UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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

Not Applicable

(Former name, former address and former fiscal year, if changed since last report)

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**

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares outstanding of the issuer's common stock as of November 4, 2025 was 265,365,993.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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;
- our pipeline and portfolio, including its potential, and our related research and development activities;
- 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 and Vafseo, including the size of eligible patient populations;
- the potential therapeutic applications of the hypoxia inducible factor pathway;
- 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;
- the direct or indirect impacts of the COVID-19 pandemic on our business, operations and the markets and communities in which we and our partners, collaborators, vendors, and customers operate;
- 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 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 due to events associated with or resulting from our prior workforce reductions or other operating expenses, including additional costs related to Vafseo 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 Quarterly Report on Form 10-Q 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 II, Item 1A. "Risk Factors" included in this Quarterly Report on Form 10-Q and elsewhere in this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q. 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 Quarterly Report on Form 10-Q 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 II, Item 1A. Risk Factors" of this Quarterly Report on Form 10-Q, 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 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.
- 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.
- 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, 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 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.
- 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.
- 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.
- 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. We rely on international third parties for the manufacture of raw materials, drug substance and drug product for the commercial supply of Auryxia and Vafseo and for early-stage research services for our product candidates, the commercialization of which may be prevented or impaired if there are interruptions or delays in obtaining the applicable products or services.
- 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.
- We have 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. If we are not able to remediate this material weakness, or if we experience additional material weaknesses or other deficiencies in our internal control over financial reporting 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.
- 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.

Akebia Therapeutics, Inc.
Form 10-Q
For the Quarter Ended September 30, 2025

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In this Quarterly Report on Form 10-Q, 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Akebia Therapeutics, Inc.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(dollars in thousands, except per share amounts)	September 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 166,444	$ 51,870
Inventories	18,643	16,243
Accounts receivable, net	66,223	34,368
Prepaid expenses and other current assets	7,026	11,350
Total current assets	258,336	113,831
Property and equipment, net	1,473	2,200
Operating right-of-use assets	4,837	8,218
Goodwill	59,044	59,044
Other long-term assets	40,462	37,377
Total assets	**$ 364,152**	**$ 220,670**
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 10,087	$ 15,180
Accrued expenses and other current liabilities	106,420	63,460
Current portion of deferred revenue	3,881	—
Working Capital Fund liability, current portion	12,991	2,274
Total current liabilities	133,379	80,914
Long-term operating lease liabilities	—	3,547
Long-term debt, net	47,641	38,693
Liability related to settlement royalties, net of current portion	52,994	46,697
Liability related to sale of future royalties, net of current portion	50,576	52,066
Working Capital Fund liability, net of current portion	27,726	38,013
Warrant liability	5,242	5,176
Other long-term liabilities	5,002	4,749
Total liabilities	**322,560**	**269,855**
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Preferred stock $0.00001 par value; 25,000,000 shares authorized at September 30, 2025 and December 31, 2024; no shares issued and outstanding at September 30, 2025 and December 31, 2024	—	—
Common stock $0.00001 par value; 350,000,000 shares authorized at September 30, 2025 and December 31, 2024; 265,226,038 and 224,848,992 shares issued and outstanding at September 30, 2025 and December 31, 2024, respectively	2	2
Additional paid-in capital	1,713,045	1,629,167
Accumulated other comprehensive income	6	6
Accumulated deficit	(1,671,461)	(1,678,360)
Total stockholders' equity (deficit)	**41,592**	**(49,185)**
Total liabilities and stockholders' equity (deficit)	**$ 364,152**	**$ 220,670**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Akebia Therapeutics, Inc.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(dollars in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Revenues				
Product revenue, net	$ 56,789	$ 35,592	$ 173,041	$ 107,810
License, collaboration and other revenue	1,977	1,836	5,533	5,873
Total revenues	58,766	37,428	178,574	113,683
Cost of goods sold				
Cost of product and other revenue	9,383	5,150	26,927	15,780
Amortization of intangible asset	—	9,011	—	27,032
Total cost of goods sold	9,383	14,161	26,927	42,812
Operating expenses:				
Research and development	14,944	8,487	35,711	25,866
Selling, general and administrative	29,094	26,516	81,391	78,870
License	896	769	2,493	2,242
Restructuring	—	—	—	58
Total operating expenses	44,934	35,772	119,595	107,036
Income (loss) from operations	**4,449**	**(12,505)**	**32,052**	**(36,165)**
Other income (expense)				
Interest expense	(4,748)	(6,661)	(19,352)	(11,308)
Other income (expense)	(10)	(17)	175	39
Change in fair value of warrant liability	1,464	(856)	(5,361)	1,345
Loss on extinguishment of debt	—	—	—	(517)
Income (loss) before income taxes	**1,155**	**(20,039)**	**7,514**	**(46,606)**
Income tax expense	(615)	—	(615)	—
Net income (loss)	**$ 540**	**$ (20,039)**	**$ 6,899**	**$ (46,606)**
Comprehensive income (loss)	**$ 540**	**$ (20,039)**	**$ 6,899**	**$ (46,606)**
Net income (loss) per share:				
Basic	$0.00	$(0.10)	$0.03	$(0.22)
Diluted	$0.00	$(0.10)	$0.03	$(0.22)
Weighted average shares of common stock outstanding:				
Basic	264,786,432	210,348,459	254,390,502	208,343,679
Diluted	274,372,722	210,348,459	262,680,943	208,343,679

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Akebia Therapeutics, Inc.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(dollars in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' (Deficit)
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	13,261,311	—	18,740	—	—	18,740
Proceeds from sale of stock under employee stock purchase plan	92,321	—	70	—	—	70
Exercise of options	280,260	—	141	—	—	141
Stock-based compensation expense	—	—	2,360	—	—	2,360
Restricted stock unit vesting	1,237,718	—	—	—	—	—
Net loss	—	—	—	—	(17,985)	(17,985)
Balance at March 31, 2024	**209,454,149**	**$ 2**	**$ 1,599,669**	**$ 6**	**$ (1,626,935)**	**$ (27,258)**
Exercise of options	23,892	—	14	—	—	14
Stock-based compensation expense	—	—	2,072	—	—	2,072
Restricted stock unit vesting	451,104	—	—	—	—	—
Net loss	—	—	—	—	(8,582)	(8,582)
Balance at June 30, 2024	**209,929,145**	**$ 2**	**$ 1,601,755**	**$ 6**	**$ (1,635,517)**	**$ (33,754)**
Issuance of common stock, net of issuance costs	1,242,662	—	1,662	—	—	1,662
Proceeds from sale of stock under employee stock purchase plan	97,411	—	83	—	—	83
Exercise of options	2,312	—	—	—	—	—
Stock-based compensation expense	—	—	1,646	—	—	1,646
Restricted stock unit vesting	270,592	—	—	—	—	—
Net loss	—	—	—	—	(20,039)	(20,039)
Balance at September 30, 2024	**211,542,122**	**$ 2**	**$ 1,605,146**	**$ 6**	**$ (1,655,556)**	**$ (50,402)**

