. Buyer shall pay, perform and discharge fully, promptly when due, all of the obligations of Seller or the Selling Affiliates in respect of such performance (other than obligations arising out of a breach by Seller or the Selling Affiliate that did not occur due to any action directed by Buyer or any of its Affiliates to be taken or not to be taken), and Buyer shall be responsible for all Assumed Liabilities related thereto.

(iii) Under no circumstances shall the Upfront Consideration be reduced or Seller or the Selling Affiliates be subject to any liability or indemnification under this Agreement solely as a result of the failure to obtain any Transfer Approval so long as Seller has fulfilled its obligations under this Agreement with respect thereto, including its obligations under this Section 1.1(g). Buyer further agrees that no representation, warranty, or covenant of Seller contained in this Agreement shall be breached or deemed breached solely as a result of the failure to obtain any Transfer Approval with respect to an Unassigned Right. Notwithstanding anything herein to the contrary, Section 4.4 (and not this Section 1.1(g)) shall govern the transfer of any Shared Contracts.

(iv) To the extent any Transferred Contract that provides Seller or the Selling Affiliate, as the case may be, the ability to extend such Transferred Contract, Buyer may request, by written notice no later than [**] prior to the date such extension must be triggered, such Seller or Selling Affiliate to exercise such extension (subject to the terms and conditions of the relevant Transferred Contract), in which case the Contract Expiration Date shall be extended in accordance with such extension; provided that no more than one such extension (whether formally requested from the applicable Third Party by Seller or the applicable Selling Affiliate or by way of an automatic or evergreen extension provision contained in such Transferred Contract) may be requested by Buyer with respect to any particular Transferred Contract; provided, further, that, Seller shall

provide written notice to Buyer no later than [**] prior to the date such extension must be triggered.

(h) Buyer's Recording and Similar Responsibilities. Notwithstanding the foregoing provisions of this Section 1.1 (*Sale and Purchase*), it shall be Buyer's responsibility (i) to prepare the applicable Patent Right assignments, which shall be in the form attached to this Agreement as Exhibit C, and to record such assignments following execution thereof by Seller or a Selling Affiliate at the Closing and (ii) to bear the fees and other costs in accordance with Section 1.12 (*Withholding*) and any Taxes arising from such activities.

Section 1.2 Closing. The closing of the sale and purchase of the Transferred Assets and the assumption of the Assumed Liabilities (the "**Closing**") shall take place remotely on the date hereof ("**Closing Date**") through the exchange of electronic copies of duly executed documents, of the documents and agreements contemplated herein. At the Closing:

(a) Seller shall deliver or cause to be delivered to Buyer (unless previously delivered), the following:

(i) duly executed counterparts of:

(A) the Assignment and Assumption Agreement;

(B) the Bill of Sale;

(C) the Patent Assignment;

(D) the License Agreement Novation Agreement;

(E) and any other Ancillary Agreements to which Seller or the Selling Affiliates is a party; and

(ii) the Security Interest Release;

(iii) evidence that requests for consents to assign of each Transferred Contract set forth on Section 2.3(b)(1) of the Seller Disclosure Letter have been sent to the applicable Third Party thereto;

(iv) evidence reasonably satisfactory to Buyer that a written notice of assignment for each Transferred Contract set forth on Section 2.3(b)(3) of the Seller Disclosure Letter was delivered to the applicable Third Party thereto prior to or on the Closing Date;

(v) an IRS Form W-9 properly executed and completed by each Selling Affiliate that owns any Transferred Asset; and

(vi) a certificate, dated as of the Closing Date and signed by the secretary or equivalent officer of the Seller (in such officer's capacity as such an officer and not in his or her individual capacity), certifying to Buyer that attached to such certificate are copies of the resolutions duly adopted by directors of Seller authorizing the execution, delivery and performance of this Agreement and each of the Ancillary Agreements and the consummation of the transactions contemplated hereby and thereby.

(b) Buyer shall deliver or cause to be delivered to Seller, or as designated by Seller, one or more of the Selling Affiliates (unless previously delivered), the following:

(i) the Upfront Closing Consideration;

(ii) duly executed counterparts of:

(A) the Assignment and Assumption Agreement;

(B) the Bill of Sale;

(C) the Patent Assignment;

(D) the License Agreement Novation Agreement; and

(E) and any other Ancillary Agreements to which Buyer or any of its Affiliates is a party;

(iii) a duly executed copy of the A&R License Agreement; and

(iv) a certificate, dated as of the Closing Date and signed by the secretary or equivalent officer of the Buyer (in such officer's capacity as such an officer and not in his or her individual capacity), certifying to Seller that attached to such certificate are copies of the resolutions duly adopted by directors of Buyer authorizing the execution, delivery and performance of this Agreement and each of the Ancillary Agreements and the consummation of the transactions contemplated hereby and thereby.

Section 1.3 Purchase Price.

(a) Purchase Price. In consideration of the sale and transfer of the Transferred Assets from Seller to Buyer at Closing, Buyer agrees to (y) assume, satisfy, and discharge the Assumed Liabilities and (z) pay the following consideration to Seller:

(i) on the Closing Date, Buyer shall pay or cause to be paid to Seller, by wire transfer of immediately available funds to the account designated in writing by Seller on or prior to the Closing Date, an amount equal to $7,000,000 (the "**Upfront Closing Consideration**");

(ii) on the sixth-month anniversary of the Closing Date (or, if such date falls on a day that is not a Business Day, then the first Business Day following such anniversary), Buyer shall pay or cause to be paid to Seller, by wire transfer of immediately available funds to the account designated in writing by Seller prior to such anniversary, an amount equal to $3,000,000 by wire transfer of immediately available funds (the "**Upfront Second Consideration**" and, together with the Upfront Closing Consideration, the "**Upfront Consideration**");

(iii) when due and payable, Buyer shall pay or cause to be paid to Seller, each of the Development and Regulatory Milestone Payments, the Commercial Milestone Payments, and the Royalties, as applicable, in accordance with this Agreement.

(b) Upfront Consideration. The Upfront Consideration shall be noncreditable, nonrefundable and not subject to set-off.

Section 1.4 Contingent Consideration.

(a) Development and Regulatory Milestone Payments.

(i) Following the Closing, subject to the remainder of this Section 1.4(a) (*Development and Regulatory Milestone Payments*), upon the first achievement by a Buyer Party of each milestone event set forth in the table below (each, a "**Development and Regulatory Milestone Event**"), Buyer shall pay, or cause to be paid, by wire transfer of immediately available funds to the Seller an amount equal to the corresponding one- time payment set forth in the table below (each, a "**Development and Regulatory Milestone Payment**") in accordance with Section 1.4(a)(v) and Section 1.4(a)(vi).

Development and Regulatory Milestone Event	**Development and Regulatory Milestone Payment**
1) Initiation of a Phase 2 Clinical Trial for a Product	$2,000,000
2) [**]	$[**]
3) [**]	$[**]
4) [**]	$[**]
5) [**]	$[**]
6) [**]	$[**]
7) [**]	$[**]
8) [**]	$[**]
9) [**]	$[**]
Total	**$94,500,000**

(ii) Notwithstanding the definition of Phase 2 Clinical Trial, the Development and Regulatory Milestone Payment for the Development and Regulatory Milestone Event 1 (*i.e.*, "Initiation of a Phase 2 Clinical Trial") is payable upon Initiation of the first Clinical Trial (or portion thereof) by a Buyer Party following the Closing where a Product is administered to patients. To the extent Development and Regulatory Milestone Event 1 has not been achieved by a Buyer Party by December 31, 2026, the associated Development and Regulatory Milestone Payment shall become due and payable as of such date. In such case, Seller will issue an invoice equal to the associated Development and Regulatory Milestone Payment and Buyer will, within [**] following receipt thereof, pay the amount set forth in such invoice by wire transfer of immediately available funds.

(iii) For clarity, each Development and Regulatory Milestone Payment shall become due and payable only once upon the first achievement of the corresponding Development and Regulatory Milestone Event by a Buyer Party regardless of the number of times it is achieved by the same or different Products. Each Development and Regulatory Milestone Payment shall be noncreditable, nonrefundable, and not subject to set-off, other than as set forth in [**].

(iv) Solely with respect to each of Development and Regulatory Milestone Events [**], the corresponding Development and Regulatory Milestone Payment shall only be payable upon the achievement of the applicable Development and Regulatory Milestone Event if such Development and Regulatory Milestone Event is achieved by Buyer or its Affiliates and *not* upon achievement of such Development and Regulatory Milestone Event by any other Buyer Party.

(v) For a given Product, if Development and Regulatory Milestone Event 2 becomes due and Development and Regulatory Milestone Event [**] has not been paid, then both Development and Regulatory Milestone Events [**] would be payable upon achievement of Development and Regulatory Milestone Event [**] by such Product. For a given Product, if the first of Development and Regulatory Milestone Event [**] becomes due and one of Development and Regulatory Milestone Event [**] have not been paid, then each unpaid Development and Regulatory Milestone Event [**], as applicable, would be payable upon the first achievement of Development and Regulatory Milestone Event [**]. For a given Product, if the first of Development and Regulatory Milestone Event [**] becomes due and Development and Regulatory Milestone Event [**] has not been paid, then Development and Regulatory Milestone Event [**] would be payable upon the first achievement of Development and Regulatory Milestone Event [**].

(vi) Buyer shall notify Seller in writing of the achievement of a Development and Regulatory Milestone Event by a Buyer Party as promptly as practicable, but no later than within [**] following the date of the achievement thereof (or following Buyer becoming aware of achievement thereof by a Buyer Party that is not Buyer or its Affiliates). Following receipt of such notice, Seller will issue an invoice equal to the applicable Development and Regulatory Milestone Payment, and, subject to [**], Buyer will, within [**] following receipt thereof, pay the amount set forth in such invoice by wire transfer of immediately available funds.

(b) Commercial Milestone Payments.

(i) Following the Closing, subject to the remainder of this Section 1.4(b) (*Commercial Milestone Payments*), upon the first achievement by a Buyer Party of each milestone event set forth in the table below (each, a "**Commercial Milestone Event**"), Buyer shall pay, or cause to be paid, by wire transfer of immediately available funds to Seller an amount equal to the corresponding one-time payment set forth in the table below (each, a "**Commercial Milestone Payment**") in accordance with Section 1.4(b)(iv) and Section 1.4(b)(v).

Commercial Milestone Event	Sales Milestone Payment
1) [**]	$[**]
2) [**]	$[**]
3) [**]	$[**]
4) [**]	$[**]
5) [**]	$[**]
6) [**]	$[**]
7) [**]	$[**]

8) [**]	$[**]
Total	**$487,500,000**

(ii) For clarity, each Commercial Milestone Payment shall become due and payable only once upon the achievement of the corresponding Commercial Milestone Event regardless of the number of times it is achieved. Each Commercial Milestone Payment shall be noncreditable, nonrefundable and not subject to set-off, other than as set forth in [**].

(iii) Solely with respect to each of Commercial Milestone Events [**], the corresponding Commercial Milestone Payment shall only be payable upon the achievement of the applicable Commercial Milestone Event if such Commercial Milestone Event is achieved by Buyer or its Affiliates and *not* upon achievement of such Commercial Milestone Event by any other Buyer Party.

(iv) For clarity, the Commercial Milestone Payments shall be additive such that if multiple Commercial Milestone Events are achieved in the same Calendar Year, then the corresponding Commercial Milestone Payments shall be payable with respect to such Calendar Year.

(v) Buyer shall notify Seller in writing of the occurrence of a Commercial Milestone Event by a Buyer Party in the Royalty Report for the Calendar Quarter in which such Commercial Milestone Event was achieved. Following receipt of such notice, Seller will issue an invoice equal to the applicable Commercial Milestone Payment, and, subject to Section 1.4(e) (*Right to Offset*), Buyer will, within [**] following receipt thereof, pay the amount set forth in such invoice by wire transfer of immediately available funds.

(c) Royalties.

(i) Royalty Rates. Subject to the remainder of this Section 1.4(c)(i) (*Royalty Rates*), on a Product-by-Product and country-by-country basis, during the Royalty Term for such Product in such country, Buyer shall pay, or cause to be paid, to the Seller, royalties based on Annual Net Sales of such Product by the Buyer Parties (subject to Section 1.4(c)(iii) [**] in each Calendar Year, at the applicable rate(s) set forth in the table below (such payments, "**Royalties**"). The Royalty payable with respect to each particular Product shall be calculated by multiplying the applicable royalty rate set forth in the table below by the corresponding amount of incremental Annual Net Sales of such Product [**] in the applicable Calendar Quarter.

Annual Net Sales	**Royalty Rate**
[**]	
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is less than or equal to $[**]	[**]

On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**]	[**]
[**]	
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**] and less than or equal to $[**]	[**]
On that portion of Annual Net Sales of a Product [**] in a Calendar Year that is greater than $[**]	[**]

By way of example, if the total Annual Net Sales of a Product [**] in a particular Calendar Year is $[**], the Royalties payable hereunder shall be calculated as follows (subject to any applicable reductions under Section 1.4(c)(iv) (*Royalty Reductions*)): [**].

(ii) Royalty Term. Royalties shall be payable, on a Product-by-Product and country-by-country basis, during the period commencing on the First Commercial Sale of such Product in such country until the later to occur of: (i) the date on which the last-to- expire Valid Claim of a Transferred Patent Right or Patent Right licensed under the A&R License Agreement that Covers such Product, in each case, in such country; [**]; and (ii) the 10th anniversary of the First Commercial Sale of such Product in such country (such period, the "**Royalty Term**" for such Product in such country).

(iii) [**].

(iv) Royalty Reductions.

(A) Lack of Valid Claims. Subject to Section 1.4(c)(iv)(E) (*Royalty Floor*), on a Product-by-Product and country-by-country basis, during the Royalty Term for such Product in such country, if such Product is not Covered by a Valid Claim of a Patent Right within the Transferred Assets or Patent Right licensed under the A&R License Agreement in such country ([**]), then the royalty rates set forth in Section 1.4(c)(i) (*Royalty Rates*) with respect to Net Sales of such Product in such country will be reduced by [**]% for the remainder of the Royalty Term in such country.

(B) Biosimilar Competition. Subject to Section 1.4(c)(iv)(E) (*Royalty Floor*), following the first Calendar Quarter in which there is a launch of a Biosimilar Product for a Product in any country in the Territory, if during the Royalty Term for such Product in a country in the Territory, the [**] of such Product in the relevant country in a Calendar Quarter decline by [**] or more relative to the [**] occurring during the [**] consecutive Calendar Quarters immediately preceding the launch of the Biosimilar Product, then, commencing upon the following Calendar Quarter and for so long as the [**] of such Product in such country in a Calendar Quarter continue to equal at least [**] less than the [**] occurring during the [**] consecutive Calendar Quarters immediately preceding the launch of the Biosimilar Product, the royalty rates set forth in Section 1.4(c)(i) (*Royalty Rates*) with respect to Net Sales of such Product in such country, will be reduced by [**].

(C) Third Party Payments. Subject to Section 1.4(c)(iv)(E) (*Royalty Floor*), on a Product-by-Product basis, if a Buyer Party obtains, after the Closing Date, in an arms' length transaction a license under or other rights to any Patent Rights (or Know-How associated with such Patent Rights) owned or controlled by a Third Party that are reasonably necessary to develop, manufacture, commercialize, or otherwise exploit such Product, then the [**] payable by Buyer to Seller with respect to [**] such Product pursuant to this Section 1.4(c) (*Royalties*) may be reduced by [**] of any amounts actually paid by such Buyer Party to such Third Party in consideration for such license; provided that this Section 1.4(c)(iv)(C) (*Third Party Payments*) shall not apply [**]; provided, further, that to the extent Buyer reduces any [**] payable by Buyer to Seller for any amounts actually paid by a Buyer Party to a Third Party under this Section 1.4(c)(iv)(C) (*Third Party Payments*), such reduction shall be Buyer's sole and exclusive remedy with respect to such amounts and Buyer shall not be entitled to indemnification, or to sue for damages, or to assert any other right or remedy under this Agreement with respect to any such amounts.

(D) Inflation Reduction Act. Subject to Section 1.4(c)(iv)(E) (*Royalty Floor*), if, on a Product-by-Product basis, if during any Calendar Quarter during the Royalty Term for such Product in the United States, such Product is designated as a "selected drug" by the Secretary of the U.S. Department of Health and Human Services pursuant to the Inflation Reduction Act of 2022 (or analogous legislation enabling the U.S. government to negotiate drug prices), and the Buyer Parties are required to negotiate, and are ultimately subject to, a "maximum fair price" that will apply to sales of such Product in the United States, then the Royalties on Net Sales of Products in the United States otherwise

payable by Buyer pursuant to this Section 1.4(c) (*Royalties*) will be reduced [**] by a [**] the price of such Product is decreased as a result of such designation and the ensuing maximum fair price (as defined in Section 1191(c)(3) of the Social Security Act) negotiation pursuant to the aforementioned Inflation Reduction Act or analogous legislation.

(E) Royalty Floor. Notwithstanding the foregoing in this Section 1.4(c)(iv) (*Royalty Reductions*), in no event shall the Royalties payable to Seller pursuant to Section 1.4(c)(i) (*Royalty Rates*) for a Product in a country in any given Calendar Quarter during the Royalty Term be reduced to less than [**] relative to what would otherwise have been due under Section 1.4(c)(i) (*Royalty Rates*) absent the reductions set forth in this Section 1.4(c)(iv) (*Royalty Reductions*); provided that if any reduction that Buyer would have otherwise been entitled to take under this Section 1.4(c)(iv) (*Royalty Reductions*) and the permitted deduction in Section 1.4(e) (*Right to Offset*) is not able to be fully deducted as a result of the application of this Section 1.4(c)(iv) (*Royalty Reductions*), then any remaining portion of such deduction may be carried forward and applied against future Royalties otherwise owed until exhausted (subject to the same [**] reduction floor).

(v) Calculation of Royalty Adjustments. [**].

(vi) Royalty Payments and Reports. Within [**] after the end of each Calendar Quarter during the Royalty Term, Buyer shall provide Seller with a royalty report providing a statement, on a Product-by-Product and country-by-country basis, of: (A) the amount of Net Sales of such Product in such country during the applicable Calendar Quarter calculated in U.S. dollars, (B) a calculation of the amount of Royalties due in U.S. dollars on such Net Sales of such Product for such Calendar Quarter, and (C) with respect to calculations applicable to countries outside of the United States, the exchange rate calculated in accordance with Section 1.4(c)(vii) (*Exchange*) and used to determine the foregoing amounts ((A)-(C)) (each such royalty report, a "**Royalty Report**"). Seller shall submit an invoice to Buyer with respect to the Royalty amount set forth therein, and Buyer will pay such amount within [**] after the receipt of such invoice.

(vii) Exchange. If any amounts that are relevant to the determination of amounts to be paid under this Agreement or any calculations to be performed under this Agreement are denoted in a currency other than U.S. dollars, then such amounts will be converted to their U.S. dollar equivalent using Buyer's or its Affiliate's then-current standard procedures and methodology, including its then-current standard exchange rate methodology for the translation of foreign currency expenses into U.S. dollars or, in the case of (Sub)licensees, such similar methodology, consistently applied in accordance with GAAP or International Financial Reporting Standards (IFRS), as applicable. Calculation of Net Sales will exclude hedging and foreign exchange gain or loss realized through a hedging program.

(d) Sharing of (Sub)license Income. Buyer shall pay Seller [**] of (Sub)license Income within [**] following the end of the Calendar Quarter in which such (Sub)license Income is received by Buyer or any of its Affiliates. In the event the rights granted to a (Sub)licensee include a grant or other transfer of rights with respect to a Product along with a grant of rights or obligations with respect to other compounds or products that are owned or otherwise controlled by Buyer or any of its Affiliates, then [**].

(e) Right to Offset. Buyer may deduct from any Development and Regulatory Milestone Payment, Commercial Milestone Payment, Royalties, (Sub)license Income, or any other payment made by Buyer to Seller under this Section 1.4 (*Contingent Consideration*), [**], an "**Eligible Offset Amount**"). Notwithstanding the foregoing, Buyer must deduct any Eligible Offset Amount from Development and Regulatory Milestone Payments, Commercial Milestone Payments, Royalties, or any other payments payable by Buyer to Seller under this Agreement at its earliest opportunity(ies) to do so [**]. To the extent Buyer deducts any Eligible Offset Amount actually paid to the Third Party licensor under an Upstream License Agreement against any payments due to Seller hereunder, such deduction shall be Buyer's sole and exclusive remedy with respect to any such Eligible Offset Amount and Buyer shall not be entitled to indemnification, or to sue for damages or to assert any other right or remedy under this Agreement, with respect to any such Eligible Offset Amount.

Section 1.5 Late Payments. In the event Seller does not receive any payment from Buyer on or before the applicable date set forth this Agreement through no fault of the Seller (including, any Development and Regulatory Milestone Payment due in accordance with Section 1.4(a) (*Development and Regulatory Milestone Payments*), Commercial Milestone Payment due in accordance with Section 1.4(b) (*Commercial Milestone Payments*), Royalties due in accordance with Section 1.4(c) (*Royalties*), (Sub)license Income payments due in accordance with Section 1.4(d) (*Sharing of (Sub)license Income*) and payment as a result of an audit due in accordance with Section 1.7 (*Inspection of Buyer Records*)), simple interest shall accrue thereafter on such overdue amount at a rate equal to the lesser of: (a) [**] per month, or (b) the maximum rate permitted by applicable Laws, in each case calculated on the number of days such payment is delinquent, compounded monthly.

Section 1.6 Records. Buyer shall keep, and shall cause the other Buyer Parties to keep, complete, true and accurate books of accounts and records sufficient to determine and establish the amounts payable incurred under this Agreement, and compliance with the other terms and conditions of this Agreement. Such books and records shall be kept reasonably accessible and shall be made available for inspection for a [**] period in accordance with Section 1.7 (*Inspection of Buyer Records*).

Section 1.7 Inspection of Buyer Records. Upon reasonable prior written notice, Buyer shall permit, and shall cause its Affiliates to permit, an independent nationally recognized certified public accounting firm (subject to obligations of confidentiality to Buyer), appointed by Seller and reasonably acceptable to Buyer, to inspect the audited financial records of Buyer during regular business hours to the extent relating to payments to Seller under this Agreement; provided, that such inspection shall not occur (a) more often than [**], unless a material error is discovered as part of such inspection in which case Seller shall have the right to conduct a more thorough inspection for such period or (b) more frequently than [**] with respect to such records covering any specific period of time. In addition, the Seller shall only be entitled to audit such records of Buyer and its Affiliates from the [**] in which the audit request is made. In addition, Buyer shall, and shall cause its Affiliates to ensure Buyer or its Affiliates have an audit right of each (Sub)licensee. Seller agrees to hold in strict confidence all information received and all information learned in the course of any audit or inspection, which information shall constitute the confidential information of Buyer, except to the extent necessary to enforce its rights under this Agreement or to the extent required to comply with any applicable Laws. Any inspection conducted under this Section 1.7 (*Inspection of Buyer Records*) shall be at the cost and expense of Seller, unless such inspection reveals any underpayment of the amounts due hereunder for the audited period by at least [**], in which case the full costs of such inspection for such period shall be borne by Buyer. Any overpayment by Buyer, at Buyer's election, shall (i) by submission of an invoice to Seller, which shall be paid by Seller within [**] following receipt thereof or (ii) be offset by Buyer against future payments due by Buyer to Seller hereunder.

Section 1.8 Commercially Reasonable Efforts.

(a) Diligence Obligations. From the Closing Date until [**] the "**Diligence Expiration Date**"), the Buyer Parties shall use (either directly or through its Affiliates and (Sub)licensees) Commercially Reasonable Efforts to obtain Regulatory Approval for one Product in the United States.

(b) Seller Acknowledgement. Seller (on behalf of itself and the Selling Affiliates) acknowledges that the development of the Products is uncertain and that the Buyer Parties may not achieve the results requiring payment of the Development and Regulatory Milestone Payments, Commercial Milestone Payments, or Royalties. Seller (on behalf of itself and the Selling Affiliates) also acknowledges and stipulates that:

(i) Buyer (A) has made no guarantees or promises and has provided no assurance that any Development and Regulatory Milestone Event or Commercial Milestone Event will be achieved at all or that any Product will generate any Net Sales upon which a Royalty will be due, and (B) has made no assessments or predictions regarding the likelihood of any such milestone being achieved or of any such sales occurring;

(ii) Buyer has not, prior to or after the date hereof, promised or projected any amounts to be received by Seller under this Agreement other than the Upfront Consideration and the Development and Regulatory Milestone 1;

(iii) none of the Seller or any Selling Affiliate is relying on or has relied on any promises, projections, representations, or warranties of any kind or other information, documents, or materials (or absence thereof) in respect of any payments described in this Agreement (other than those expressly set forth in this Agreement);

(iv) the Buyer Parties are not prohibited from developing or commercializing (or acquiring or in-licensing) assets or businesses related to other products that may compete with the Products; and

(v) except for the obligations set forth in Section 1.8 (*Commercially Reasonable Efforts*), the Buyer Parties shall have sole control and authority to operate the Business, develop Products, and otherwise use and exploit the Transferred Assets in any way that Buyer deems appropriate in its sole business judgment and in its sole and absolute discretion.

Section 1.9 Development Updates.

(a) Development Plan. Within [**] following the Closing, Buyer will deliver to Seller a development plan (including [**]) that sets forth the planned development of the Products through [**] (the "**Development Plan**"). Buyer may, from time to time, make adjustments to the Development Plan as Buyer believes, in its good faith judgment, are appropriate under the then-current circumstances consistent with its diligence obligations set forth in Section 1.8 (*Diligence Obligations*).

(b) Development Reports. From and after the Closing until the earlier or the First Commercial Sale of Product in the United States or the Diligence Expiration Date, within [**] following the end of each Calendar Year beginning with the [**], Buyer shall provide to Seller a reasonably detailed written summary that describes material development activities for the Product(s) conducted by or on behalf of the Buyer Parties since the last report. In addition, from and after Closing until [**], within [**] following the end of each Calendar Year beginning

with the [**], Buyer shall provide to Seller an updated Development Plan. In addition, upon the reasonable written request by Seller, Buyer will provide Seller with further details related to the foregoing.

Section 1.10 Milestone Event Disputes. Buyer shall keep, and shall cause the Buyer Parties to keep, adequate books and records of accounting for the purpose of confirming whether a Development and Regulatory Milestone Event has occurred for a period of [**] following the end of the Calendar Year to which each pertains. If the Seller believes that any Development and Regulatory Milestone Event has occurred and Buyer has not yet provided notice to Seller of the occurrence of such Development and Regulatory Milestone Event, then the Seller shall deliver to Buyer written notice thereof (a "**Milestone Dispute Notice**"), in reasonable detail, within [**] following the date upon which the Seller alleges the applicable Development and Regulatory Milestone Event occurred. Following the delivery of a Milestone Dispute Notice, Buyer and Seller shall first attempt in good faith to resolve by negotiation and consultation between themselves, any dispute as to whether any Development and Regulatory Milestone Event has occurred and whether any Development and Regulatory Milestone Payment is payable. If Buyer and Seller do not reach agreement with respect to any dispute relating to any such matter within [**] after a Milestone Dispute Notice is delivered to Buyer by Seller, then the Parties shall submit for arbitration all matters that remain in dispute to a disinterested individual who has appropriate scientific, technical and regulatory expertise (as relevant) to resolve any disputes referred to him or her under this Section 1.10 (*Milestone Event Dispute*) (a "**Scientific Expert**") who is mutually agreed to by Buyer and Seller; provided, however, that such Scientific Expert shall not be or have been at any time within the previous [**] an Affiliate, employee, consultant, officer or director of Buyer, Seller or any of their respective Affiliates. If Buyer and Seller cannot agree on a mutually acceptable Scientific Expert within [**] after either Party has determined that the Parties cannot reach agreement with respect to a dispute, then within [**] after the expiration of such [**] period, each of Buyer and Seller shall appoint one Scientific Expert who shall jointly select a third Scientific Expert within [**] after the last to occur of their respective appointments to arbitrate the referred matter. The Scientific Expert mutually agreed by the Parties or, if the Parties cannot agree, the third Scientific Expert selected by the Party-appointed Scientific Experts is referred to as the "**Selected Scientific Expert.**" Buyer and Seller shall instruct the Selected Scientific Expert to determine as promptly as practicable but in no event later than [**] after such person's appointment (the "**Determination Period**") whether the disputed Development and Regulatory Milestone Event or Commercial Milestone Event has occurred. The Selected Scientific Expert's determination shall be made based on the submission of documents and evidence by the Parties (including any such documentation or evidence reasonably requested by the Selected Scientific Expert, which Seller or Buyer shall provide upon request) and, upon the Selected Scientific Expert's request, by Third Parties, unless the Selected Scientific Expert determines that an oral hearing is necessary. The Selected Scientific Expert shall determine deadlines (which Buyer and Seller shall deem to be fair and appropriate) within the Determination Period for submitting documents and dates, if any, of oral hearings. The prevailing Party shall pay all of the expenses of arbitration, and the fees, costs and expenses of the Selected Scientific Expert.

Section 1.11 Currency. Except as otherwise expressly provided in this Agreement, all payments under or in connection with this Agreement (including this Article 1) shall be in U.S. dollars.

Section 1.12 Withholding. Buyer and any other applicable withholding agent shall be entitled to make all payments under this Agreement net of all deductions and withholdings in respect of Taxes required by Law. If any Taxes are required by Law in effect at the time of payment to be deducted from or in respect of any amount payable under this Agreement: (a) such amounts shall be deducted and withheld, and treated as paid to the person in respect of which such deduction or withholding was made, (b) Buyer shall make such deductions and timely pay

the full amount deducted to the Governmental Authority in accordance with applicable Law and (c) Buyer shall use commercially reasonable efforts to provide any documentation or information reasonably requested by Seller to evidence such Tax payments. Notwithstanding the foregoing, other than withholding applied in respect of compensatory amounts or for failure to deliver an IRS Form W- 9, Buyer will provide written notice to Seller promptly upon any determination that withholding may be required on any payments under this Agreement and shall cooperate in good faith and use commercially reasonable efforts to take such steps as Seller may reasonably request to reduce or eliminate such deduction or withholding. Notwithstanding any provision to the contrary in this Agreement, the Parties acknowledge and agree that [**].

Section 1.13 Transfer Taxes and Other Costs. All Transfer Taxes payable under applicable Law on or in connection with the transfer of the Transferred Assets to Buyer, if any, shall be paid by Buyer and Buyer shall indemnify Seller against any liability for such Transfer Taxes. Buyer shall prepare and file all necessary Tax Returns and other documentation required to be filed by it with respect to all Transfer Taxes, and, if required by applicable Law, the Parties will, and will cause their Affiliates to, join in the execution of any such Tax Returns and other documentation.

Section 1.14 Allocation of the Consideration. Within [**] after the Closing, Buyer shall prepare and finalize an allocation of the purchase price paid (for Tax purposes) among the Transferred Assets in accordance with Tax Law (including Section 1060 of the Code), the principles of Schedule 1.14, and in accordance with the remainder of this Section 1.14 (*Allocation of the Consideration*). Promptly following the Closing, Buyer shall deliver a proposed allocation of the purchase price in accordance with this Section 1.14 (*Allocation of the Consideration*) to Seller for Seller's review and comment, and Buyer shall consider any comments received from Seller in good faith. Seller shall provide Buyer with such evidence as Buyer may reasonably request to support the proposed allocation. The purchase price allocation, as finalized pursuant to the terms of this Section 1.14 (*Allocation of the Consideration*), shall be binding on the Parties, and the Parties shall (and shall cause their Affiliates to) file all Tax Returns and take all Tax positions in a manner consistent with the final purchase price allocation, unless otherwise required by a final determination within the meaning of Section 1313(a) of the Code or in connection with a good faith resolution of a Tax audit. Any adjustments to the purchase price (for Tax purposes) shall be allocated in accordance with the procedures and principles of this Section 1.14 (*Allocation of the Consideration*).

ARTICLE 2

REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the applicable section identified in the Seller Disclosure Letter, Seller represents and warrants to Buyer as follows:

Section 2.1 Organization. Each of Seller and the Selling Affiliates is duly organized, validly existing and in good standing (to the extent such concept is recognized in the relevant jurisdiction) under the Laws of its respective jurisdiction of formation, and has full corporate or other applicable legal power and authority to enter into the transactions contemplated by this Agreement.

Section 2.2 Corporate and Governmental Authorization.

(a) Seller has full corporate power and authority to enter into this Agreement and each of the Selling Affiliates have, or will have at Closing, full corporate or other applicable legal power and authority to enter into the Ancillary Agreements to which it is to be a party and

to perform its obligations hereunder and thereunder (as the case may be). This Agreement has been, and the Ancillary Agreements to which the Selling Affiliates are to be a party will be by Closing, duly authorized and approved by all necessary corporate action.

(b) Seller has duly executed and delivered this Agreement and on the Closing Date will have duly executed and delivered the Ancillary Agreements.

(c) The transactions contemplated under this Agreement do not constitute a sale of all or substantially all of Seller's assets. Except as set forth on Section 2.2(c) of the Seller Disclosure Letter, no consent, approval, order or authorization of, action by or in respect of, or registration, declaration or filing with, any Governmental Authority is required by or with respect to Seller, the Business, or the Transferred Assets for, or in connection with, (i) the execution and delivery of this Agreement by Seller, (ii) the transfer of the Transferred Assets to Buyer or (iii) the consummation of transactions contemplated hereunder.

(d) Assuming the due authorization, execution and delivery of this Agreement by Buyer, this Agreement constitutes a legal, valid and binding obligation of Seller, enforceable against Seller in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equity principles. Assuming the due authorization, execution and delivery of the Ancillary Agreements by Buyer, each Ancillary Agreement to be executed by any Selling Affiliate, when delivered hereunder, will be duly and validly executed and delivered, and will constitute a legal, valid and binding obligation of such Selling Affiliate, enforceable in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equity principles.

Section 2.3 Non-Contravention. The execution and delivery of this Agreement by Seller, the execution and delivery of the Ancillary Agreements by any Selling Affiliate thereto and the consummation of the transactions contemplated hereby or thereby, do not and will not

(a) violate in any material respect any provision of the Organizational Documents of Seller or any Selling Affiliate, (b) conflict with, result in the breach of, constitute a default under or result in the termination, cancellation or acceleration (whether after the giving of notice or the lapse of time or both) of any right or obligation of Seller or any Selling Affiliate under any Transferred Contract to which it is a party or to which its assets are subject, or result in the creation or the imposition of any Lien (other than a Permitted Lien) upon any of the Transferred Assets, or (c) violate, in any material respect, any Law of any Governmental Authority applicable to Seller or any Selling Affiliate, or any of the Transferred Assets or any Order against Seller or any Selling Affiliate or the Transferred Assets. Section 2.3 of the Seller Disclosure Letter sets forth a list of all Transferred Contracts that require a Transfer Approval to be assigned to Buyer.

Section 2.4 Solvency. As of the date hereof and as of immediately after giving effect to the consummation of the transactions contemplated by this Agreement, Seller and its Affiliates will be Solvent.

Section 2.5 Absence of Material Adverse Effect. Since December 31, 2024, there have not been any changes, effects, events, occurrences, states or facts or developments that, individually or in the aggregate, have resulted or would be reasonably likely to result in a Material Adverse Effect. Without limiting the generality of the foregoing, since December 31, 2024, the Seller and any of the Selling Affiliates have not, with respect to the Business:

(a) sold, assigned, pledged, hypothecated or otherwise transferred any assets, properties or rights related to the Product, except those which, when taken together with all assets, properties or rights disposed of, are immaterial to the Business taken as a whole;

(b) suffered any material damage, destruction or other casualty loss (whether or not covered by insurance);

(c) changed in any material way the manner in which accounts receivable related to the Product have been collected;

(d) materially and adversely modified or changed its relationship with its suppliers or customers; or

(e) entered into an agreement to do any of the foregoing.

Section 2.6 Material Contracts.

(a) Except for the Contracts disclosed in the applicable subsection of Section 2.6 of the Seller Disclosure Letter (which is arranged in subsections to correspond to the subsections of this Section 2.6) and Contracts with employees, consultants, or advisors, as of the date hereof, there are no Contracts relating (whether solely or in part) to the operation and conduct of the Business, the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product, or any of the Transferred Assets that constitute:

(i) any joint venture, partnership, limited liability company or other similar agreements or arrangements (providing for joint research, development or marketing of any of the Products);

(ii) any agreement or series of related agreements, including any option agreement, relating to the acquisition or disposition of any business or assets of any other Person or any material real property (whether by merger, sale of stock, sale of assets or otherwise related to the Business);

(iii) any agreement that (A) materially limits the freedom of Seller or its Affiliates to operate the Business or with any Person or in any area or that would so limit the freedom of Buyer or its Affiliates after the Closing (other than customary exclusive distribution agreements for the Products), (B) contains material exclusivity obligations or restrictions binding on Seller or the Selling Affiliates or that would be binding on Buyer or any of its Affiliates after the Closing, (C) contains any right of first refusal, right of first negotiation or right of first offer in favor of a party other than Sellers; or (D) otherwise restricts the research, development, manufacture, marketing, distribution, sale, supply, license or marketing of the products and services of Seller or that either Seller or any Selling Affiliate develops;

(iv) any agreement or series of related agreements for the purchase of materials, supplies, goods, services, equipment or other assets related to the Business that is reasonably expected to involve annual payments on the part of Seller or the Selling Affiliates in excess of $[**] from and after the Closing;

(v) any sales, distribution, agency or other similar agreement providing for the sale by the Business of Products, materials, supplies, goods, services, equipment or other assets that is reasonably expected to involve annual payments to Seller or the Selling Affiliates from and after the Closing over the remaining term of the agreement of $[**];

(vi) any agreement under which the Business has (A) granted a Lien on any material Transferred Asset, other than a Lien that will be released as of the Closing or (B) provided for the sale of any material Transferred Asset, or granted any preferential rights to purchase any material Transferred Asset, in each case outside the ordinary course of business;

(vii) any agreement providing any person or entity with pricing, discounts, or benefits that change based on the pricing, discounts, or benefits offered to other Third Parties, including any agreement containing "most favored nation";

(viii) any agreement in which either Seller has agreed to purchase a minimum quantity of goods or services or has agreed to purchase goods or services exclusively from a certain party;

(ix) any agreement providing for any royalty, milestone, or similar payments by the Seller or any Selling Affiliates; and

(x) any agreement between either Seller and a governmental authority.

(b) Section 2.6(b) of the Seller Disclosure Letter sets forth a true and complete list of all Contracts relating solely to the operation and conduct of the Business, to the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product, or to any of the Transferred Assets, in each case, as currently conducted. For the avoidance of doubt, such list does not include any Excluded Asset listed in clauses (i) through (xv) of Annex 9.1(b) attached hereto, any Shared Contract, or any Contracts with employees, consultants, or advisors, even if related to the operation and conduct of the Business as currently conducted, and includes Contracts that are no longer in effect.

(c) Section 9.1(b)(vi) of the Seller Disclosure Letter sets forth a true and complete list of all Shared Contracts.

(d) Seller has made available to Buyer true, correct, and complete copies of each of the Transferred Contracts and Shared Contracts.

(e) Each agreement, commitment, arrangement or plan disclosed in the Seller Disclosure Letter pursuant to this Section 2.6 (*Material Contracts*) or Section 2.9 (*Intellectual Property*) (each, a "**Material Contract**") is a valid and binding agreement of Seller or the Selling Affiliate thereto (subject to the effects of applicable bankruptcy, insolvency, fraudulent conveyance, or other Laws relating to or affecting creditors' rights generally and to general principles of equity, whether considered at law or in equity) and is in full force and effect, and neither Seller nor any of the Selling Affiliates or, to the Knowledge of Seller, any other party thereto is in default or breach in any material respect under (or is alleged to be in default or breach in any material respect under) the terms of, or has provided or received any notice of any intention to terminate, any such Material Contract, and, to the Knowledge of Seller, no event or circumstance has occurred since December 31, 2024 that, with notice or lapse of time or both, would constitute an event of default thereunder or result in a termination thereof or would cause or permit the acceleration of or other changes of or to any right or obligation or the loss of any benefit thereunder that has not been cured or waived.

Section 2.7 Title to Transferred Assets. Seller or the Selling Affiliate has exclusive, good, marketable, title to all the Transferred Assets, and has the complete and unrestricted power and unqualified right to sell, assign, transfer and deliver to Buyer the Transferred Assets. There are no adverse claims of ownership to the Transferred Assets and neither Seller has received notice that any person or entity has asserted a claim of ownership or right of possession or use in

or to any of the Transferred Assets, nor are there any facts, circumstances or conditions on which, to the Knowledge of the Seller, such a claim could be brought in the future. At the Closing, Buyer will acquire from Seller sole and exclusive, good and marketable title to all of the Transferred Assets free and clear of all Liens (other than a Permitted Lien).

Section 2.8 Completeness of Transferred Assets. Except for the Excluded Assets described on Annex 9.1(b) clause (i) through clause (xv) the Transferred Assets, together with any Unassigned Rights, the rights pursuant to the Ancillary Agreements, and Contracts with employees, consultants, or advisors, include all of the assets and rights in the possession and control of Seller or its Affiliates that are related to the Business or are used or held for use by Seller or the Selling Affiliates as of the Closing Date in connection with the operation or conduct of the Business, including the development, manufacture, or commercialization of Acquired Molecules and Acquired Products.

Section 2.9 Intellectual Property.

(a) Section 9.1(a)(viii) of the Seller Disclosure Letter sets forth, as of the date hereof, a complete and accurate list of all Transferred Patent Rights, including the patent application or patent number, filing date, expiration date, country or territory, applicant and owner of record in respect of each such item of Transferred Patent Right, other than the Excluded Assets. No Person, including any Governmental Authority is making a written adverse claim of ownership or inventorship to the Transferred Patent Rights or is challenging the right, title or interest of Seller or any Selling Affiliate in, to or under any Transferred Patent Rights, or the validity or enforceability of any Transferred Patent Rights. The Transferred Patent Rights are not subject to any outstanding order of, judgment of, decree of or agreement with any Governmental Authority adversely affecting the use thereof by Seller or the Selling Affiliates or their rights thereto.

(b) Seller or a Selling Affiliate owns or has the right to use each item of Transferred IP free and clear of Liens. Immediately following the Closing, Buyer shall have the same rights, interest, and title in and to each item of the Transferred IP as held by Seller or the Selling Affiliates immediately prior to the Closing without the payment of any additional amounts or consideration other than fees, royalties or payments which Seller or the Selling Affiliates would otherwise have been required to pay had the transactions contemplated herein not occurred.

(c) The Transferred IP includes all of the IP Rights owned or controlled by Seller or its Affiliates used or held for use as of the Closing Date in the Business or the development, manufacture, or commercialization of Acquired Molecules and Acquired Products.

(d) Seller and the Selling Affiliates have taken commercially reasonable measures to protect and maintain the Transferred Know-How that constitutes trade secrets and other material confidential information included in the transferred Assets. To the Knowledge of Seller, (i) all current and former officers and employees of, and consultants, advisors and independent contractors to, Seller and the Selling Affiliates who have contributed to the creation, development or invention of any Transferred IP, while employed or engaged by the Seller or a Selling Affiliate, as applicable, have executed and delivered to Seller or a Selling Affiliate a valid and enforceable agreement regarding the protection of proprietary information and the present assignment to Seller or a Selling Affiliate, as applicable, of any Transferred IP arising from services performed for Seller or a Selling Affiliate, by such persons, and (ii) no such officer, employee, consultant, advisor or independent contractors of Seller or any Selling Affiliate is in violation of any term of such agreement. No current or former officer, employee, consultant, advisor or independent contractors of Seller or any Selling Affiliate has made or threatened to make any claim or challenge against the Seller or any of its Affiliates in connection

with his or her contribution to the creation, development or invention of any Transferred IP, and no circumstances exist which would reasonably be expected to lead to any such claim or challenge.

(e) [**]. There are no adverse Third Party actions or claims or any written allegations to the effect that the operation or conduct of the Business constitutes an infringement or violation of the Patent Rights or Know-How of any third Person.

(f) To the Knowledge of Seller, no Third Party has infringed, diluted, misappropriated or otherwise violated or is or are infringing upon, diluting, misappropriating or otherwise violating the Transferred IP.

(g) None of the Transferred IP is the subject of any written objection or claim received by Seller or any Selling Affiliate or published with respect to its ownership, validity, or enforceability thereof, and, to the Knowledge of Seller, there does not exist any valid basis for such an objection or claim.

(h) Except with respect to non-exclusive licenses granted in the ordinary course of business, agreements with distributors entered into in the ordinary course of business, other generally available commercial licenses, or Contracts otherwise included in Material Contracts, Section 2.9(h) of the Seller Disclosure Letter lists, as of the date of this Agreement, all of the written agreements (i) pursuant to which Seller and the Selling Affiliates obtained the right to use or practice rights under IP Rights owned by third Persons (excluding Copyright rights) that are used or held for use as of the Closing Date in the conduct of the Business or the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product or (ii) by which Seller or any of the Selling Affiliates has licensed or otherwise authorized a Third Party to use any Patent Right or Know-How included in the Transferred IP (collectively, the "**Licensed IP Contracts**"), including license agreements, settlement agreements, and covenants not to sue.

(i) There are no outstanding amounts payable by Seller or its Affiliates to [**] under the License Agreement to reimburse [**] for expenses incurred in the prosecution and maintenance of Patent Rights licensed to Seller or its Affiliates thereunder.

Section 2.10 Litigation. As of the date hereof, except as set forth on Section 2.9 of the Seller Disclosure Letter, (a) no Litigation or investigation relating to the Business, the Transferred Assets, the Acquired Molecules, or Acquired Products is pending against or, to the Knowledge of Seller, threatened in writing against Seller or any Selling Affiliate and (b) neither Seller nor any Selling Affiliate, in connection with the Business, Transferred Assets, Acquired Molecule, or Acquired Product, is subject to any outstanding Order.

Section 2.11 Transferred Materials. The Transferred Materials are usable in the ordinary course of business, subject to their respective shelf life and customary wear and tear, and with respect to such Transferred Materials that is finished product inventory for use in Clinical Studies that complies with GMP, such Transferred Materials: (a) were manufactured, stored and to the extent packaged and labeled, packaged and labeled in accordance with the specifications for the Acquired Product, good manufacturing practices and applicable Law in all material respects; (b) are not adulterated or misbranded and, to the Knowledge of Seller, is not damaged or obsolete; (c) are not held on consignment; and (d) have been tested in accordance with established protocol sufficient to release the Acquired Product.

Section 2.12 Compliance with Laws; Licenses and Permits.

(a) Since [**], Seller and the Selling Affiliates have conducted the Business in compliance with applicable laws, statutes, ordinances, rules, regulations, policies, mandates, guidelines, judgments, injunctions, requirements, orders and decrees of applicable Governmental Authorities ("**Laws**") and, to the Knowledge of Seller, are not under investigation by any Governmental Authority with respect to any violation of any Laws applicable to the Business or any Transferred Asset except, in each case, as would not reasonably be expected, individually or in the aggregate, to be material to the Business, the Transferred Assets, or the Development, Manufacture, or Commercialization of Acquired Molecule and Acquired Products.

(b) Seller (together with the Selling Affiliates) has all licenses, franchises, permits, certificates, approvals or other similar authorizations issued by applicable Governmental Authorities that are necessary for the operation of the Business (the "**Permits**") except, in each case, as would not reasonably be expected, individually or in the aggregate, to be material to the Business or the Transferred Assets, or the Development, Manufacture, or Commercialization of Acquired Molecule and Acquired Products. The Permits are valid and in full force and effect and none of the Permits will be terminated as a result of the transactions contemplated by this Agreement, except, in each case, as would not reasonably be expected, individually or in the aggregate, to be material to the Business or the Transferred Assets, or the Development, Manufacture, or Commercialization of Acquired Molecule and Acquired Products. No proceeding is pending or, to the Knowledge of Seller, threatened regarding the withdrawal, suspension, material modification or revocation of any such Permit. As of the date hereof, Seller has not received any written communication from any Governmental Authority threatening to withdraw, materially modify or suspend any Permit. Seller is not in violation of the terms of any Permit.

(c) Neither Seller or any Selling Affiliate, or, to the Knowledge of Seller, the Seller or any of the Selling Affiliate's officers, employees, or other representatives (i) has used or is using any funds for any unlawful contributions, unlawful gifts, unlawful entertainment or other unlawful expenses; (ii) has made any direct or indirect unlawful payments to any foreign or domestic Governmental Authority; (iii) has violated and is not violating any Anti-Corruption Laws; (iv) has established or maintained, or is maintaining, any unlawful or unrecorded fund of monies or other properties; (v) has made, or is making, any false or fictitious entries on its accounting books and records; (vi) has made, or is making, any bribe, rebate, payoff, influence payment, kickback or other unlawful payment of any nature, or has paid, or is paying, any fee, commission or other payment that has not been properly recorded on its accounting books and records as required by the Anti-Corruption Laws; or (vii) has otherwise given or received anything of value to or from any official of any Governmental Authority, an intermediary for payment to any individual including officials of any Governmental Authority, any political party or customer for the purpose of obtaining or retaining business, in each case ((i) through (vii)), in connection with the Business or any Acquired Molecule or Acquired Product.

(d) All payments made by Seller or any Selling Affiliate to healthcare providers pursuant to any Transferred Contract or Shared Contract (i) were made for bona fide services actually rendered by such healthcare provider, (ii) were, in all material respects, consistent with fair market value for the services provided to the extent required by applicable Laws; (iii) were commercially reasonable based on the facts and circumstances known at the time the applicable arrangements were entered into, and (iv) were not structured in a manner that would, in any material respect, take into account the volume or value of referrals, prescriptions, orders, or other business generated in violation of applicable Laws.

(e) Notwithstanding the foregoing, Seller makes no representation or warranty in this Section 2.12 (*Compliance with Laws; Licenses and Permits*) with respect to Litigation

matters, regulatory matters or Tax matters, which matters are exclusively addressed in Section 2.10 (*Litigation*) and Section 2.14 (*Tax Matters*), respectively.

Section 2.13 Pre-clinical Development and Clinical Trials.

(a) The studies, tests, pre-clinical development, and Clinical Trials conducted by or on behalf of the Seller with respect to the Transferred Assets, and, to the Knowledge of the Seller, all activities related to the manufacture of compounds and products for use therein, have been conducted in all material respects in accordance with established protocols, procedures and controls pursuant to accepted professional and scientific standards for products or product candidates comparable to those being developed by the Seller and all applicable Laws, including the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. parts 50, 54, 56, 58 and 312. Neither Seller nor any Selling Affiliates or, to the Knowledge of Seller, any of their officer or employees, has received any written communication from FDA or any other Governmental Authority (including any warning letter or untitled letter) that alleges that the Business is not in compliance with any applicable requirements under Laws.

(b) The INDs included in the Transferred Assets are current and in full force and effect, and no suspension, revocation, or cancellation of such INDs is pending or threatened in writing. Seller has made available to Buyer true and complete copies of each such IND and all material governmental correspondence (including copies of official notices, citations or decisions) in the files of Seller or the Selling Affiliates relating to such INDs.

(c) There is no Clinical Trial currently being conducted with respect to any Acquired Molecule or Acquired Product or under any IND that is included in the Transferred Assets.

(d) Neither Seller, nor to the Knowledge of Seller, any of its officers, employees or Selling Affiliates has been, or is currently, subject to any enforcement proceedings by the FDA or any other Governmental Authority as relates to the Business. Since November 1, 2021, there has not been and there is not now in effect any Form 483 observation, civil, criminal or administrative action, suit, demand, claim, complaint, hearing, investigation, demand letter, warning letter, untitled letter, proceeding or request for information pending regarding any Acquired Product against Seller or, to the Knowledge of Seller, any of its officers, employees or Selling Affiliates, and Seller has no current liability (whether actual or contingent) for failure to comply with the applicable Laws with respect to the operation of the Business.

(e) Neither Seller, nor to the Knowledge of Seller, any of its officers, employees, agents, or Selling Affiliates, has made an untrue statement of material fact or fraudulent statement to the FDA or any other Governmental Authority, failed to disclose a material fact required to be disclosed to the FDA or any other Governmental Authority, or committed an act, made a statement, or failed to make a statement, including with respect to any scientific data or information, that, at the time such disclosure was made or failure to disclose occurred, would reasonably be expected to provide a basis for the FDA or any other Governmental Authority to invoke the FDA Application Integrity Policy respecting "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities," set forth in FDA's Compliance Policy Guide Sec. 120.100 (CPG 7150.09) or any similar policy, in each case as related to the Acquired Product.

(f) No studies, tests, pre-clinical development, or Clinical Trials conducted by or on behalf of the Seller with respect to the Transferred Assets have (i) been conducted using any clinical investigators who have (A) been debarred or have been convicted of any crime or engaged in any conduct that did result in debarment under 21 U.S.C. § 335a or disqualification as a clinical investigator under 21 C.F.R. § 312.70 or any similar Law or (B) been excluded or

convicted of any crime which would reasonably be expected to result in being excluded from participating in the Federal health care programs under Section 1128 of the Social Security Act of 1935, as amended, or (ii) been terminated or suspended prior to completion. To the knowledge of Seller, no clinical investigator that has participated or is participating in, or institutional review board that has or has had jurisdiction over, any studies, tests, pre-clinical development, or Clinical Trials conducted by or on behalf of Seller has placed a clinical hold order on, or otherwise terminated, suspended, or materially delayed, such study, test, pre-clinical development, or Clinical Trial based on an actual or alleged lack of safety or efficacy or a failure to conduct such activity in compliance with applicable Laws.

(g) Seller has not received any notices or correspondence from the FDA or other Governmental Authority or any institutional review board or comparable authority requiring the termination, suspension or material modification of any studies, tests, pre-clinical development or Clinical Trials conducted by or on behalf of the Seller with respect to the Transferred Assets.

Section 2.14 Tax Matters.

(a) All material Tax Returns that are required to be filed on or before the date of this Agreement in respect of the Transferred Assets or the operation of the Business have been filed (taking into account any applicable extensions). All such Tax Returns were correct and complete in all material respects and were prepared and filed in material compliance with all applicable Laws.

(b) All material Taxes in respect of the Transferred Assets or the operation of the Business that are due and payable with respect to Pre-Closing Tax Periods have been paid in full.

(c) There are no Liens for any Taxes upon any of the Transferred Assets.

(d) The representations and warranties set forth in this Section 2.14 (*Tax Matters*) are the sole representations and warranties relating to Taxes and no other representations or warranties contained in this Agreement shall be construed to cover any matter involving Taxes.

Section 2.15 Finders' Fees. Except as set forth in Section 2.15 of the Seller Disclosure Letter, there is no investment banker, broker, finder or other intermediary retained by or authorized to act on behalf of Seller who might be entitled to any fee or commission from Buyer or any of its Affiliates upon consummation of the transactions contemplated by this Agreement.

Section 2.16 [**].

Section 2.17 No Other Representations and Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, (A) NONE OF SELLER OR ANY OF ITS AFFILIATES IS MAKING OR HAS MADE ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, AT LAW OR IN EQUITY, WITH RESPECT TO THIS AGREEMENT, THE ANCILLARY AGREEMENTS, SELLER, THE SELLING AFFILIATES, THE TRANSFERRED ASSETS, THE ASSUMED LIABILITIES, THE BUSINESS, THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT (INCLUDING ANY CONSENTS OR APPROVALS REQUIRED IN CONNECTION THEREWITH) OR ANY INFORMATION PROVIDED OR MADE AVAILABLE TO BUYER IN CONNECTION WITH THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT (INCLUDING ANY FORECASTS, PROJECTIONS, ESTIMATES, BUDGETS, PRESENTATIONS CONCERNING THE BUSINESS (INCLUDING WITHOUT LIMITATION, THE

CONFIDENTIAL INFORMATION MEMORANDA AND ANY "TEASER" DOCUMENTS), OR DUE DILIGENCE OR OTHER "DATA ROOM" MATERIALS), INCLUDING ANY WARRANTY WITH RESPECT TO MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE, AND ALL OTHER REPRESENTATIONS OR WARRANTIES ARE HEREBY EXPRESSLY DISCLAIMED AND SHALL NOT BE DEEMED TO BE OR TO INCLUDE REPRESENTATIONS OR WARRANTIES OF ANY OF THE FOREGOING PARTIES AND HAVE NOT BEEN RELIED UPON BY BUYER OR ANY OF ITS AFFILIATES IN EXECUTING, DELIVERING AND PERFORMING THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY; AND (B) ALL OF THE ASSETS AND LIABILITIES TO BE SOLD, CONVEYED, ASSIGNED, TRANSFERRED OR ASSUMED, AS APPLICABLE, IN ACCORDANCE WITH THIS AGREEMENT, SHALL BE SOLD, CONVEYED, ASSIGNED, TRANSFERRED OR ASSUMED ON AN "AS IS, WHERE IS" BASIS.

ARTICLE 3

REPRESENTATIONS AND WARRANTIES OF BUYER

Except as set forth in the applicable section identified in the Buyer Disclosure Letter, Buyer represents and warrants to Seller as follows:

Section 3.1 Organization. Buyer is a duly organized corporation, validly existing and in good standing (to the extent such concept is recognized in the relevant jurisdiction) under the Laws of its respective jurisdiction of formation, and has full corporate or other applicable legal power and authority to carry on its business in the places where such businesses are now being conducted, except where the absence of such power and authority would not be expected to be material to Buyer, taken as a whole.

Section 3.2 Corporate and Governmental Authorization.

(a) Buyer has full corporate power and authority to enter into this Agreement and the Ancillary Agreements, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. This Agreement has been, and the Ancillary Agreements will be by Closing, duly authorized and approved by all necessary corporate action by Buyer. The performance of Buyer's obligations hereunder and thereunder and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all requisite corporate action of Buyer. Buyer has duly executed and delivered this Agreement and on the Closing Date will have duly executed and delivered the Ancillary Agreements.

(b) Assuming the due authorization, execution and delivery of this Agreement by Seller, this Agreement constitutes a legal, valid and binding obligation of Buyer, enforceable against Buyer in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equity principles. Assuming the due authorization, execution and delivery of the Ancillary Agreements by Seller or such applicable Selling Affiliate, each Ancillary Agreement to be executed by Buyer, when delivered hereunder, will be duly and validly executed and delivered, and will constitute a legal, valid and binding obligation of Buyer, enforceable in accordance with its terms, except as enforcement may be limited by bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general equity principles.

Section 3.3 Non-Contravention. The execution and delivery of this Agreement and the Ancillary Agreements by Buyer, and the performance of its obligations hereunder and thereunder do not (a) violate in any material respect any provision of the Organizational Documents of Buyer, (b) violate any Law of any Governmental Authority applicable to Buyer or any Order against Buyer or (c) require any consent, authorization, approval, waiver or other action by any Person under any provision of any material agreement or other instrument to which Buyer is a party.

Section 3.4 Sufficiency of Funds. Buyer has, and at Closing will have, sufficient funds on hand to consummate the transactions contemplated by this Agreement and the Ancillary Agreements and to deliver the Upfront Closing Consideration and all fees and expenses related to the transactions contemplated by this Agreement and the Ancillary Agreements at Closing, and thereafter to pay and discharge the Assumed Liabilities as they become due through the [**] anniversary of the Closing Date. Buyer acknowledges and agrees that its obligations under this Agreement, including its obligation to consummate the transactions contemplated by this Agreement are not contingent upon Buyer's ability to obtain financing.

Section 3.5 Solvency. As of the date hereof and as of immediately after giving effect to the consummation of the transactions contemplated by this Agreement, Buyer and its Affiliates will be Solvent.

Section 3.6 Litigation. There is no Litigation pending, or, to the knowledge of Buyer, threatened against or affecting Buyer before any court or arbitrator or any Governmental Authority that in any manner challenges or seeks to prevent, enjoin, alter, or materially delay the transactions contemplated by this Agreement or any Ancillary Agreement.

Section 3.7 Finders' Fees. There is no investment banker, broker, finder or other intermediary retained by or authorized to act on behalf of Buyer who might be entitled to any fee or commission from Seller or any of the Selling Affiliates upon consummation of the transactions contemplated by this Agreement.

ARTICLE 4

CERTAIN COVENANTS

Section 4.1 Access to Information; Books and Records.

(a) From and after the Closing, each Party shall promptly afford the other Party and such other Party's respective agents reasonable access to such Party's books and records, information, employees and auditors related to the Transferred Assets and Assumed Liabilities to the extent necessary or useful for such Party in connection with any audit, investigation, dispute or Litigation related to the Business unless it is related to an audit, investigation, dispute or Litigation between Buyer and Seller; provided that such Party agrees to reimburse the other Party promptly for all reasonable and documented out-of-pocket costs and expenses incurred in connection with any such request.

(b) Notwithstanding anything to the contrary in Section 4.1(a) (*Access to Information; Books and Records*), (i) access rights pursuant to Section 4.1(a) (*Access to Information; Books and Records*) shall be exercised in such manner as not to interfere unreasonably with the conduct of the Business or any other business of the Party granting such access, and (ii) the Party granting access to the other Party may withhold any document (or portions thereof) or information (A) that is subject to the terms of a non-disclosure agreement with a Third Party, (B) that may constitute privileged attorney-client communications or attorney work product and the transfer of which, or the provision of access to which, as reasonably

determined by such Party's counsel, constitutes a waiver of any such privilege or (C) if the provision of access to such document (or portion thereof) or information, as determined by such Party's counsel, would reasonably be expected to conflict with applicable Laws.

Section 4.2 Confidentiality.

(a) Each of Buyer and Seller acknowledges that the information provided to them in connection with this Agreement and the consummation of the transactions hereunder is subject to the terms of the Confidentiality Agreement. Effective upon, and only upon, the Closing, the Confidentiality Agreement shall terminate with respect to information included in or related to the Transferred Assets.

(b) From and after the Closing, Seller and Selling Affiliates shall, and shall cause their respective Affiliates and representatives to, maintain in confidence any written, oral, or other information relating to the Business (including all Transferred Know-How and Data included therein) ("**Confidential Business Information**"), and Seller and Selling Affiliates shall not disclose to any Third Party or use for any purpose such Confidential Business Information without the Buyer's prior written consent; provided, however, that Confidential Business Information will not include information that Seller or the applicable Selling Affiliate can demonstrate with documentary evidence that such information (i) is publicly available other than as a result of a disclosure by the Seller or Selling Affiliate or any of its officers, directors, managers, employees, agents or other representatives in violation of this Section 4.2 (*Confidentiality*), (ii) is obtained by the Seller or any Selling Affiliate or their respective representatives after the Closing from a Third Party that, at such time, was not under a legal, contractual or fiduciary duty of confidentiality with respect to such information, or (iii) was independently developed by the Seller or the Selling Affiliates after the Closing without reference to or use of any Transferred Know-How or other confidential information in relation to the Transferred Assets. Notwithstanding the foregoing, Seller and Selling Affiliates may disclose Confidential Business Information to the extent (x) it is required to be disclosed pursuant to Law or any listing agreement with or the rules of any applicable securities exchange, or (y) it is required to disclose such information by judicial order or administrative process or pursuant to applicable Law; provided that Seller (A) notifies Buyer of the disclosure requirement promptly after Seller becomes aware of the judicial order or other requirement (unless such notification would be unlawful); (B) cooperates with Buyer in seeking a protective order or similar relief to protect the confidentiality of the information to be disclosed (in each case at the expense of Buyer); and (C) limits the disclosure to what is requested by the judicial order or other requirement. Notwithstanding the foregoing, Seller may retain one (1) copy of Confidential Business Information in its confidential files for archival or compliance purposes and may retain such additional copies of or any computer records or files containing Confidential Business Information or any of its Affiliates' confidential information that have been created solely by automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with the Seller's standard archiving and back-up procedures, but not for any other use or purpose. All such Confidential Business Information shall continue to be subject to the terms of this Agreement.

(c) Subject to the foregoing, after the Closing and following transfer of the Transferred Assets and Assumed Liabilities in accordance with this Agreement, each Party shall, and shall cause its Affiliates and representatives to, promptly (and in any event within [**] after the Closing) remove, erase, delete or otherwise destroy (i) all information of or relating to the other Party (other than, with respect to Buyer, information relating to the Business, including any Transferred Assets or Assumed Liabilities) (whether in print, electronic or other forms) in the possession of any of its representatives and (ii) in the case of Selling Affiliates, all Confidential Business Information; in each case ((i) and (ii)), provided that, subject to Section 4.2(b) (*Confidentiality*), Seller and the Selling Affiliates shall have the right to retain copies of all

books, data, files, information and records of the Business in any media (including, for the avoidance of doubt, Tax Returns and other information and documents relating to Tax matters, provided that Tax Returns relating solely to the Transferred Assets or the Business will be Transferred Assets) (other than any trade secrets and technical or scientific information included in the Transferred Know-How) relating to periods ending on or prior to the Closing Date (i) as may be required by any Governmental Authority or (ii) as may be necessary for Seller or the Selling Affiliates to perform their respective obligations pursuant to this Agreement or any of the Ancillary Agreements, in each case subject to compliance with all applicable privacy Laws.

Section 4.3 Public Announcement.

(a) No Party to this Agreement shall originate any publicity, news release or other similar public announcement or disclosure, written or oral, relating to this Agreement or any documents or transactions contemplated hereby or the existence of any arrangement between the Parties, without the prior written consent of the other Party (not to be unreasonably withheld, conditioned, or delayed) whether or not named in such publicity, news release or other similar public announcement, except (a) each Party may issue a press release to announce the execution of this Agreement in a form agreed to the other Party (such agreement not to be unreasonably, withheld, conditioned, or delayed) and (b) either Party may originate any such publicity, news release or other similar public announcement as may be required by Law or any listing or trading agreement concerning its publicly traded securities; provided that, in such event, the issuing Party shall still be required to consult with the other Party, whether or not named in such publicity, news release or other similar public announcement, at least [**] prior to its release (or such shorter period as may be reasonable under the circumstances) to allow the other Party to comment thereon; provided, further, that if such non-issuing Party shall not have provided its consent to the issuing Party's request for consent and/or consultation pursuant to the foregoing after [**] (or such shorter period as may be reasonable under the circumstances), then the issuing Party shall be deemed to have fulfilled its obligations pursuant to this Section 4.3 (*Public Announcement*) and shall be free to issue such publicity, news release or other similar public announcement, and each Party may each disclose to Third Parties any information contained in a previously approved press release without the need for further approval by the other Party.

(b) Without limiting the foregoing, following the Closing, if Buyer intends to issue any such public news release or other similar public announcement or disclosure, whether written or oral, with respect to (i) the achievement of any Development and Regulatory Milestone Event or Commercial Milestone Event, (ii) disclosure of top line data from a study conducted by Buyer or its Affiliates or (Sub)licensees that is intended to support initial regulatory approval of, or a new indication for, any Product, (iii) unknown adverse events related to any Products, (iv) the receipt of Regulatory Approval of any Product, (v) the commercial launch of any Product, or (vi) ceasing all development and commercialization activities related to any Product, in each case, solely with respect to the development, commercialization, or other exploitation of a Product in any of [**], then, in each case, Buyer will, to the extent legally permitted, notify Seller of such disclosure at least [**] prior to the anticipated date of such public disclosure. Notwithstanding the foregoing, Buyer will not be required to notify Seller of any public disclosure (A) set forth in any ordinary course registration statement, form, report, schedule, statement, exhibit or other document (including exhibits, financial statements and schedules thereto and all other information incorporated therein and amendments and supplements thereto, but for clarity excluding reports on form 8-K) required to be filed or furnished by Buyer to the Securities and Exchange Commission pursuant to the Exchange Act or the Securities Act of 1933, as amended, or (B) contained in a previously approved public announcement or disclosure.

(c) If Buyer or Seller, based on the advice of its counsel, determines that this Agreement, or any of the Ancillary Agreements, must be publicly filed with a Governmental

Authority, then Seller or Buyer, prior to making any such filing, shall provide the other Party and its counsel with a redacted version of this Agreement (and any other Ancillary Agreement) which it intends to file, and will give due consideration to any comments provided by such Party or its counsel and use commercially reasonable efforts to ensure the confidential treatment by such Governmental Authority of those sections specified by such Party or its counsel.

Section 4.4 Shared Contracts. The Parties desire for the benefit of Seller and Buyer, respectively, to have and obtain the rights and benefits under each Shared Contract set forth on Section 9.1(b)(vi) of the Seller Disclosure Letter. Following the Closing, Buyer shall elect what Shared Contracts it desires to obtain the rights and benefits under, including, to the extent permissible and practicable, through partial assignment of the applicable portions of such Shared Contracts, and the Parties shall cooperate with each other to provide Seller and the Selling Affiliates and Buyer and its Affiliates with their applicable rights and benefits under each such Shared Contract *first*, by effecting a partial assignment of such Shared Contract; provided that Seller will use commercially reasonable efforts to obtain any required counterparty consent to effect such partial assignment, or, if unable to effect such partial assignment, *second*, by assisting Buyer in entering into a new Contract or Contracts with the applicable Third Party on substantially similar terms (a "**Separated Contract**"). Without limiting the foregoing, the Parties will reasonably cooperate to contact the Third Party counterparty to (A) each Shared Contract to the extent it is still in effect and has not been concluded with respect to the Transferred Assets, within [**] following the Closing, and (B) any other Shared Contract, including any Shared Contract that is no longer in effect or has been concluded with respect to the Transferred Assets, to the extent requested by Buyer, within [**] following Seller's receipt of such request, in each case, to notify such Third Party of Buyer's purchase of the Transferred Assets and to notify such Third Party that it may interact with the Buyer regarding such Shared Contract to the extent it relates to the Acquired Molecules, Acquired Products, or Transferred Assets, and only with respect to the applicable parts and provisions of such Shared Contract. Buyer acknowledges that, with respect to subclause (B) in the foregoing sentence, reasonable cooperation by Seller may be limited by the availability of current contact information for any applicable Third Party. The Third Party costs of entering into a new Contract or Contract(s) shall be borne by Buyer. If any Shared Contract set forth on Section 9.1(b)(vi) of the Seller Disclosure Letter cannot be partially assigned or separated into a Separated Contract following Closing, then Seller and Buyer shall, and shall cause each of their respective Affiliates to, use their commercially reasonable efforts to cause, for the period after the Closing until such Shared Contract is separated into a Separated Contract, (i) the rights and benefits under each Shared Contract to the extent relating to the Business to be enjoyed by Buyer; (ii) the liabilities under each Shared Contract to the extent relating to the Business after Closing to be borne by Buyer; (iii) the rights and benefits under each Shared Contract to the extent relating to any business other than the Business to be enjoyed by Seller; and (iv) the liabilities under each Shared Contract to the extent relating to either (a) the Business before Closing or (b) any business other than the Business, in each case, to be borne by Seller. If and to the extent that a Shared Contract set forth on Section 9.1(b)(vi) of the Seller Disclosure Letter contains a separate and severable agreement, statement of work, purchase order, or other distinct component that (a) relates solely to the Acquired Molecules, Acquired Products, or Transferred Assets and (b) is capable of being independently assigned without breaching or otherwise affecting the remaining portions of such Shared Contract, then, upon the valid assignment of such separate and severable portion to Buyer, such portion shall be deemed a Transferred Contract for all purposes hereunder.

Section 4.5 Further Assurances. From time to time after the Closing Date, at the reasonable request of a Party, without further consideration and at the expense of the Party so requesting, the other Party shall execute and deliver to such requesting Party, or shall cause to be executed and delivered to such requesting Party, such additional instruments or documents, and shall take or cause to be taken such other action, as such requesting Party may reasonably request in order to consummate more effectively the transactions contemplated by this Agreement. Seller

shall, execute and deliver, or cause to be executed and delivered, to Buyer any confirmatory assignment, invention assignment, inventor's declaration, or other documentation, and provide, or cause to be provided, any good faith testimony (by affidavit, declaration, or in person), in each case, as reasonably necessary or desirable to complete the chain-of-title of the Transferred IP to Seller and then, in accordance with to this Agreement, to Buyer and to otherwise perfect, defend, or enforce Buyer's rights, title, and interests in and to the Transferred IP (including all inventions claimed or disclosed in the Transferred Patent Rights).