(dollars in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2024	**224,848,992**	**$ 2**	**$ 1,629,167**	**$ 6**	**$ (1,678,360)**	**$ (49,185)**
Issuance of common stock, net of issuance costs	34,437,364	—	64,907	—	—	64,907
Proceeds from sale of stock under employee stock purchase plan	93,362	—	78	—	—	78
Exercise of options	604,325	—	482	—	—	482
Stock-based compensation expense	—	—	2,187	—	—	2,187
Restricted stock unit vesting	1,660,547	—	—	—	—	—
Net income	—	—	—	—	6,112	6,112
Balance at March 31, 2025	**261,644,590**	**$ 2**	**$ 1,696,821**	**$ 6**	**$ (1,672,248)**	**$ 24,581**
Issuance of common stock, net of issuance costs	850,000	—	1,542	—	—	1,542
Exercise of options	95,996	—	178	—	—	178
Stock-based compensation expense	—	—	2,676	—	—	2,676
Restricted stock unit vesting	451,246	—	—	—	—	—
Net income	—	—	—	—	247	247
Balance at June 30, 2025	**263,041,832**	**$ 2**	**$ 1,701,217**	**$ 6**	**$ (1,672,001)**	**$ 29,224**
Warrants exercised, cashless	1,408,588	—	7,494	—	—	7,494
Proceeds from sale of stock under employee stock purchase plan	94,060	—	151	—	—	151
Exercise of options	438,300	—	962	—	—	962
Stock-based compensation expense	—	—	3,221	—	—	3,221
Restricted stock unit vesting	243,258	—	—	—	—	—
Net income	—	—	—	—	540	540
Balance at September 30, 2025	**265,226,038**	**$ 2**	**$ 1,713,045**	**$ 6**	**$ (1,671,461)**	**$ 41,592**

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Akebia Therapeutics, Inc.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(dollars in thousands)	Nine Months Ended September 30, 2025	2024
Operating Activities:		
Net income (loss)	$ 6,899	$ (46,606)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	948	1,127
Amortization of intangible asset	—	27,032
Bad debt expense	1,385	—
Change in fair value of warrant liability	5,361	(1,345)
Non-cash royalty revenue related to sale of future royalties	(1,325)	(1,390)
Non-cash interest expense	17,056	7,475
Non-cash operating lease expense	3,381	3,116
Non-cash loss on extinguishment of debt	—	294
Write-down of inventory	645	2,403
Change in excess inventory purchase commitments	—	2,068
Gain on the sale of property and equipment	(172)	—
Stock-based compensation expense	8,084	6,078
Changes in operating assets and liabilities:		
Accounts receivable	(33,240)	7,120
Inventory	(5,707)	(19,905)
Prepaid expenses and other current assets	6,019	6,805
Other long-term assets	141	625
Accounts payable	(7,337)	(3,758)
Accrued expense and other current liabilities	34,602	(17,652)
Operating lease liabilities	(4,011)	(3,212)
Deferred revenue	3,881	—
Other long-term liabilities	253	(6,468)
Net cash provided by (used in) operating activities	**36,863**	**(36,193)**
Investing Activities:		
Purchases of equipment	(221)	(31)
Proceeds from the sale of property and equipment	172	—
Net cash used in investing activities	**(49)**	**(31)**
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 issuance of common stock, net of issuance costs	66,449	20,402
Proceeds from issuance of stock under employee stock purchase plan	230	153
Proceeds from the exercise of stock options	1,621	155
Repayment of term debt	(462)	(37,100)
Net cash provided by financing activities	**77,775**	**27,338**
Increase (decrease) in cash, cash equivalents and restricted cash	114,589	(8,886)
Cash, cash equivalents and restricted cash — beginning of period	53,550	44,579
Cash, cash equivalents and restricted cash — end of period	**$ 168,139**	**$ 35,693**
Non-cash financing activities		
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	$ —

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Akebia Therapeutics, Inc.

NOTES TO THE UNAUDITED CONDENSED 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 marketed 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. In addition, the Company continues to explore additional development opportunities to expand its pipeline and portfolio of novel therapeutics.

As of September 30, 2025, the Company had cash and cash equivalents of approximately $166.4 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 for at least twelve months from the filing of this Quarterly Report on Form 10-Q, or Form 10-Q. 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

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2024, and notes thereto, which are included in the Company's Annual Report on Form 10-K, that was filed with the Securities and Exchange Commission, or SEC, on March 13, 2025, or the 2024 Form 10-K. Since the date of those financial statements, there have been no material changes to the Company's significant accounting policies.

In the opinion of management, all adjustments, consisting of normal recurring accruals and revisions of estimates, considered necessary for a fair presentation of the unaudited condensed consolidated financial statements have been included. Interim results for the three and nine months ended September 30, 2025 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2025 or any other future period.

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed 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 unaudited condensed 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 condensed consolidated financial statements herein.

Certain monetary amounts, percentages, and other figures included elsewhere in these unaudited condensed 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 unaudited condensed 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 reserves 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 September 30, 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 September 30, 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 shown in the consolidated statements of cash flows:

(in thousands)	**September 30, 2025**	**December 31, 2024**
Cash and cash equivalents	$ 166,444	$ 51,870
Restricted cash	1,695	1,680
Total cash, cash equivalents and restricted cash	$ 168,139	$ 53,550

Concentration of 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 $2.6 million and $1.2 million as of September 30, 2025 and December 31, 2024, respectively.

The following table summarizes the activity related to the Company's allowance for credit losses (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Beginning balance	$ 1,212	$ 1,029
Provision for bad debts	1,385	194
Recoveries/(write-offs)	—	(695)
Ending balance	$ 2,597	$ 528

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.

Recent Accounting Pronouncements Not Yet 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 will be effective for the annual reporting periods in fiscal years beginning after December 15, 2024. The Company is currently evaluating ASU 2023-09 and does not expect it to have a material effect on the Company’s consolidated financial statements.

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 income (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 GAAP that would need to be integrated within the new tabular disaggregated expense disclosures. Additionally, the amendments 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 OF FINANCIAL INSTRUMENTS

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):

	September 30, 2025			
	Level 1	Level 2	Level 3	Total Fair Value
Cash equivalents:				
Money market funds	$ 154,256	$ —	$ —	$ 154,256
Long-term liability:				
Warrant liability	$ —	$ 5,242	$ —	$ 5,242

	December 31, 2024			
	Level 1	Level 2	Level 3	Total Fair Value
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.