Section 4.6 Insurance. The coverage under all insurance policies related to the Business and arranged or maintained by Seller or the Selling Affiliates following Closing is only for the benefit of Seller and the Selling Affiliates, and not for the benefit of Buyer or the Business. As of the Closing Date, Buyer agrees to arrange for its own insurance policies with respect to the Business and agrees not to seek, through any means, to benefit from any of Seller's or the Selling Affiliates' insurance policies which may provide coverage for claims relating in any way to the Business following the Closing.

Section 4.7 Wrong Pockets. For a period of up to [**] after the Closing Date, if either Buyer or Seller becomes aware that (w) any of the Transferred Assets has not been transferred to Buyer, (x) any of the Excluded Assets has been transferred to Buyer, (y) any Contract relating solely to the operation and conduct of the Business, the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product, or any of the Transferred Assets was not included in Section 9.1(a)(vi) of the Seller Disclosure Letter, or (z) any Shared Contract that has not been, or attempted to be, assigned-in-part to Buyer or separated into a Separated Contract, in each case, it shall promptly notify the other and the Parties shall, as soon as reasonably practicable and, subject to Section 1.1(e) (*Business Transfer Documents*), cause such property to be:

(a) upon the written request of the Buyer, and with any necessary prior Third Party consent or approval, transferred to Buyer, in the case of any Transferred Asset that was not transferred to Buyer at the Closing;

(b) with any necessary prior Third Party consent or approval, transferred to Seller, in the case of any Excluded Asset that was transferred to Buyer at or after the Closing;

(c) upon the written request of the Buyer, and with any necessary prior Third Party consent or approval, transferred to Buyer, in the case of any Contracts described in clause (y) above; or

(d) upon the written request of the Buyer, in the case of Contracts described in clause (z) above, assigned-in-part to Buyer or separated into a Separated Contract, in each case, in accordance with Section 4.4 (*Shared Contracts*).

Section 4.8 Transfer Plan; Transition Assistance. Following the Closing, Seller shall (a) conduct certain transfer and transition activities to transfer the Transferred Assets to and transition the Acquired Program to Buyer as set forth in the transfer plan on Exhibit D the ("**Transfer Plan**"), and (b) upon Buyer's reasonable written request following Closing, provide reasonable assistance to Buyer and the other Buyer Parties in connection with understanding and using the Transferred Assets and conducting the Business, including making appropriate full-time employees of Seller available to assist Buyer or its designee from time to time as reasonably requested by Buyer (such assistance, the "**Transition Assistance**"). Seller shall provide Buyer with access to the Data Room for at least [**] following the Closing and allow Buyer to download all of the contents of the Data Room. If and to the extent Seller provides the Buyer Parties (i) more than [**] hours of Transition Assistance but not more than [**] hours of Transition Assistance, in the aggregate, pursuant to this Section 4.8 (*Transfer Plan; Transition*

Assistance), then Buyer will reimburse Seller for the cost of its employees' performance of such additional Transition Assistance at [**], and (ii) more than [**] hours of Transition Assistance, in the aggregate, then Buyer will reimburse Seller for the cost of its employees' performance of such additional Transition Assistance at the Hourly Rate. The total hours of Transition Assistance provided by Seller pursuant to this Section 4.8 (*Transfer Plan; Transition Assistance*) shall not exceed [**] hours in the aggregate. If applicable, Seller shall invoice Buyer for any such additional Transition Assistance provided at [**] thereof, as applicable, and Buyer shall pay all such undisputed amounts within [**] after receipt of an applicable invoice from Seller. Notwithstanding anything herein to the contrary, Buyer shall reimburse Seller for any reasonable and documented out-of-pocket costs, including fees payable to consultants, that Seller incurs in connection with any Transition Assistance; provided, that Seller shall not incur any such out-of- pocket costs without the prior written consent of Buyer; and provided further that any such services provided by consultants and reimbursed by Buyer will not count towards the hourly limits in the third sentence of this Section 4.8 (*Transfer Plan; Transition Assistance*). Seller shall invoice Buyer for any such out-of-pocket costs, and Buyer shall pay all such undisputed amounts within [**] after receipt of an applicable invoice from Seller. If any Know-How is created by or on behalf of Seller or any Selling Affiliate, solely or jointly, in the conduct of activities set forth in the Transfer Plan or otherwise pursuant to this Section 4.8 (*Transfer Plan; Transition Assistance*), then, if such Know-How primarily relates to an Acquired Molecule or Acquired Product, such Know-How will be deemed to be Transferred Know-How for the purposes of this Agreement and will be owned by Buyer and, [**].

Section 4.9 License. Effective as of the Closing and subject to the terms, conditions, and provisions of this Agreement, Buyer hereby grants to Seller, and Seller hereby accepts, a non- transferable, non-exclusive license, with the right to grant sublicenses solely to Seller's applicable Affiliates, under the Transferred Assets, solely for the purposes of during the applicable term of the Ancillary Agreements, performing Seller's obligations under such Ancillary Agreements and under the Transfer Plan.

Section 4.10 [**].

[**].

Section 4.11 Payments from Third Parties; Correspondence.

(a) Except as expressly provided in any Ancillary Agreement, in the event that, on or after the Closing Date, either Party receives from a Third Party any payments or other funds due to the other pursuant to the terms of this Agreement or of any Ancillary Agreement, then the Party receiving such funds shall promptly forward such funds to the other Party. The Parties acknowledge and agree there is no right of offset regarding any such payments, and a Party may not withhold any such funds received from a Third Party for the account of the other Party in satisfaction of any claim or dispute pursuant to this Agreement or any Ancillary Agreement. For purposes of this Agreement, any payments or other funds received by Buyer or any of its Affiliates from a Third Party in respect of any Product(s) shall first be applied against any outstanding receivable held by Seller or any applicable Selling Affiliate in respect of such Product(s) for any period prior to Closing and only after all such receivables have been satisfied shall any payments or other funds received by Buyer or any of its Affiliates from a Third Party in respect of any Product(s) be deemed in respect of receivables for any period after the Closing.

(b) From and after the Closing until the [**] of the Closing Date, (i) Seller shall use commercially reasonable efforts to cause to be delivered to Buyer any mail or other communications received by Seller or any of the Selling Affiliates from any Person in respect of any Product with respect to the period after the Closing and (ii) Buyer shall use commercially

reasonable efforts to cause to be delivered to Seller or its applicable Selling Affiliate any mail or other communications received by Buyer or its Affiliates from any Person either intended for Seller or any of the Selling Affiliates and not related to any Product or Transferred Asset or regarding any Product or Transferred Asset with respect to the period prior to the Closing. The provisions of this Section 4.11(b) (*Payments from Third Parties; Correspondence*) are not intended to, and shall not be deemed to, constitute an authorization by any of Seller or Buyer to permit the other to accept service of process on its behalf and neither Seller nor Buyer are or shall be deemed to be the agent of the other for service of process purposes.

Section 4.12 Use of Trademarks. Neither Party nor any of its Affiliates shall use in any manner any Trademark or trade dress of the other Party or any of its Affiliates.

Section 4.13 Mutual Non-Solicitation. From and after the Closing Date, Seller and Buyer each agree that they shall not, and they shall each cause their respective Subsidiaries and Affiliates to not, for a period of [**] after the Closing Date, directly or indirectly, encourage, induce, or solicit (a) in the case of Seller, any employee of Buyer to leave employment with Buyer or any of its Affiliates or (b) in the case of Buyer, any employee of Seller or any of the Selling Affiliates who as of the Closing Date provided services to the Business; provided, that this clause shall not preclude Seller, Buyer or any of their respective Subsidiaries or Affiliates from (i) posting a general solicitation through a public medium or general or mass mailing by or on behalf of Seller, Buyer or any of their respective Subsidiaries or Affiliates, as applicable, that is not targeted at employees of such other Party or (ii) soliciting any former employee of such other Party.

Section 4.14 Competition.

(a) Seller acknowledges and agrees that, subject to the remainder of this Section 4.14 (*Competition*), during the Exclusive Period, Seller and its Affiliates shall not, directly or indirectly, by itself or for or with any Third Party, research, develop, manufacture, or commercialize [**], in the Field in the Territory.

(b) The Parties hereby acknowledge and agree that Section 4.14(a) (*Competition*) shall not apply to any activities intended by Seller or any of its Affiliates to ensure its compliance with this Section 4.14 (Competition) (e.g., counter screening).

(c) Notwithstanding anything to the contrary in this Section 4.14 (*Competition*), if a Change of Control occurs with respect to Seller or any of its Affiliates with an Acquirer, and the Acquirer (or any of such Acquirer's successors or assigns, other than Seller and its Affiliates as of the Change of Control) [**] a program or product (or rights thereto) that would otherwise violate Section 4.14(a) (*Competition*) (each, an "**Seller COC Program**"), then (i) Section 4.14(a) (*Competition*) will not apply with respect to such Seller COC Program, and (ii) such Third Party, or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, as applicable, will be permitted to pursue, and continue such Seller COC Program after such Change of Control and such pursuit and continuation will not constitute a violation of Section 4.14(a) (*Competition*); provided that such Third Party or any of such Third Party's Affiliates (including Seller and Selling Affiliates) or any or any successors or assigns of such Third Party or such Third Party's Affiliates, as applicable, will (A) not use any Transferred Know-How or other confidential information of Buyer or the Buyer Parties, or otherwise practice, use, or exploit any Transferred Assets in connection with such Seller COC Program and (B) Segregate the Seller COC Program from the Transferred Assets.

(d) In addition, notwithstanding Section 4.14(a) (*Competition*), if (i) Seller or its Affiliate acquires a Third Party (by merger, sale, consolidation, reorganization, or otherwise)

so that such Third Party becomes an Affiliate over which Seller or its Affiliate has control, or (ii) Seller or its Affiliate acquires all or substantially all of the assets of a Third Party (including any subsidiaries or divisions thereof) (each of (i) and (ii), a "**Seller Acquisition**"), and, in each case, the Third Party (or any of such Third Party's Affiliates or any successors or assigns of such Third Party or such Third Party's Affiliates, other than Seller and its Affiliates as of the Seller Acquisition) already has, or the acquired assets contain, as applicable, a program or product that existed prior to the Seller Acquisition that would otherwise violate Section 4.14(a) (a "**Seller Acquisition Program**"), then Seller or such Affiliate will elect whether to (A) divest its rights to such Seller Acquisition Program, or (B) cease the development or commercialization of such Seller Acquisition Program, and will provide Buyer written notice of the existence of such Seller Acquisition Program and such decision within [**] after the closing of such Seller Acquisition. If Seller provides notice as described in clause (A) of the preceding sentence, then Seller, and its Affiliates if applicable, will divest such Seller Acquisition Program within [**] after the closing of the applicable Seller Acquisition, and if Seller provides notice that it will terminate such Seller Acquisition Program as described in clause (B) of the preceding sentence, then Seller, and its Affiliates if applicable, will (1) cease the development and commercialization of such Seller Acquisition Program as soon as reasonably practicable and in any event within [**] of the closing of the applicable Seller Acquisition, giving due consideration to ethical concerns and requirements under applicable Law and any agreements with Third Parties and (2) until such Seller Acquisition Program can be divested or terminated, (x) not use any Transferred Know-How or other confidential information of Buyer or the Buyer Parties, or otherwise practice, use, or exploit any Transferred Assets in connection with such Seller Acquisition Program, and (y) Segregate the Seller Acquisition Program from the Transferred Assets.

(e) The restrictions set forth in Section 4.14(a) (*Competition*) shall no longer apply to Seller and its Affiliates upon the earliest to occur of (i) Buyer's public announcement that it is permanently abandoning all development and commercialization of all Products, and (ii) Seller's receipt of written notice from Buyer that, consistent with Buyer's use of Commercially Reasonable Efforts, Buyer has made the determination to permanently abandon all exploitation of all Products. Buyer shall promptly notify Seller in writing following any determination by Buyer to permanently abandon all exploitation of all Products. In addition, the restrictions set forth in Section 4.14(a) (*Competition*) shall cease to apply to Seller and its Affiliates in the event that Buyer's fails to perform and satisfy its undisputed payment obligations under this Agreement for as long as such breach remains uncured.

Section 4.15 Transferred Patent Rights; Negative Covenant. Buyer acknowledges and agrees that the execution and delivery of this Agreement will provide the Buyer Parties with unrestricted rights to use and exploit the Transferred Patent Rights only in connection with the development, manufacture, promotion, marketing, distribution and/or sale of any Acquired Molecule or any Acquired Product and no other compound or product, including, for clarity, any [**]. Buyer hereby covenants and agrees not to, and shall cause the other Buyer Parties not to, practice any (a) Transferred Patent Right or (b) Patent Right licensed under the A&R License Agreement, in each case ((a) and (b)), to develop, manufacture, promote, market, distribute, or sell any compound or product other than an Acquired Molecule or Acquired Product.

Section 4.16 Maintenance and Enforcement of the Transferred Patent Rights. Following the Closing, Buyer shall either (a) not disclaim, allow to lapse, abandon, or terminally disclaim or fail to take any action necessary or desirable to prevent the disclaimer, lapse or abandonment of, an issued Patent Right in the Transferred Patent Rights if such issued Transferred Patent Right is the only remaining Transferred Patent Right with a Valid Claim that Covers the sale of a Product in a country (except for good faith abandonment in the ordinary course of prosecution) or (b) if Buyer does disclaim, allow to lapse, abandon, or terminally disclaim or fail to take any action necessary or desirable to prevent the disclaimer, lapse or abandonment of such issued Transferred Patent Right (except for good faith abandonment in the ordinary course of

prosecution), the Buyer will continue to pay Royalties on Net Sales of Products in such country as if such Transferred Patent Right continued to be issued until such time such Transferred Patent Right would have expired but for such action by Buyer.

Section 4.17 Transferred Materials. At or as promptly as practicable following the Closing and as set forth under Annex 9.1(a)(v), Seller shall cause the Transferred Materials to be made available for delivery to Buyer from Seller's or its applicable vendor, by Buyer or its carrier and at Buyer's cost and expense.

ARTICLE 5

TAX MATTERS

Section 5.1 Tax Allocation. In the case of any Taxes that are imposed on a periodic basis and are payable for a Straddle Period, the portion of such Tax that relates to the portion of the Straddle Period ending on the Closing Date shall (a) in the case of any Taxes other than Taxes based upon or related to income, gains or receipts, sales or use, employment, withholding, transaction-based Taxes, or similar items, be deemed to be the amount of such Tax for the entire Straddle Period multiplied by a fraction, the numerator of which is the number of calendar days from the beginning of such Straddle Period through the Closing Date and the denominator of which is the number of calendar days in the entire Straddle Period, and (b) in the case of any Tax based upon or related to income, gains or receipts, sales or use, employment, withholding, withholding- based Taxes, or similar items, be deemed equal to the amount of Tax which would be payable if the relevant Tax period ended on the Closing Date. Any Tax refunds or credits for overpayment for a Straddle Period shall be determined in a manner consistent with this Section 5.1 (*Tax Allocation*), and any such amounts that relate to a Pre-Closing Tax Period (or are otherwise described in Annex 9.1(b)(x)) shall be for the account of Seller. Buyer shall, or shall cause its Affiliates, to promptly remit to Seller the net amount of any such refund (or any other amounts described in Annex 9.1(b)(x)), net of any out of pocket costs or expenses of Buyer or its Affiliates on obtaining, receiving, or paying over any such refund.

Section 5.2 Cooperation. Each of Buyer and Seller shall provide the other with such information and records, and make such of its officers, directors, employees and agents available, as may reasonably be requested by such other Party in connection with the preparation of any Tax Return or the conduct of any Tax Proceeding of the Transferred Assets for any Pre-Closing Tax Period or a Straddle Period.

Section 5.3 Contingent Consideration. The Parties agree for all U.S. Tax purposes that the Contingent Consideration shall be treated as deferred contingent purchase price eligible for installment sale treatment under Section 453 of the Code and any corresponding provision of state and local or non-U.S. Law (subject to any imputation of interest under Section 483 or Section 1274 of the Code). The Parties shall file all Tax Returns consistent with the foregoing.

ARTICLE 6

INDEMNIFICATION

Section 6.1 Survival. All representations and warranties made in this Agreement shall survive the Closing Date for a period of [**] after the Closing Date; provided that the representations and warranties of Seller set forth in [**] (collectively, the "**Fundamental Representations**") and [**] shall survive until [**] following the expiration of the applicable statute of limitations. The respective covenants and agreements of Seller and Buyer contained in this Agreement contemplated or required to be performed or complied with from and after the Closing (each, a "**Post-Closing Covenant**") shall survive the Closing Date hereunder for such

period of time as may be specified therein, but in no event will Buyer be permitted to bring an indemnity claim with respect to any breach of a Post-Closing Covenant after the expiration of the applicable statute of limitations. An Indemnifying Party shall have no indemnification obligation in respect of claims made pursuant to this Article 6 unless the Indemnified Party gives written notice of the claim to the Indemnifying Party in accordance with the procedures set forth in this Agreement on or prior to the expiration of the applicable survival period. If the Indemnified Party delivers such written notice of a claim on or prior to the expiration of the applicable survival period, then the Indemnifying Party's indemnification obligations shall continue with respect to such claim until the final resolution and satisfaction of such claim in accordance with the provisions of this Article 6.

Section 6.2 Indemnification by Seller. From and after the Closing, and subject to this Article 6, Seller shall defend, indemnify and hold harmless Buyer, and each of its Subsidiaries and Affiliates, and their respective officers, directors, employees, agents, successors and assigns (collectively, the "**Buyer Indemnitees**") from and against, and pay or reimburse the Buyer Indemnitees for all Losses resulting from (a) any inaccuracy in or breach of any representation or warranty by Seller set forth in this Agreement, (b) any breach or default in performance by Seller of any Post-Closing Covenant of Seller, (c) the ownership and operation of the Transferred Assets and the Business prior to the Closing Date, and (d) any Excluded Liability. Notwithstanding that a claim for Losses may fall into multiple categories of this Section 6.2 (*Indemnification by Seller*), Buyer Indemnitees may recover such Losses only one time.

Section 6.3 Indemnification by Buyer. From and after the Closing, and subject to this Article 6, Buyer shall defend, indemnify and hold harmless Seller and each of its Subsidiaries and Affiliates and their respective officers, directors, employees, agents, successors and assigns (collectively, the "**Seller Indemnitees**") from and against, and pay or reimburse the Seller Indemnitees for, any and all Losses resulting from (a) any inaccuracy in or breach of any representation or warranty by Buyer set forth in this Agreement, (b) any breach or default in performance by Buyer of any Post-Closing Covenant of Buyer, (c) the ownership and operation of the Transferred Assets and the Business after the Closing and (d) the Assumed Liabilities. Notwithstanding that a claim for Losses may fall into multiple categories of this Section 6.3 (*Indemnification by Buyer*), Seller Indemnitees may recover such Losses only one time.

Section 6.4 Limitations on Indemnity. Buyer and Seller agree, for themselves and on behalf of the Buyer Indemnitees and the Seller Indemnitees, respectively, that:

(a) Except in the case of fraud, no Buyer Indemnitee will assert any claims for, nor shall any Buyer Indemnitee be entitled to, indemnification under Section 6.2(a) (*Indemnification by Seller*) until such time as the aggregate of all Losses that Buyer Indemnitees may have under Section 6.2(a) (*Indemnification by Seller*) exceeds $[**] (*i.e.,* [**]) (the "**Indemnity Threshold**"), at which time the Buyer Indemnitees may assert claims for all Losses. The aggregate liability of Seller in respect of claims for indemnification pursuant to Section 6.2(a) (*Indemnification by Seller*) will not exceed $[**] (*i.e.,* [**]) (the "**Upfront Cap**"). Notwithstanding the foregoing, to the extent that Buyer Indemnitees have Losses for which it is entitled to indemnification under Section 6.2(a) (*Indemnification by Seller*) in excess of the Upfront Cap up to a total of $[**] (*i.e.,* [**]) (such excess the "**Excess Indemnifiable Losses**"), any Buyer Indemnitee may assert a claim against Seller for such Excess Indemnifiable Losses and/or may offset or recover from Seller such Excess Indemnifiable Losses against any Development and Regulatory Milestone Payments, Commercial Milestone Payments, Royalty, or (Sub)license Income owed by Buyer to Seller under this Agreement after, with respect to the Royalties, the application of all other reductions applicable pursuant to Section 1.4(c)(iv) (*Royalty Reductions*), but in each case, only to the extent provided in Section 6.4(b) (*Limitations on Indemnity*).

(b) To the extent a Buyer Indemnitee asserts a claim against Seller for Excess Indemnifiable Losses, Seller will not be required to pay or reimburse any Excess Indemnifiable Losses to the extent that such Excess Indemnifiable Losses exceed an amount equal to [**] actually received by Seller as of the time such Excess Indemnifiable Losses are payable to the Buyer Indemnitees. To the extent any Excess Indemnifiable Losses are not paid or reimbursed by Seller, whether as a result of the foregoing limitation or otherwise, Buyer may offset them in accordance with this Section 6.4(b) (*Limitations on Indemnity*) against subsequent future Development and Regulatory Milestone Payments, Commercial Milestone Payments, Royalties, or (Sub)license Income payments owed by Buyer to Seller until exhausted; provided, that, no Development and Regulatory Milestone Payment, Commercial Milestone Payment, Royalty, or (Sub)license Income payment will be reduced by more than [**] relative to what it otherwise would have been absent the reductions in this Section 6.4(b) (*Limitations on Indemnity*). If and to the extent that any Excess Indemnifiable Losses are not either paid by Seller or offset against any Development and Regulatory Milestone Payments, Commercial Milestone Payments, Royalties, or (Sub)license Income payment as a result of the foregoing limitation, then Buyer may carry forward and offset such amounts against future Development and Regulatory Milestone Payments, Commercial Milestone Payments, Royalties, or (Sub)license Income payments otherwise owed by Buyer to Seller (subject to the foregoing [**] per-payment reduction limit) until exhausted.

(c) Notwithstanding anything to the contrary set forth herein, the provisions of Section 6.4(a) (*Limitations on Indemnity*) will not apply in respect of claims for breach of any Fundamental Representation or fraud; provided that in no event shall the aggregate liability of Seller in respect of claims for indemnification pursuant to Section 6.2(a), Section 6.2(b) and Section 6.2(c) (*Indemnification by Seller*) exceed the Purchase Price actually received by Seller, other than for fraud.

(d) No Buyer Indemnitee shall be entitled to indemnification, to sue for damages or to assert any other right or remedy under this Agreement with respect to any Loss, cause of action or other claim to the extent it (i) is a potential Loss that may be asserted rather than an actual Loss that has, in fact, been incurred by such Party or (ii) is a Loss with respect to which such Party or any of its Affiliates has taken action (or caused action to be taken) to accelerate the time period in which such matter is asserted or payable. Notwithstanding the foregoing, pursuant to Section 6.1 (*Survival*) above, if a written notice of any claim for indemnification hereunder has been delivered in accordance with this Agreement prior to the expiration of the applicable survival period set forth above, the indemnification obligations of Buyer Indemnitee shall continue with respect to such claim until the final resolution and satisfaction of such claim in accordance with the provisions of this Article 6.

(e) No Buyer Indemnitee shall be entitled to recover any amount relating to any matter arising under one provision of this Agreement to the extent such Buyer Indemnitee has already recovered such amount with respect to such matter pursuant to such provision or any other provisions of this Agreement.

(f) With respect to each indemnification obligation in this Agreement: (i) in no event shall an Indemnifying Party have liability to the Indemnified Party for damages that are waived pursuant to Section 8.4(c) (*Waiver of Certain Damages*); and (ii) the Parties shall treat any indemnification payment made under this Agreement as an adjustment to the Upfront Consideration, or Development and Regulatory Milestone Payments, Commercial Milestone Payments, or Royalties, or (Sub)license Income (as applicable).

(g) If the Indemnified Party receives any payment from an Indemnifying Party in respect of any Losses pursuant to Section 6.2 or Section 6.3 and the Indemnified Party could have recovered all or a part of such Losses from a Third Party (a "**Potential Contributor**")

based on the underlying claim asserted against the Indemnifying Party, the Indemnified Party shall assign such of its rights to proceed against the Potential Contributor as are necessary to permit the Indemnifying Party to recover from the Potential Contributor the amount of such payment.

(h) Any Indemnified Party shall take all commercially reasonable steps under applicable Law to mitigate any Losses incurred by such Party upon and after becoming aware of any event or condition that would reasonably be expected to give rise to any indemnification rights hereunder.

Section 6.5 Notification of Claims; Third Party Claims.

(a) A Person that may be entitled to be indemnified under this Agreement (the "**Indemnified Party**") shall promptly notify the Party or Parties liable for such indemnification (the "**Indemnifying Party**") in writing of any claim in respect of which indemnity may be sought under this Article 6 (*Indemnification*), describing in reasonable detail the facts and circumstances with respect to the subject matter of such claim; provided, however, that (i) the failure to provide such notice shall not release the Indemnifying Party from any of its obligations under this Article 6 (*Indemnification*) except to the extent the Indemnifying Party is prejudiced by such failure and (ii) the Indemnified Party will not be permitted to deliver a such notice (and will not be entitled to indemnification pursuant to this Article 6 (*Indemnification*)) with respect to breaches of a representation and warranty unless such notice is delivered prior to the expiration of any applicable survival period specified in Section 6.1 (*Survival*) for such representation or warranty.

(b) Upon receipt of notice of a claim for indemnity from an Indemnified Party pursuant to this Section 6.5 (*Notification of Claims; Third Party Claims*) in respect of a pending or threatened claim or demand by a Third Party that the Indemnified Party has determined has given or could reasonably give rise to a right of indemnification under this Agreement (such claim or demand being a "**Third Party Claim**" and including a pending or threatened claim or demand asserted by a Third Party against the Indemnified Party), the Indemnifying Party may, by notice to the Indemnified Party delivered within [**] of the receipt of notice of such Third Party Claim, assume the defense and control of such Third Party Claim, with its own counsel and at its own expense, but shall allow the Indemnified Party a reasonable opportunity to participate in the defense of such Third Party Claim with its own counsel and at its own expense. The Indemnified Party may take any actions reasonably necessary to defend such Third Party Claim prior to the time that it receives notice from the Indemnifying Party as contemplated by the preceding sentence. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party (which shall not be unreasonably withheld, conditioned, or delayed), consent to a settlement, compromise or discharge of, or the entry of any judgment arising from, any Third Party Claim. Without limitation, the Parties stipulate and agree that it would be reasonable for the Indemnified Party to withhold such consent if (i) the Indemnifying Party does not pay or cause to be paid all amounts arising out of such settlement, compromise, or judgment concurrently with its effectiveness, (ii) the settlement, compromise, or discharge judgment involves any finding or admission of any violation of Law or admission of any wrongdoing by the Indemnified Party, encumbers any asset of any Indemnified Party, or requires the Indemnified Party agree to any restriction or condition that would apply to or materially adversely affect any Indemnified Party, or (iii) the settlement, compromise, or judgment does not contain a complete and unconditional release of each Indemnified Party from any and all liability in respect of such Third Party Claim. The Indemnified Party shall not settle, compromise or consent to the entry of any judgment with respect to any claim or demand for which it is seeking indemnification from the Indemnifying Party or admit to any liability with respect to such claim or demand without the prior written consent of the Indemnifying Party.

(c) Notwithstanding anything to the contrary in this Article 6 (*Indemnification*) (including Section 6.2 (*Indemnification by Seller*) and Section 6.3 (*Indemnification by Buyer*)), no Indemnifying Party shall have any liability under this Article 6 (*Indemnification*) for any Losses arising out of or in connection with any Third Party Claim that is settled or compromised by an Indemnified Party without the prior written consent of such Indemnifying Party.

(d) In the event any Indemnifying Party receives notice of a claim for indemnity from an Indemnified Party pursuant to this Section 6.5 (*Notification of Claims; Third Party Claims*) that does not involve a Third Party Claim, the Indemnifying Party shall notify the Indemnified Party within [**] following its receipt of such notice whether the Indemnifying Party disputes its liability to the Indemnified Party under this Article 6 (*Indemnification*). The Indemnified Party shall reasonably cooperate with and assist the Indemnifying Party in determining the validity of any such claim for indemnity by the Indemnified Party.

Section 6.6 Exclusive Remedy. Notwithstanding any provision to the contrary in this Agreement, Seller and Buyer hereby agree that following the Closing, subject to Section 8.10 (*Specific Performance*), the sole and exclusive financial remedy of a Party for any breach or inaccuracy of any representation, warranty, covenant, or agreement contained in this Agreement shall be the indemnification rights set forth in this Article 6 (*Indemnification*), regardless of the legal theory under which any liability or obligation may be sought to be imposed, whether sounding in contract or tort, or whether at law or in equity, or otherwise. The Parties hereto agree that the provisions of this Agreement relating to indemnification, and the limits imposed on Buyer's and the Buyer Indemnitees' and Seller's and Seller Indemnities' rights and remedies with respect to this Agreement and the transactions contemplated hereby (including this Article 6 (*Indemnification*)) were specifically bargained for between sophisticated parties and were specifically taken into account in the determination of the amounts to be paid to Seller hereunder. Without limiting the generality of the foregoing, the Parties to this Agreement hereby irrevocably waive any right of rescission they may otherwise have or to which they may become entitled with respect to this Agreement and the transactions contemplated hereby.

ARTICLE 7

DEFINITIONS

Section 7.1 Certain Terms. The following terms have the respective meanings given to them below:

"**[**]**" means, [**].

"**[**]**" means, [**].

"**A&R License Agreement**" means that certain Amended and Restated Exclusive License Agreement between [**] and Buyer, dated as of the Closing Date.

"**Acquired Backup Molecule**" means each molecule described on Part C of Exhibit E.

"**Acquired Molecule**" means (a) ADX-097, (b) the Acquired Backup Molecules, or (c) any other molecule that includes, comprises or contains (i) an Antibody that directly binds to C3d, or a fragment or portion thereof and (ii) CFH (ENSG00000000971), or a fragment or portion thereof.

"**Acquired Product**" means, as of the applicable time, any product, in all forms, presentations, formulation, methods of administration and dosage forms, that includes, comprises or contains (a) ADX-097 or (b) any other Acquired Molecule that is owned or controlled by Seller or its Affiliates, in each case (a)-(b), including its peptide and nucleic acid sequences, and any fragments, variants and derivatives of, and modified (including post-translationally modified) forms of, the foregoing (in each case, alone or in combination with other active ingredients).

"**Acquired Program**" means the Seller's and the Selling Affiliates' program of research and development related to Acquired Molecules and Acquired Products.

"**Acquirer**" means, collectively, with respect to the acquisition of a Party by a Third Party, a Third Party referenced in the definition of Change of Control and such Third Party's Affiliates, other than the applicable Party in the definition of Change of Control and such Party's Affiliates (determined as of immediately prior to the closing of such Change of Control).

"**[**]**" means [**]

"**ADX-097**" means the molecule described on Part B of Exhibit E.

"**Affiliate**" means, with respect to any Person, any other Person that now or hereinafter controls, is controlled by, or is under common control with, such Person. For purposes of this definition, "control" shall mean direct or indirect ownership of at least fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest, in the case of any other type of legal entity, status as a general partner in any partnership or any other arrangement whereby the Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to direct the management and policies of a corporation or other entity. The Parties acknowledge that, in the case of entities organized under the laws of certain countries where the maximum percentage ownership permitted by law for a foreign investor is less than fifty percent (50%), such lower percentage shall be substituted in the preceding sentence; provided that such foreign investor has the power to direct the management and policies of such entity.

"**Agreement**" has the meaning set forth in the Preamble.

"**Ancillary Agreements**" means the (a) Business Transfer Documents, (b) the Assignment and Assumption Agreement, (c) the Bill of Sale, (d) the Patent Assignment, (e) the License Agreement Novation Agreement, and (f) all other agreements, documents and instruments executed and delivered in connection with the transactions contemplated by this Agreement.

"**Annual Net Sales**" means, on a Product-by-Product basis, the total Net Sales of such Product in a given Calendar Year.

"**Anti-Corruption Laws**" means the Foreign Corrupt Practices Act of 1977, as amended, the Anti-Kickback Act of 1986 or any applicable laws of similar effect, and the related regulations and published interpretations thereunder.

"**Antibody**" means an antibody or immunoglobulin molecule (whether human, murine, humanized, chimeric, monoclonal, polyclonal, full-length, functional fragment, or any other type of antibody or antibody derivative), whether multiple or single chain, recombinant or naturally occurring or a combination of the foregoing, whole or fragment.

"**Assignment and Assumption Agreement**" means that certain assignment and assumption agreement entered into by the Parties substantially in the form as attached as Exhibit A assigning the Assumed Liabilities to the Buyer.

"**Assumed Liabilities**" means the obligations and liabilities set forth or described on Annex 9.1(c).

"**Bill of Sale**" means that certain bill of sale entered into by the Parties substantially in the form as attached as Exhibit B transferring the tangible personal property included in the Transferred Assets to the Buyer.

"**Biosimilar Product**" means, with respect to a Product in a country, biologic product (a) whose licensing, approval, or marketing authorization relies in whole or in part on (i) a prior Regulatory Approval granted for such Product or (ii) any clinical data related to such Product generated for evidence of the safety and efficacy of such product, or (b) is determined by the applicable Regulatory Authority in such a country to be a biosimilar to or have no clinically meaningful differences from a Product, as set forth in 42 U.S.C. § 262(k)(4) in the United States, Section 10 of Directive 2001/83/EC in the European Union, or other applicable Law.

"**Business**" has the meaning set forth in the Recitals.

"**Business Day**" means any day that is not (a) a Saturday, (b) a Sunday or (c) any other day on which commercial banks are authorized or required by law to be closed in New York, New York or Boston, Massachusetts.

"**Business Transfer Documents**" has the meaning set forth in Section 1.1(e) (*Business Transfer Documents*).

"**Buyer**" has the meaning set forth in the Preamble.

"**Buyer Disclosure Letter**" means the letter, dated as of the date hereof, delivered by Buyer to Seller prior to the execution of this Agreement and identified as the Buyer Disclosure Letter.

"**Buyer Indemnitees**" has the meaning set forth in Section 6.2 (*Indemnification by Seller*).

"**Buyer Party**" means Buyer and its Affiliates and any (Sub)licensee.

"**Calendar Quarter**" means each of the three-month periods ending March 31, June 30, September 30 and December 31; provided that the first Calendar Quarter under this Agreement will extend from the Closing Date to the end of the then-current Calendar Quarter.

"**Calendar Year**" means the one (1) year period beginning on January 1 and ending on December 31; provided that the first Calendar Year under this Agreement will extend from the Closing Date to the end of the then-current Calendar Year.

"**Change of Control**" means, with respect to a Party (on a consolidated basis), that: (a) any Third Party acquires directly or indirectly the legal or beneficial ownership of any voting security of such Party, or if the percentage ownership of such Third Party in the voting securities of such Party is increased through stock redemption, cancellation, or other recapitalization, and immediately after such acquisition or increase such Third Party is, directly or indirectly, the legal or beneficial owner of voting securities representing more than fifty (50%) of the total voting power of all of the then outstanding voting securities of such Party or its ultimate parent, other than through issuances by Party of securities of such Party in a financing transaction or series of related financing transactions, (b) a merger, consolidation, recapitalization, or reorganization of such Party is consummated which results in shareholders or equity holders of such Party (or its ultimate parent) immediately prior to such transaction, no longer owning at least fifty (50%) of the outstanding voting securities of the surviving entity (or its parent entity) immediately following such transaction, or (c) there is a sale or transfer to a Third Party of all or substantially all of such Party's consolidated assets taken as a whole or substantially all of such Party's business or assets relates, through one or more related transactions.

"**Clinical Trial**" means any clinical investigation conducted on human subjects, as that term is defined in FDA regulations at U.S. 21 C.F.R. § 312.3, or a similar clinical investigation conducted on human subjects, as defined under applicable Law outside the United States, that is designed to generate data in support on an application or submission for a product filed with a Regulatory Authority in a country or group of countries to obtain Regulatory Approval for such product in such country or group of countries.

"**Closing**" has the meaning set forth in Section 1.2 (*Closing*).

"**Closing Date**" has the meaning set forth in Section 1.2 (*Closing*).

"**Code**" means the Internal Revenue Code of 1986, as amended.

"**Commercial Milestone Event**" has the meaning set forth in Section 1.4(b) (*Commercial Milestone Payments*).

"**Commercial Milestone Payment**" has the meaning set forth in Section 1.4(b) (*Commercial Milestone Payments*).

"**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Buyer Party with respect to the development of the Products, that level of efforts and resources commonly applied by biotechnology companies [**]. Seller acknowledges that [**].

"**Confidential Business Information**" has the meaning set forth in Section 4.2(b) (*Confidentiality*).

"**Confidentiality Agreement**" means the Confidential Disclosure Agreement, dated as of February 27, 2025, between Seller and Buyer.

"**Contract Expiration Date**" means, with respect to any Contract, the expiration date of the current term of such Contract, subject to any extensions pursuant to (iii) (*Transferred Assets Subject to Third-Party Consent*).

"**Contracts**" has the meaning set forth in clause (iv) of Annex 9.1(a).

"**Copyrights**" means copyrights and copyrightable works, including all rights of authorship, use, publication, reproduction, distribution, performance, transformation, moral rights and rights of ownership of copyrightable works, and all registrations and rights to register and obtain renewals and extensions of registration, together with all other interests accruing by reason of international copyright.

"**Cover**" or "**Covered by**" means, with respect to a Patent Right and a compound or product in a country, that, in the absence of ownership of or a license under such Patent Right, the manufacture, making, use, sale, offer for sale, or import of such compound or product in such country would infringe one or more Valid Claims of such Patent Right.

"**Data**" means all scientific data of any kind, including clinical and non-clinical data and data relating to chemistry, manufacturing, and controls.

"**Data Room**" means the electronic data room hosted by Progress Share File and entitled "[**]" that was provided by or on behalf of Seller to Buyer, which contains documents and materials relating to the Business, Acquired Molecules, and Acquired Products, as constituted as of 11:00 p.m. (Eastern time) [**] prior to of the Closing Date, the index of which is attached hereto as Exhibit I.

"**Determination Period**" has the meaning set forth in Section 1.10 (*Milestone Dispute Notice*).

"**Development and Regulatory Milestone Event**" has the meaning set forth in Section 1.4(a) (*Development and Regulatory Milestone Payments*).

"**Development and Regulatory Milestone Payment**" has the meaning set forth in Section 1.4(a) (*Development and Regulatory Milestone Payments*).

"**Development Plan**" has the meaning set forth in Section 1.9(a) (*Development Plan*).

"**Diligence Expiration Date**" has the meaning set forth in Section 1.8(a) (*Diligence Obligation*s).

"**Divested Assets**" has the meaning set forth in Section 8.6 (*Divestitures*).

"**Divestiture**" has the meaning set forth in Section 8.6 (*Divestitures*).

"**Eligible Offset Amount**" has the meaning set forth in Section 1.4(e) (*Right to Offset*).

"**Environmental Law**" means any present and future applicable federal, state, and local laws, statutes, ordinances, rules, regulations and the like, as well as common law, (a) relating to (i) protection of human health (as it relates to Hazardous Substances) or the environment, (ii) Hazardous Substances, or (iii) liability for or costs of actual or threatened danger to the environment, (b) conditioning transfer of property upon a negative declaration or other approval of a Governmental Authority of the environmental condition of any individual property, (c) requiring notification or disclosure of releases of Hazardous Substances or other environmental condition of any individual property to any Governmental Authority or other Person, whether or not in connection with the transfer of title to or interest in such individual property, (d) imposing conditions or requirements in connection with permits or other authorization for lawful activity associated with Hazardous Substances, and (e) related to a nuisance or trespass related to any individual property and associated with Hazardous Substances.

"**EU Approval**" means, with respect to a Product, receipt of Regulatory Approval from the European Commission for such Product in the EU under the centralized EMA filing procedure; provided, however, that if the centralized EMA filing procedure is not used, EU Approval will be achieved upon receipt of Regulatory Approval from the applicable Governmental Authority for such Product in any [**] of the following countries: [**].

"**Excess Indemnifiable Losses**" has the meaning set forth in Section 6.2(a) (*Indemnification by Seller*).

"**Excluded Assets**" means the property of Seller and the Selling Affiliates set forth or described on Annex 9.1(b), which property is not to be transferred to Buyer hereunder.

"**Excluded Contracts**" has the meaning set forth in clause (vi) of Annex 9.1(b).

"**Excluded Liabilities**" means all liabilities and obligations of Seller and the Selling Affiliates set forth or described on Annex 9.1(d), which are not to be assumed by Buyer hereunder.

"**Exclusive Period**" means the period commencing on the Closing Date and ending on the Diligence Expiration Date; provided that, [**].

"**Expert**" has the meaning set forth in Exhibit H.

"**FDA**" means the U.S. Food and Drug Administration or any successor entity thereto.

"**Field**" means the treatment, prevention or diagnosis of any disease or condition in humans.

"**First Commercial Sale**" means, on a country-by-country and Product-by-Product basis, the first sale of such Product by a Buyer Party for end use or consumption in such country

following receipt of Regulatory Approval of such Product in such country; provided, however, that none of the following shall constitute a "First Commercial Sale": (a) any sale, transfer, or use of such Product in clinical trials or non-clinical development activities with respect to such Product; (b) disposal or transfer of such Product for compassionate use or a *bona fide* charitable purpose; or (c) sales of such Product made on a named patient basis, in early access programs, or for similar uses.

"**Fundamental Representations**" has the meaning set forth in Section 6.1 (*Survival*).

"**GAAP**" means generally accepted accounting principles in the United States.

"**Governmental Authority**" means any nation or government, any state or other political subdivision thereof, any entity, authority or body exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, any court, tribunal or arbitrator and any self-regulatory organization.

"**Hazardous Substance**" means any and all material or substance (whether solid, liquid, or gas) defined, listed, regulated or otherwise classified as toxic or hazardous, or as a pollutant or containment, under any applicable Environmental Law.

"**Hourly Rate**" means the rate of $[**] per hour.

"**IND**" means an investigational new drug application, Clinical Trial application, Clinical Trial exemption, or similar application or submission filed with or submitted to a Regulatory Authority in a jurisdiction that is necessary to initiate human clinical testing of a pharmaceutical product in such jurisdiction, including any such application filed with the FDA pursuant to 21 C.F.R. Part 312, as well as all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

"**Indemnified Party**" has the meaning set forth in Section 6.5(a) (*Notification of Claims; Third Party Claims*).

"**Indemnifying Party**" has the meaning set forth in Section 6.5(a) (*Notification of Claims; Third Party Claims*).

"**Indemnity Threshold**" has the meaning set forth in Section 6.4(a) (*Limitations on Indemnity*).

"**Indication**" means any distinct disease or condition. For purposes of determining whether a given disease or condition is distinct from another disease or condition so as to constitute a separate Indication and be eligible to trigger a Development and Regulatory Milestone Event based on its being a distinct Indication, the applicable disease or condition must be clearly distinct from any other disease or condition, which means that each applicable disease or condition must bear a distinct reference number under the International Statistical Classification of Diseases and Related Health Problems codes, such as ICD-11 or any successor thereto, as defined by the World Health Organization, to the left of the decimal point.

"**Initiation**" means, with respect to a Clinical Trial of a Product, the administration of the first dose of such Product to the first patient participating in such Clinical Trial.

"**IP Rights**" means (a) Patent Rights, (b) Trademarks, (c) Copyrights and (d) trade secrets, Know-How and Data and databases.

"**Know-How**" means (a) any scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including non-public inventions, discoveries, databases, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, trade secrets, skill, experience, test data (including pharmacological, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data), analytical and quality control data, stability data, studies and procedures, and manufacturing process and development information, results and data, and (b) any biological, chemical, or physical materials. Know-How expressly excludes Patent Rights.

"**Knowledge of Seller**" means the actual knowledge, as of the date hereof, of the Persons specified in Section 7.1(a) of the Seller Disclosure Letter and the knowledge such Persons would be expected to have after reasonably inquiry.

"**Laws**" has the meaning set forth in Section 2.11(a) (*Litigation*).

"**License Agreement Novation Agreement**" means that certain Novation Agreement among the Seller, Buyer, and [**], dated as the date hereof, substantially in the form as attached as Exhibit G.

"**Licensed IP Contracts**" has the meaning set forth in Section 2.9(h) (*Intellectual Property)*.

"**Lien**" means, with respect to any property or asset, any mortgage, lien, pledge, charge, security interest, lease, encumbrance or other adverse claim of any kind in respect of such property or asset.

"**Litigation**" means any action, demand, suit, arbitration proceeding, administrative or regulatory proceeding, citation, summons or subpoena of any nature, civil, criminal, regulatory or otherwise, in law or in equity.

"**Losses**" means any and all damages, judgments, Taxes, awards, liabilities, losses, obligations, claims of any kind or nature, fines and costs and expenses (including reasonable fees and expenses of attorneys, auditors, consultants and other agents).

"**Material Adverse Effect**" means any material adverse change in, or effect on, the Transferred Assets or the financial condition, results of operations, or prospects of the Business, taken as a whole; provided that any such change or effect resulting from any of the following, individually or in the aggregate, shall not be considered when determining whether a Material Adverse Effect has occurred: [**].

"**Material Contract**" has the meaning set forth in Section 2.6(e) (*Material Contracts*).

"**Milestone Dispute Notice**" has the meaning set forth in Section 1.10 (*Milestone Dispute Notice*).

"**Net Sales**" means the [**].

"**Order**" means any order, writ, judgment, injunction, decree, ruling, assessment, stipulation, determination or award entered by or with any court or other Governmental Authority or arbitrator.

"**Organizational Documents**" means the articles of incorporation, constitution, certificate of incorporation, charter, bylaws, articles of formation, certificate of formation, regulations, operating agreement, certificate of limited partnership, partnership agreement and all other similar documents, instruments or certificates executed, adopted or filed in connection with the creation, formation or organization of a Person, including any amendments thereto.

"**[**]**" means [**].

"**Party**" and "**Parties**" has the meaning set forth in the Preamble.

"**Patent Assignment**" means that certain patent assignment between the Parties substantially in the form as attached as Exhibit C.

"**Patent Rights**" means patents (as well as the relevant complementary protection certificates where applicable) and patent applications (including any divisions, continuations, continuations-in-part, provisional applications, reexamined versions or reissues thereof) whether or not patents are issued on any such applications and whether or not any such applications are modified, withdrawn or resubmitted.

"**Permits**" has the meaning set forth in Section 2.11(b) (*Compliance with Laws; Licenses and Permits*).

"**Permitted Liens**" means (a) mechanics', carriers', workers', repairers' and similar statutory liens arising or incurred in the ordinary course of business or in connection with construction contracts for amounts that are not delinquent or are being contested in good faith and that would not individually or in the aggregate be materially adverse to the Business, and (b) any liens arising or incurred by the terms and conditions of the Transferred Contracts set forth on Annex 9.1(a)(vi).

"**Person**" means an individual, corporation, partnership, limited liability company, association, trust or other entity or organization, including a government or political subdivision or an agency or instrumentality thereof.

"**Phase 2 Clinical Trial**" means any Clinical Trial of the effectiveness of a product for a particular indication or indications in patients with the disease or condition under study and to determine the short-term side effects and risks associated with such product and with the purpose to obtain sufficient information about the Product's efficacy to permit the design of Phase 3 Clinical Trials, and which is consistent with 21 C.F.R. § 312.21(b) or a comparable clinical study

requested by the relevant Regulatory Authority in a country other than the United States, including a phase 2a Clinical Trial, phase 2b Clinical Trial, the second portion of a phase 1/2 Clinical Trial or the first portion of a phase 2/3 Clinical Trial.

"**Phase 3 Clinical Trial**" means a Clinical Trial of the efficacy and safety of a product, which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular Indication in a manner with the aim to obtain Regulatory Approval for such Product in any country, as described in 21 C.F.R. § 312.21(c) or a comparable clinical study requested by the relevant Regulatory Authority in a country other than the United States, including the second portion of a phase 2/3 Clinical Trial.

"**Post-Closing Covenant**" has the meaning set forth in Section 6.1.

"**Post-Closing Tax Period**" means any taxable period beginning after the Closing Date and the portion of a Straddle Period beginning after the Closing Date.

"**Potential Contributor**" has the meaning set forth in Section 6.4(g).

"**Pre-Closing Accounts Payable**" has the meaning set forth in clause (i) of Annex 9.1(d).

"**Pre-Closing Accounts Receivable**" has the meaning set forth in clause (i) of Annex 9.1(b).

"**Pre-Closing Tax Period**" means any Tax period ending on or before the Closing Date and the portion of the Straddle Period ending at the completion of the Closing Date.

"**Product**" means any Acquired Product that incorporates, constitutes or contains an Acquired Molecule that is either (a) ADX-097, including its peptide and nucleic acid sequences, and any fragments, variants and derivatives, and modified (including post-translationally modified) forms thereof or (b) Covered by [**], in each case ((a) and (b)), in any formulation or dosage strength. For clarity, any [**] is not a Product.

"**Proposal**" has the meaning set forth in Exhibit H.

"**Purchase Price**" means the aggregate of all consideration paid or payable to Seller pursuant to Section 1.3 (*Purchase Price*).

"**Regulatory Approval**" means approval of a Regulatory Approval Application by the applicable Regulatory Authority.

"**Regulatory Approval Application**" means: (a) a New Drug Application (as more fully defined in 21 CFR 314.5, et seq.) filed with the FDA, or any successor application thereto in the U.S. ("**NDA**") or a Biologics License Application submitted to the FDA pursuant to Section 351(a) of the Public Health Service Act ("**BLA**"); (b) an application for authorization to market or sell a pharmaceutical or biological product submitted to a Regulatory Authority in any country or jurisdiction other than the U.S., including, with respect to the EU, a marketing authorization application filed with the EMA pursuant to the Centralized Approval Procedure or with the

applicable Regulatory Authority of a country in the European Economic Area with respect to the decentralized procedure, mutual recognition procedure, or any national approval procedure ("**MAA**"); or (c) with respect to any product for which a NDA, BLA or MAA has been approved by the applicable Regulatory Authority, an application to supplement or amend such NDA, BLA or MAA to expand the approved label for such pharmaceutical or biological product to include use of such pharmaceutical or biological product for an additional indication.

"**Regulatory Authority**" means with respect to a country in the Territory, any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other Governmental Authority involved in assessing or granting Regulatory Approvals (including pricing approvals) for pharmaceutical products in such country, including the FDA in the United States, the European Commission (and any successor entity thereto) in the European Union, [**] and any corresponding national or regional regulatory authorities in any country that is a counterpart to the foregoing agencies.

"**Royalties**" has the meaning set forth in Section 1.4(c) (*Royalties*).

"**Royalty Report**" has the meaning set forth in Section 1.4(c)(vi) (*Royalty Payments and Reports*).

"**Royalty Term**" has the meaning set forth in Section 1.4(c)(ii) (*Royalty Term*).

"**Scientific Expert**" has the meaning set forth in Section 1.10 (*Milestone Dispute Notice*).

"**Securitization Transaction**" has the meaning set forth in Section 8.5(b) (*Securitization*).

"**Security Interest Release**" means evidence provided by Seller, in a form reasonably acceptable to Buyer, that First-Citizens Bank and Trust Company releases its security interest in all rights, title, and interests in and to the Transferred Assets.

"**Segregate**" means, with respect to any Seller COC Program or Seller Acquisition Program, systems and safeguards to segregate the use of Transferred Know-How or other confidential information of Buyer or the Buyer Parties and the practice, use, or exploitation of any Transferred Assets from the activities conducted under any Seller COC Program or Seller Acquisition Program, including ensuring that: [**]. When used as a noun, "Segregation" means any and all activities involved in Segregating any Seller COC Program or Seller Acquisition Program.

"**Selected Scientific Expert**" has the meaning set forth in Section 1.10 (*Milestone Dispute Notice*).

"**[**]**" means that certain [**], which will be assigned by Buyer to Seller as a Transferred Contract in accordance with this Agreement.

"**Seller**" has the meaning set forth in the Preamble.

"**Seller Acquisition**" has the meaning set forth in Section 4.14(d) (*Competition*).

"**Seller Acquisition Program**" has the meaning set forth in Section 4.14(d) (*Competition*).

"**Seller COC Program**" has the meaning set forth in Section 4.14(b) (*Competition*).

"**Seller Disclosure Letter**" means the letter, dated as of the date hereof, delivered by Seller to Buyer prior to the execution of this Agreement and identified as the Seller Disclosure Letter.

"**Seller Indemnitees**" has the meaning set forth in Section 6.3 (*Indemnification by Buyer*).

"**Selling Affiliates**" means all of the Affiliates of Seller that own any Transferred Assets or have obligations or liabilities in respect of any Assumed Liabilities.

"**Separated Contract**" has the meaning set forth in Section 4.4 (*Shared Contracts*).

"**Shared Academic Contracts**" means the Shared Contracts listed on Section 9.1(b)(vi)(4) of the Seller Disclosure Letter.

"**Shared Academic Contract Know How**" means, with respect to a given Shared Academic Contract, any Know How licensed or otherwise made available to Seller under such Shared Academic Contract.

"**Shared Contract**" means each Contract that relates to both (a) the Business, the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product, or any Transferred Assets and (b) one or more other businesses or products of Seller or any Selling Affiliate, including the Contracts listed on Section 9.1(a)(vi) of the Seller Disclosure Letter and clearly labeled as "Shared Contracts".

"**Solvent**" means, with respect to any Person, that:

(a) the fair saleable value (determined on a going-concern basis) of the assets of such Person shall be greater than the total amount of such Person's liabilities (including all liabilities, whether or not reflected in a balance sheet prepared in accordance with GAAP and whether direct or indirect, fixed or contingent, secured or unsecured, disputed or undisputed);

(b) such Person shall be able to pay its debts and obligations in the ordinary course of business as they become due; and

(c) such Person shall have adequate capital to carry on its businesses and all businesses in which it is about to engage.

"**Straddle Period**" means any Tax period that includes, but does not end on, the Closing Date.

"**(Sub)license Income**" means consideration in any form received by Buyer or its Affiliates from or on behalf of any (Sub)licensee that is granted rights [**] in return for the grant of such license or sublicense outside the United States, including (a) upfront payments, regulatory approval milestone payments, commercial sales milestone payments, and royalties or profit share payments, and (b) payments for options for a license or sublicense or for the exercise of such options. (Sub)license Income shall not include [**]. For the avoidance of doubt, (Sub)license Income shall not apply to any sale of all or substantially all of Buyer's assets related to the Business, whether by merger, sale of assets, or otherwise or to a Change of Control of Buyer.

"**(Sub)licensee**" means any Third Party to which Buyer or an Affiliate of Buyer, directly or indirectly, grants a license the right to develop, use, import, promote, offer for sale, sell, have sold, and/or otherwise commercialize any Product. For clarity,

"**(Sub)licensee**" excludes wholesalers, distributors, contract research organizations, contract manufacturing organizations, contract development and manufacturing organizations, and other service providers.

"**Subsidiary**" means, with respect to any Person, any entity of which securities or other ownership interests (a) having voting power to elect a majority of the board of directors or other persons performing similar functions or (b) representing more than fifty percent of such securities or ownership interests are at the time directly or indirectly owned by such Person.

"**Support Memo**" has the meaning set forth in Exhibit H.

"**Tax**" means any federal, state, local or foreign income, alternative, minimum, accumulated earnings, personal holding company, franchise, capital stock, profits, windfall profits, gross receipts, sales, use, goods and services, value added, transfer, registration, stamp, premium, excise, severance, real property, personal property, ad valorem, occupancy, license, occupation, employment, payroll, social security, disability, unemployment, workers' compensation, withholding, estimated or other charge, assessment, or other expense in the nature of or similar to a tax (including all interest and penalties thereon and additions thereto).

"**Tax Proceeding**" means any audit, request for information, investigation, hearing, litigation, legal action, or judicial contest relating to Taxes.

"**Tax Return**" means any federal, state, local or foreign tax return, declaration, statement, report, schedule, form or information return or any amendment to any of the foregoing relating to Taxes.

"**Taxing Authority**" means any Governmental Authority exercising any authority to collect, impose, regulate or administer the imposition of Taxes.

"**Territory**" means anywhere in the world.

"**Third Party**" means, after the Closing, any Person other than Buyer or an Affiliate of Buyer.

"**Third Party Claim**" has the meaning set forth in Section 6.5(b) (*Notification of Claims; Third Party Claims*).

"**Trademarks**" means trademarks, service marks, trade names, trade dress, logos, slogans, and other similar designations of source or origin, together with the goodwill associated with any of the foregoing, and all applications, registrations and renewals therefor.

"**Transfer Approval**" has the meaning set forth in Section 1.1(g)(i) (*Transferred Assets Subject to Third-Party Consent*).

"**Transfer Plan**" has the meaning set forth in Section 4.8 (*Transfer Plan; Transition Assistance*).

"**Transfer Taxes**" mean any federal, state, county, local, foreign and other sales, use, transfer, goods and services, value added, conveyance, documentary transfer, stamp duty, recording or other similar Tax, fee or charge imposed on or in connection with the transactions contemplated by or the instruments executed under or in connection with this Agreement or the recording of any sale, transfer, or assignment of property (or any interest therein) effected pursuant to this Agreement.

"**Transferee**" has the meaning set forth in Section 8.6 (*Divestitures*).

"**Transferred Academic Contracts**" means the Transferred Contracts listed on Section 9.1(a)(vi)(3) of the Seller Disclosure Letter.

"**Transferred Academic Contract Know How**" means, with respect to a given Transferred Academic Contract, any Know How licensed or otherwise made available to Buyer under such Transferred Academic Contract.

"**Transferred Assets**" means the assets and other personal property of Seller and the Selling Affiliates related to the Business set forth or described on Annex 9.1(a).

"**Transferred Contracts**" has the meaning set forth in clause (v) of Annex 9.1(a).

"**Transferred IP**" has the meaning set forth in clause (vii) of Annex 9.1(a).

"**Transferred Know-How**" has the meaning set forth in clause (vii) of Annex 9.1(a).

"**Transferred Materials**" has the meaning set forth in clause (vi) of Annex 9.1(a).

"**Transferred Patent Rights**" has the meaning set forth in clause (vii) of Annex 9.1(a).

"**Transition Assistance**" has the meaning set forth in Section 4.8 (*Transfer Plan; Transition Assistance*).

"**Unassigned Right**" has the meaning set forth in Section 1.1(g)(i) (*Transferred Assets Subject to Third-Party Consent*).

"**Upfront Cap**" has the meaning set forth in Section 6.4(a) (Limitations on Liability).

"**Upfront Closing Consideration**" has the meaning set forth in Section 1.3(a)(i) (*Purchase Price*).

"**Upfront Consideration**" has the meaning set forth in Section 1.3(a)(ii) (*Purchase Price*).

"**Upfront Second Consideration**" has the meaning set forth in Section 1.3(a)(i) (*Purchase Price*).

"**Upstream License Agreement**" means each of the A&R License Agreement or the [**], as applicable.

"**Valid Claim**" means a claim of (a) an issued, unexpired patent that has not been revoked or held unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no appeal can be taken, or with respect to which an appeal is not taken within the time allowed for appeal, and that has not been disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise, or (b) any patent application that has not been cancelled, withdrawn or abandoned, without being re-filed in another application in the applicable jurisdiction; provided that a patent application pending for more than [**] from the priority date with respect thereto will not be considered to have any Valid Claim for purposes of this Agreement, unless and until a patent that meets the criteria set forth in clause (a) above issues from such application.

Section 7.2 Construction. The words "hereof", "herein" and "hereunder" and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. References to Articles, Sections and Exhibits are to Articles, Section and Exhibits of this Agreement unless otherwise specified. All Exhibits and Disclosure Letters annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any capitalized term used in any Exhibit or the Seller's Disclosure Letter but not otherwise defined therein shall have the meaning given to such term in this Agreement. Any singular term in this Agreement shall be deemed to include the plural, and any plural term the singular. Whenever the words "include", "includes" or "including" are used in this Agreement, they shall be deemed to be followed by the words "without limitation", whether or not they are in fact followed by those words or words of like import. "Writing", "written" and comparable terms refer to printing, typing and other means of reproducing words (including electronic media) in a visible form. References to any agreement or contract are to that agreement or contract as amended, modified or supplemented from time to time in accordance with the terms hereof and thereof. References to any Person include the successors and permitted assigns of that Person. References from or through any date mean, unless otherwise specified, from and including or through and including, respectively. Any reference to "days" means calendar days unless Business Days are expressly specified. If any action under this Agreement is required to be done or taken on a day that is not a

Business Day, then such action shall be required to be done or taken not on such day but on the first succeeding Business Day thereafter.

ARTICLE 8

MISCELLANEOUS

Section 8.1 Notices. All notices, requests and other communications to any Party hereunder shall be in writing and will be (a) delivered by hand or by overnight courier with tracking capabilities, or (b) mailed postage prepaid first class, registered, or certified mail, and, in either case ((a) or (b)), may also be delivered electronically via email, in each case, addressed as set forth below unless changed by written notice so given:

if to Buyer,

Akebia Therapeutics, Inc.
245 First Street, Suite 1400
Cambridge, Massachusetts 02142
Attention: General Counsel
Telephone: 617-871-2098
E-mail: [**]

with a copy (which shall not constitute notice) to:

Ropes & Gray LLP
Prudential Tower
800 Boylston Street
Boston, Massachusetts 02199-3600
Attention: David McIntosh
Telephone: [**]
E-mail: [**]

if to Seller,

Q32 Bio Inc.
830 Winter St.
Waltham, MA 02451
Attention:
Telephone:
E-mail:

with a copy (which shall not constitute notice) to:

Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Attention: Jacqueline Mercier and Erini Svokos

Telephone: [**]
E-mail: [**]

or such other address or e-mail address as such Party may hereafter specify for the purpose by notice to the other Parties hereto. All such notices, requests and other communications shall be deemed received on the date of receipt by the recipient thereof if received prior to 5:00 p.m. on a Business Day in the place of receipt. Otherwise, any such notice, request or communication shall be deemed to have been received on the next succeeding Business Day in the place of receipt.

Section 8.2 Amendment; Waivers, etc. No amendment, modification or discharge of this Agreement, and no waiver hereunder, shall be valid or binding unless set forth in writing and duly executed by the Party against whom enforcement of the amendment, modification, discharge or waiver is sought. Any such waiver shall constitute a waiver only with respect to the specific matter described in such writing and shall in no way impair the rights of the Party granting such waiver in any other respect or at any other time. Neither the waiver by any of the Parties hereto of a breach of or a default under any of the provisions of this Agreement, nor the failure by any of the Parties, on one or more occasions, to enforce any of the provisions of this Agreement or to exercise any right or privilege hereunder, shall be construed as a waiver of any other breach or default of a similar nature, or as a waiver of any of such provisions, rights or privileges hereunder. The rights and remedies herein provided are cumulative and none is exclusive of any other, or of any rights or remedies that any Party may otherwise have at law or in equity.

Section 8.3 Expenses. Except as otherwise provided herein, all costs, fees and expenses incurred in connection with this Agreement, the Ancillary Agreements and the transactions contemplated hereby and thereby, whether or not consummated, shall be paid by the Party incurring such cost or expense.

Section 8.4 Governing Law, etc.

(a) Governing Law and Jurisdiction. THIS AGREEMENT SHALL BE GOVERNED IN ALL RESPECTS, INCLUDING AS TO VALIDITY, INTERPRETATION AND EFFECT, BY THE LAWS OF THE STATE OF THE STATE OF NEW YORK, WITHOUT GIVING EFFECT TO ITS PRINCIPLES OR RULES OF CONFLICT OF LAWS, TO THE EXTENT SUCH PRINCIPLES OR RULES ARE NOT MANDATORILY APPLICABLE BY STATUTE AND WOULD PERMIT OR REQUIRE THE APPLICATION OF THE LAWS OF ANOTHER JURISDICTION. Buyer and Seller hereby irrevocably submit to the jurisdiction of the courts of the State of New York and the federal courts of the United States of America located in the State of New York solely in respect of the interpretation and enforcement of the provisions of this Agreement and in respect of the transactions contemplated hereby. Each of Buyer and Seller irrevocably agrees that all claims in respect of the interpretation and enforcement of the provisions of this Agreement and in respect of the transactions contemplated hereby, or with respect to any such action or proceeding, shall be heard and determined in such a New York state or federal court, and that such jurisdiction of such courts with respect thereto shall be exclusive, except solely to the extent that all such courts shall lawfully decline to exercise such jurisdiction. Each of Buyer and Seller hereby waives, and agrees not to assert, as a defense in any action, suit or proceeding for the interpretation or enforcement hereof or in respect of any such transaction, that it is not subject to such jurisdiction. Each of Buyer and Seller hereby waives, and agrees not to assert, to the maximum extent permitted by law, as a defense in any action, suit or proceeding for the interpretation or enforcement hereof or in respect of any such transaction, that such action, suit or proceeding may not be brought or is not maintainable in such courts or that the venue thereof may not be

appropriate or that this Agreement may not be enforced in or by such courts. Buyer and Seller hereby consent to and grant any such court jurisdiction over the person of such Parties and over the subject matter of any such dispute and agree that service of process or other papers in connection with any such action or proceeding in the manner provided in Section 8.1 (*Notices*) or in such other manner as may be permitted by law, shall be valid and sufficient service thereof. Notwithstanding anything in this Section 8.4 (*Governing Law, etc.*) to the contrary, each Party to this Agreement may bring an action to seek equitable relief as provided in Section 8.10 (*Specific Performance*) in such jurisdiction as it may deem appropriate to enforce its rights hereunder and each Party hereby consents to each such applicable jurisdiction for purposes of such equitable relief.

(b) Waiver of Jury Trial. EACH PARTY HEREBY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT SUCH PARTY MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

(c) Waiver of Certain Damages. IN CONNECTION WITH ANY DISPUTE HEREUNDER, EACH PARTY HERETO WAIVES ANY CLAIM OF CONSEQUENTIAL, SPECIAL, INCIDENTAL, INDIRECT, SPECULATIVE, TREBLE OR PUNITIVE DAMAGES, LOSS OF BUSINESS REPUTATION OR OPPORTUNITY, LOST REVENUE, INCOME OR PROFITS, DIMINUTION IN VALUE OR SIMILAR ITEMS FROM THE OTHER PARTY HERETO (OR ANY AFFILIATE OF SUCH OTHER PARTY HERETO), EXCEPT THAT THE COURT SHALL HAVE THE POWER TO AWARD ANY RELIEF PROVIDED BY GOVERNING STATUTE. NOTWITHSTANDING THE FOREGOING, THIS WAIVER WILL NOT APPLY TO LIMIT ANY CLAIM FOR (A) CONSEQUENTIAL, SPECIAL, INCIDENTAL, INDIRECT DAMAGES, LOST PROFITS, DIMINUTION IN VALUE, OR SIMILAR ITEMS PAYABLE TO ANY THIRD PARTY BY AN INDEMNIFIED PARTY PURSUANT TO A THIRD PARTY CLAIM, OR (B) CONSEQUENTIAL, INCIDENTAL, OR INDIRECT DAMAGES WHICH ARE A REASONABLY FORESEEABLE RESULT OF THE FACTS AND CIRCUMSTANCES GIVING RISE TO THE CLAIM, ARISING FROM (I) EITHER PARTY'S BREACH OF SECTION 4.2 (*CONFIDENTIALITY*), SECTION 4.5 (*FURTHER ASSURANCES*), OR SECTION 4.10 (*[**]*), OR (II) SELLER'S OR ITS AFFILIATES' BREACH OF THE RESTRICTIONS SET FORTH IN SECTION 4.14 (*COMPETITION*) OR ITS OBLIGATIONS SET FORTH IN SECTION 4.8 (*TRANSFER PLAN; TRANSITION ASSISTANCE*) OR (III) ANY INACCURACY OR BREACH OF REPRESENTATION BY SELLER SET FORTH IN THIS AGREEMENT.

(d) Neither this Agreement nor any right or obligation of any of the Parties under this Agreement shall be governed by the U.N. Convention on Contracts for the International Sale of Goods, and the Parties to this Agreement expressly waive or disclaim, as the case may be, any right or obligation they may have under this Agreement pursuant to the U.N. Convention on Contracts for the International Sale of Goods.

Section 8.5 Successors and Assigns.

(a) General. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective heirs, successors and permitted assigns; provided that neither Party to this Agreement may assign any of its rights or obligations under this Agreement, including by sale of stock, operation of Law in connection with a merger or sale of substantially all the assets, without the prior written consent of the other Party, except that (i) either Party may, without such consent, assign its rights to, or have its obligations discharged by, an Affiliate, and (ii) subject to Section 8.6 (*Divestitures*), Buyer may, without such consent, assign its rights or obligations hereunder, in whole or in part, to a successor of all or substantially all of its

business or assets to which this Agreement relates, whether in a merger, sale of stock, sale of assets, or any other transaction. With respect to an assignment to an Affiliate, the assigning Party will remain responsible for the performance by such Affiliate of the rights and obligations hereunder. All validly assigned and delegated rights and obligations of the Parties hereunder will be binding and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Seller or Buyer, as the case may be. The permitted assignee or transferee will assume all obligations of its assignor or transferor under this Agreement. Any attempted assignment or transfer in violation of this Section 8.5(a) (*General*) shall be null and void.

(b) Securitization. Notwithstanding anything to the contrary in Section 8.5(a) (General) or elsewhere in this Agreement, Seller may assign to a Third Party its right to receive the payments owed under Section 1.4 (*Contingent Consideration*) (such assignment, a "**Securitization Transaction**") without the prior written consent of any Buyer Party. Seller shall notify Buyer in writing if it initiates a competitive process to enter into a Securitization Transaction with any Third Party, and Buyer shall be permitted to participate in such process to the extent as any other Third Party. Further, in connection with a contemplated Securitization Transaction, Seller may disclose to such Third Party the Royalty Reports contemplated under Section 1.4(c)(vi) (*Royalty Payments and Reports*) (without the prior written consent of any Buyer Party), to the extent reasonably necessary to enable such Third Party to evaluate the Securitization Transaction opportunity (provided that such Third Party is under written obligations of confidentiality and non- use with respect to such confidential information that are no less stringent than the terms of the Confidentiality Agreement), and to allow such Third Party to exercise its rights under this Section 8.5(b) (*Securitization*). As part of any consummated Securitization Transaction, Seller may assign, without the prior written consent of any Buyer Party, its right to receive the Royalty Reports under Section 1.4(c)(vi) (*Royalty Payments and Reports*) and to conduct audits under Section 1.7 (*Inspection of Buyer Records*) to the counterparty in such Securitization Transaction, and to allow such counterparty to exercise its rights under such Section.

Section 8.6 Divestitures. If at any time after the Closing until all Development and Regulatory Milestone Payments have been received by Seller, a Buyer Party divests or transfers (by way of merger, consolidation, asset acquisition or sale, exclusive license, exclusive sublicense, assignment or other similar transfer) (a "**Divestiture**") to a Third Party all of Buyer Parties' right, title and interest in and to all Products and the IP Rights related to the same (collectively, "**Divested Assets**" and the Third Party receiving any Divested Assets, the "**Transferee**"), Buyer will: (i) make provision for the Transferee to assume and succeed to the obligations of Buyer set forth in Section 1.4 (*Contingent Consideration*); and (ii) prior to or simultaneously with the consummation of any such Divestiture, cause such Transferee to provide to the Seller an instrument of assumption of the Transferred Liabilities in a form substantially similar to the form of assignment and assumption agreement as attached as Exhibit A effecting the assumption and succession described in the foregoing clause (i). Buyer will only remain liable to the Seller for the obligations set forth in Section 1.4 (*Contingent Consideration*) following any such Divestiture if, at the time of such Divestiture, such Transferee has a lesser ability than Buyer to satisfy its payment obligations as they become due and payable, as indicated by the balance sheets of such Transferee and Buyer at the time of the Divestiture.