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):

	September 30, 2025	December 31, 2024
Inventories, current:		
Work-in-process	$ 15,715	$ 12,031
Finished goods	2,928	4,212
Inventories, current	$ 18,643	$ 16,243
Long-term inventories included in other long-term assets:		
Raw materials	$ 900	$ 381
Work-in-process	38,960	34,572
Inventories, long-term	$ 39,860	$ 34,953
Total inventories	$ 58,503	$ 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 unaudited condensed consolidated statements of operations and comprehensive income (loss) was $0.5 million and $0.6 million during the three and nine months ended September 30, 2025, respectively, and $1.3 million and $2.4 million during the three and nine months ended September 30, 2024, respectively. For the three and nine months ended September 30, 2024, the Company realized lower cost of product and other revenue of $3.7 million and $12.3 million, respectively, 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 $9.0 million and $27.0 million in amortization expense for the three and nine months ended September 30, 2024, respectively, related to the developed product rights for Auryxia.

Goodwill

As of each of September 30, 2025 and December 31, 2024, the Company had goodwill of $59.0 million in connection with the December 2018 merger with 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):

Description	September 30, 2025	December 31, 2024
Prepaid manufacturing	$ —	$ 4,029
Restricted cash	1,695	—
Other	5,331	7,321
Total prepaid expenses and other current assets	$ 7,026	$ 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, prepaid clinical trial costs and prepaid information technology costs.

Other long-term assets are as follows (in thousands):

Description	September 30, 2025	December 31, 2024
Long-term inventories	$ 39,860	$ 34,953
Restricted cash	—	1,680
Other	602	744
Total other long-term assets	$ 40,462	$ 37,377

See Note 4, *Inventories*, for further information on long-term inventories.

Accrued expenses and other current liabilities consists of the following (in thousands):

Description	September 30, 2025	December 31, 2024
Product revenue allowances excluding rebates	$ 8,972	$ 9,657
Product rebates	50,267	6,070
Product return reserves, current portion	5,076	5,295
Clinical trial costs	1,346	1,885
Compensation and related benefits	9,315	9,194
Operating lease liabilities, current portion	4,936	5,400
Royalties due to Panion & BF Biotech, Inc.	3,628	3,543
Professional fees	1,533	1,452
Accrued manufacturing costs	1,124	1,468
Restructuring costs	—	489
BioVectra, Inc. termination fees	—	7,204
Liability related to sale of future royalties, current portion	2,144	2,039
Settlement royalties liability, current portion	14,286	5,924
Other	3,793	3,840
Total accrued expenses and other current liabilities	$ 106,420	$ 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 September 30, 2025, the Company's interest rate was 11.00%. The Company recognized interest expense related to the BlackRock Credit Agreement of $2.1 million and $6.2 million during the three and nine months ended September 30, 2025, respectively, and $1.7 million and $5.5 million during the three and nine months ended September 30, 2024, 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. If prepayment is made during the first year, the Company also is required to pay the amount of otherwise due interest payments for the twelve-month period following prepayment.

As of September 30, 2025, future principal payments under the BlackRock Credit Agreement are as follows (in thousands):

	Principal Payments
2025	$ —
2026	—
2027	50,558
2028	1,881
Total before unamortized discount and issuance costs	$ 52,439
Less: unamortized discount and issuance costs	(4,798)
Total term loans	$ 47,641

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.

Warrants

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 additional warrants 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 shall be exercisable for eight years from the date of issuance.

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 unaudited condensed consolidated statements of operations and comprehensive income (loss). The fair value of the warrant liability was $5.2 million as of September 30, 2025 and December 31, 2024. See Note 3, *Fair Value of Financial Instruments*, for information on the fair value determination.

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 to the Warrant Holder under the Initial Warrant.

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 each 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 Loans (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 nine months ended September 30, 2024, the Company recorded a debt extinguishment loss of $0.5 million.

The Company recognized no interest expense during the three and nine months ended September 30, 2025 and immaterial interest expense during the nine months ended September 30, 2024, in each case related to the Pharmakon Loan Agreement.

See Note 7, *Indebtedness*, of the Notes to the Consolidated Financial Statements in the 2024 Form 10-K for further details.

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 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 the Company and CSL Vifor in which the Company would receive approximately 66% of the profits, 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.

See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, of the Notes to the Consolidated Financial Statements in the 2024 Form 10-K for a more detailed description of the Vifor License Agreement.

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 premium 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, its affiliates or third-party licensees 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, or OB, 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 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, 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 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 September 30, 2025 was 24.6% which is reflected as interest expense in the unaudited condensed consolidated statements of operations and comprehensive income (loss). The Company recognized interest expense related to the settlement royalties liability of $3.9 million and $14.7 million for the three and nine months ended September 30, 2025,

respectively, and $4.4 million for the three and nine months ended September 30, 2024. As of September 30, 2025 and December 31, 2024, the balances related to the settlement royalties liability were as follows (in thousands):

Description	September 30, 2025	December 31, 2024
Current portion (included in accrued expenses and other current liabilities)	$ 14,286	$ 5,924
Long-term portion	52,994	46,697
Total settlement royalties liability	$ 67,280	$ 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 was considered a debt arrangement with zero coupon interest and the Company imputed 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 on the condensed 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 amortized to interest expense using the effective interest method over the WCF Royalty Term. The deferred gain is amortized to interest income on a straight-line basis over the WCF Royalty Term. The amortization of the discount was $1.2 million and $3.5 million for the three and nine months ended September 30, 2025, respectively, and $1.1 million and $2.7 million for the three and nine months ended September 30, 2024, respectively. The amortization of the deferred gain was $1.1 million and $3.1 million for the three and nine months ended September 30, 2025, respectively, and $0.9 million and $2.6 million for the three and nine months ended September 30, 2024, respectively.

As of September 30, 2025 and December 31, 2024, the balances related to the Working Capital Fund liability were as follows (in thousands):

Description	September 30, 2025	December 31, 2024
Current portion	$ 12,991	$ 2,274
Long-term portion	27,726	38,013
Total Working Capital Fund liability	$ 40,717	$ 40,287

Liability Related to Sale of Future Royalties

On February 25, 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 MTPC Territory, and such payments collectively the Royalty Interest Payments, in each case, payable to the Company under the MTPC Agreement (as defined below). 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 MTPC Agreement.

At the transaction date, the Company recorded 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 reassesses the effective interest rate and adjusts the rate prospectively as needed. The annual effective interest rate as of September 30, 2025 was 0% and, therefore the Company did not recognize any non-cash interest expense in the unaudited condensed consolidated statements of operations and comprehensive income (loss). As a result of its ongoing involvement in the cash flows related to the royalties and sales milestones in the MTPC Territory, the Company will continue to account for these royalties as non-cash royalty revenue which is reflected in license, collaboration and other revenue in the unaudited condensed consolidated statements of operations and comprehensive income (loss). See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, of the Notes to the Consolidated Financial Statements in the 2024 Form 10-K for a more detailed description of the Royalty Agreement.

The Company paid royalties to HCR of $0.5 million during each of the three months ended September 30, 2025 and 2024 and $1.4 million during each of the nine months ended September 30, 2025 and 2024. As of September 30, 2025 and December 31, 2024 the balances were as follows (in thousands):

Liability related to sale of future royalties	September 30, 2025	December 31, 2024
Current portion (included in accrued expenses and other current liabilities)	$ 2,144	$ 2,039
Long-term portion	50,576	52,066
Total liability related to sale of future royalties	$ 52,720	$ 54,105

9. LEASES

Cambridge Lease

Under the Cambridge Lease, the Company leases approximately 65,167 square feet of office, storage and lab 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 lab space expires on September 11, 2026, with one two-year extension option available.

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 are not reasonably certain. The Cambridge Lease does not contain residual value guarantees. 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 or the effective date of any subsequent lease term extensions. As of September 30, 2025, the remaining lease term for the Cambridge Lease was 0.95 years.

Operating lease costs were $1.2 million and $3.7 million for each of the three and nine months ended September 30, 2025 and 2024, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $1.5 million and $4.4 million for the three and nine months ended September 30, 2025, respectively, and $1.4 million and $4.3 million for the three and nine months ended September 30, 2024, 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 accompanying unaudited condensed consolidated balance sheet as of September 30, 2025 and in other long-term assets in the accompanying unaudited condensed consolidated balance sheet as of December 31, 2024.

Future Lease Commitments

Future commitments under the Cambridge Lease are as follows (in thousands):

	Operating Lease Commitments
2025	$ 1,460
2026	3,613
Total lease commitments	$ 5,073
Less: present value adjustment	(137)
Current and long-term operating lease liabilities	$ 4,936

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 SA, 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 at a predetermined price. As of September 30, 2025, the Company is required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $15.3 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 commitment liability recorded in other long-term liabilities was $3.6 million as of September 30, 2025 and December 31, 2024.

Patheon Manufacturing

On March 11, 2020, the Company entered into a Supply Agreement with Patheon Inc., or Patheon, or the Patheon Agreement, under which Patheon will manufacture Vafseo drug product for commercial use under a volume-based pricing structure through June 30, 2026, 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 September 30, 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 September 30, 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.

Additionally, 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 September 30, 2025, the Company has committed to purchase $0.8 million of Vafseo drug product from WuXi STA through the first quarter

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, Mitsubishi Tanabe Pharma Corporation, or MTPC, and Esteve executed the Esteve Assignment Agreement, pursuant to which the Esteve Agreement was assigned to MTPC. The Esteve Assignment Agreement transferred the rights and obligations of the Esteve Agreement to MTPC, specifically including the obligations under certain purchase orders issued by the Company and accepted by Esteve.

Although the Esteve Agreement was assigned to MTPC in December 2022, the Company and Esteve have agreed to negotiate the terms of a new commercial supply relationship. As of September 30, 2025, the Company has committed to purchase $7.6 million of Vafseo drug substance from Esteve through the end of 2025.

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 recognized to 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 on 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 is being amortized to interest expense using the effective interest rate method over the term of the liability. The amortization of the discount was immaterial and $0.3 million for the three and nine months ended September 30, 2025, respectively, and $0.4 million and $1.3 million for the three and nine months ended September 30, 2024, 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 the 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 with the right 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 the Company-owned patents, with the right 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. See Note 10, *Commitments and Contingencies*, of the Notes to the Consolidated Financial Statements in the 2024 Form 10-K for a more detailed description of this license agreement.

The Company incurred royalty payments due to Panion of approximately $2.7 million and $8.4 million during the three and nine months ended September 30, 2025, respectively, and $2.1 million and $6.4 million during the three and nine months ended September 30, 2024, respectively, 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 aggregate of $198.5 million from the Company 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 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.

Other Third-Party Contracts

The Company contracts with various organizations to conduct R&D activities with remaining contract costs to the Company of approximately $86.8 million at September 30, 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.

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 three and nine months ended September 30, 2025 and 2024, the Company did not experience any losses related to these indemnification obligations, and no claims were outstanding as of September 30, 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 RESERVES 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 Company recognized the following revenue from Vafseo and Auryxia (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Product	**2025**	**2024**	**2025**	**2024**
Vafseo	$ 14,322	$ —	$ 39,635	$ —
Auryxia[1]	42,467	35,592	133,406	107,810
Total product revenues	$ 56,789	$ 35,592	$ 173,041	$ 107,810

(1) Includes the authorized generic version of Auryxia sold and distributed by the Company's authorized generic distribution partner, Mylan Therapeutics, Inc., or AG Partner, during the three and nine months ended September 30, 2025.

The following table presents changes in the Company's contract assets and liabilities related to the Company's sales to its AG Partner (in thousands):

	Nine Months Ended September 30, 2025			
	Balance at Beginning of Period	**Additions**	**Deductions**	**Balance at End of Period**
Contract assets:				
Accounts receivable	$ —	$ 9,255	$ (9,255)	$ —
Contract liabilities:				
Deferred revenue	$ —	$ 8,118	$ (5,250)	$ 2,868

The Company recognized the following revenues related to the Company's sales to its AG Partner as a result of changes in the contract asset and contract liability balances in the respective periods (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Revenue Recognized in the Period:	**2025**	**2024**	**2025**	**2024**
Deferred revenue — beginning of the period	$ 2,664	$ —	$ —	$ —

Product revenue allowance and reserve categories were as follows:

(in thousands)	Chargebacks and Discounts	Rebates, Fees and Other Deductions	Product Returns	Total
Balance at December 31, 2024	$ 1,436	$ 15,726	$ 6,442	$ 23,604
Current provisions related to sales in current year	2,200	62,571	552	65,323
Adjustments related to prior year sales	69	336	(164)	241
Credits/payments made	(3,151)	(19,395)	(359)	(22,905)
Balance at September 30, 2025	$ 554	$ 59,238	$ 6,471	$ 66,263

(in thousands)	Chargebacks and Discounts	Rebates, Fees and Other Deductions	Product Returns	Total
Balance at December 31, 2023	$ 1,607	$ 22,991	$ 6,916	$ 31,514
Current provisions related to sales in current year	5,990	28,950	3,104	38,044
Adjustments related to prior year sales	377	153	(1,336)	(806)
Credits/payments made	(6,631)	(36,778)	(4,177)	(47,586)
Balance at September 30, 2024	$ 1,343	$ 15,316	$ 4,507	$ 21,166

Chargebacks, discounts and estimated product returns are recorded as a reduction of revenue in the period the related product revenue is recognized in the unaudited condensed consolidated statements of operations and comprehensive income (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 on the condensed 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 unaudited condensed consolidated balance sheets.