Section 8.7 Entire Agreement. This Agreement, the Ancillary Agreements (when executed and delivered) and the Confidentiality Agreement constitute the entire agreement and supersede all prior agreements, understandings and representations, both written and oral, between the Parties with respect to the subject matter hereof.

Section 8.8 Severability. If any provision, including any phrase, sentence, clause, section or subsection, of this Agreement is determined by a court of competent jurisdiction to be invalid, inoperative or unenforceable for any reason, such circumstances shall not have the effect

of rendering such provision in question invalid, inoperative or unenforceable in any other case or circumstance, or of rendering any other provision herein contained invalid, inoperative or unenforceable to any extent whatsoever. Upon any such determination, the Parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in an acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the fullest extent possible.

Section 8.9 Counterparts; Effectiveness; Third Party Beneficiaries. This Agreement may be executed in several counterparts, each of which, including those received via facsimile transmission or email (including in PDF format), shall be deemed an original and all of which shall together constitute one and the same instrument. This Agreement shall become effective when each Party shall have received a counterpart hereof signed by all of the other Parties. Until and unless each Party has received a counterpart hereof signed by the other Party, this Agreement shall have no effect and no Party shall have any right or obligation hereunder (whether by virtue of any other oral or written agreement or other communication). Except as provided under Article 6, no provision of this Agreement is intended to confer any rights, benefits, remedies, obligations or liabilities hereunder upon any Person other than the Parties and their respective successors and assigns.

Section 8.10 Specific Performance. The Parties agree that irreparable damage would occur if any provision of this Agreement were not performed in accordance with the terms hereof and that the Parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement or to enforce specifically the performance of the terms and provisions hereof in any court specified in Section 8.4 (*Governing Law, etc.*), in addition to any other remedy to which they are entitled at law or in equity. The Parties hereby waive, in any action for specific performance, the defense of adequacy of a remedy at law and the posting of any bond or other security in connection therewith.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the date first above written.

Q32 BIO INC.

By: /s/ Jodie Morrison
Name: Jodie Morrison
Title: Chief Executive Officer

Q32 BIO OPERATIONS INC.

By: /s/ Jodie Morrison
Name: Jodie Morrison
Title: Chief Executive Officer

AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler
Name: John P. Butler
Title: President and Chief Executive Officer

Annex 9.1(a)
Transferred Assets

The Transferred Assets consist only of Seller's and the Selling Affiliates' right, title and interest in, to and under the following assets as they exist at the time of the Closing, but in each case specifically excluding any assets described in clauses (i) through (xv) of Annex 9.1(b) (*Excluded Assets*):

(i) Regulatory Approvals. The INDs exclusively related to the sale of the Product in the Territory, including the INDs set forth on Section 9.1(a)(i) of the Seller Disclosure Letter, all pre-clinical data, clinical data and laboratory data relating to the Products and referenced in such INDs.

(ii) Books and Records. All books and records related to the Acquired Program or any Acquired Molecule, or Acquired Product including lab notebooks, invention disclosures, any relevant training materials or product presentations, market research data, market intelligence reports, and Clinical Trial-related assets, including data, databases, clinical study reports (if any) and ongoing patient management, pertaining to Clinical Trials of any Acquired Product, including those that were made available by Seller in the Data Room.

(iii) Regulatory Documentation. All (A) periodic safety reports or benefit risk evaluation reports, (B) correspondence between Seller or any of Seller's Affiliates, on the one hand, and any Governmental Authority, on the other hand, relating to any Acquired Molecule or Acquired Product, including any correspondence related to Clinical Trial design, safety reports or updates, complaint files and product quality reviews, (C) other governmental reports, inspectional notices, Form 483 observations and customs notices, (D) medical inquiries, standard response or non-standard letters or talking points, (E) complaints, investigations and corrective and preventive actions, (F) documents, reports, records, information and materials relating to any post-marketing requirements and post-marketing commitments, (G) Trial Master Files related to any Clinical Trials for any Acquired Product conducted by or on behalf of Seller, and (H) any outstanding or ongoing regulatory item, in each case ((A) through (H)), to the extent owned or controlled by Seller or its Affiliates as of the Closing Date.

(iv) Safety Database. Any safety database maintained by Seller or its Affiliates as of the Closing Date for the Products (or any other Acquired Molecule or Acquired Product).

(v) Goodwill. The goodwill generated by or associated with the Business.

(vi) Transferred Contracts. All leases, licenses, bids, tenders, purchase orders, consulting and other service agreements, supply agreements, distribution contracts, manufacturing contracts, maintenance contracts, agreements, commitments, and other contracts (collectively, "**Contracts**") relating solely to the operation and conduct of the Business, the development, manufacture, commercialization, or other exploitation of any Acquired Molecule or Acquired Product, or any of the Transferred Assets as set forth on Section 9.1(a)(vi) of the Seller Disclosure Letter, (collectively, the "**Transferred Contracts**").

(vii) Transferred Materials. (a) All inventory of Acquired Molecules and Acquired Products, (b) all inventory of all raw materials and lab supplies specific to making the Acquired Molecules and Acquired Products, all work-in-progress related thereto, and all clinical samples and packaging materials specifically related to the Acquired Molecules and Acquired Products, (c) the non-clinical samples related to the Acquired Molecules and Acquired Products as agreed to by the Parties in accordance with the Transfer Plan, and (d) [**], in each case ((a) through

(d)), in Seller's possession or control (including such items held by contract manufacturers or other contractors), including all materials set forth on Section 9.1(a)(vii) of the Seller Disclosure Letter (the "**Transferred Materials**").

(viii) Intellectual Property. All Know-How (including Data) related to the Acquired Program or any Acquired Molecule or Acquired Product, and all intellectual property rights therein (including trade secret rights) (the "**Transferred Know-How**"), all Copyrights related to the Acquired Program or any Acquired Molecule or Acquired Product (the "**Transferred Copyrights**"), and any Patent Right that claims or discloses any Acquired Molecule or Acquired Product or any method of manufacturing or using any Acquired Molecule or Acquired Product, including the Patent Rights set forth on Section 9.1(a)(viii) of the Seller Disclosure Letter and all Patent Rights that claim priority thereto or share common priority therewith throughout the world (the "**Transferred Patent Rights**" and together with the Transferred Know-How and Transferred Copyrights the "**Transferred IP**"), and all claims and causes of action related thereto, including for past, present, and future infringement or misappropriation. For clarity, Transferred Know-How does not include Know-How (including Data) related to [**].

(ix) Domain Names. The Internet domain names set forth on Section 9.1(a)(ix) of the Seller Disclosure Letter (the "**Transferred Domain Names**").

Annex 9.1(b)
Excluded Assets

The Excluded Assets consist of any assets of Seller or any of the Selling Affiliates that do not constitute Transferred Assets as described on Annex 9.1(a), including without limitation, the following:

(i) Accounts Receivable. All accounts receivable, notes receivable and similar rights to receive payments of Seller or any of the Selling Affiliates existing on the Closing Date and arising out of the operation or conduct of the Business prior to the Closing Date (the "**Pre-Closing Accounts Receivable**").

(ii) Cash and Cash Equivalents. All cash, cash equivalents and deposits (including marketable securities and other investment assets and all monies received in respect of the sale of warranty programs) held by Seller or any of the Selling Affiliates on the Closing Date.

(iii) Hedging or Other Currency Exchange Agreements. All rights to receive payments of Seller or any of the Selling Affiliates pursuant to a hedging or other currency exchange agreement existing on the Closing Date.

(iv) Benefit Plans. All the assets of and all the assets relating to and all rights under any employee compensation, benefit or welfare plan or any related contract between any Person and Seller or any of the Selling Affiliates (including Business employee benefit plans).

(v) Certain Records. Any records and files not related to the Acquired Program or any Acquired Molecule or Acquired Product, including, but not limited to, (A) the personnel records maintained by Seller or any of the Selling Affiliates, (B) Tax Returns (except for Tax Returns relating solely to the Transferred Assets or the Business), (C) records (including accounting records) relating to Taxes paid or payable by Seller or any of the Selling Affiliates and all financial and Tax records relating to the Business that form part of Seller's or any of the Selling Affiliates' general ledger or otherwise constitute accounting records not relating solely to the Transferred Assets or the Business, and (D) records prepared in connection with the transactions contemplated by this Agreement or the Ancillary Agreements, including bids received from other Persons and analyses relating to the Business communications among Seller and its advisors.

(vi) Certain Contracts and Contract Rights. All rights of Seller and the Selling Affiliates under (A) this Agreement and the Ancillary Agreements, (B) any Shared Contract, including the Contracts set forth on Section 9.1(b)(vi) of the Seller Disclosure Letter, (C) any Contracts related to shared services and systems provided by Seller or the Selling Affiliates to the Business, other than Buyer's rights under the Ancillary Agreements, and (D) any contracts between or among Seller and any of the Selling Affiliates or between or among the Selling Affiliates, whether arising before or after the Closing Date (collectively, the "**Excluded Contracts**").

(vii) Insurance. All current and prior insurance policies arranged or maintained by Seller or any of the Selling Affiliates and all rights of any nature with respect thereto, including all rights to insurance recoveries thereunder and to assert claims with respect to any such insurance recoveries, whether arising before or after the Closing Date.

(viii) Corporate Organizational Records. The organizational documents, qualifications to do business as a foreign corporation, arrangements with registered agents relating to foreign qualifications, taxpayer and other identification numbers, seals, minute books, stock transfer

books, blank stock certificates and other documents relating to the organization, maintenance and existence of Seller and each of the Selling Affiliates as a corporation or other entity.

(ix) Capital Stock. All shares of capital stock of Seller and the Selling Affiliates.

(x) Tax Claims. (A) Refunds and credits, claims for refunds or credits and rights to receive refunds or credits from any Taxing Authority with respect to Taxes arising out of, relating to or in respect of the Business or the Transferred Assets for any Pre-Closing Tax Period and (B) all VAT credits, refunds, or reclaim rights held by Seller or any of the Selling Affiliates on the Closing Date.

(xi) Real Property. Each of the following: (A) any real property and any buildings, improvements and fixtures thereon; and (B) any leasehold interests, including any prepaid rent, security deposits and options to renew or purchase in connection therewith, of Seller or any of the Selling Affiliates.

(xii) Intellectual Property. Except for Transferred IP, all other IP Rights.

(xiii) Domain Names. All Internet domain names other than the Transferred Domain Names.

(xiv) Excluded IT Systems. All property in the nature of databases, software programs, computer hardware, source code and object code owned or licensed by Seller or any of the Selling Affiliates, in each case that is not otherwise specifically set forth on Section 9.1(a) of the Seller Disclosure Letter.

(xv) Furniture, Equipment, and Supplies. All furniture and office and laboratory equipment and supplies (other than Transferred Materials).

Annex 9.1(b)

Annex 9.1(c)
Assumed Liabilities

The Assumed Liabilities consist of the following liabilities and obligations of Seller or any of the Selling Affiliates, but, in each case, specifically excluding any liabilities described in clause (i) through clause Annex 9.1(d)(ix) of Annex 9.1(d) (*Excluded Liabilities*):

(i) Accounts Payable. All accrued receipts and accounts payable arising out of or relating to the operation or conduct of the Business after the Closing Date.

(ii) Transferred Contract Liabilities. All liabilities and obligations arising out of or relating to the Transferred Contracts arising after the Closing Date or relating to any period after the Closing Date, but excluding those in respect of the Pre-Closing Accounts Payable; provided, however, that the Shared Contracts shall be subject to the provisions of Section 4.4 (*Shared Contracts*). All liabilities arising under the A&R License Agreement will be Assumed Liabilities.

(iii) Taxes and Transfer Taxes. (A) All Taxes directly arising out of the Transferred Assets for all Post-Closing Tax Periods and (B) all Taxes apportioned to the Buyer pursuant to Section 1.13 (*Transfer Taxes and Other Costs*) and Section 5.1 (*Tax Allocation*) of this Agreement.

(iv) Asset Ownership. All liabilities and obligations arising out of or relating to any Transferred Asset or the ownership by Buyer and its Affiliates of any Transferred Asset, in each case, to the extent arising after the Closing Date.

(v) Product Claims. All liabilities and obligations arising after the Closing Date from or relating to lawsuits or other claims, regardless of when commenced or made and irrespective of the legal theory asserted, arising from or relating to the design, manufacture, testing, advertising, marketing, distribution or sale of the Products, including all liabilities and obligations arising from or relating to (A) warranty obligations, (B) infringement, dilution, misappropriation or other violation of IP Rights, (C) alleged or actual hazard or defect, physical injury, death, medical care or medical monitoring or loss or damage to property, arising out of or in connection with the design, manufacture, materials or workmanship, testing, advertising, marketing, distribution, sale or use of the Products in the Territory, including any failure to warn or alleged or actual breach of express or implied warranty or representation; or (D) any recall, withdrawal, retrieval or post-sale warning, in each case ((A) through (D)), with respect to Products (or any other Acquired Molecule or Acquired Product) sold or distributed after the Closing Date by or on behalf of Buyer or its Affiliates.

(vi) Business Claims. Except as otherwise set forth in this Agreement and except for the matters specifically identified as Excluded Liabilities, all obligations and liabilities in respect of any criminal, civil or administrative suit, action or proceeding, pending or threatened, and claims, whether or not presently asserted, arising out of or relating to the operation or conduct of the Business after the Closing Date.

(vii) Clinical Trials. All liabilities and obligations arising from or relating to Clinical Trials for the Products after the Closing Date.

Annex 9.1(d)
Excluded Liabilities

The Excluded Liabilities consist of the liabilities and obligations of Seller or any of the Selling Affiliates, other than the Assumed Liabilities described in Annex 9.1(c) (*Assumed Liabilities*), including the following:

(i) Accounts Payable. All accrued receipts and accounts payable arising out of the ordinary course operation or conduct of the Business before the Closing Date (the "**Pre-Closing Accounts Payable**").

(ii) Transferred Contract Liabilities. All liabilities and obligations arising out of or relating to the Transferred Contracts arising prior to the Closing Date or relating to any period prior to the Closing Date, including those in respect of the Pre-Closing Accounts Payable; provided, however, that the Shared Contracts shall be subject to the provisions of Section 4.4. All liabilities arising under the Exclusive License Agreement dated as of [**] between Seller and [**] (as amended prior to the Closing Date) will be Excluded Liabilities, including any amounts due by Seller or its Affiliates to [**].

(iii) Taxes. All Taxes (A) of Seller or the Selling Affiliates relating to the Transferred Assets or the Business for Pre-Closing Tax Periods, and (B) of any other Person (including as a transferee, or successor, or as a result of being a member of an affiliated, consolidated, combined or unitary group), in each case, as a result of a transaction occurring or circumstance existing prior to the Closing, but, excluding any Transfer Taxes that are Assumed Liabilities pursuant to Annex 9.1(c)(iii) (*Taxes and Transfer Taxes*).

(iv) Employment Matters. All employment, labor, compensation, pension, retirement savings plans (including 401-Ks), employee welfare and employee benefits related liabilities, obligations, commitments, claims and losses relating to each employee of Seller and its Affiliates, including all former employees of the Business (or any dependent or beneficiary of any such employee), in each case, that arise out of an event or events that occur at any time prior to, on, or after the Closing Date.

(v) Excluded Asset Liabilities. Each liability, obligation or commitment that relates exclusively to, or that arises exclusively out of, any Excluded Asset, or that arises out of the distribution to, or ownership by, Seller or any of the Selling Affiliates of any Excluded Asset or associated with the realization of the benefits of any Excluded Asset, whether arising before or after the Closing Date.

(vi) Real Estate Liabilities; Environmental Liabilities. All liabilities and obligations in respect of any real property, including, without limitation, those arising under or relating to any Environmental Law or Hazardous Substances, whether arising prior to, on, or after the Closing Date.

(vii) Asset Ownership. All liabilities and obligations arising out of or relating to any Transferred Asset or the ownership by Buyer and its Affiliates of any Transferred Asset to the extent arising, or relating to the period, prior to the Closing Date.

(viii) Product Claims. All liabilities and obligations arising from or relating to lawsuits or other claims, regardless of when commenced or made and irrespective of the legal theory asserted, arising from or relating to the design, manufacture, testing, advertising, marketing, distribution or sale of the Products, including all liabilities and obligations arising from or relating to (A) warranty obligations, (B) infringement, dilution, misappropriation or other

violation of IP Rights, (C) alleged or actual hazard or defect, physical injury, death, medical care or medical monitoring or loss or damage to property, arising out of or in connection with the design, manufacture, materials or workmanship, testing, advertising, marketing, distribution, sale or use of the Products in the Territory, including any failure to warn or alleged or actual breach of express or implied warranty or representation; or (D) any recall, withdrawal, retrieval or post-sale warning, in each case ((A) through (D)), with respect to Products (or any other Acquired Molecule or Acquired Product) sold or distributed prior to the Closing Date by or on behalf of Seller or its Affiliates.

(ix) Business Claims. Except as otherwise set forth in this Agreement and except for the matters specifically identified as Assumed Liabilities, all obligations and liabilities in respect of any criminal, civil or administrative suit, action or proceeding, pending or threatened, and claims, whether or not presently asserted, arising out of or related to the operation or conduct of the Business prior to the Closing Date.

(x) Clinical Trials. All liabilities and obligations arising from or relating to the Clinical Trials for a Product conducted by or on behalf of the Seller or its Affiliates prior to the Closing Date.

Annex 9.1(d)

Exhibit 10.97

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

LICENSE AGREEMENT

This License Agreement (this "**Agreement**") is made effective as of June 3, 2021 (the "**Effective Date**") by and between Cyclerion Therapeutics, Inc., a Massachusetts corporation ("**Cyclerion**") and Akebia Therapeutics, Inc., a Delaware corporation ("**Akebia**") (each of Cyclerion and Akebia being a "**Party**", and collectively, the "**Parties**").

WHEREAS, Cyclerion controls certain intellectual property rights with respect to the Licensed Compounds (as defined herein) and Products (as defined herein) in the Territory (as defined herein); and

WHEREAS, Cyclerion wishes to grant to Akebia, and Akebia wishes to be granted, an exclusive license under such intellectual property rights to Exploit (as defined herein) Licensed Compounds and Products in the Territory, in each case, in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

Article 1
DEFINITIONS

The following terms, whether used in the singular or the plural, shall have the meanings designated to them under this Article unless otherwise specifically indicated.

1.1 "**Additional Development Materials**" has the meaning set forth in Section 5.5.

1.2 "**Affiliate**" means, with respect to a Party, any Person controlled by, controlling, or under common control with such Party. For purposes of this Section 1.2 only, "control" and, with corresponding meanings, the terms "controlled by," "controlling," and "under common control with" means (a) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities, participating profit interest, or other ownership interests of a legal entity, or (b) the possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities or by contract relating to voting rights or corporate governance.

1.3 "**Agreement**" has the meaning set forth in the preamble hereto.

1.4 "**Akebia**" has the meaning set forth in the preamble hereto.

1.5 "**Akebia Indemnitees**" has the meaning set forth in Section 12.1.

1.6 "**Akebia Intellectual Property**" means (a) any Know-How Controlled by Akebia or any of its Affiliates as of the effective date of termination of this Agreement that is used in the Exploitation of any Product as of such effective date of termination, and (b) any Patents Controlled by Akebia or any of its Affiliates as of the effective date of termination of this Agreement that would be infringed by the Exploitation of any Product.

1.7 "**Akebia Primary Patents**" has the meaning set forth in Section 9.2(b)(i).

1.8 "**Assigned Trademarks**" means the Trademarks set forth on Schedule 1.8.

1.9 "**Business Day**" means any day except (a) Saturday, (b) Sunday, (c) any day that is a federal legal holiday in the U.S., or (d) any day on which banking institutions in the Commonwealth of Massachusetts are authorized or required by law or other governmental action to close.

1.10 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.11 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.12 "**Centralized Approval Procedure**" means the procedure through which a MAA filed with the EMA results in a single marketing authorization valid throughout the European Union.

1.13 "**Clinical Trial**" means a study in humans to obtain information regarding a pharmaceutical or biological product, including information relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging or efficacy of such product, including a Phase 2 Clinical Trial and a Phase 3 Clinical Trial.

1.14 "**Combination Product**" means a Product that is comprised of or contains a Licensed Compound as an active ingredient together with one or more other active ingredients and is sold either as a fixed dose or as separate doses but in any event for a single price.

1.15 "**Commercialization**" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of a Product, including activities related to pricing and reimbursement (including obtaining and maintaining Pricing Approval), marketing, promoting, distributing, and importing, and interacting with Regulatory Authorities regarding any of the foregoing, but excluding activities directed to Development, Manufacturing, and Medical Affairs. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization, and "**Commercialized**" has a corresponding meaning.

1.16 "**Commercial Sublicense Income**" means any consideration received by Akebia or any of its Affiliates solely on the basis of sales of the Products by any Significant Sublicensee in any of the Major Countries (and sales by such Significant Sublicensee in any other countries or other jurisdictions in the Territory to the extent included in the grant of such a sublicense for any Major Country), including [**]. Notwithstanding any provision to the contrary set forth in this Agreement, Commercial Sublicense Income shall exclude [**]. To the extent that Akebia or its Affiliates receives any amounts not solely related to the sale of the Products, then the "Commercial Sublicense Income" attributable to the Products will be apportioned between [**].

1.17 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party with respect to any objective or activity, [**].

1.18 "**Confidential Information**" means, subject to Section 10.1, (a) the terms of this Agreement and (b) with respect to each Party, Know-How and any technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other information that may be disclosed by one Party to the other Party pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the that certain Confidential Disclosure Agreement between the Parties, [**]), regardless of whether such information is specifically designated as confidential or proprietary and regardless of whether such information is in written, oral, electronic, or other form.

1.19 "**Control**" means, with respect to any item of Know-How, Patent, or any intellectual property right, that a Party owns or has a license to such item or right and has the ability to grant to the other Party a license or sublicense under such item or right as provided for in this Agreement without breaching or otherwise violating the terms of any agreement or other arrangement with any Third Party in existence as of the time such Party or its Affiliates would first be required hereunder to grant the other Party such access, right to use, license, or sublicense. Notwithstanding the foregoing, a Party and its Affiliates will not be deemed to "Control" any Know-How, Patent, or any intellectual property right that, (i) prior to the consummation of an acquisition of such Party (whether by merger, stock purchase, or purchase of assets), is owned or in-licensed by a Third Party that becomes an Affiliate of such acquired Party (or that merges or consolidates with such Party) after the Effective Date as a result of such acquisition, or (ii) is generated or discovered after such an acquisition independent of this Agreement by employees or consultants of the Third Party that becomes an Affiliate of a Party who conduct no activities under this Agreement and who have no access to the Confidential Information disclosed or generated under this Agreement, unless (A) prior to the consummation of such acquisition, such acquired Party or any of its Affiliates also Controlled such Know-How, Patent, or intellectual property right, or (B) after the consummation of such acquisition, such acquired Party or any of its Affiliates determines to use or uses any such Know-How, Patent, or intellectual property right in the performance of its obligations or exercise of its rights under this Agreement, in each of which cases ((A) and (B)), such Know-How, Patent, or intellectual property right, as applicable, will be "Controlled" by such Party for purposes of this Agreement. "**Controlled**" and "**Controlling**" have corresponding meanings.

1.20 "**Control Transferring Patent**" has the meaning set forth in Section 9.2(a)(i).

1.21 "**Convicted Entity**" has the meaning set forth in Section 11.3(d).

1.22 "**Convicted Individual**" has the meaning set forth in Section 11.3(d).

1.23 "**Cover**" means, when used to refer to the relationship between a particular Patent and particular subject matter, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in, or is otherwise claimed by, such Patent.

1.24 "**Cyclerion**" has the meaning set forth in the preamble hereto.

1.25 "**Cyclerion Competing Product**" means any pharmaceutical product that contains [**].

1.26 "**Cyclerion Indemnitee**" has the meaning set forth in Section 12.2.

1.27 "**Cyclerion Indication**" means [**].

1.28 "**Cyclerion Intellectual Property**" means the Cyclerion Patents and Cyclerion Know-How and Cyclerion's interest in the Joint Intellectual Property Rights.

1.29 "**Cyclerion Know-How**" means any Know-How, other than Joint Know-How, Controlled by Cyclerion or any of its Affiliates as of the Effective Date or during the Term that is necessary or reasonably useful for the Exploitation of any Licensed Compound or Product.

1.30 "**Cyclerion Patent**" means any Patent, other than a Joint Patent, Controlled by Cyclerion or its Affiliates as of the Effective Date or [**].

1.31 "**Debarred Entity**" has the meaning set forth in Section 11.3(b).

1.32 "**Debarred Individual**" has the meaning set forth in Section 11.3(a).

1.33 "**Development**" means all internal and external research, development, and regulatory activities regarding the Licensed Compound or the Products. This includes (a) research, preclinical testing, toxicology, route of synthesis, non-clinical activities, formulation, and clinical studies of such Licensed Compound or Products; and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct Clinical Trials and to obtain or maintain Regulatory Approval of a Product. Development also includes development and regulatory activities for additional forms, formulations or Indications for a Product, including Clinical Trials initiated following receipt of Regulatory Approval or any Clinical Trial to be conducted after a Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved Indication including post-marketing studies and observational studies, if required by any Regulatory Authority in any country in the Territory to maintain Regulatory Approval for a Product in such country, but Development excludes all activities directed to Manufacturing, Medical Affairs, and Commercialization. "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

1.34 "**Development Materials**" has the meaning set forth in Section 5.4.

1.35 "**Development Plan**" has the meaning set forth in Section 3.1.

1.36 "**Dollars**" means U.S. dollars.

1.37 "**Drug Product**" means that certain finished Product manufactured [**].

1.38 "**Effective Date**" has the meaning set forth in the preamble hereto.

1.39 "**EMA**" means the European Medicine Agency or any successor agency thereto or authority having substantially the same function.

1.40 "**E.U. Regulatory Approval**" means (a) receipt of Regulatory Approval by the EMA through the Centralized Approval Procedure or (b) receipt of Regulatory Approval from the applicable Regulatory Authorities in [**] Major European Countries.

1.41 "**European Union**" or "**E.U.**" means the economic, scientific, and political organization of member states known as the European Union, as its membership may be altered from time to time, and any successor thereto; *provided* that for the purposes of this Agreement, the European Union shall be deemed to include the United Kingdom.

1.42 "**Excluded Entity**" has the meaning set forth in Section 11.3(c).

1.43 "**Excluded Individual**" has the meaning set forth in Section 11.3(c).

1.44 "**Excluded Indication**" means [**].

1.45 "**Executive Officer**" means, with respect to Cyclerion, its Chief Executive Officer and, with respect to Akebia, its Chief Executive Officer.

1.46 "**Existing Drug Substance**" means the existing inventory of praliciguat drug substance that Cyclerion has on hand as of the Effective Date, [**].

1.47 "**Exploit**" means to Develop, Manufacture, perform Medical Affairs with respect to, Commercialize, and otherwise make, use, sell, offer for sale, or import.

1.48 "**FDA**" means the U.S. Food and Drug Administration or any successor agency thereto or authority having substantially the same function.

1.49 "**FDA's Disqualified/Restricted List**" has the meaning set forth in Section 11.3(d).

1.50 "**FFDCA**" means the U.S. Federal Food, Drug, and Cosmetics Act (21 U.S.C. Section 301 *et seq.*), as amended from time to time, together with any rules, regulations and requirements promulgated thereunder.

1.51 "**Field**" means the treatment, prevention, or diagnosis of any diseases or conditions in humans.

1.52 "**First Commercial Sale**" means, with respect to a Product and a country or other jurisdiction in the Territory, the first *bona fide*, arm's length sale of such Product in such country after Regulatory Approval has been obtained for such Product in such country or other jurisdiction. First Commercial Sale excludes any sale or other distribution of a Product for Clinical Trial or other Development purposes, early access programs (such as to provide patients with such Product prior to Regulatory Approval pursuant to treatment INDs or protocols, named patient programs or compassionate use programs) or any similar use.

1.53 "**GAAP**" means U.S. generally accepted accounting principles (or such accounting principles adopted by Akebia for the calculation of Net Sales, as applicable), consistently applied.

1.54 "**Generic Product**" means, with respect to a Product and a particular country, any pharmaceutical product that (a) is sold in such country by a Third Party that is not a Sublicensee of Akebia or its

Affiliates, or any of their Sublicensees, under a Regulatory Approval granted by the applicable Regulatory Authority to a Third Party, (b) contains as an active ingredient the same active ingredient as such Product, and (c) is approved in part in reliance on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of such Product (i) in the U.S., pursuant to Section 505(b)(2) or Section 505(j) of the FFDCA (21 U.S.C. 355(b)(2) and 21 U.S.C. 355(j), respectively), or (ii) in any other country or jurisdiction in the Territory, pursuant to all equivalents of any of the foregoing. Notwithstanding the foregoing, [**].

1.55 "**Good Clinical Practices**" or "**GCP**" means the then-current standards, practices and procedures for designing, conducting, recording and reporting Clinical Trials as required by applicable Regulatory Authorities or applicable law in the relevant jurisdiction of such Clinical Trial, including, in the U.S., those promulgated or endorsed by the FDA and in the E.U. those required by the EMA under comparable applicable laws in the European Union, as set forth in the guidelines entitled "Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance," and including related regulatory requirements imposed by the FDA or EMA, as applicable.

1.56 "**Good Manufacturing Practices**" or "**GMP**" means the then-current good manufacturing practices applicable from time to time to the Manufacturing of the Licensed Compounds or the Products or any intermediate thereof pursuant to applicable law in the jurisdiction of Manufacture, including in the U.S. those required by the FDA, as set forth in the FFDCA and the regulations promulgated thereunder, and in the E.U. those required by the EMA under comparable applicable laws in the European Union, for the manufacture, testing and release of pharmaceutical materials, as they may be updated from time to time, and applicable quality guidelines promulgated under the ICH (International Council for Harmonization).

1.57 "**IND**" means (a) an Investigational New Drug Application as defined in the FFDCA and applicable regulations promulgated thereunder by the FDA, the filing of which is necessary to commence a Clinical Trial, and equivalent filings with Regulatory Authorities outside the U.S., including the EMA and PMDA, and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.58 "**Indemnitee**" has the meaning set forth in Section 12.3.

1.59 "**Indemnitor**" has the meaning set forth in Section 12.3.

1.60 "**Indication**" means each separate and distinct disease, disorder, or condition. Notwithstanding any provision to the contrary set forth in this Agreement: (a) with respect to a Product, if such Product has received Regulatory Approval for which at least one adequate and well-controlled Clinical Trial is required to support the addition of a disease, disorder, or condition to the indication statement on the Regulatory Authority-approved labeling for such Product, such approval shall be deemed to be Regulatory Approval for a new Indication; (b) each of the following will be treated as the same Indication and not a distinct Indication: (i) the treatment of a disease, disorder, or condition in a particular patient population and the treatment of the same disease, disorder, or condition in another population (*e.g.*, adult population and pediatric population); (ii) different subtypes or lines of therapy for the same disease, disorder, or condition; and (iii) different doses or dosing schedules for the same disease, disorder, or condition; and (c) each of the following will be treated as distinct Indications: [**].

1.61 "**Initial Supply**" has the meaning set forth in Section 5.1.

1.62 "**Initial Supply Notice Date**" has the meaning set forth in Section 5.1.

1.63 "**Initiating Party**" has the meaning set forth in Section 9.4(d).

1.64 "**Initiation**" means, with respect to a given Clinical Trial, the administration of the first dose of a Product to the first duly screened and enrolled subject in accordance with the study protocol for such Clinical Trial.

1.65 "**Joint Intellectual Property Rights**" has the meaning set forth in Section 9.1(b).

1.66 "**Joint Know-How**" has the meaning set forth in Section 9.1(b).

1.67 "**Joint Patents**" has the meaning set forth in Section 9.1(b).

1.68 "**Know-How**" means any (a) proprietary information or materials, including records, improvements, modifications, techniques, assays, processes, methods, utilities, formulations, compositions of matter, articles of manufacture, materials (including chemical or biological materials), creation, discovery or finding, designs, protocols, formulas, data (including physical data, chemical data, toxicology data, animal data, raw data, clinical data, and analytical and quality control data), dosage regimens, control assays, product specifications, marketing, pricing and distribution costs, algorithms, technology, forecasts, profiles, strategies, plans, results in any form whatsoever, know-how, and trade secrets (in each case, whether or not patentable, copyrightable, or otherwise protectable), and (b) any physical embodiments of any of the foregoing.

1.69 "**Knowledge**" means the actual knowledge, as of the Effective Date, of the individuals of Cyclerion [**].

1.70 "**Licensed Compound**" means (a) the pharmaceutical compound known as praliciguat, which has the chemical structure set forth on Schedule 1.71, and (b) any metabolite, salt, ester, hydrate, solvate, isomer, enantiomer, free acid form, free base form, crystalline form, co-crystalline form, amorphous form, pro-drug (including ester pro-drug) form [**], racemate, polymorph, chelate, stereoisomer, tautomer, or optically active form of any of the foregoing.

1.71 "**MAA**" or "**Marketing Authorization Application**" means (a) a New Drug Application as defined in the FFDCA, or any corresponding foreign application in the Territory, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the Centralized Approval Procedure or with the applicable Regulatory Authority of any country in the European Union with respect to the mutual recognition or any other national approval procedure, and (b) all supplements and amendments to any of the foregoing.

1.72 "**Major Countries**" means [**].

1.73 "**Major European Countries**" means [**].

1.74 "**Manufacture**" and **"Manufacturing**" means, with respect to any product (including active pharmaceutical ingredient and other intermediate or material contained therein), any and all activities related to the manufacture of such product, including qualification, validation and scale-up, pre-clinical, clinical and commercial manufacture, packaging, labeling, filling, finishing, assembly, processing, in-process and finished product testing, release of such product or any component or ingredient thereof, quality assurance, quality control and audit activities related to manufacturing, testing and release of such product, ongoing stability tests, storage, shipping, supply or storage of such product (or any components or process steps involving such product or any companion diagnostic), placebo or comparator agent, as the case may be, product characterization, technical support activities, and regulatory activities related to any of the foregoing, but excluding any activities directed to Development, Medical Affairs, and Commercialization of such product.

1.75 "**Manufacturing Process**" means the process for the Manufacture of the Licensed Compounds and Products, including the then-current process for the Manufacture of the Licensed Compounds and Products.

1.76 "**Manufacturing Process Improvements**" means any [**].

1.77 "**Manufacturing Process Patents**" means any Patents Controlled by Akebia that Cover any Manufacturing Process Improvements.

1.78 "**Manufacturing Transfer Plan**" has the meaning set forth in Section 5.7.

1.79 "**Medical Affairs**" means, with respect to a Product, any and all activities performed by or on behalf of a Party's or its Affiliates' medical affairs departments interacting with physicians or other healthcare professionals who utilize or conduct research related to a drug or biological product, including: supporting continuing medical education and other medical programs and communications; development, publication, and dissemination of publications; development and fulfillment of medical information responses; development and execution of disease awareness education including symposia and digital education initiatives; sponsorship and booth exhibition at key congresses; conducting health economic, burden of illness/disease, natural history and real world evidence studies;; supporting educational fellowships and research grants, supporting external research efforts such as scientific research agreements and investigator initiated trials (following Regulatory Approval); medical resourcing, training and allocation; medical and scientific platform, content development, publications, and communications; conducting appropriate activities involving opinion leaders, including communications and engagement; conducting medical science liaison activities; advisory boards (to the extent related to medical affairs or clinical guidance) and conducting advisory board meetings or other consultant programs; establishing patient registries and expanded access programs; post-approval investigator initiated trials or scientific research agreements; life cycle management activities and clinical research and investigator initiated research (IIR), expressly excluding activities directed to Development, Manufacturing, and Commercialization.

1.80 [**].

1.81 [**].

1.82 [**].

1.83 [**].

1.84 "**Net Sales**" means the [**].

1.85 "**New License Agreement**" has the meaning set forth in Section 8.5.

1.86 "**Non-Commercial Sublicense Income**" means any consideration (including in the form of upfront payments, license fees, milestone payments, including any milestone payments for the receipt of Regulatory Approval but excluding [**], and the fair market value of any non-cash consideration as determined in accordance with Section 7.6(c).) received by Akebia or any of its Affiliates from any Significant Sublicensee in consideration for the grant by Akebia or any of its Affiliates of a sublicense to such Significant Sublicensee of any of the rights granted to Akebia under this Agreement with respect to the Licensed Compounds or the Products or under any of the Cyclerion Intellectual Property in any of the Major Countries (and any other countries or other jurisdictions in the Territory to the extent included in the grant of such a sublicense for any Major Country), including [**]. Notwithstanding any provision to the contrary set forth in this Agreement, Non-Commercial Sublicense Income shall exclude [**].

1.87 "**Non-Control Transferring Patent**" has the meaning set forth in Section 9.2(c)(i).

1.88 "**Party**" or "**Parties**" has the meaning set forth in the preamble hereto.

1.89 "**Patent(s)**" means (a) any and all national, regional and international patents, certificates of invention, applications for certificates of invention, priority patent filings and patent applications, including provisional patent applications, and (b) any renewal, divisional, continuation (in whole or in part), or request for continued examination of any of such patents, certificates of invention and patent applications, and any and all patents (including utility models, petty patents and design patents) or certificates of invention issuing thereon, and any and all reissues, reexaminations, extensions, divisions, renewals, substitutions, confirmations, registrations, revalidations, revisions, and additions of or to any of the foregoing.

1.90 "**Patent Challenge**" has the meaning set forth in Section 13.2(c).

1.91 "**Patent Contact**" has the meaning set forth in Section 9.3.

1.92 "**Patent Linkage**" has the meaning set forth in Section 9.2(f).

1.93 "**Patent Term Extension**" has the meaning set forth in Section 9.2(f).

1.94 "**Patent Transfer Date**" means the earlier of [**], and (b) such date that the Parties may agree, following request by Akebia or Cyclerion.

1.95 "**Person**" means any individual, corporation, partnership, limited liability company, trust, governmental entity, or other legal entity of any nature whatsoever.

1.96 "**Phase 2 Clinical Trial**" means a human clinical trial of a product, which trial the FDA permits to be conducted under an open IND, with the endpoint of evaluating its effectiveness for a particular Indication or Indications in one or more specified doses or its short term tolerance and safety, as well as its pharmacokinetic and pharmacodynamic information in patients with the Indications under study, that is prospectively designed to generate sufficient data (if successful) to commence a Phase 3 Clinical Trial for such product, and that satisfies the requirements of U.S. federal regulation 21 C.F.R. § 312.21(b) and its successor regulation or equivalents in other jurisdictions.

1.97 "**Phase 3 Clinical Trial**" means a human clinical trial of a product on a sufficient number of patients, which trial the FDA permits to be conducted under an open IND, and that is designed to: (a) establish that the product is safe and efficacious for its intended use; (b) define warnings, precautions, and adverse reactions that are associated with the product in the dosage range to be prescribed; and (c) enable, without additional clinical trials, the submission of an MAA to a Regulatory Authority for the product, and that satisfies the requirements of U.S. federal regulation 21 C.F.R. § 312.21(c) and its successor regulation or equivalents in other jurisdictions.

1.98 "**PMDA**" means the Pharmaceuticals and Medical Devices Agency of Japan or any successor agency thereto or authority having substantially the same function.

1.99 "**Pricing Approval**" means such approval, agreement, determination, or decision establishing prices for a Product that can be charged to consumers or reimbursed by Regulatory Authorities in a country or regulatory jurisdiction where the applicable Regulatory Authorities of such country or regulatory jurisdiction approve or determine the pricing or reimbursement of pharmaceutical products.

1.100 "**Product**" means any pharmaceutical product containing a Licensed Compound, alone or in combination with one or more other active ingredients (including all Combination Products), in any and all forms, presentations, delivery systems, dosages, and formulations.

1.101 "**Product Infringement**" has the meaning set forth in Section 9.4(a).

1.102 "**Reduction Floor**" has the meaning set forth in Section 7.5(e)(iv).

1.103 "**Regulatory Approval**" means, with respect to a country or other jurisdiction in the Territory, any and all approvals (including approval of an MAA), licenses, registrations, or authorizations of any Regulatory Authority necessary to commercially distribute, sell, and market a Licensed Compound or Product in such country or other jurisdiction, excluding any Pricing Approvals in such country or other jurisdiction (where applicable).

1.104 "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory agencies, departments, bureaus, commissions, councils, or other government entities (*e.g.*, the FDA, EMA, and PMDA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement, including the Development, Manufacture, or Commercialization of pharmaceutical products.

1.105 "**Regulatory Exclusivity**" means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Product in a country or jurisdiction in the Territory other than Patents that (a) prohibit any Person from relying on safety or efficacy data generated by or on behalf of a Party with respect to such Product in an application for Regulatory Approval of a Generic Product, or (b) confer an exclusive Commercialization period during which Akebia or its Affiliates or Sublicensees have the exclusive right to market and sell a Licensed Compound or a Product in such country or jurisdiction, including rights conferred in the U.S. under the Hatch-Waxman Act or the FDA Modernization Act of 1997 (including pediatric exclusivity), orphan drug exclusivity, or rights similar thereto outside the U.S.

1.106 "**Regulatory Submissions**" means all (a) applications (including all INDs and MAAs), registrations, licenses, authorizations, and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files; and (c) clinical and other data contained or relied upon in any of the foregoing, in each case ((a), (b), and (c)) relating to a Licensed Compound or Product.

1.107 "**Residual Knowledge**" has the meaning set forth in Section 10.5.

1.108 "**Restricted Product**" has the meaning set forth in Section 8.8(c).

1.109 "**Royalty Term**" means, with respect to each Product and each country or other jurisdiction in the Territory, the period beginning on the date of the First Commercial Sale of such Product in such country or other jurisdiction, and ending on the latest to occur of (a) the expiration of the last-to-expire Valid Claim of a Cyclerion Patent or Joint Patent, in each case, that Covers the composition of matter or approved method of use in the label of such Product and that would be infringed by the sale of such Product in such country or jurisdiction; (b) the expiration of Regulatory Exclusivity in such country or jurisdiction for such Product; and (c) the tenth (10th) anniversary of the First Commercial Sale of such Product in such country or other jurisdiction.

1.110 "**Sell-Down Period**" has the meaning set forth in Section 13.3(g).

1.111 "**Significant Sublicensee**" means any Sublicensee to whom Akebia or an Affiliate of Akebia grants a sublicense of any of the rights granted to Akebia in Section 8.1 as permitted under Section 8.4 (a) in any of the Major Countries (and in any other countries or other jurisdictions in the Territory to the extent included in the grant of such a sublicense for any Major Country), and (b) that includes a grant of rights to sell one or more Products on such Sublicensee's own behalf in such Major Countries and Sublicensee has the right to record such Product sales in its financial statements in accordance with U.S. GAAP or similar accounting standards in countries outside of the U.S..

1.112 "**Sublicensee**" means any Third Party to whom Akebia or an Affiliate of Akebia grants a sublicense of any of the rights granted to Akebia in Section 8.1 as permitted under Section 8.4, but expressly excluding all Third Party Distributors.

1.113 "**Supply Agreement**" has the meaning set forth in Section 5.1.

1.114 "**Term**" has the meaning set forth in Section 13.1.

1.115 "**Territory**" means worldwide.

1.116 "**Third Party**" means any person or entity other than Cyclerion, Akebia, and their respective Affiliates.

1.117 "**Third Party Claims**" has the meaning set forth in Section 12.1.

1.118 "**Third Party Distributor**" means, with respect to a country, any Third Party that purchases its requirements for Products in such country from Akebia or its Affiliates or Sublicensees and is appointed as a distributor to distribute, market, and resell such Product in such country, even if such Third Party is granted ancillary rights to Develop, package, or obtain Regulatory Approval of such Product in order to distribute, market, or sell such Product in such country.

1.119 "**Trademarks**" means any word, name, symbol, color, shape, designation or any combination thereof that functions as an identifier of source or origin, including any trademarks, trade names, trade dress, service marks, domain names, logos, slogans and brandings, registered or unregistered, whether at common law or statutory, and all registrations and applications therefor, and all goodwill associated with the foregoing.

1.120 "**U.S.**" means the United States of America, including its territories and possessions.

1.121 "**Valid Claim**" (a) a claim of any issued and unexpired Patent whose validity, enforceability, or patentability has not been affected by any of the following: (i) irretrievable lapse, abandonment, revocation, dedication to the public, or disclaimer; or (ii) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction, such holding, finding, or decision being final and unappealable or unappealed within the time allowed for appeal, or (b) a claim of a pending Patent application, which claim has not been pending for more than [**] since the earliest date such Patent application is entitled to claim priority, unless and until such claim becomes an issued claim of an issued patent in which case it will again be considered a Valid Claim under the foregoing clause (a).

Article 2
INFORMATION SHARING

2.1 **Good Faith Information Sharing.** The Parties agree that they will cooperate in good faith to share relevant information and expertise regarding the Development (including CMC), Manufacturing, Medical Affairs, and Commercialization of the Product through discussions between appropriate representatives of the Parties as may be arranged from time to time. On an [**] basis, through a presentation to representatives of Cyclerion, Akebia will provide Cyclerion with an update with respect to the Development, Manufacturing, Medical Affairs, and Commercialization activities that it has performed, or caused to be performed, for the Products in the Field in the Territory on a Major Country-by-Major Country basis since the preceding update

and a summary of the key Development, Manufacturing, Medical Affairs, and Commercialization activities that Akebia expects to perform, or caused to be performed, for the Products in the Field in the Territory on a Major Country-by-Major Country basis during the then-current Calendar Year. Following each such [**] meeting, Akebia shall provide to Cyclerion with a written copy of such presentation as was presented by Akebia to the representatives of Cyclerion.

Article 3
DEVELOPMENT

3.1 **Overview of Development**. Subject to the terms and conditions of this Agreement, Akebia shall have sole control over and decision-making authority with respect to the Development of the Licensed Compounds and Products in the Field in the Territory in accordance with this Article 3, including obtaining and maintaining Regulatory Approval therefor.

3.2 **Diligence.** Akebia shall, and shall cause its Affiliates to, perform any and all Development activities under this Agreement in compliance in all material respects with applicable laws and regulations, including as applicable GCP and GMP. Akebia shall use Commercially Reasonable Efforts to [**]. Akebia shall have the right to satisfy its diligence obligations under this Section 3.2 through its Affiliates or Sublicensees. If at any time Cyclerion has a reasonable basis to believe that Akebia is [**].

3.3 **Development Plan**. All Development of the Products in the Territory will be governed by a written development plan, as such development plan may be revised by Akebia in its sole discretion from time to time (the "**Development Plan**"). The initial Development Plan is attached hereto as Schedule 3.3. For the avoidance of doubt, Akebia is under no obligation to provide Cyclerion notice of, or copies of, any changes to the Development Plan.

3.4 **Third Party Contractors.** Akebia may engage any Third Party subcontractor to perform any or all of its obligations hereunder, *provided* that (a) Akebia will (i) remain primarily liable to Cyclerion for the performance of all of its obligations under, and Akebia's compliance with all provisions of, this Agreement, and (ii) be fully responsible and liable for any conduct by any of its subcontractors that would amount to a breach of the terms of this Agreement if performed by Akebia, in each case, to the same extent as if Akebia itself has committed such breach, and (b) the agreement pursuant to which Akebia engages any Third Party subcontractor must (i) be consistent in all material respects with this Agreement, (ii) contain terms with respect to intellectual property that are consistent with the intellectual property provisions of this Agreement, and (iii) contain obligations of confidentiality and non-use no less stringent that the confidentiality terms of this Agreement.

3.5 **Development Costs.** Except as otherwise provided in this Agreement, Akebia shall be responsible for all of its costs and expenses in connection with the Development of, and obtaining and maintaining Regulatory Approvals for, the Products in the Field in the Territory.

3.6 **Records.** Akebia shall maintain records in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, and in compliance with applicable law, which shall reflect all work done and results achieved in the performance of its Development activities for the Products in the Field in the Territory. Such records shall be retained by Akebia for at least

[**] after the termination of this Agreement, or for such longer period as may be required by applicable law.

Article 4
REGULATORY MATTERS

4.1 **Transfer of Regulatory Submissions.** [**] following the Effective Date, Cyclerion shall transfer to Akebia all INDs for the Products listed on Schedule 4.1 (unless otherwise agreed by the Parties) and any other Regulatory Submissions for the Licensed Compounds and Products in the Field in the Territory, and in connection with such transfer Cyclerion shall take all actions required to assign, convey, transfer, and deliver to Akebia, all of Cyclerion's rights, title, and interests in and to such Regulatory Submissions (including executing and delivering such endorsements, assignments, and other documents as may be necessary). Without limiting Cyclerion's obligations under this Section 4.1, [**] the Effective Date, Cyclerion will submit to the applicable Regulatory Authorities a letter or other necessary documentation (with copy to Akebia) notifying such Regulatory Authorities of such transfer. Following transfer to Akebia, Akebia shall thereafter be responsible for the maintenance of such INDs and any other Regulatory Submissions for the Licensed Compounds and the Products in the Field in the Territory at its sole cost and expense.

4.2 **Regulatory Responsibilities.** Subject to the terms and conditions of this Agreement, as between the Parties, Akebia shall have sole control over and decision-making authority with respect to, at its own expense, preparing, filing, and maintaining all Regulatory Submissions for Licensed Compounds and Products in the Field in all countries and regulatory jurisdictions of the Territory, including preparing all reports required in connection with the submission of any application for Regulatory Approval. All Regulatory Submissions for the Licensed Compounds and the Products in the Field shall be filed in the name of Akebia or one of its Affiliates or Sublicensees, or in the case of an investigator-sponsored trial, in the name of the investigator or institution conducting the study, and, as between the Parties, Akebia shall sole control over and decision-making authority with respect to all communications and other dealings with the Regulatory Authorities relating to the Licensed Compounds and the Products in the Field in the Territory. As between the Parties, following completion of the assignment and transfer contemplated in Section 4.1, Akebia shall be the legal and beneficial owner of all Regulatory Submissions and Regulatory Approvals for the Licensed Compounds and the Products in the Field in all countries and regulatory jurisdictions of the Territory.

Article 5
MANUFACTURE AND SUPPLY OF PRODUCT AND PRE-CLINICAL MATERIALS

5.1 **Initial Supply of Products**. Unless otherwise agreed to in writing by the Parties, the Parties shall enter into a supply agreement (the "**Supply Agreement**") [**] the Effective Date, which will include the terms set forth in this Article 5 as well as other terms customary for supply arrangements between licensees and licensors pursuant to which licensor receives milestone and royalty payments. Pursuant to the Supply Agreement, Cyclerion [**]. The Parties shall use Commercially Reasonable Efforts to ensure that delivery of the Initial Supply shall occur no later than [**] from the Initial Supply Notice Date, or at such a time agreed upon by the Parties in writing. The term of the Supply Agreement shall conclude [**].

5.2 **Compliance; Warranties**. The Supply Agreement will contain terms and conditions regarding compliance with applicable law and specifications for the Existing Drug Substance and Drug Product, delivery, acceptance, recalls, indemnification, and limitations of liability.

5.3 **Price.** The Initial Supply shall be supplied to Akebia or its designee at Cyclerion's actual fully-burdened Manufacturing [**]. The fully-burdened Manufacturing cost will include [**], solely to the extent incurred after the Effective Date. The approximate cost of the Initial Supply is [**], assuming an Initial Supply as set forth in Schedule 5.3. If Cyclerion becomes aware that the cost of the Initial Supply is anticipated to materially increase from this estimate, then Cyclerion shall promptly provide notice to Akebia of such anticipated cost change and the new estimated cost of the Initial Supply. Promptly thereafter, the Parties will meet and discuss in good faith any steps that either Party may take to mitigate such cost increase.

5.4 **Development Materials**. The Parties acknowledge that, as of the Effective Date, Cyclerion is in the physical possession of that inventory of [**] (collectively, [**] the "**Development Materials**"), in each case, as set forth on Schedule 11.1(u). Promptly after the Effective Date and pursuant to the terms of the Supply Agreement, Cyclerion shall supply Akebia with all Development Materials that Cyclerion controls, including those materials in the possession of Cyclerion's Third Party contract manufacturers, and that are listed on Schedule 11.1(u), at no cost to Akebia, and Cyclerion shall transfer title to Akebia to all such Development Materials in accordance with the terms of the Supply Agreement. Cyclerion hereby agrees to manage any storage, handling, and shipment of such inventory in accordance with Akebia's reasonable written directions and, as applicable, the terms of the Supply Agreement, including by transferring such Development Materials to Akebia or its designee at Akebia's direction.

5.5 **Additional Development Materials**. The Parties acknowledge that as of the Effective Date Cyclerion is in physical possession of that inventory of [**] (the "**Additional Development Materials**"). At any time during the period commencing on the Effective Date and continuing until the date that is [**] thereafter, Akebia may elect to purchase and take delivery of any or all of such inventory, in units that are readily available and at the applicable price set forth on Schedule 11.1(u), by providing written notice to Cyclerion of the Additional Development Materials Akebia elects to purchase and have delivered, and Cyclerion shall deliver such inventory to Akebia or its designee at Akebia's direction, at Akebia's cost and expense, and title to such Additional Development Materials shall transfer to Akebia at the time of delivery. Cyclerion shall use reasonable efforts to manage any storage and handling of all Additional Development Materials in accordance with standard industry practice. Akebia shall reimburse Cyclerion all reasonable costs incurred by Cyclerion or its Affiliates in connection with the storage of such Additional Development Materials during such [**] period until delivery thereof to Akebia, within [**] after receipt of an invoice therefor. Notwithstanding the foregoing, on a material-by-material basis Akebia may waive its option to purchase some or all of such Additional Development Materials by providing written notice of such waiver, and from the date of delivery of such notice Akebia shall no longer reimburse Cyclerion for the costs incurred by Cyclerion or its Affiliates in connection with the storage of such material.

5.6 **Manufacture of Licensed Compounds and Products after Initial Supply**. As between the Parties, after successful supply to Akebia or its designee of all Initial Supply and after the Supply Agreement expires or is terminated, Akebia shall have sole control over and decision-making

authority with respect to, at its expense, (a) Manufacturing (or having Manufactured) the Licensed Compounds and Products and (b) Manufacturing (or having Manufactured) [**], and all other intermediates and other precursors of the Licensed Compounds and the Products, solely for the purpose of Manufacturing the Licensed Compounds and the Products for Development and Commercialization in the Field in the Territory by Akebia and its Affiliates and Sublicensees.

5.7 **Transfer of Responsibility for Manufacturing**. Upon request by Akebia (but no later than the date of delivery of the Initial Supply to Akebia or its designee, as the case may be), on a manufacturer-by-manufacturer and material-by-material basis, the Parties shall collaborate to [**], each a "**Manufacturing Transfer Plan**"). For the avoidance of doubt, Akebia may request the [**].

5.8 **Non-Manufacturing Information Sharing**. In addition to Cyclerion's obligations set forth in Section 5.7, Cyclerion will provide to Akebia copies of all Cyclerion Know-How that is necessary or reasonably useful for Akebia to Develop, perform Medical Affairs with respect to, Commercialize, and otherwise use, sell, offer for sale, or import the Licensed Compounds or Products in the Territory in accordance with the terms and conditions of this Agreement no later than [**] after the Effective Date. Thereafter, Cyclerion will provide to Akebia copies of all Cyclerion Know-How that is made, conceived, discovered, or otherwise generated following such initial transfer of Cyclerion Know-How and is necessary or reasonably useful to continue to enable Akebia to Develop, perform Medical Affairs with respect to, Commercialize, and otherwise use, sell, offer for sale, or import any Licensed Compounds and Products in the Territory in accordance with the terms and conditions of this Agreement. In addition to providing copies of the Cyclerion Know-How in accordance with this Section 5.8, Cyclerion will, to the extent reasonably requested by Akebia, make its personnel reasonably available to Akebia for the purposes of assisting on issues arising during Akebia's Exploitation under the Cyclerion Intellectual Property of the Licensed Compounds and Products in the Territory.

Article 6
MEDICAL AFFAIRS AND COMMERCIALIZATION

6.1 **Medical Affairs and Commercialization**. Subject to the terms of this Agreement, Akebia shall have sole control over and decision-making authority with respect to the performance of Medical Affairs and Commercialization of the Products in the Field in the Territory, including the establishment and implementation of its commercial strategy. Akebia shall be solely responsible for all costs and expenses associated with its performance of Medical Affairs and Commercialization of the Products in the Field in the Territory.

6.2 **Diligence.** Akebia shall use Commercially Reasonable Efforts to [**].

6.3 **Statements and Compliance with Applicable Law.** Akebia shall, and shall cause its Affiliates to, comply with all applicable law with respect to the Commercialization of Products.

Article 7
PAYMENTS

7.1 **Upfront Payment.** No later than [**] following the Effective Date, Akebia shall pay Cyclerion an upfront amount equal to Three Million Dollars ($3,000,000). Such payment shall be nonrefundable and noncreditable against any other payments due hereunder.

7.2 **Development and Regulatory Milestone Payments.** In partial consideration of the rights granted by Cyclerion to Akebia hereunder and subject to the terms and conditions set forth in this Agreement, including Section 7.2, Akebia shall pay to Cyclerion the applicable milestone payment set forth in Table 7.2 within [**] after the first achievement of each of the following milestones by Akebia or its Affiliates for the first Product:

Table 7.2 – Development and Regulatory Milestones	
U.S.	***Development and Regulatory Milestone Payment***
Initiation of a Phase 2 Clinical Trial in the U.S. for a Product for the first Indication	[**]
Initiation of a Phase 3 Clinical Trial in the U.S. for a Product for the first Indication	[**]
Initiation of a Phase 3 Clinical Trial in the U.S. for a Product for the second Indication	[**]
Receipt of Regulatory Approval by the FDA for a Product for the first Indication	[**]
Receipt of Regulatory Approval by the FDA for a Product for the second Indication	[**]
[**]	[**]
[**]	***Development and Regulatory Milestone Payment***
Receipt of [**] Regulatory Approval for a Product for the first Indication	[**]
Receipt of [**] Regulatory Approval for a Product for the second Indication	[**]
[**]	[**]
[**]	***Development and Regulatory Milestone Payment***
Receipt of Regulatory Approval by [**] for a Product for the first Indication	[**]
Receipt of Regulatory Approval by [**] for a Product for the second Indication	[**]
[**]	[**]

(i) Each milestone payment in this Section 7.2 shall be payable one time only upon the first achievement of such milestone by the first Product.

If Akebia or its Affiliates achieves any milestone set forth in this Section 7.2 for a particular Product in a particular Indication before an earlier listed milestone for the same Product in the same Indication, then the earlier listed milestone shall become payable at the same time as the achieved milestone for the same Product in such Indication. No milestone payments in this Section 7.2 shall be due based on the achievement of any of the foregoing milestone events by any Significant Sublicensee.

7.3 **Delayed Phase 2 Milestone Payment**. If Akebia or its Affiliates have not Initiated a Phase 2 Clinical Trial in the U.S. for any Product by the date that is [**] from the Initial Supply Notice Date, then within [**] of such date Akebia shall pay Cyclerion a one-time milestone of [**], which payment shall be [**] for the Initiation of a Phase 2 Clinical Trial in the U.S. for a Product for the first Indication. If (a) Akebia has not [**].

7.4 **Sales Milestone Payments.**

(a) In partial consideration of the rights granted by Cyclerion to Akebia hereunder, subject to the terms and conditions of this Agreement, including Section 7.4(b), on [**], in the event the aggregate Net Sales of all Products recorded by Akebia, or any of its Affiliates [**] in [**] first exceeds each of the three sales milestone events set forth in Table 7.4 below, Akebia shall pay to Cyclerion the sales milestone payment in the corresponding amount set forth in the right-hand column of the table. In the event that Akebia or its Affiliates [**] that is exceeded [**]. Each such milestone payment shall be due within [**] of the end of [**] in which such milestone was achieved.

Table 7.4 – Sales Milestones	
[**]	***[**]***
[**]	[**]
[**]	[**]
[**]	[**]

(b)

For the avoidance of doubt, each sales milestone payment in this Section 7.4(a) shall be payable one time only upon the first achievement of such sales milestone event [**]. For the avoidance of doubt, (i) the maximum aggregate amount payable by Akebia pursuant to this Section 7.4(a) [**], and (ii) the maximum aggregate amount payable by Akebia pursuant to this Section 7.4(a) worldwide is [**].

(c) [**].

7.5 **Royalty Payments.**

(a) **Akebia Royalty Rate – [**].** As further consideration for the rights granted to Akebia hereunder, subject to the terms and conditions of this Agreement, including the other terms of this Section 7.5, [**], during the Royalty Term for a Product [**], Akebia shall

pay to Cyclerion tiered royalties based on Net Sales recorded by Akebia or its Affiliates of all Products in [**] in a [**] at the applicable royalty rates set forth below:

Table 7.5 – Akebia Royalties [**]	
[**]	*[**]*
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

(b) **Significant Sublicensee.** [**]. In addition, notwithstanding any provision to the contrary set forth in this Agreement, Akebia shall have no obligation pay Cyclerion any royalties based on sales of Products sold by any such Significant Sublicensees other than as set forth in Section 7.6.

(c) **ROW Royalty Rate.** As further consideration for the rights granted to Akebia hereunder, subject to the other terms of this Section 7.5, during the Royalty Term of a Product [**], unless Akebia has entered into an agreement with a Significant Sublicensee that includes a grant of rights [**], Akebia shall pay to Cyclerion a royalty of [**] on Net Sales recorded by Akebia or its Affiliates or Sublicensees (other than a Significant Sublicensee) of all Products [**] in a [**].

(d) **Royalty Term.** Akebia shall have no obligation to pay any royalty pursuant to this Section 7.5 with respect to sales of any Product in any country or other jurisdiction after the Royalty Term for such Product in such country or other jurisdiction has expired.

(e) **Reductions.**

(i) **Expiration of Valid Claims**. Subject to Section 7.5(e)(iv), on a Product-by-Product and country-by-country basis, during [**] following [**], the royalty rate set forth in this Section 7.5 with respect to such country shall be reduced by [**].

(ii) **Generic Product Entry**. Subject to Section 7.5(e)(iv), in the event that (A) a Generic Product for a Product is made commercially available in any country in the Territory during the Royalty Term and (B) the Net Sales of such Product in such country [**] are [**] of the royalties otherwise due to Cyclerion with respect to such Product in such country.

(iii) **Third Party Intellectual Property**. If Akebia makes any payment under any agreement with a Third Party pursuant to which Akebia is granted a license, sublicense or other rights under a Patent or other intellectual property right owned or controlled by a Third Party [**] to Exploit one or more Products, then Akebia may offset against the royalties due to Cyclerion for such Product(s) an amount equal to [**] of the amounts paid in consideration for, or in connection

with obtaining, such rights from such Third Party (including any upfront payments, milestone payments, royalties, litigation costs, settlement fees, or other expenses relating to the foregoing) in all cases, subject to Section 7.5(e)(iv).

(iv) **Maximum Payment Adjustments**. [**], in no event will the adjustments under Section 7.5(e)(i), Section 7.5(e)(ii), and Section 7.5(e)(iii) taken together reduce the royalties due to Cyclerion in a country [**] with respect to a Product by more than [**] of the amount that would have been due [**] for such Product in such country but for the application of the reductions in this Section 7.5(e) (the "**Reduction Floor**"); *provided* that [**].

(f) **Royalty Payments and Reports.** Akebia shall calculate all amounts payable to Cyclerion pursuant to this Section 7.5 at the end of each Calendar Quarter, which amounts shall be converted to Dollars in accordance with Section 7.8. Within [**] after the end of each Calendar Quarter after the First Commercial Sale of a Product in the Territory, Akebia shall provide to Cyclerion a written, good faith estimate of the amount of Net Sales of each Product made by Akebia and its Affiliates in each country or other jurisdiction in the Territory during the applicable Calendar Quarter for which royalties pursuant to this Section 7.5 are payable. Akebia shall pay to Cyclerion the royalty amounts due with respect to a given Calendar Quarter within (i) [**] after the end of such Calendar Quarter or (ii) for the portion of any such payment is due to sales by a Sublicensee, as soon as practicable after Akebia is paid by such Sublicensee. Each payment of royalties due to Cyclerion shall be accompanied by a statement of the amount of Net Sales of each Product made by Akebia and its Affiliates and its Sublicensees (other than Significant Sublicensees) in each country or other jurisdiction in the Territory during the applicable Calendar Quarter for which royalties pursuant to this Section 7.5 are payable (including such amounts expressed in local currency and as converted to Dollars), and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter.

7.6 **Sublicense Income.**

(a) Akebia shall pay to Cyclerion an amount equal to [**].

(b) Akebia shall pay to Cyclerion an amount equal to [**].

(c) For purposes of calculating [**].

(d) Akebia shall pay Cyclerion its portion of all [**].

7.7 **Payment Method**. All payments due under this Agreement to Cyclerion shall be made by bank wire transfer in immediately available funds to an account as designated by Cyclerion from time to time by notice to Akebia. All payments hereunder shall be made in Dollars.

7.8 **Exchange Rate**. The rate of exchange to be used in computing the amount of currency equivalent in Dollars owed under this Agreement shall be equal to the exchange rate between each currency of origin and Dollars as reported by Citibank, N.A., or an equivalent resource as agreed by the

Parties, on the last Business Day of the Calendar Quarter in which the applicable Net Sales were made.

7.9 **Taxes**.

(a) **[**]**.

(b) **[**]**.

7.10 **Interest**. If Akebia fails to make any payment due to Cyclerion under this Agreement, then interest shall accrue on a daily basis at the annual rate equal to [**] above the then-applicable prime commercial lending rate of Citibank, N.A., New York, New York, or at the maximum rate permitted by applicable law, whichever is the lower.

7.11 **Financial Records; Audit.**

(a) **Retention.** Akebia shall, and shall cause its Affiliates and Sublicensees to, keep for at least [**] following the end of the Calendar Year to which they pertain accurate records of the Net Sales of the Products in the Territory, the number of Product units sold, and other matters relating to the calculation of Net Sales and the royalties paid to Cyclerion hereunder, and matters relating to Non-Commercial Sublicense Income and Commercial Sublicense Income paid to Cyclerion hereunder, in sufficient detail to calculate relevant amounts payable hereunder and to verify compliance with its obligations under this agreement.

(b) **Access to Records.** At the request of Cyclerion, Akebia shall, and shall cause its Affiliates and Sublicensees to, permit an independent auditor designated by Cyclerion and reasonably acceptable to Akebia, at reasonable times and upon at least [**] advance notice, to audit the books and records maintained pursuant to Section 7.11(a) to ensure the accuracy of all reports and payments made hereunder relating to Net Sales, royalties, Non-Commercial Sublicense Income, and Commercial Sublicense Income. Except as provided below, the cost of this audit shall be borne by Cyclerion, unless the audit reveals a variance of more than [**] from the reported amounts, in which case Akebia shall bear the cost of the audit. If such audit concludes that (i) additional amounts were owed by Akebia, then Akebia shall pay the additional amounts, with interest from the date originally due as provided in Section 7.10, or (ii) excess payments were made by Akebia, then Cyclerion shall reimburse such excess payments, in either case ((i) or (ii)), within [**] after the date on which such audit is completed by Cyclerion.

Article 8
LICENSE RIGHTS AND LIMITATIONS

8.1 **Licenses to Akebia.** Subject to the terms and conditions of this Agreement, including 8.2 and Cyclerion's retained rights under Section 8.7, Cyclerion hereby grants and will grant to Akebia and its Affiliates an exclusive royalty-bearing, worldwide license (with the right to sublicense solely in accordance with Section 8.4) under the Cyclerion Intellectual Property, solely to Exploit the Licensed Compounds and the Products in the Field in the Territory, which license shall

include the exclusive right to Develop, Manufacture, make, use or import [**] and all other intermediates and other precursors to the Licensed Compounds and the Products solely for the purpose of Manufacturing the Licensed Compounds and the Products in the Field in the Territory in accordance with this Agreement.

8.2 **Certain Restrictions**. Akebia shall not, and shall cause its Affiliates not to (a) directly or indirectly Exploit any Licensed Compound or Product, or any intermediate or other precursor thereof, in any Excluded Indication in any country or other jurisdiction in the Territory, or (b) license, authorize, appoint, or otherwise enable any Third Party to directly or indirectly Exploit any Licensed Compound or Product, or any intermediate or other precursor thereof, in any [**].

8.3 **Assigned Trademarks.** Cyclerion hereby assigns to Akebia all of its rights, title, and interests in and to the Assigned Trademarks, and agrees to take all actions reasonably requested by Akebia, at Akebia's expense, to evidence such assignment. Akebia hereby accepts such assignment.

8.4 **Rights to Sublicense**. Akebia shall have the right to grant to any Third Party or Affiliate sublicenses of the rights granted with respect to the Products or Cyclerion Intellectual Property under Section 8.1 [**] without the prior written consent of Cyclerion, *provided* that each sublicense agreement with a Third Party must (a) be consistent with and expressly made subject to the applicable terms and conditions of this Agreement, (b) contain terms obligating any Third Party to whom a sublicense is granted to comply with the intellectual property provisions of this Agreement, and (c) contain obligations of confidentiality and non-use no less stringent that the confidentiality terms of this Agreement. Akebia shall remain primarily liable to Cyclerion for the performance of all its obligations under, and Akebia's compliance with all the provisions of, this Agreement, and shall be responsible and liable for any conduct by any of its Sublicensees that would amount to a breach of the terms of this Agreement if performed by Akebia, in each case to the same extent as if Akebia itself has committed any such breach. [**] after execution of any sublicense of the rights granted to Akebia hereunder to a Sublicensee, Akebia will provide Cyclerion with a true and complete copy of any executed sublicense agreement with any Sublicensee, subject to Akebia's right to redact any confidential information contained therein that is not necessary for Cyclerion to determine compliance with the terms of this Agreement.

8.5 **Survival of Sublicenses**. Upon [**] not then in breach of its sublicense agreement or the terms of this Agreement applicable to such Sublicensee, Cyclerion will enter into a direct license from Cyclerion to such Sublicensee on the same terms as this Agreement, taking into account any difference in license scope, territory, and duration of sublicense grant (each a "**New License Agreement**"); *provided*, *however*, that, [**]. Under any such New License Agreement between Cyclerion and such former Sublicensee, such Sublicensee will be required to pay to Cyclerion the same amounts in consideration for such direct grant as Cyclerion would have otherwise received from Akebia pursuant to this Agreement on account of such Sublicensee's Exploitation of the Products had this Agreement not been terminated. Under such New License Agreement, the Parties agree that Cyclerion will not be bound by any grant of rights broader than, and will not be required to perform any obligation other than those rights and obligations contained in, this Agreement and all applicable rights of Cyclerion set forth in this Agreement will be included in such New License Agreement.

8.6 **No Implied Licenses.** Neither Party grants (or agrees to grant) to the other Party any right or license to use any of its intellectual property, Know-How, or other proprietary information, materials or technology, or to practice any of its Patents, except as expressly set forth in this Agreement, or any of its Trademarks (other than the Assigned Trademarks).

8.7 **Retained Rights**. Notwithstanding any provision to the contrary set forth in this Agreement, Cyclerion (on behalf of itself and its licensees, other than Akebia and its Sublicensees) expressly retains the right under the Cyclerion Intellectual Property to (a) exercise its rights and perform its obligations under this Agreement, (b) Manufacture the Licensed Compounds and Products (including the right to Develop, Manufacture, make, use or import [**] and all other intermediates and precursors to the Licensed Compounds and the Products for the purposes of Manufacturing Licensed Compound and Products) solely for the purpose of supplying the same to Akebia or its Affiliates in accordance with this Agreement, and (c) Exploit [**] and all other intermediates and precursors to the Licensed Compounds and the Products for the purpose of Exploiting compounds and products that are not Licensed Compounds or Products. Any rights not expressly granted to Akebia by Cyclerion under this Agreement are hereby retained by Cyclerion.