Accounts receivable, net related to product sales, was approximately $63.2 million and $32.4 million as of September 30, 2025 and December 31, 2024, respectively.

12. LICENSE, COLLABORATION AND OTHER REVENUE

The Company recognized the following revenue from its license, collaboration and other revenue agreements (in thousands):

		Three Months Ended September 30,		Nine Months Ended September 30,	
Entity	**Description**	**2025**	**2024**	**2025**	**2024**
Medice	License and royalties related to the sale of Vafseo in the EU	$ 28	$ 29	$ 52	$ 29
MTPC	License and Product Supply of Vafseo in Japan	455	525	1,325	2,106
JT and Torii	License and royalties related to the sale of Riona in Japan	1,494	1,282	4,156	3,738
Total license and other revenue		$ 1,977	$ 1,836	$ 5,533	$ 5,873

The following tables present changes in the Company’s contract assets and liabilities related to license and other revenue (in thousands):

	Nine Months Ended September 30, 2025			
	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract asset:				
Accounts receivable[1]	$ 2,010	$ 6,577	$ (5,527)	$ 3,060
Contract liability:				
Deferred revenue	$ —	$ 1,013	$ —	$ 1,013

	Nine Months Ended September 30, 2024			
	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract assets:				
Accounts receivable[1]	$ 3,333	$ 5,873	$ (7,381)	$ 1,825
Contract liabilities:				
Deferred revenue[2]	$ 43,296	$ —	$ (43,296)	$ —

(1) Excludes accounts receivable related to amounts due to the Company from product sales of Auryxia and Vafseo which are included in the accompanying unaudited condensed consolidated balance sheets as of September 30, 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.

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):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Revenue Recognized in the Period:	2025	2024	2025	2024
Deferred revenue — beginning of the period	$ —	$ —	$ —	$ —

During each of the three and nine months ended September 30, 2025 and 2024, 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 on the audited consolidated balance sheets. The $1.4 million was received during the nine months ended September 30, 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 unaudited condensed consolidated statements 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 each of the three and nine months ended September 30, 2025 and 2024, the Company recognized immaterial revenue from Medice royalties. As of September 30, 2025, there were $0.1 million in contract assets, and no accounts receivable, payables or deferred revenue in connection with the Medice License 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 will supply 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 did not recognize any revenue under the Medice Supply Agreement during the three and nine months ended September 30, 2025 or 2024.

MTPC Collaboration Agreement

On December 11, 2015, the Company and MTPC entered into a Collaboration Agreement, or the MTPC Agreement, providing MTPC with exclusive development and commercialization rights to Vafseo in the MTPC Territory, which was amended effective as of December 2, 2022. In addition, the Company supplies Vafseo to MTPC for both clinical and commercial use in the MTPC 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 MTPC 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 additional information and Note 12, *License, Collaboration and Other Revenue*, of the Notes to the Consolidated Financial Statements in the 2024 Form 10-K for a more detailed description of the MTPC Agreement.

The Company evaluated the elements of the MTPC Agreement in accordance with the provisions of ASC 606 and concluded that the contract counterparty, MTPC, is a customer. The Company identified two performance obligations in connection with its material promises under the MTPC 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 MTPC for the Phase 3 studies, (iv) $10.0 million in development milestones received, (v) $25.0 million in regulatory milestones received and (vi) $8.2 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 September 30, 2025, all development milestones and $25.0 million in regulatory

milestones have been achieved. No other regulatory milestones have been assessed as probable of being achieved and as a result have been fully constrained.

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 MTPC Agreement is being recognized using a proportional performance method, for which all deliverables have been completed. The Company recognizes any revenue from MTPC royalties in the period in which the sales occur. The Company recognized revenue from MTPC royalties of $0.5 million during each of the three months ended September 30, 2025 and 2024, and $1.3 million and $1.4 million during the nine months ended September 30, 2025 and 2024, 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 MTPC 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 additional information. The revenue is classified as license and other revenue in the accompanying unaudited condensed consolidated statements of operations and comprehensive income (loss). As of September 30, 2025, there were no accounts receivable, payables or deferred revenue and $0.5 million in contract assets recorded in connection with the MTPC Agreement.

Supply of Drug Product to MTPC

On July 15, 2020, the Company and MTPC entered into a supply agreement, or the MTPC Supply Agreement, under which the Company supplies Vafseo drug product to MTPC for commercial use in Japan and certain other Asian countries, as contemplated by the MTPC Agreement. See Note 12, *License, Collaboration and Other Revenue*, of the Notes to the Consolidated Financial Statements in the 2024 Form 10-K for a more detailed description of this supply agreement.

On December 16, 2022, the Company, MTPC 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 MTPC. 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 MTPC and delivery has occurred and MTPC has accepted the product. The Company recognized no revenue under the MTPC Supply Agreement during the three and nine months ended September 30, 2025 and no revenue and $0.7 million in revenue under the MTPC Supply Agreement during the three and nine months ended September 30, 2024, respectively. As of September 30, 2025, there was $1.0 million in accounts receivable and $1.0 million in deferred revenue recorded in connection with the MTPC 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. See Note 12, *License, Collaboration and Other Revenue*, of the Notes to the Consolidated Financial Statements in the 2024 Form 10-K for a more detailed description of this sublicense agreement.

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 allocated the entire transaction price to the License and Supply Performance Obligation.

The Company recognized license revenue of $1.5 million and $4.2 million during the three and nine months ended September 30, 2025, respectively, and $1.3 million and $3.7 million during the three and nine months ended September 30, 2024, respectively, related to royalties earned on net sales of ferric citrate hydrate in Japan under the trade name Riona. 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.

13. CAPITAL STOCK

Authorized and Outstanding Capital Stock

As of September 30, 2025, the authorized capital stock of the Company included 350,000,000 shares of common stock, $0.00001 par value per share, of which 265,226,038 and 224,848,992 shares were issued and outstanding as of September 30, 2025 and December 31, 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 as of September 30, 2025 and December 31, 2024.

At-the-Market Facility

On April 7, 2022, the Company entered into an at-the-market, or 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 with gross proceeds of $6.8 million ($6.7 million, net of offering expenses). During the nine months ended September 30, 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 nine months ended September 30, 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 of the Shares were $46.5 million, after deducting underwriting discounts and commissions and estimated offering expenses and net proceeds from the Offering of the Additional Shares were $1.6 million, after deducting underwriting discounts and commissions and estimated 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 and, 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 to the Warrant Holder under the Initial Warrant.