8.8 **Non-Competition**.

(a) **Cyclerion Obligations**. Cyclerion shall not, and shall cause its Affiliates not [**].

(b) **Cyclerion Indications**. Notwithstanding Section 8.8(a), [**].

(c) **Acquisition of Restricted Product.** Notwithstanding Section 8.8(a), [**].

Article 9
INTELLECTUAL PROPERTY

9.1 **Ownership of Intellectual Property.**

(a) **Ownership of Technology**. As between the Parties, each Party shall own and retain all rights, title, and interests in and to any and all: (i) inventions and other Know-How conceived, discovered, developed, or otherwise made by or on behalf of such Party (or its Affiliates or Sublicensees) under or in connection with this Agreement, whether or not patented or patentable, and any and all Patents Covering any such Know-How, and (ii) other inventions and other Know-How, Patents, and other intellectual property rights that are owned or otherwise Controlled (other than pursuant to the license grants set forth herein) by such Party, its Affiliates, or its licensees or Sublicensees.

(b) **Ownership of Joint Patent and Joint Know-How.** As between the Parties, the Parties shall each own an equal, undivided interest in any and all (i) inventions and other Know-How that are conceived, discovered, developed, or otherwise made jointly by or on behalf of Cyclerion or its Affiliates, on the one hand, and Akebia or its Affiliates or Sublicensees, on the other hand, in connection with the work conducted under or in connection with this Agreement, whether or not patented or patentable (the "**Joint Know-How**"), and (ii) Patents (the "**Joint Patents**") and other intellectual property rights with respect to the inventions and other Know-How described in clause (i) (together with Joint

Know-How and Joint Patents, the "**Joint Intellectual Property Rights**"). Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates, (and in the case of Akebia, its Sublicensees) to so disclose, the development, making, conception, or reduction to practice of any Joint Know-How or Joint Patents. Subject to the licenses and rights of reference granted herein and each Party's respective exclusivity obligations hereunder, each Party shall have the right to exploit the Joint Intellectual Property Rights without a duty of seeking consent or accounting to the other Party.

(c) **Manufacturing Process Improvements.**

(i) **Unblocking Manufacturing Process Patent License**. Akebia hereby grants Cyclerion a [**], under any Manufacturing Process Patents for any and all purposes, other than to Develop or Commercialize a Product in the Field in the Territory.

(ii) **Right to Negotiate for a License to Manufacturing Process Improvements**. Upon Cyclerion's [**], the Parties will discuss in good faith the terms on which Akebia would grant to Cyclerion a [**] to any Manufacturing Process Improvements.

(iii) All Manufacturing Process Improvements shall be the Confidential Information of Akebia and Akebia shall be under no obligation to disclose the technical details or other information required to enable Cyclerion to practice any Manufacturing Process Improvements, except pursuant to the terms of a license agreement negotiated between the Parties as provided herein. [**].

(d) **United States Law.** The determination of whether Know-How and inventions are conceived, discovered, developed, or otherwise made by a Party for the purpose of allocating proprietary rights (including Patent, copyright, or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with applicable law in the U.S., irrespective of where such conception, discovery, development or making occurs.

9.2 **Patent Prosecution and Maintenance**.

(a) **Prosecution of Control Transferring Patents Before Patent Transfer Date.**

(i) As between the Parties, from the Effective Date until the Patent Transfer Date, unless otherwise agreed by the Parties, Cyclerion shall control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of those Cyclerion Patents, other than the Non-Control Transferring Patent, including those Cyclerion Patents set forth on Schedule 9.2(a) (the "**Control Transferring Patents**"), at its sole cost and expense and by Cyclerion's counsel as of the Effective Date, *provided* that:

(1) If Cyclerion chooses to use counsel other than its counsel as of the Effective Date, then such counsel shall be reasonably acceptable to Akebia;

(2) Cyclerion shall consult with Akebia on all prosecution strategies, including what subject matter to pursue in an application, strategies for responding to substantive communications from a patent office, and divisional filing strategies with respect to the Control Transferring Patents;

(3) Cyclerion shall provide Akebia copies of all correspondence received from the relevant patent office regarding the Control Transferring Patents;

(4) Cyclerion shall provide Akebia copies of all documents relevant to such filing and prosecution at least [**] prior to submission of such documents to the applicable patent office;

(5) Cyclerion shall incorporate all reasonable comments with respect to any Control Transferring Patent provided by Akebia no later than [**] prior to the next deadline for the applicable action that must be taken with respect to such Control Transferring Patent, except that the foregoing obligation will not be construed to require Cyclerion to take any course of action that would negatively impact patent protection for Cyclerion's proprietary compound, olinciguat, unless such course of action may be necessary to maintain patent protection for praliciguat;

(6) Cyclerion shall not, without the prior written consent of Akebia, file a divisional application for any Control Transferring Patent; provided, however, that, no such consent shall be required to file any divisional application that contains claims solely Covering Cyclerion's proprietary compound, olinciguat, unless such divisional filing could negatively impact any issued patent or pending application Covering praliciguat, in which case, prior written consent of Akebia is required;

(7) Cyclerion shall not, without the prior written consent of Akebia, abandon or cease prosecution or maintenance of any Control Transferring Patent;

(8) Cyclerion shall use reasonable efforts to prepare, file, prosecute, and maintain the Control Transferring Patents so as to maximize the protection offered by such Control Transferring Patents for the Licensed Compounds and Products;

(9) the Control Transferring Patents shall be deemed the Confidential Information of both Parties;

(10) Cyclerion shall not, without the prior written consent of Akebia, (A) grant any Third Party control over the preparation, filing, prosecution, or maintenance of any Control Transferring Patent or (B) any right to comment on Cyclerion's preparation, filing, prosecution, or maintenance of any Control Transferring Patent that either (I) would permit such Third Party to provide comments directly to Akebia after the Patent Transfer Date, or (II) exceeds or is otherwise incompatible with Cyclerion's right to provide comments after the Patent Transfer Date as provided under Section 9.2(b)(i); and

(11) Cyclerion shall not, without the prior written consent of Akebia, take or fail to take any action (whether alone or in conjunction with other actions) in the course of preparation, filing, prosecution, and maintenance of any Control Transferring Patent that could materially diminish or limit the scope of such Control Transferring Patent's protection of one or more Licensed Compounds or Products (if such Control Transferring Patent were to issue in its then-current form) in favor of increasing the protection of any other compound or product, including for the avoidance of doubt, Cyclerion's proprietary compound, olinciguat. If at any time any course of action taken by Cyclerion may negatively impact patent protection for the Licensed Compounds or Products, then upon Akebia's request Cyclerion shall cease such action.

(b) **Prosecution of Control Transferring Patents After Patent Transfer Date and Joint Patents**.

(i) As between the Parties, Akebia shall have the first right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of (A) after the Patent Transfer Date, the Control Transferring Patents and (B) after the Effective Date, Joint Patents (collectively, ((A) and (B)), the "**Akebia Primary Patents**"), in each case, at its sole cost and expense and by counsel of its own choice that is reasonably acceptable to Cyclerion. Akebia shall (x) keep Cyclerion reasonably informed of all substantive matters relating to prosecution and maintenance of those Akebia Primary Patents that Cover Cyclerion's proprietary compound, olinciguat, including by providing Cyclerion copies of all documents relevant to such filing and prosecution at least [**] prior to submission of such documents to the applicable patent office with respect to any such Akebia Primary Patents for Cyclerion's review and comment and by providing Cyclerion reasonable advance written notice of [**].

(ii) In the event that Akebia desires to abandon or cease prosecution or maintenance of any Akebia Primary Patent, Akebia shall provide reasonable prior written notice to Cyclerion of such intention to abandon (which notice shall, to the extent possible, be given no later than [**] prior to the next deadline for any action that must be taken with respect to any such Akebia Primary Patent in the relevant patent office). In such case, upon Cyclerion's written election provided no later than [**] after such notice from Akebia, Cyclerion shall have the right to assume the prosecution and maintenance of such Akebia Primary Patent at Cyclerion's expense.

(c) **Prosecution of Non-Control Transferring Patent**.

(i) As between the Parties, Cyclerion shall have the first right, but not the obligation, to control the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, oppositions, invalidation proceedings, and defense of validity or enforceability challenges, in each case, except as provided in Section 9.4(c)) of the Cyclerion Patents set forth on Schedule 9.2(c) (the "**Non-Control Transferring Patent**"), at its sole cost and

expense and by counsel of its own choice. Cyclerion will keep Akebia reasonably informed of all substantive matters relating to prosecution and maintenance of the Non-Control Transferring Patent, including by providing Akebia copies of all documents relevant to such filing and prosecution at least [**] prior to submission of such documents to the applicable patent office with respect to any such Non-Control Transferring Patent for Akebia's review and comment and will incorporate any reasonable comments with respect thereto provided by Akebia no later than [**] prior to the next deadline for the applicable action that must be taken with respect to any such Non-Control Transferring Patent. Cyclerion shall not take any action that could jeopardize the validity or enforceability of the Akebia Primary Patents or any action may negatively impact the Akebia Primary Patents.

(ii) In the event that Cyclerion desires to abandon or cease prosecution or maintenance of any Non-Control Transferring Patent, Cyclerion shall provide reasonable prior written notice to Akebia of such intention to abandon (which notice shall, to the extent possible, be given no later than [**] prior to the next deadline for any action that must be taken with respect to any such Non-Control Transferring Patent in the relevant patent office). In such case, upon Akebia's written election provided no later than [**] after such notice from Cyclerion, Akebia shall have the right to assume the prosecution and maintenance of such Non-Control Transferring Patent at Akebia's expense. If Akebia does not provide such election within [**] after such notice from Cyclerion, Cyclerion may, in its sole discretion, continue or discontinue prosecution and maintenance of such Non-Control Transferring Patent.

(d) **Update to Schedule 1.30 upon Patent Transfer.** [**] after the Patent Transfer Date, but in any event within [**], Cyclerion shall provide Akebia an updated Schedule 1.30 setting forth all Cyclerion Patents existing as of the Patent Transfer Date.

(e) **Cooperation.** Each Party shall provide the other Party all reasonable assistance and cooperation, at the other Party's request and expense, in the patent prosecution efforts provided above in this Section 9.2, including providing any necessary powers of attorney, executing any other required documents or instruments for such prosecution, and making its personnel with appropriate scientific expertise available to assist in such efforts.

(f) **Patent Term Extensions and Patent Linkage.** Akebia will have the sole right and discretion to determine and control (i) all filings of requests for patent term extensions, supplementary protection certificates, or equivalents thereto in any country in the Territory with respect to the Akebia Primary Patents (each a "**Patent Term Extension**") and (ii) linking of Patents to an approved Product such as in the FDA's "Orange Book" or its foreign equivalent in any country in the Territory with respect to Cyclerion Patents (each "**Patent Linkage**"). [**]. Upon the request of Akebia [**], Cyclerion will provide support, assistance, and all necessary documents, in full executed form if needed, to Akebia for the purpose of supporting, filing, obtaining, and maintaining Patent Term Extensions and Patent Linkage.

9.3 **Patent Contacts**. Each Party will designate patent counsel representatives who will be responsible for coordinating the activities between the Parties in accordance with this Article 9 (each a "**Patent Contact**"). Each Party will designate its initial Patent Contact within [**] following the Effective Date and will promptly thereafter notify the other Party of such designation. Each Party will promptly notify the other Party of any substitution of another person as its Patent Contact. The Patent Contacts will, from time to time, discuss the respective Patent strategies of the Parties relating to this Agreement. In particular the Patent Contacts will discuss the global intellectual property activities under this Agreement and review and update the list of Cyclerion Patents from time to time. The Patent Contacts will meet at least [**], or as otherwise agreed to by the Parties until the Patent Transfer Date, and thereafter at least annually.

9.4 **Infringement by Third Parties.**

(a) **Notice**. Each of Akebia and Cyclerion shall promptly notify the other Party in writing of any alleged or threatened infringement of any Non-Control Transferring Patent or Akebia Primary Patent by a Third Party in the Territory of which the Party becomes aware (including alleged or threatened infringement based on the Exploitation of a product that could be competitive with a Product in the Territory (a "**Product Infringement**")).

(b) **Right to Bring Suit**. [**] shall have the first right to bring and control any action or proceeding with respect to any alleged or threatened infringement of a Cyclerion Patent or Joint Patents in the Territory. If [**] does not bring and continue pursuing diligently an action or proceeding against, or otherwise cause the cessation of, a Product Infringement of any Cyclerion Patent or Joint Patent by or after (A) [**] before the time limit, if any, set forth in the appropriate laws and regulations for the filing of such an action, whichever comes first, then [**] shall have the right to bring and control an infringement action under the applicable Cyclerion Patents or Joint Patents with respect to such Product Infringement at its own expense and by counsel of its own choice.

(c) **Defense of Patents in Related Proceedings**. Notwithstanding Section 9.2(c), as between the Parties, [**] shall have the first right, but not the obligation, to control the defense (including any interferences, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of Non-Control Transferring Patent if such defense is related to any actual or threatened enforcement of such Patents by [**] under this Section 9.4, at [**] sole cost and expense and by counsel of its own choice; *provided* that [**] shall obtain the written consent of [**] prior to settling or compromising such defense, such consent not to be unreasonably withheld, conditioned or delayed. [**] may participate in any such claim, suit, or proceeding in the Territory with counsel of its choice at its own expense. If [**] elects not to defend or control the defense of any such Non-Control Transferring Patent in a suit brought in the Territory, or otherwise fails to initiate and maintain the defense of any such claim, suit, or proceeding, then [**] may conduct and control the defense of any such claim, suit, or proceeding at its own expense. As between the Parties Akebia shall have the first right, but not the obligation, to control the defense (including any interferences, oppositions, invalidation proceedings, and defense of validity or enforceability challenges) of Akebia Primary Patents if such defense is related to any actual or threatened enforcement of such Patents by Akebia

under this Section 9.4 and any settlement or compromise of such defense related to the Akebia Primary Patents shall be in Akebia's sole discretion.

(d) **Cooperation; Settlement**. For any action or proceeding brought by a Party under this Section 9.4 (the "**Initiating Party**"), regardless of which Party brings such action or proceeding, the other Party (the "**Non-Initiating Party**") hereby agrees to cooperate reasonably in any such effort, all at the Initiating Party's expense, and the Parties shall reasonably cooperate to address new facts or circumstances that come to light during the course of any such action or proceeding that may affect the need for one Party or the other to participate in such action. The Non-Initiating Party agrees to be joined as a party plaintiff, at the Initiating Party's expense, in any such action if needed for the Initiating Party to bring or continue an infringement action hereunder. Cyclerion shall, at its own expense and with its own counsel, have the right to participate in any action brought by Akebia under this Section 9.4. Akebia shall, at its own expense and with its own counsel, have the right to participate in any action brought by Cyclerion involving a Product Infringement. Neither Party may settle any action or proceeding brought under this Section 9.4 in a manner that, or knowingly take any other action in the course thereof that, materially adversely affects the other Party's interest in the Non-Control Transferring Patent or Akebia Primary Patents, without the written consent of such other Party, such consent not to be unreasonably withheld, conditioned or delayed.

(e) **Recoveries**. Any recovery realized as a result of such litigation described in Section 9.4 (whether by way of settlement or otherwise) shall be first, allocated to [**]. Any remainder after [**] shall be [**]; provided, however, that to the extent that any award or settlement (whether by judgment or otherwise) is attributable to loss of sales with respect to a Product, then such award or settlement will be treated [**].

9.5 **Third Party Claims for Infringement or Misappropriation.** If the Exploitation of a Licensed Compound or Product in the Territory under this Agreement results in, or may result in, any claim, suit, or proceeding by a Third Party alleging patent infringement by Akebia (or its Affiliates or Sublicensees), then the Party with knowledge of such actual or potential claim shall [**] notify the other Party thereof in writing. [**] shall have the first right, but not the obligation, to defend and control the defense of any such claim, suit, or proceeding at its own expense, using counsel of its own choice. [**] may participate in any such claim, suit, or proceeding with counsel of its choice at its own expense. If [**] elects (in a written communication submitted to [**] within a reasonable amount of time after notice of the alleged patent infringement) not to defend or control the defense of, or otherwise fails to initiate and maintain the defense of, any such claim, suit, or proceeding, within such time periods so that [**] is not prejudiced by any delays, [**] may conduct and control the defense of any such claim, suit, or proceeding at its own expense. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit, or proceeding. Any recoveries by [**] of any sanctions awarded to [**] and against a party asserting a claim being defended under this Section 9.5 shall be applied first to reimburse [**] and [**] for its reasonable out-of-pocket costs of defending such claim, suit, or proceedings. The balance of any such recoveries shall be retained by [**], provided, however, [**].

9.6 **Product Trademarks**. Akebia will have the right to brand the Products using Trademarks it determines appropriate for the Product, which may vary by region or within a region (the "**Product Marks**"). Akebia will own all rights in the Product Marks in the Territory and will register and maintain the Product Marks in the Territory that it determines reasonably necessary, at its expense. Akebia will be solely responsible, at its expense, for enforcing such Product Marks against any Third Party infringement as Akebia reasonably determines in its sole discretion.

Article 10

Article 11 CONFIDENTIALITY

11.1 **Confidentiality Obligations**. At all times during the Term and for a period of [**] following termination or expiration hereof, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use for any purpose any Confidential Information furnished or otherwise made known to it by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is reasonably necessary for the performance of, or the exercise of such Party's rights under, this Agreement. The terms of this Agreement shall be the Confidential Information of both Parties, and each Party shall be deemed to be the receiving Party thereto. To the extent the receiving Party can demonstrate by documentation or other competent proof, the following information will not be deemed Confidential Information and the confidentiality and non-use obligations under this Section 10.1 will not apply to any such information that:

(a) has been published by a Third Party or is or hereafter becomes part of the public domain by public use, publication, general knowledge, or the like through no wrongful act, fault, or negligence on the part of the receiving Party;

(b) has been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information;

(c) is subsequently received by the receiving Party from a Third Party without restriction and without breach of any agreement between such Third Party and the disclosing Party; or

(d) has been independently developed by or for the receiving Party without reference to, or use or disclosure of the disclosing Party's Confidential Information.

(e) Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

11.2 **Permitted Disclosures.** Each Party may disclose Confidential Information to the extent that such disclosure is:

(a) required to be disclosed pursuant to law, regulation, applicable stock exchange rule or made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial, and local governmental or regulatory body of competent jurisdiction, including under subpoena, document requests related to litigation, or by reason of filing with securities regulators (including, for the avoidance of doubt, filing this Agreement as a material agreement as may be required pursuant to securities regulations); *provided*, *however*, that the receiving Party shall first have given prompt written notice (and to the extent practicable, at least [**] notice) to the disclosing Party and provides reasonable assistance to the disclosing Party in taking whatever action the disclosing Party deems necessary to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or the disclosing Party waives compliance with the terms of this Section 10.2(a), the receiving Party shall furnish only that portion of Confidential Information that the receiving Party is required to disclose. Notwithstanding the foregoing, at [**] prior to either Party filing this Agreement with securities regulators, such filing Party will furnish a proposed redacted copy of this Agreement to the other Party for review, and such filing Party will incorporate all reasonable additional redactions requested by the other Party;

(b) made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with any Regulatory Submission or in connection with any inspection or audit by any Regulatory Authority;

(c) made by the receiving Party or its Affiliates or sublicensees to its or their actual or *bona fide* potential advisors, consultants, clinicians, vendors, service providers, contractors, licensees, collaborators, or sublicensees (and to each of their respective bankers, lawyers, accountants, or agents) as may be [**] in connection with the Exploitation of the Licensed Compounds or the Products, or otherwise in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement; *provided*, *however*, that such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 10;

(d) subject to Section 9.4, made by or on behalf of the receiving Party to a patent authority as may be reasonably [**] for purposes of filing, prosecuting, maintaining, enforcing, or defending a Patent as permitted under this Agreement; or

(e) made by or on behalf of the receiving Party to actual or *bona fide* potential investors or acquirers or other Third Party transactional parties (and to each of their respective bankers, lawyers, accountants, or agents), as may be necessary in connection with their evaluation of such potential or actual investment or acquisition; *provided*, *however*, that such Third Parties shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information no less stringent than the obligations of confidentiality and non-use of the receiving Party pursuant to Section 10.1 (with durations of confidentiality and non-use as appropriate).

11.3 **Use of Name.** Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo, or Trademark of the other Party or any of its Affiliates (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material, or other form of publicity, without the prior written approval of such other Party in each instance, except for either Party's references to the other as the licensor or licensee (as applicable) or a collaboration partner under this Agreement. The restrictions imposed by this Section 10.3 shall not prohibit either Party from making any disclosure identifying the other Party that, in the opinion of the disclosing Party's counsel, is required by applicable law; *provided* that such Party shall use reasonable efforts to submit the proposed disclosure identifying the other Party in writing to the other Party as far in advance as reasonably practicable so as to provide a reasonable opportunity to comment thereon.

11.4 **Public Announcements.** The Parties will cooperate in good faith and agree upon the content of a press release, which may be issued by Cyclerion following the Effective Date. Except as set forth in Section 10.2, neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent. Without limiting the foregoing, to the extent permitted by applicable law and any applicable stock exchange rules, [**]. After the permitted public disclosure by a Party, either Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such public announcement remains true, correct, and the most current information with respect to the subject matters set forth therein.

11.5 **Residual Knowledge**. Notwithstanding any provision to the contrary set forth in this Agreement, Confidential Information will not include any knowledge, technique, experience, or Know-How that is retained in the unaided memory of any authorized representative of the receiving Party after having access to such Confidential Information ("**Residual Knowledge**"). Any use made by the receiving Party of any such Residual Knowledge is on an "as is, where is" basis, with all faults and all representations and warranties disclaimed and at its sole risk.

11.6 **Return of Confidential Information.** Upon the effective date of the termination of this Agreement for any reason, either Party may request in writing, and the other Party shall either, with respect to Confidential Information to which such first Party does not retain rights under the surviving provisions of this Agreement: (a) promptly destroy all copies of such Confidential Information in the possession of the other Party and confirm such destruction in writing to the requesting Party; or (b) promptly deliver to the requesting Party, at the other Party's expense, all copies of such Confidential Information in the possession of the other Party; provided, however, the other Party shall be permitted to retain copies of such Confidential Information for the sole purpose of performing any continuing obligations hereunder or for archival purposes. Notwithstanding the foregoing, such other Party also shall be permitted to retain such additional copies of or any computer records or files containing such Confidential Information that have been created solely by such Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such other Party's standard archiving and back-up procedures, but not for any other use or purpose.

Article 12

Article 13 REPRESENTATIONS AND WARRANTIES

13.1 **Representations and Warranties by Cyclerion.** Cyclerion hereby represents and warrants to Akebia as of the Effective Date as follows:

(a) the execution, delivery, and performance of this Agreement have been duly authorized by all necessary corporate actions;

(b) this Agreement constitutes a valid obligation of Cyclerion and is binding and enforceable against Cyclerion in accordance with the terms hereof;

(c) Cyclerion and, to Cyclerion's Knowledge, its contractors and consultants, have complied in all material respects with all applicable law in the Development and Manufacture of the Licensed Compound and Product prior to the Effective Date;

(d) Cyclerion has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and there is no contractual restriction or other legal obligation binding on Cyclerion that would be contravened by execution and delivery of this Agreement or by the performance or observance of its terms;

(e) Cyclerion has not granted, and will not grant during the Term, a license or sublicense to any Affiliate or Third Party under the Cyclerion Intellectual Property that would conflict with the rights granted to Akebia hereunder;

(f) all Cyclerion Patents existing as of the Effective Date are set forth on Schedule 1.30, and such Cyclerion Patents represent all Patents Cyclerion Controls that are necessary or reasonably useful for Akebia's Exploitation of the Licensed Compounds or the Products as contemplated by this Agreement;

(g) Cyclerion is the sole and exclusive owner of the entire right, title, and interest in the Cyclerion Patents set forth on Schedule 1.30, free of any encumbrance, lien, or claim of ownership by any Third Party;

(h) (i) there are no claims, judgments or settlements against Cyclerion pending or, to Cyclerion's Knowledge, threatened, that invalidate or seek to invalidate the Cyclerion Patents set forth on Schedule 1.30, (ii) there is no opposition pending in any jurisdiction outside of the United States that challenges the validity or enforceability of, or Cyclerion's ownership rights in, any of the Cyclerion Patents set forth on Schedule 1.30 in that jurisdiction, (iii) there is no litigation pending against Cyclerion or any Affiliate of Cyclerion that alleges that any of the activities contemplated by this Agreement will violate any Patent or other intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation), and (iv) Cyclerion has not received any written correspondence from a Third Party alerting Cyclerion of any intellectual property rights that allegedly would be infringed by Akebia's Exploitation of a Licensed Compound or Product or asserting that any claim in the Cyclerion Patents set forth on Schedule 1.30 is invalid or unenforceable;

(i) to Cyclerion's Knowledge, the Cyclerion Patents set forth on Schedule 1.30 have been diligently prosecuted with the respective patent offices where such Cyclerion Patents have been filed in the Territory in accordance with applicable law, and all applicable fees necessary to maintain the Cyclerion Patents set forth on Schedule 1.30 have been paid on or before the due date for such payment;

(j) each individual who is an inventor of or otherwise has or has had any rights in or to any Cyclerion Patents identified as being owned by Cyclerion on Schedule 1.30 has assigned to Cyclerion all of his or her interest therein;

(k) Cyclerion is entitled to grant the licenses specified herein;

(l) the conception, development, and reduction to practice of any of the Cyclerion Intellectual Property have not constituted or involved the misappropriation of trade secrets or other intellectual property rights of any Third Party;

(m) the process used by Cyclerion to Manufacture the Licensed Compounds or Products (as applicable) as of the Effective Date does not require the use of any Third Party intellectual property right;

(n) to Cyclerion's Knowledge, the practice by Cyclerion or Akebia under the Cyclerion Intellectual Property or the Exploitation by Cyclerion or Akebia (or their respective Affiliates or Sublicensees) of any Licensed Compound or Product, in each case, as contemplated under this Agreement, does not and will not infringe, misappropriate, or otherwise violate any intellectual property rights of any Third Party;

(o) no Third Party has challenged the ownership, scope, duration, validity, enforceability, priority, or right to use any Cyclerion Patent (including, by way of example, through the institution of or written threat of institution of interference, *inter partes* review, reexamination, protest, opposition, nullity, or similar invalidity proceeding before the United States Patent and Trademark Office or any foreign patent authority or court);

(p) Cyclerion has not previously assigned, transferred, conveyed, or granted any license or other rights under the Cyclerion Intellectual Property, except in each case where such assignment, transfer, conveyance, or grant is not inconsistent with the rights and licenses granted to Akebia under this Agreement;

(q) all rights in all inventions and discoveries made, developed or conceived by any employee or independent contractor of Cyclerion during the course of their employment (or other retention) by Cyclerion and included in the Cyclerion Know-How or that are the subject to one (1) or more Cyclerion Patents have been (or to the extent present assignment of future inventions is not permitted by applicable law, will be) assigned in writing to Cyclerion pursuant to a written agreement to assign such inventions and discoveries to Cyclerion;

(r) the Cyclerion Know-How that constitutes trade secrets under applicable law has been kept confidential or has been disclosed to Third Parties only under terms of

confidentiality. To Cyclerion's Knowledge, no breach of such confidentiality has been committed by any Third Party;

(s) the inventions Covered by the Cyclerion Patents on Schedule 1.30 were not created pursuant to, subject to, or otherwise made in connection with any research activities funded, in whole or part, by the federal government of the United States or any agency thereof or any other governmental authority worldwide, and are not subject to the requirements of the Bayh-Dole Act or any similar provision of any applicable law;

(t) all INDs owned or Controlled by Cyclerion that cover any Licensed Compound are listed on Schedule 4.1;

(u) Cyclerion has provided to Akebia true, complete, and correct (redacted) copies of all agreements between Cyclerion or an Affiliate of Cyclerion and a Third Party relating to the Manufacture or supply of the Licensed Compounds and Products and components thereof (as applicable) that are in effect as of the Effective Date, a complete list of which are listed on Schedule 11.1(u); there are no [**] between Cyclerion or its Affiliates, on the one hand, and any Third Party relating to the Manufacture or supply of the Licensed Compounds or Products and components thereof (as applicable) to Cyclerion, on the other hand, that would limit Akebia's ability to Manufacture, or have the Licensed Compounds or Products and components thereof (as applicable) Manufactured;

(v) Cyclerion has obtained the right (including under any Patent and other intellectual property right) to use all materials (including any formulations and Manufacturing processes and procedures) [**] for the Exploitation of the Licensed Compounds or the Products, as contemplated by this Agreement, in each case that was developed or delivered by any Third Party under any agreements between Cyclerion and any such Third Party with respect to the Licensed Compounds or Products, and Cyclerion has the rights under each such agreement to transfer such materials to Akebia and its designees and to grant Akebia the right to use such materials in the Exploitation of the Licensed Compounds and Products without restriction and without payments required by Akebia beyond those set forth in this Agreement;

(w) there are no amounts that will be required to be paid by Akebia to any Third Party as a result of the Exploitation of the Licensed Compounds or Products (as applicable) that arise out of any agreements to which Cyclerion or its Affiliates are a party;

(x) all works of authorship and all other materials subject to copyright protection included in Cyclerion Know-How are original and were either created by employees of Cyclerion or its Affiliates within the scope of their employment or are otherwise works made for hire, or all right, title, and interest in and to such materials have been legally and fully assigned and transferred to Cyclerion or such Affiliate, and all rights in all Know-How and discoveries developed or invented by any employee or independent contractor of Cyclerion or such Affiliate during the course of their employment (or other retention) by Cyclerion or such Affiliate, and included in Cyclerion Know-How, or that are the subject of one or more Cyclerion Patents, have been assigned in writing to Cyclerion or its Affiliate;

(y) to Cyclerion's Knowledge: (i) there are no scientific or technical facts or circumstances that have not been disclosed to Akebia, and that would [**] the scientific, therapeutic, or commercial potential of the Products; (ii) there is nothing within Cyclerion's control that has not been disclosed to Akebia and that could [**] the acceptance, or the subsequent approval, by any Regulatory Authority of any Regulatory Submissions with respect to any Product; and (iii) except as disclosed to Akebia in Cyclerion's virtual data room, there are no [**]; and

(z) Cyclerion has provided Akebia with the opportunity to review all written material data in Cyclerion's possession relating to the subject matter of this Agreement, and has not intentionally concealed from Akebia any such material data.

13.2 **Representations and Warranties by Akebia.** Akebia hereby represents and warrants to Cyclerion as of the Effective Date as follows:

(a) The execution, delivery, and performance of this Agreement have been duly authorized by all necessary corporate actions;

(b) This Agreement constitutes a valid obligation of Akebia and is binding and enforceable against Akebia in accordance with the terms hereof; and

(c) Akebia has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and there is no contractual restriction or obligation binding on Akebia that would be contravened by execution and delivery of this Agreement or by the performance or observance of its terms.

13.3 **Debarment.** Neither Party has ever been, is not currently, nor is it the subject of a proceeding that could lead to it becoming a Debarred Entity, Excluded Entity, or Convicted Entity and it will not use in any capacity, in connection with the obligations to be performed under this Agreement, any person who is a Debarred Individual, Excluded Individual or a Convicted Individual, nor are they listed on the FDA's Disqualified/Restricted List for clinical investigators. Each Party further covenants that if, during the Term, it becomes a Debarred Entity, Excluded Entity, or Convicted Entity or if any employee or agent performing any of its obligations hereunder becomes a Debarred Individual, Excluded Individual, or a Convicted Individual, or added to FDA's Disqualified/Restricted List for clinical investigators, then such Party shall immediately notify the other Party. For purposes of this provision, the following definitions shall apply:

(a) A "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug or biological product application.

(b) A "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

(c) An "**Excluded Individual**" or "**Excluded Entity**" is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(d) A "**Convicted Individual**" or "**Convicted Entity**" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

(e) "**FDA's Disqualified/Restricted List**" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor.

13.4 **Disclaimer**. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

Article 14
INDEMNIFICATION

14.1 **Indemnification by Akebia**. Akebia shall indemnify Cyclerion, its Affiliates, and its and their respective directors, officers, employees, and agents ("**Akebia Indemnitees**"), and defend and hold each of them harmless, from and against any and all losses, damages, liabilities, penalties, costs, and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims, or demands of Third Parties (collectively, "**Third Party Claims**") incurred by or rendered against the Akebia Indemnitees arising from or relating to: (a) the breach by Akebia of this Agreement, (b) the gross negligence, reckless conduct, or willful misconduct on the part of Akebia or its Affiliates or Sublicensees in performing its or their obligations under this Agreement, or (c) the Exploitation by Akebia or any of its Affiliates or Sublicensees of any Licensed Compound or Product in the Territory, except, in each case ((a) – (c)), for those Losses for which Cyclerion, in whole or in part, has an obligation to indemnify Akebia pursuant to Section 12.2 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

14.2 **Indemnification by Cyclerion**. Cyclerion shall indemnify Akebia, its Affiliates, and its and their respective directors, officers, employees, and agents (the "**Cyclerion Indemnitees**"), and defend and hold each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims incurred by or rendered against the Cyclerion Indemnitees arising from or relating to: (a) the breach by Cyclerion of this Agreement, (b) the gross negligence, reckless conduct or willful misconduct on the part of Cyclerion or its Affiliates in performing its obligations under this Agreement, or (c) the Exploitation by Cyclerion or any of its Affiliates, licensees (other than Akebia), or Sublicensees of any Licensed Compound or Product in the Territory, except, in each case ((a) – (c)), for those Losses for which Akebia, in whole or in part, has an obligation to indemnify Cyclerion pursuant to Section 12.1 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

14.3 **Indemnification Procedures**. A Party seeking indemnification under Section 12.1 or Section 12.2 hereof (the "**Indemnitee**") shall promptly notify the other Party (the "**Indemnitor**") in writing of any claim, lawsuit, or other action in respect of which the Indemnitee, its Affiliates, or any of their respective directors, officers, employees, or agents intend to claim such indemnification. [**]. The Indemnitee, its Affiliates and their respective directors, officers, employees and agents shall cooperate fully with the Indemnitor and its legal representatives in the investigation and defense of any claim, lawsuit or other action covered by this indemnification. The Indemnitee shall have the right, but not the obligation, to be represented by counsel of its own selection and expense.

14.4 **Special, Indirect, and Other Losses.** EXCEPT FOR WILLFUL MISCONDUCT AND EXCEPT IN THE EVENT OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 10 OR SECTIONS 8.2 OR 8.8, AND EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 12, NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE FOR INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, OR LOSS OF PROFITS OR BUSINESS INTERRUPTION, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE IN CONNECTION WITH OR ARISING IN ANY WAY OUT OF THE TERMS OF THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

14.5 **Insurance.** The Parties shall maintain insurance with creditworthy insurance companies against such risks and in such amounts as are usually maintained or insured against by other companies of established repute and in the same or a similar business.

Article 15
TERM AND TERMINATION

15.1 **Term.** This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect, on a Product-by- Product and country-by-country basis, in full force and effect until the expiration of the Royalty Term applicable to such

Product and such country and will expire in its entirety upon the expiration of the last Royalty Term (such period, the "**Term**").

15.2 **Termination.**

(a) **Convenience**. At any time after the date one (1) year after the Effective Date, Akebia may terminate this Agreement in its entirety, by providing written notice to Cyclerion thereof, which termination will be effective one hundred eighty (180) days following the date of such notice, except, in the event that Akebia has received Regulatory Approval for a Product in any Major Country, such notice period will be [**] prior written notice.