14. STOCK-BASED COMPENSATION AND BENEFIT PLAN

Stock-Based Compensation and Benefit Plans

The Company incurred stock-based compensation expenses of $3.2 million and $8.1 million during the three and nine months ended September 30, 2025, respectively, and $1.6 million and $6.1 million for the three and nine months ended September 30, 2024, respectively.

Equity Incentive Plans

The following table contains information about the Company's equity plans:

			September 30, 2025		December 31, 2024	
Title of Plan	Group Eligible	Type of Award Granted (or to be Granted)	Awards Outstanding	Additional Awards Authorized for Grant	Awards Outstanding	Additional Awards Authorized for Grant
Keryx Equity Plans[1][2]	Employees, directors and consultants	Stock options and restricted stock units (RSUs)	153,346	—	163,765	—
Akebia Therapeutics, Inc. 2014 Incentive Plan, as amended [2] [3] (the 2014 Plan)	Employees, directors, consultants and advisors	Stock options, RSUs, stock appreciation rights (SARs) and performance awards	8,612,119	—	11,559,708	—
Akebia Therapeutics, Inc. 2023 Stock Incentive Plan, as amended[3] [4] (the 2023 Plan) *(replaced 2014 Plan)*	Employees, officers, directors, consultants and advisors	Stock options, SARs, restricted stock, unrestricted stock, RSUs, performance awards, other share-based awards and dividend equivalents	16,351,570	24,329,514	10,390,642	11,340,648

(1) The Keryx Equity Plans consist of the Keryx Biopharmaceuticals, Inc. 1999 Share Option Plan, 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 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: 1,074,082 options included as outstanding under the 2014 Plan in the table and 3,064,976 options included as outstanding under the 2023 Plan in the table as of September 30, 2025 and 1,151,127 options included as outstanding under the 2014 Plan and 2,534,775 options included as outstanding under the 2023 Plan in the table 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 nine months ended September 30, 2025, the Company issued 3,634,400 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 nine months ended September 30, 2025, the Company granted 1,182,176 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 1,133,176 options remained outstanding as of September 30, 2025.

The Company grants annual service-based stock options to employees and directors and SARs to certain executives under the 2023 Plan and previously granted options to employees and directors under the 2014 Plan. In addition, the Company issues stock options to directors, new hires and occasionally to other employees not in connection with the annual grant process.

Finally, the Company 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 nine months ended September 30, 2025, is as follows:

	Stock Options	Weighted Average Exercise Price	Weighted-Average Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	16,684,325	$ 3.19	7.17 years	$ 6,797
Granted	5,191,776	$ 2.52	—	—
Exercised	(1,138,621)	$ 1.42	—	—
Expired	(1,142,350)	$ 8.72	—	—
Canceled and forfeited	(1,126,622)	$ 1.74	—	—
Outstanding at September 30, 2025	18,468,508	$ 2.86	7.29 years	$ 15,160
Exercisable at September 30, 2025	9,360,308	$ 3.68	5.84 years	$ 7,746

As of September 30, 2025, there was approximately $13.5 million of unrecognized compensation costs related to stock options, which is expected to be recognized over a weighted average period of 2.82 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, or (iii) 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 Fair Value	Number of Shares	Weighted Average Fair Value
Unvested as of December 31, 2024	1,321,423	$ 0.95	4,108,367	$ 1.59
Granted	—	$ —	4,460,300	$ 2.31
Vested	(790,281)	$ 1.10	(1,564,770)	$ 1.55
Forfeited and canceled	(120,409)	$ 1.05	(766,103)	$ 1.80
Unvested as of September 30, 2025	410,733	$ 0.63	6,237,794	$ 2.09

As of September 30, 2025, there was $9.7 million of unrecognized compensation costs related to time-based RSUs and PSUs, which is expected to be recognized over a weighted-average period of 1.90 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 offering period. As of September 30, 2025 and December 31, 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 under the ESPP during the nine months ended September 30, 2025.

Stock-Based Compensation Expense

The Black-Scholes option pricing model is used to estimate the fair value of the 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Stock Options	**2025**	**2024**	**2025**	**2024**
Risk-free interest rate	3.79 % - 4.03%	3.60 % - 3.95%	3.79% - 4.38%	3.60% - 4.66%
Expected volatility	111.72 % - 120.16%	111.37 % - 117.40%	111.61% - 123.58%	109.98% - 118.61%
Expected term (years)	6.25 years - 6.25 years	6.25 years - 6.25 years	5.51 years - 6.25 years	5.51 years - 6.25 years
Expected dividend yield	—%	—%	—%	—%
Weighted average grant date fair value	$2.80	$1.17	$2.18	$1.35

The Company has classified stock-based compensation in its unaudited condensed consolidated statements of operations and comprehensive income (loss) as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Cost of goods sold	$ 169	$ 115	$ 491	$ 284
Research and development	677	338	1,675	1,153
Selling, general and administrative	2,375	1,193	5,918	4,603
Restructuring	—	—	—	38
Total stock-based compensation	$ 3,221	$ 1,646	$ 8,084	$ 6,078

15. NET INCOME (LOSS) PER SHARE

The following summarizes the calculation of net income (loss) per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(Dollars in thousands, except per share amounts)	**2025**	**2024**	**2025**	**2024**
Numerator				
Net income (loss)	$ 540	$ (20,039)	$ 6,899	$ (46,606)
Denominator				
Denominator for basic net income (loss) per share - weighted average outstanding shares of common stock	264,786,432	210,348,459	254,390,502	208,343,679
Dilutive effect of common stock options and SARs	4,416,904	—	3,351,562	—
Dilutive effect of RSUs	3,243,785	—	2,995,205	—
Dilutive effect of warrants	1,924,435	—	1,942,508	—
Dilutive effect of ESPP	1,166	—	1,166	—
Denominator for diluted net income (loss) per share - weighted average outstanding shares of common stock and assumed conversions	274,372,722	210,348,459	262,680,943	208,343,679
Basic net income (loss) per share	$ 0.00	$ (0.10)	$ 0.03	$ (0.22)
Diluted net income (loss) per share	$ 0.00	$ (0.10)	$ 0.03	$ (0.22)

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. Therefore, for the three and nine months ended September 30, 2024 in which the Company reported 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:

	Three and Nine Months Ended September 30, 2024
Warrants	3,076,923
Outstanding common stock options	16,120,512
Unvested RSUs	5,616,584
Stock appreciation rights	635,313
Total	25,449,332

16. 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 the 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 chief operating decision maker, or 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 from operations. Net income 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 three and nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenues	$ 58,766	$ 37,428	$ 178,574	$ 113,683
Less:				
Direct cost of product and other revenue	6,683	3,039	18,569	7,270
Panion royalty	2,700	2,111	8,358	6,442
Excess firm purchase commitment charge	—	—	—	2,068
Amortization of intangible asset	—	9,011	—	27,032
Research and development	14,944	8,487	35,711	25,866
Selling, general and administrative	29,094	26,516	81,391	78,870
License	896	769	2,493	2,242
Restructuring	—	—	—	58
Income (loss) from operations	4,449	(12,505)	32,052	(36,165)
Other income (expense)				
Interest expense	(4,748)	(6,661)	(19,352)	(11,308)
Other (expense) income	(10)	(17)	175	39
Change in fair value of warrant liability	1,464	(856)	(5,361)	1,345
Loss on extinguishment of debt	—	—	—	(517)
Income (loss) before income taxes	1,155	(20,039)	7,514	(46,606)
Income tax expense	(615)	—	(615)	—
Net income (loss)	$ 540	$ (20,039)	$ 6,899	$ (46,606)

17. SUBSEQUENT EVENTS

The Company has evaluated events and transactions occurring after the balance sheet date through the filing date of this Form 10-Q with the Securities and Exchange Commission, to ensure that the unaudited condensed consolidated financial statements include appropriate disclosure of events both recognized in the accompanying unaudited condensed consolidated financial statements as of September 30, 2025, and events which occurred subsequently but were not recognized in the consolidated financial statements.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2024 filed with the United States, or U.S., Securities and Exchange Commission, or the SEC, on March 13, 2025, or the 2024 Form 10-K. In addition to historical information, the following discussion and analysis contains forward-looking statements that reflect our plans, estimates, beliefs and explanations that involve significant risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Part II, Item 1A. of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

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 serves as a foundation for future growth. Our team has significant expertise in hypoxia-inducible factor, or HIF, science having developed and commercialized Vafseo® (vadadustat), an oral HIF factor prolyl hydroxylase, or HIF-PH, inhibitor and have selected two additional HIF-based molecules for preclinical development.

We have established the company as a leader in the kidney community, and we believe our cross-organizational expertise in renal disease positions the company 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 U.S. healthcare system, potentially affecting approximately 37 million patients and costing Medicare nearly $125 billion annually for treating Medicare beneficiaries with CKD or end-stage renal disease, or ESRD, according to the Centers for Disease Control and Prevention. Our two commercial products address certain complications of kidney disease.

Our current portfolio includes:

Vafseo 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. Shipment of Vafseo commenced in January 2025. We have commercial supply agreements for the purchase of Vafseo in place with dialysis organizations caring for nearly 100% of dialysis patients in the U.S. 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 and Vafseo is the only oral HIF-based treatment available in the U.S.

We recently completed a Type C meeting with the FDA and, while we have not yet received final minutes from the meeting, based on the FDA feedback, we have not come to alignment regarding 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. As a result, we do not plan to initiate VALOR and therefore do not expect to pursue a broad label for Vafseo for CKD non-dialysis dependent patients.

In the European Union, or EU, the United Kingdom, or UK, Switzerland and Australia, Vafseo is approved for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis. Our partner MEDICE Arzneimittel Pütter GmbH & Co. KG, or Medice, has an exclusive license to develop and commercialize Vafseo for the treatment of anemia in patients with CKD in defined territories and launched Vafseo in Germany, Austria, Switzerland, the Netherlands and certain other countries in Europe.

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 Mitsubishi Tanabe Pharma Corporation, or MTPC. In Taiwan, Vafseo is approved for the treatment of symptomatic anemia due to CKD in adult patients on chronic maintenance dialysis and launched in October 2024 by Tai Tien Pharmaceutical Company, an affiliate of MTPC. In Korea, Vafseo is approved as an anemia treatment for patients with CKD on hemodialysis.

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 lost exclusivity, or LoE. We believe the dynamics of Auryxia reimbursement being included in the ESRD bundle could result in a slower revenue decline after the LoE date

than in other LoE situations, but 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.

Ferric citrate hydrate has also been approved in Japan, and is marketed and sold by our Japanese sublicensee, Japan Tobacco, Inc., and its subsidiary, Torii Pharmaceutical Co., Ltd., collectively, JT and Torii, 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 in Japan. Averoa SAS, or Averoa, has an exclusive license to develop and commercialize ferric citrate in the European Economic Area, or EEA, Turkey, Switzerland, the UK, the Balkans and certain countries in Eastern Europe and the Middle East. Averoa applied for marketing authorization for ferric citrate in Europe in April 2024. 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, to approve Averoa's marketing authorization. The EC granted marketing authorization 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.

Our HIF-based product candidates and other pipeline assets are being evaluated to target areas of unmet needs. The discovery of HIF laid the foundation to explore 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. We have selected two additional HIF molecules for preclinical development: AKB-9090, potentially for cardiac surgery-related acute kidney injury, or CS-AKI, or acute respiratory distress syndrome, or ARDS, and AKB-10108 for retinopathy of prematurity, or ROP, in neonates.

In June 2021, we acquired from Cyclerion Therapeutics, Inc., or Cyclerion, an exclusive global license under certain intellectual property rights to research, develop and commercialize praliciguat, an investigational oral soluble guanylate cyclase, or sGC, stimulator. We believe there is potential to explore the use of praliciguat for indications within kidney disease.

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 Partner. 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 Partner 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, MTPC, JT and Torii and any other collaborations into which we have entered or may enter.

Cost of Goods Sold

Cost of goods sold, or COGS - 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 MTPC and Medice for commercial sales 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 Partner. 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, COGS 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;
- 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 the FDA approval in March 2024.

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 September 30, 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 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 II, Item 1A of this Form 10-Q. 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 Expenses

License expenses relate 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 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 unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information on the BioVectra Termination Agreement. Other income (expense) 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 unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q 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 unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information on the warrant liability.

Recent Events

Public Offering of Common Stock

On March 19, 2025, we 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 our common stock. The offering price was $2.00 per share, and the Underwriters agreed to purchase the Shares from us pursuant to the Underwriting Agreement at a price of $1.88 per share. Under the terms of the Underwriting Agreement, we 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 of the Shares were $46.5 million, after deducting underwriting discounts and commissions and estimated offering expenses and net proceeds from the Offering of the Additional Shares were $1.6 million, after deducting underwriting discounts and commissions and estimated offering expenses.