(b) **Material Breach.**

(i) **Termination**. Either Party may terminate this Agreement at any time upon written notice to the other Party if the other Party is in material breach of this Agreement and such material breach is not cured within [**] after written notice thereof is delivered to the defaulting or breaching Party *provided*, *however*, if such breach is not reasonably curable within [**] and if the breaching Party is making a *bona fide* effort to cure such breach, such termination shall be delayed for a time period to be agreed by the Parties in order to permit the breaching Party a reasonable period of time to cure such breach (but in no event will such additional time period be more than [**]. Any notice provided pursuant to this Section 13.2(b) shall identify with particularity the alleged breach and state the non-breaching Party's intent to terminate this Agreement if such breach is not cured. If the material breach described in the notice of such material breach solely pertains to one or more specific Major Countries, then the other Party may terminate this Agreement solely with respect to those Major Countries to which such breach pertains.

(ii) **Disputes Regarding Material Breach**. If the Parties reasonably and in good faith disagree as to whether there has been a material breach, then the breaching Party that disputes whether there has been a material breach may contest the allegation in accordance with Section 14.12, and the applicable cure period will toll upon the initiation of such dispute resolution procedures. If, as a result of such dispute resolution process, it is finally determined pursuant to Section 14.12 that the breaching Party committed a material breach of this Agreement, then the applicable cure period will resume and if the breaching Party does not cure such material breach within the remainder of such cure period (as such cure period may be extended pursuant to Section 13.2(b)(i)), then this Agreement will terminate effective as of the expiration of such cure period. This Agreement will remain in full force and effect during the pendency of any such dispute resolution proceeding and the applicable cure period. Any such dispute resolution proceeding will not suspend any obligations of either Party hereunder and each Party will use reasonable efforts to mitigate any damages. Any payments that are made by one Party to the other Party pursuant to this Agreement pending resolution of the dispute will be promptly refunded if it is determined pursuant to Section 14.12 that such payments are to be refunded by one Party to the other

Party. If, as a result of such dispute resolution proceeding, it is determined that the breaching Party did not commit such material breach (or such material breach was cured in accordance with this Section 13.2(b)(i)), then no termination of this Agreement will be effective, and this Agreement will continue in full force and effect.

(c) **Patent Challenge.** If Akebia or any of its Affiliates or Sublicensees commences any interference or opposition proceeding with respect to, challenges the validity or enforceability of, or opposes any extension of or the grant of a supplementary protection certificate with respect to, any Cyclerion Patent in any court, tribunal, patent office, or other proceeding in a country or other jurisdiction in the Territory (a "**Patent Challenge**"), then Cyclerion will have the right to terminate this Agreement on [**] written notice to Akebia; such termination of such license to be effective immediately following such notice period; *provided* that, if Akebia or its Affiliate or Sublicensee withdraws (or causes to be withdrawn) such Patent Challenge within [**] after being requested to do so by Cyclerion in writing (which termination notice will be deemed a request), then Cyclerion will have no right to terminate this Agreement pursuant to this Section 13.2(c). For the avoidance of doubt, Cyclerion may not terminate this Agreement pursuant to this Section 13.2(c) if Akebia or its Affiliate or Sublicensee is required by legal process to be joined as a party in any Patent Challenge by a Third Party. In addition, notwithstanding the foregoing, Cyclerion will have no right to terminate this Agreement pursuant to this Section 13.2(c) with respect to: (i) any affirmative defense or other validity, enforceability, or non-infringement challenge, whether in the same action or in any other agency or forum of competent jurisdiction advanced by Akebia, or any of its Affiliates or Sublicensees in response to any claim or action brought in the first instance by, on behalf of, Cyclerion or any of its Affiliates or licensees; (ii) any Patent Challenge to the extent commenced by a Third Party that after the Effective Date acquires or is acquired by Akebia or any of its Affiliates or its of their business or assets, whether by stock purchase, merger, asset purchase or otherwise; *provided* that such proceeding commenced prior to the closing of such acquisition; or (iii) any Patent Challenge that is commenced by a Sublicensee; *provided* that Akebia demands that such Sublicensee withdraw such Patent Challenge promptly after Akebia becomes aware of such Patent Challenge and terminates the sublicense agreement with the applicable Sublicensee if such Sublicensee does not withdraw such Patent Challenge [**] after receipt of notice from Akebia.

(d) **Bankruptcy**. All rights and licenses now or hereafter granted by Cyclerion to Akebia under or pursuant to this Agreement, including, for the avoidance of doubt, the licenses granted to Akebia pursuant to Section 8.1, are, for all purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined in the U.S. Bankruptcy Code. Upon the filing or institution of bankruptcy, reorganization, liquidation, or receivership proceedings, upon the appointment of a receiver or trustee over all or substantially all property, or upon an assignment of a substantial portion of the assets for the benefit of creditors by Cyclerion, Cyclerion agrees that Akebia, as licensee of such rights under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. Without limiting the generality of the foregoing, Cyclerion and Akebia intend and agree that any sale of Cyclerion's assets

under Section 363 of the Bankruptcy Code shall be subject to Akebia's rights under Section 365(n), that Akebia cannot be compelled to accept a money satisfaction of its interests in the intellectual property licensed pursuant to this Agreement, and that any such sale therefore may not be made to a purchaser "free and clear" of Akebia's rights under this Agreement and Section 365(n) without the express, contemporaneous consent of Akebia. Further, each Party agrees and acknowledges that all payments by Akebia to Cyclerion hereunder, other than the royalty payments pursuant to Section 7.5 and the sales milestones pursuant to Section 7.4, do not constitute royalties within the meaning of Section 365(n) of the U.S. Bankruptcy Code or relate to licenses of intellectual property hereunder. Cyclerion will, during the Term, create and maintain current copies or, if not amenable to copying, detailed descriptions or other appropriate embodiments, to the extent feasible, of all such intellectual property rights. Each Party acknowledges and agrees that "embodiments" of intellectual property rights within the meaning of Section 365(n) include laboratory notebooks, cell lines, product samples, and inventory, research studies and data, all Regulatory Approvals (and all applications for Regulatory Approval) and rights of reference therein, the Cyclerion Intellectual Property, and all information related to the Cyclerion Intellectual Property. If (A) a case under the U.S. Bankruptcy Code is commenced by or against Cyclerion, (B) this Agreement is rejected as provided in the U.S. Bankruptcy Code, and (C) Akebia elects to retain its rights hereunder as provided in Section 365(n) of the U.S. Bankruptcy Code, then Cyclerion (in any capacity, including debtor-in-possession) and its successors and assigns (including a trustee) will:

(1) provide Akebia with all such intellectual property rights (including all embodiments thereof) held by Cyclerion and such successors and assigns, or otherwise available to them, immediately upon Akebia's written request. Whenever Cyclerion or any of its successors or assigns provides to Akebia any of the intellectual property rights licensed hereunder (or any embodiment thereof) pursuant to this Section 13.2(d), Akebia will have the right to perform Cyclerion's obligations hereunder with respect to such intellectual property rights, but neither such provision nor such performance by Akebia will release Cyclerion from liability resulting from rejection of the license or the failure to perform such obligations; and

(2) not interfere with Akebia's rights under this Agreement, or any agreement supplemental hereto, to such intellectual property rights (including such embodiments), including any right to obtain such intellectual property rights (or such embodiments) from another entity, to the extent provided in Section 365(n) of the U.S. Bankruptcy Code.

(i) All rights, powers, and remedies of Akebia provided herein are in addition to and not in substitution for any and all other rights, powers, and remedies now or hereafter existing at law or in equity (including the U.S. Bankruptcy Code) in the event of the commencement of a case under the U.S. Bankruptcy Code with respect to Cyclerion. The Parties agree that they intend the following rights to extend to the maximum extent permitted by law, and to be enforceable under U.S. Bankruptcy Code Section 365(n):

(1) the right of access to any intellectual property rights (including all embodiments thereof) of Cyclerion, or any Third Party with whom Cyclerion contracts to perform an obligation of Cyclerion under this Agreement, and, in the case of the Third Party, which is necessary for the manufacture, use, sale, import, export or other Exploitation of any Licensed Compound or Product; and

(2) the right to contract directly with any Third Party to complete the contracted work.

15.3 **Consequences of Termination.** In the event of a termination of this Agreement in its entirety for any reason, the following will apply:

(a) all rights and licenses granted by Cyclerion hereunder shall immediately terminate;

(b) unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, then Akebia shall, and hereby does effective as of the effective date of termination, grant Cyclerion an non-exclusive, royalty-free license, with the right to grant multiple tiers of sublicenses, under the Akebia Intellectual Property to Exploit in the Territory any Licensed Compound or Product;

(c) in the event there are any on-going Clinical Trials of the Products:

(i) the Parties shall work together in good faith to either adopt, and (A) if Cyclerion has become the sponsor in such Clinical Trial, then Cyclerion shall have the final decision-making authority with respect to, or (B) if Cyclerion has not become the sponsor in such Clinical Trial, then Akebia shall after good faith consultation with Cyclerion and taking into account reasonable suggestions from Cyclerion, have the final decision-making authority with respect to, a plan to (A) wind-down the Development activities in the Territory in an orderly fashion, with due regard for patient safety and the rights of any subjects that are participants in any Clinical Trials of the Products and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all applicable laws and regulations or (B) transfer such on-going Clinical Trials in the Territory to Cyclerion;

(ii) all costs and expenses incurred from the effective date of the termination notice in winding down the Development and Commercialization activities with respect to the Products shall be borne solely by Akebia, unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, in which case such costs and expenses shall be borne by Cyclerion;

(d) unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, then Akebia shall assign or cause to be assigned to Cyclerion or its designee (or to the extent not so assignable, Akebia shall take all reasonable actions as soon as practicable to make available to Cyclerion or its designee the benefits of) all Regulatory Submissions (including Regulatory Approvals) filed, submitted or received after the

Effective Date solely for the Products in the Territory Controlled by Akebia or its Affiliates;

(e) unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, then Akebia shall, and hereby does, effective on the effective date of such termination, assign to Cyclerion all of Akebia's and its Affiliates' right, title, and interest in and to the Product Marks, including all goodwill therein, and Akebia shall promptly take such actions and execute such instruments, assignments, and documents as may be necessary to effect, evidence, register, and record such assignment, at Akebia's cost; *provided*, *however*, that the foregoing obligations shall not apply to any Product Marks that include, in whole or part, any corporate name or logo of Akebia or its Affiliates;

(f) unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, then upon Cyclerion's request, Akebia shall assign to Cyclerion any agreements with Third Party suppliers, contract research organizations, or other vendors that solely relate to the supply or sale of the Products in the Territory; *provided* that if any such contract between Akebia and a Third Party is not assignable to Cyclerion (whether by such contract's terms or because such contract does not relate specifically to the Product) but is otherwise [**] for Cyclerion to commence Developing or Commercializing the Products in the Territory, then Akebia shall reasonably cooperate with Cyclerion to negotiate for the continuation of services or supply from such entity for a period not to [**]; and

(g) Akebia shall have the right to sell in the Territory any remaining inventory over a period of [**] after the effective date of termination, or such other period as may be agreed by the Parties or required by applicable Regulatory Authorities (the "**Sell-Down Period**"). Notwithstanding the foregoing, if Akebia has not received Regulatory Approval for any Product before the effective date of termination or expiration of this Agreement, the Sell-Down Period shall be [**] after the effective date of termination or expiration of this Agreement. Unless the Agreement is terminated by Akebia pursuant to Section 13.2(b) for Cyclerion's breach, [**], Akebia shall report such inventory as of the end of the Sell-Down Period, and Cyclerion shall have the right to purchase from Akebia all or part of the inventory of Licensed Compound, Product, or any intermediate thereof held by Akebia as of the end of the Sell-Down Period at a price equal to the price paid by Akebia for the supply of such inventory.

15.4 **Cumulative Remedies.** Except as expressly stated otherwise herein, termination of this Agreement or other jurisdiction(s) in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

15.5 **Accrued Obligations**. Except as set forth herein, any termination or expiration of this Agreement shall not relieve either Party of any obligation that has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect for the period provided therein.

15.6 **Survival.** The terms of Sections 7.7 through 7.11, 8.5, 9.1(a), 9.1(b), 9.1(c)(i), 9.1(d), 11.4, 13.3, 13.4, 13.5, 13.6, 14.1, 14.2, 14.3, 14.7, 14.8, 14.9, 14.10, 14.11, 14.12 14.13, 14.14 and Article 1, Article 10 and Article 12 shall survive any termination or expiration of this Agreement.

Article 16
MISCELLANEOUS

16.1 **Notices.** Any notice, request, demand, waiver, consent, approval, or other communication which is required or permitted to be given to any Party shall be in writing and shall be deemed given only if delivered to the Party personally, sent to the Party by registered mail, return receipt requested, postage prepaid, sent by a nationally recognized courier service guaranteeing next-day or second-day delivery, charges prepaid, or by email with affirmative confirmation of receipt, in each case addressed to the Party at its address set forth below, or at such other address as such Party may from time to time specify by notice given in the manner provided herein to the Party entitled to receive notice hereunder:

If to Akebia, to:
Akebia Therapeutics, Inc.
245 First Street
14th Floor
Cambridge, MA 02142
Attention: [**]
Email: [**]

with a copy (which shall not constitute notice) to:
Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142
Attention: [**]
Email: [**]

And

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attention: [**]
Email: [**]

If to Cyclerion, to:

Cyclerion Therapeutics, Inc.
245 First Street
Riverview II, 18th Floor
Cambridge, MA 02142
Attention: [**]

with a copy (which shall not constitute notice) to:

Cyclerion Therapeutics, Inc.
245 First Street
Riverview II, 18th Floor
Cambridge, MA 02142
Attention: [**]

16.2 **Entire Agreement; Amendment.** This Agreement (including any Schedules or other attachments hereto) constitutes the entire agreement between the Parties with respect to the subject matter hereof, and no oral or written statement may be used to interpret or vary the meaning of the terms and conditions hereof. This Agreement supersedes any prior or contemporaneous agreements and understandings, whether written or oral, between the Parties with respect to the subject matter hereof, including that certain Confidential Disclosure Agreement between the Parties, dated August 18, 2020, which is hereby terminated. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

16.3 **Assignment.** Without the prior written consent of the other Party, neither Party shall sell, transfer, assign, delegate, pledge, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; *provided*, *however*, that a Party may make such an assignment without the other Party's prior written consent to (a) its Affiliate (b) to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of the business to which this Agreement relates or (c) in connection with a collateral assignment as a security to any lender or financial institution. Notwithstanding the forgoing, each Party shall have the right to sell, transfer, assign, delegate, pledge, encumber, or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, such Party's rights to receive payments under this Agreement (including as part of a royalty monetization transaction) without the other Party's consent. Any attempted assignment or delegation in violation of this Section 14.2 shall be void and of no effect. All validly assigned and delegated rights and obligations of the Parties hereunder shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Cyclerion or Akebia, as the case may be. The permitted assignee or permitted transferee shall assume in writing all obligations of its assignor or transferor under this Agreement. Without limiting the foregoing, the grant of rights set forth in this Agreement shall be binding upon any successor or permitted assignee of Cyclerion, and the obligations of Cyclerion, including the payment obligations, shall run in favor of any such successor or permitted assignee of Cyclerion's benefits under this Agreement.

16.4 **Designation of Affiliates**. Each Party may discharge any obligations and exercise any rights hereunder through delegation of its obligations or rights to any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

16.5 **Further Assurance**. Each of Cyclerion and Akebia agrees to duly execute and deliver, or cause to be duly executed or delivered, such further instruments and do and cause to be done such

further acts, including the filing of additional assignments, agreements, documents, and instruments, as the other Party may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

16.6 **Force Majeure**. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, pandemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date (including related government orders) may be invoked as a force majeure for the purposes of this Agreement even though the pandemic is ongoing and those effects may be reasonably foreseeable (but are not known for certain) as of the Effective Date. In addition, a force majeure may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to any epidemic, pandemic, or spread of infectious disease (including the COVID-19 pandemic), such as requiring employees to stay home, closures of facilities, delays of Clinical Trials, or cessation of activities in response to an epidemic or other force majeure event. The non-performing Party shall notify the other Party of such force majeure within [**] after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is reasonably necessary and the non-performing Party shall use reasonable efforts to remedy its inability to perform.

16.7 **No Strict Construction; Headings.** The headings of clauses contained in this Agreement preceding the text of the sections, subsections, and paragraphs hereof are inserted solely for convenience and ease of reference only and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words “include”, “includes” and “including” will be deemed to be followed by the phrase “without limitation,” (c) the word “will” will be construed to have the same meaning and effect as the word “shall,” (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any person or entity will be construed to include the person’s or entity’s successors and assigns, (f) the words “herein,” “hereof,” and “hereunder”, and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to Sections or Schedules will be construed to refer to Sections or Schedules of this Agreement, and references to this Agreement include all Schedules hereto, (h) the word “notice”

means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (k) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or," and (l) references to any Sections include Sections and subsections that are part of the related Section (*e.g.*, a section numbered "Section 2.2" would be part of "Section 2", and references to "Section 2.2" would also refer to material contained in the subsection described as "Section 2.2(a)"). Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist. This Agreement has been prepared in the English language and the English language shall control its interpretation. In addition, all notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement shall be in the English language.

16.8 **Relationship of the Parties.** It is expressly agreed that Cyclerion, on the one hand, and Akebia, on the other hand, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture, or agency. Neither Cyclerion, on the one hand, nor Akebia, on the other hand, shall have the authority to make any statements, representations, or commitments of any kind, or to take any action, which shall be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

16.9 **Severability.** If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, then (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by applicable law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

16.10 **No Third-Party Beneficiaries.** Covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons.

16.11 **Governing Law.** This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of New

York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

16.12 **Dispute Resolution.** In the event of any dispute under this Agreement, the Parties shall refer such dispute to the Executive Officers for attempted resolution by good faith negotiations within [**] after such referral is made. If the Executive Officers are unable to resolve the dispute within the time allotted, either Party may proceed as set forth below.

(a) **Alternative Dispute Resolution.** Any dispute that cannot be resolved pursuant to Section 14.12 above shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce [**] appointed in accordance with said Rules, [**]. The place of arbitration shall be Boston, Massachusetts and the language to be used in any such proceeding (and for all testimony, evidence and written documentation) shall be English. The IBA Rules on the Taking of Evidence in International Arbitration shall apply on any evidence to be taken up in the arbitration.

(b) **Waiver of Jury Trial**. EACH PARTY HERETO HEREBY IRREVOCABLY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED IN CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE ACTIONS OF ANY PARTY HERETO IN THE NEGOTIATION, ADMINISTRATION, PERFORMANCE AND ENFORCEMENT HEREOF. NOTWITHSTANDING THE FOREGOING, NEITHER PARTY WAIVES ANY RIGHT TO A JURY PROCEEDING FOR THE DETERMINATION OF DAMAGES ARISING FROM ANY SUCH ACTION PROCEEDING OR COUNTERCLAIM.

(c) **Disputes Related to Patent Rights**. Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the validity and enforceability of any Patent shall be determined in a court or other tribunal, as the case may be, of competent jurisdiction under the applicable Patent laws of such country, with a jury trial being however excluded. If such dispute involves such Patent matters and other matters, the arbitrators will have the right to stay the arbitration until determination of such Patent matters material to the resolution of the dispute as to the other matters is resolved.

(d) **Injunctive Relief**. Nothing contained in the Agreement shall deny either Party the right to injunctive relief, equitable relief, interim or provisional relief including a temporary restraining order, specific performance, preliminary or permanent injunction or other interim equitable relief from a court of competent jurisdiction in the context of a breach or threatened breach of any provision of the Agreement, *bona fide* emergency or prospective irreparable harm, or as reasonable and necessary to protect its legitimate interests. Such an action may be filed and maintained, notwithstanding any ongoing discussions between the Parties or any ongoing arbitration proceeding concerning a dispute if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding.

16.13 **No Waiver.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a

written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable law or otherwise available except as expressly set forth herein.

16.14 **Counterparts.** This Agreement may be executed in one or more counterparts, and by the respective Parties in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same Agreement. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[SIGNATURES PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed as of the Effective Date by their respective duly authorized officers.

CYCLERION PHARMACEUTICALS, INC.

By: /s/ Cheryl Gault

Name: Cheryl Gault

Title: Chief Operating Officer

AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler

Name: John P. Butler

Title: Chief Executive Officer

By: /s/ David A. Spellman

Name: David A. Spellman

Title: Chief Financial Officer

Schedule 1.8

Assigned Trademarks

[**]

Schedule 1.30

Cyclerion Patents

Cyclerion Reference	Title	Country	Status	Application No.	Filing Date	Publication No.	Publication Date	Patent No.	Issue Date
A total of 21 pages were omitted. [**]									

Schedule 1.71

Licensed Compounds

[**]

Schedule 1.82

[**]

Schedule 3.3

Initial Development Plan

[**]

Schedule 4.1

Existing INDs

[**]

Schedule 5.3

Estimated Initial Supply

[**]

Schedule 9.2(a)

Control Transferring Patents

[**]

Schedule 9.2(c)

Non-Control Transferring Patent

[**]

Schedule 11.1(u)

Agreements relating to the Manufacture or supply of the Licensed Compounds and Products

Development Materials and related contracts:

[**]

Exhibit 10.98
Confidential

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

AMENDMENT #1 TO LICENSE AGREEMENT

This Amendment #1 (the "**Amendment**") to the License Agreement (the "**License Agreement**") dated June 3, 2021 by and between **Akebia Therapeutics, Inc.,** a Delaware corporation ("**Akebia**"), and Cyclerion Therapeutics, Inc., a Massachusetts corporation ("**Cyclerion**") is effective as of **December 13, 2024** (the "**Amendment Effective Date**"). Akebia and Cyclerion are each referenced individually herein as a "**Party**" and together as the "**Parties**". Any capitalized terms used but not herein defined shall have the meaning set forth for such term in the License Agreement.

WHEREAS, Akebia and Cyclerion are parties to the License Agreement pursuant to which Cyclerion granted Akebia an exclusive license under certain intellectual property rights to Exploit Licensed Compounds and Products in the Territory (each as defined in the License Agreement), in each case, in accordance with the terms and conditions set forth in the License Agreement;

WHEREAS, pursuant to the License Agreement, the Parties entered into that certain Supply Agreement dated as of August 3, 2021; and

WHEREAS, the Parties now desire to amend certain provisions of the License Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

1. **Amendment Payments**. In consideration for the rights granted by Cyclerion to Akebia under this Amendment:

    a. No later than December 31, 2024, Akebia shall pay Cyclerion an upfront amount equal to One Million Two Hundred and Fifty Thousand Dollars ($1,250,000). Such payment shall be nonrefundable and noncreditable against any other payments due hereunder.

    b. No later than September 30, 2025, Akebia shall pay Cyclerion an amount equal to Five Hundred Thousand Dollars ($500,000). Such payment shall be nonrefundable and noncreditable against any other payments due hereunder.

2. **Section 1.62** of the License Agreement is hereby deleted in its entirety and replaced with the following:

    "1.62 [**Reserved]**."

3. **Section 1.94** of the License Agreement is hereby deleted in its entirety and replaced with the following:

    "1.62 "**Patent Transfer Date**" means the earlier of (a) April 1, 2025 and (b) such date that the Parties may agree, following request by Akebia or Cyclerion.

4. **Section 5.1** of the License Agreement is hereby deleted in its entirety and replaced with the following:

    "5.1 **Initial Supply of Products**. Notwithstanding the terms of the Supply Agreement dated August 3, 2021 between the Parties (the "**Supply Agreement**") pursuant to which

Cyclerion agreed to deliver Drug Product (as defined in the Supply Agreement) and placebo to Akebia for clinical use (the "**Initial Supply**"), the Parties acknowledge and agree that Cyclerion did not deliver the Initial Supply to Akebia, and as of the Amendment Effective Date, Akebia will have sole control over and decision-making authority with respect to the Manufacture of all Drug Product in accordance with Section 5.6. Akebia hereby further agrees that it is not entitled to any damages of any kind that could be awarded as a result of Cyclerion's failure to deliver the Initial Supply.

5. **Section 5.2** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"5.2 [Reserved]."

6. **Section 5.3** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"5.3 [Reserved]."

7. **Section 5.5** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"5.5 Additional Development Materials. The Parties acknowledge that as of the Effective Date, Cyclerion was in physical possession of that inventory of [**] (the "Additional Development Materials"), in each case as set forth on Schedule 11.1(u). Following the Amendment Effective Date, Cyclerion shall provide Akebia with a written update regarding the quantity and type of Additional Development Materials in Cyclerion's physical possession as of the Amendment Effective Date. Cyclerion shall perform testing on [**] at its sole cost and expense, and shall deliver a written summary of the type of tests conducted and the results of such testing to Akebia in the form of a Certificate of Analysis or Results Summary issued by the contract manufacturing organization performing such testing (the "**Test Results**").

For a period of [**] following Cyclerion's delivery of the Test Results to Akebia (the "Purchase Period"), Akebia may elect, in its sole discretion, to purchase and take delivery of any or all of such inventory of Additional Development Materials, in units that are readily available and, notwithstanding any provision to the contrary in Schedule 11.1(u), at a purchase price for the Additional Development Materials to be negotiated in good faith by the Parties prior to Akebia's election to purchase the Additional Development Materials. If Akebia elects to purchase the Additional Development Materials, Akebia shall also reimburse Cyclerion for the cost of such testing as part of such negotiated transfer price. If Akebia elects to purchase the Additional Development Materials in this manner, it shall do so by providing written notice to Cyclerion that Akebia elects to purchase and have delivered the Additional Development Materials, and Cyclerion shall deliver such inventory to Akebia or its designee at Akebia's direction, at Akebia's sole cost and expense, which for the sake of clarity, shall include any tariffs. Title to such Additional Development Materials shall transfer to Akebia at the time of delivery. Cyclerion shall use reasonable efforts to manage any storage and handling of Additional Development Materials in its physical possession as of the Amendment Effective Date in accordance with standard industry practice. Akebia shall reimburse Cyclerion all reasonable costs incurred by Cyclerion or its Affiliates in connection with the storage of such Additional Development Materials during such period until delivery thereof to Akebia, within [**] after receipt of an invoice therefor. Notwithstanding the foregoing, prior to Akebia's delivery of an election to purchase notice

to Cyclerion, on a material-by-material basis Akebia may waive its option to purchase some or all of such Additional Development Materials by providing written notice of such waiver, and from the date of delivery of such notice Akebia shall no longer reimburse Cyclerion for the costs incurred by Cyclerion or its Affiliates in connection with the storage of such material.

In the event Akebia does not elect to purchase the Additional Development Materials during the Purchase Period, Akebia shall have no obligation with respect to such Additional Development Materials and Cyclerion shall remain responsible for the costs of such testing.

8. **Section 5.6** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"5.6 **Manufacture of Licensed Compounds and Products**. As between the Parties, Akebia shall have sole control over and decision-making authority with respect to, at its expense, (a) Manufacturing (or having Manufactured) the Licensed Compounds and Products and (b) Manufacturing (or having Manufactured) [**], and all other intermediates and other precursors of the Licensed Compounds and the Products, solely for the purpose of Manufacturing the Licensed Compounds and the Products for Development and Commercialization in the Field in the Territory by Akebia and its Affiliates and Sublicensees."

9. **Section 7.2** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"7.2 **Development and Regulatory Milestone Payments.** In partial consideration of the rights granted by Cyclerion to Akebia hereunder and subject to the terms and conditions set forth in this Agreement, including Section 7.2, Akebia shall pay to Cyclerion the applicable milestone payment set forth in Table 7.2 within [**] after the first achievement of each of the following milestones by Akebia or its Affiliates for the first Product:

Table 7.2 – Development and Regulatory Milestones	
U.S.	***Development and Regulatory Milestone Payment***
Initiation of a Phase 2 Clinical Trial in the U.S. for a Product for the first Indication	$1,000,000
Initiation of a Phase 3 Clinical Trial in the U.S. for a Product for the first Indication	[**]
Initiation of a Phase 3 Clinical Trial in the U.S. for a Product for the second Indication	[**]
Receipt of Regulatory Approval by the FDA for a Product for the first Indication	[**]
Receipt of Regulatory Approval by the FDA for a Product for the second Indication	[**]
[**]	[**]
[**]	***Development and Regulatory Milestone Payment***

Receipt of [**] Regulatory Approval for a Product for the first Indication	[**]
Receipt of [**] Regulatory Approval for a Product for the second Indication	[**]
[**]	[**]
[**]	***Development and Regulatory Milestone Payment***
Receipt of Regulatory Approval by [**] for a Product for the first Indication	[**]
Receipt of Regulatory Approval by [**] for a Product for the second Indication	[**]
[**]	[**]

Each milestone payment in this Section 7.2 shall be payable one time only upon the first achievement of such milestone by the first Product.

If Akebia or its Affiliates achieves any milestone set forth in this Section 7.2 for a particular Product in a particular Indication before an earlier listed milestone for the same Product in the same Indication, then the earlier listed milestone shall become payable at the same time as the achieved milestone for the same Product in such Indication. No milestone payments in this Section 7.2 shall be due based on the achievement of any of the foregoing milestone events by any Significant Sublicensee."

10. **Section 7.3** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"7.3. [Reserved]."

11. **Section 7.5(a)** of the License Agreement is hereby deleted in its entirety and replaced with the following:

(a) "(a) **Akebia Royalty Rate – [**].** As further consideration for the rights granted to Akebia hereunder, subject to the terms and conditions of this Agreement, including the other terms of this Section 7.5, [**], during the Royalty Term for a Product [**], Akebia shall pay to Cyclerion tiered royalties based on Net Sales recorded by Akebia or its Affiliates of all Products [**] in a Calendar Year at the applicable royalty rates set forth below:

Table 7.5 – Akebia Royalties [**]	
Net Sales by Akebia or its Affiliates of all Products in a Major Country in a Calendar Year	***Applicable Royalty Rate (Percentage of Net Sales)***
[**]	[**]
[**]	[**]
[**]	Twenty Percent (20%)

12. **Section 7.6** of the License Agreement is hereby deleted in its entirety and replaced with the following:

"7.6 **Sublicense Income.**

(a) Akebia shall pay to Cyclerion an amount equal to [**].

(b) Akebia shall pay to Cyclerion an amount equal to [**].

(c) For purposes of calculating [**].

(d) Akebia shall pay Cyclerion its portion of [**]."

13. **Miscellaneous**.

a. All capitalized terms used but not defined herein shall have meanings set forth in the License Agreement.

b. Except as otherwise provided herein, all provisions of the License Agreement, as amended hereby, shall remain in full force and effect.

c. This Amendment, the Supply Agreement and the License Agreement (including any schedules or other attachments hereto or thereto) constitute the entire agreement between the Parties with respect to the subject matter hereof and thereof, and no oral or written statement may be used to interpret or vary the meaning of the terms and conditions hereof or thereof. This Amendment supersedes any prior or contemporaneous agreements and understandings, whether written or oral, between the Parties with respect to the subject matter hereof. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

d. This Amendment may only be assigned in connection with any permitted assignment of the License Agreement, and shall be binding upon and inure to the benefit of and be enforceable by and against the successors and permitted assigns of Cyclerion or Akebia, as the case may be.

e. In the event of any conflict between the provisions of this Amendment and the License Agreement, the provisions of this Amendment shall control as to the subject matter set forth herein.

f. This Agreement or the performance, enforcement, breach or termination hereof shall be interpreted, governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

g. This Amendment may be executed in one or more counterparts, and by the respective Parties in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same Amendment. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal

ESIGN Act of 2000, and any counterpart so delivered be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Amendment.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Parties have executed this Amendment effective as of the Amendment Effective Date written above.

AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler

Print Name: John P. Butler

Title: President & CEO

CYCLERION THERAPEUTICS, INC.

By: /s/ Regina S. Graul

Print Name: Regina S. Graul

Title: President and Chief Executive Officer

[Signature page to Amendment #1 to License Agreement]

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-196748) pertaining to the Amended and Restated 2008 Equity Incentive Plan, the 2014 Incentive Plan, and the 2014 Employee Stock Purchase Plan of Akebia Therapeutics, Inc.,

(2) Registration Statement (Form S-8 No. 333-209469) pertaining to the 2014 Incentive Plan and the 2014 Employee Stock Purchase Plan of Akebia Therapeutics, Inc.,

(3) Registration Statements (Form S-8 Nos. 333-216475 and 333-222728) pertaining to the 2014 Incentive Plan and the 2016 Inducement Award Program of Akebia Therapeutics, Inc.,

(4) Registration Statement (Form S-8 No. 333-228772) pertaining to the 2014 Incentive Plan of Akebia Therapeutics, Inc. and the 1999 Share Option Plan, 2004 Long-Term Incentive Plan, 2007 Incentive Plan, Amended and Restated 2013 Incentive Plan, and 2018 Equity Incentive Plan of Keryx Biopharmaceuticals, Inc.,

(5) Registration Statement (Form S-8 No. 333-229366) pertaining to the 2014 Incentive Plan, the 2014 Employee Stock Purchase Plan, and the Inducement Grant Awards (January 2018 – December 2018) of Akebia Therapeutics, Inc.,

(6) Registration Statement (Form S-8 No. 333-233140) pertaining to the Amended and Restated 2014 Employee Stock Purchase Plan of Akebia Therapeutics, Inc.,

(7) Registration Statement (Form S-8 No. 333-236060) pertaining to the 2014 Incentive Plan and the Inducement Grant Awards (January 2019 – December 2019) of Akebia Therapeutics, Inc.,

(8) Registration Statement (Form S-8 No. 333-252336) pertaining to the 2014 Incentive Plan and the Inducement Grant Awards (January 2020 – December 2020) of Akebia Therapeutics, Inc.,

(9) Registration Statement (Form S-8 No. 333-262392) pertaining to the 2014 Incentive Plan, as amended, and the Inducement Stock Option Awards (January 2021 – December 2021) of Akebia Therapeutics, Inc.,

(10) Registration Statement (Form S-8 No. 333-269457) pertaining to the 2014 Incentive Plan, as amended, and the Inducement Stock Option Awards (January 2022 – December 2022) of Akebia Therapeutics, Inc.,

(11) Registration Statement (Form S-8 No. 333-272453) pertaining to the 2023 Stock Incentive Plan of Akebia Therapeutics, Inc.,

(12) Registration Statement (Form S-8 No. 333-276770) pertaining to the Inducement Stock Option Awards (January 2023 – December 2023) of Akebia Therapeutics, Inc.,

(13) Registration Statement (Form S-3 No. 333-281903) of Akebia Therapeutics, Inc.,

(14) Registration Statement (Form S-8 No. 333-284590) pertaining to the Inducement Stock Option Awards (January 2024 – December 2024) of Akebia Therapeutics, Inc., and

(15) Registration Statement (Form S-8 No. 333-289340) pertaining to the 2023 Stock Incentive Plan, as amended, and the Inducement Stock Option Awards (January 2025 – July 2025) of Akebia Therapeutics, Inc.;

of our reports dated February 26, 2026, with respect to the consolidated financial statements of Akebia Therapeutics, Inc. and the effectiveness of internal control over financial reporting of Akebia Therapeutics, Inc. included in this Annual Report (Form 10-K) of Akebia Therapeutics, Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 26, 2026

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John P. Butler, certify that:

1. I have reviewed this Annual Report on Form 10-K of Akebia Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2026

By: /s/ John P. Butler

John P. Butler
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Erik J. Ostrowski, certify that:

1. I have reviewed this Annual Report on Form 10-K of Akebia Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 26, 2026

By: /s/ Erik J. Ostrowski

Erik J. Ostrowski
Senior Vice President, Chief Financial Officer, Chief Business Officer and Treasurer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. Section 1350)

In connection with the accompanying Annual Report of Akebia Therapeutics, Inc., or the Company, on Form 10-K for the fiscal year ended December 31, 2025, or the Report, I, John P. Butler, as Chief Executive Officer and President of the Company, and I, Erik J. Ostrowski, as Senior Vice President, Chief Financial Officer, Chief Business Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 26, 2026 By: /s/ John P. Butler

John P. Butler
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: February 26, 2026 By: /s/ Erik J. Ostrowski

Erik J. Ostrowski
Senior Vice President, Chief Financial Officer, Chief Business Officer and Treasurer
(Principal Financial Officer)