Borrowing Under BlackRock Term Loans

On February 3, 2025, we and Kreos, which are funds and accounts managed by BlackRock Inc., collectively, BlackRock, entered into the Second Amendment to the Agreement for the Provision of a Loan Facility, or the Second Amendment, which amended certain provisions of the Agreement for the Provision of a Loan Facility, dated January 29, 2024, or the BlackRock Credit Agreement. The BlackRock Credit Agreement provides for a senior secured term loan facility in the aggregate principal amount of up to $55.0 million, subject to certain customary conditions, or the Term Loan Facility.

The Term Loan Facility provided us access to three tranches: (i) an initial tranche of $37.0 million, which was funded on January 29, 2024, (ii) an additional tranche of $8.0 million, which was funded on April 19, 2024, and (iii) a final tranche of $10.0 million, which was available in a single draw through an expiry date of December 31, 2024, or the Prior Tranche C Loan. As a result of the Second Amendment, the Prior Tranche C Loan expiry date was extended until February 3, 2025, or the Extended Tranche C Loan. The terms of the Extended Tranche C Loan are substantially similar to the terms of the Prior Tranche C Loan, however, interest accrued on the Extended Tranche C Loan as if it was advanced on December 31, 2024.

On February 3, 2025, we received $9.3 million on the Extended Tranche C Loan, after deducting debt issuance costs, interest, fees and expenses.

On February 3, 2025, in connection with the drawdown of the Extended Tranche C Loan, in accordance with the warrant agreement, dated as of January 29, 2024, between the Company and Kreos Capital VII Aggregator SCSp, or the Warrant Holder, we issued a warrant to the Warrant Holder to purchase 1,153,846 shares of our common stock, at an exercise price per share of $1.30. The warrant shall be 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 to the Warrant Holder.

See Note 7, *Indebtedness,* in the accompanying notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information.

At-the-Market (ATM) Offering

On September 3, 2024, in connection with the filing of a new shelf registration statement on Form S-3, we filed a prospectus related to our amended and restated sales agreement with Jefferies LLC (which amended and restated the prior sales agreement), pursuant to which we are able to offer and sell up to $75.0 million of our common stock at current market prices from time to time. 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 under this program with gross proceeds of $24.3 million ($23.8 million, net of offering expenses). During the nine months ended September 30, 2025, we sold 9,437,364 shares of our common stock under this program with gross proceeds of $18.7 million ($18.4 million, net of offering expenses).

Results of Operations

Comparison of the Three Months Ended September 30, 2025 and 2024

	Three Months Ended September 30,		Change	
(dollars in thousands)	**2025**	**2024**	**$**	**%**
Revenues				
Product revenue, net	$ 56,789	$ 35,592	$ 21,197	60 %
License, collaboration and other revenue	1,977	1,836	141	8 %
Total revenues	58,766	37,428	21,338	57 %
Cost of goods sold				
Cost of product and other revenue	9,383	5,150	4,233	82 %
Amortization of intangible asset	—	9,011	(9,011)	(100)%
Total cost of goods sold	9,383	14,161	(4,778)	(34)%
Operating expenses				
Research and development	14,944	8,487	6,457	76 %
Selling, general and administrative	29,094	26,516	2,578	10 %
License	896	769	127	17 %
Total operating expenses	44,934	35,772	9,162	26 %
Income (loss) from operations	4,449	(12,505)	16,954	(136)%
Other expense, net	(4,758)	(6,678)	1,920	(29)%
Change in fair value of warrant liability	1,464	(856)	2,320	(271)%
Income (loss) before income taxes	1,155	(20,039)	21,194	(106)%
Income tax expense	(615)	—	(615)	*
Net income (loss)	$ 540	$ (20,039)	$ 20,579	(103)%

*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 Partner.

Net product revenue was $56.8 million for the three months ended September 30, 2025, compared to $35.6 million for the three months ended September 30, 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. We believe the dynamics of Auryxia reimbursement being included in the ESRD bundle could result in a slower revenue decline after the LoE date than in other LoE scenarios. Additionally, since March 2025, our AG Partner has been selling an authorized generic version of Auryxia in the U.S., which may slightly offset a revenue decline following the LoE. However, our ability to continue to generate revenue from sales of Auryxia following LoE 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 by product for the three months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,	
Product	**2025**	**2024**
Vafseo[(1)]	$ 14,322	$ —
Auryxia[(2)]	42,467	35,592
Total product revenues	$ 56,789	$ 35,592

(1) Vafseo entered the U.S. market in January 2025.

(2) Includes the authorized generic version of Auryxia sold and distributed by our AG Partner during the three months ended September 30, 2025.

License, Collaboration and Other Revenue—License, collaboration and other revenue was $2.0 million for the three months ended September 30, 2025, compared to $1.8 million for the three months ended September 30, 2024.

Cost of Goods Sold—Cost of Product and Other Revenue—Cost of product and other revenue was $9.4 million for the three months ended September 30, 2025 compared to $5.2 million for the three months ended September 30, 2024. The increase was primarily due to higher Auryxia volume during the three months ended September 30, 2025. In addition, cost of product and other revenue for the three months ended September 30, 2024 was offset by a $3.7 million benefit that we recorded due to our ability to sell inventory previously written-down as excess inventory during the three months ended September 30, 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 $0.5 million for the three months ended September 30, 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 three months ended September 30, 2025 was valued at cost, our cost of product and other revenue would have been $1.6 million. As of September 30, 2025, we had $25.4 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 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 $9.0 million in amortization expense for the three months ended September 30, 2025 and 2024, respectively, related to the developed product rights for Auryxia.

R&D Expenses—R&D expenses were $14.9 million for the three months ended September 30, 2025, compared to $8.5 million for the three months ended September 30, 2024. The increase was primarily driven by increased clinical trial activities related to Vafseo and higher headcount related costs.

The following table summarizes our external research and development expenses by program, as well as costs not allocated to programs, for the three months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,	
	2025	**2024**
Vafseo clinical trial and other external costs	$ 7,154	$ 3,046
External costs for other programs, including feasibility and new processes and methods associated with commercial product	1,386	1,462
Total external R&D expenses	8,540	4,508
Internal personnel, consulting, facilities and other	6,404	3,979
Total R&D expenses	$ 14,944	$ 8,487

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—Selling, general and administrative expenses were $29.1 million for the three months ended September 30, 2025, compared to $26.5 million for the three months ended September 30, 2024. The increase was largely due to higher marketing costs in connection with the Vafseo U.S. launch and increased headcount related costs during the three months ended September 30, 2025.

License Expenses—License expenses related to royalties due to Panion relating to sales of Riona in Japan were $0.9 million and $0.8 million for the three months ended September 30, 2025 and 2024, respectively.

Other Expense, Net—Other expense, net, was $4.8 million for the three months ended September 30, 2025, compared to $6.7 million for the three months ended September 30, 2024. The decrease was primarily due to increased interest income related to our money market funds which offset interest expense during the three months ended September 30, 2025.

Change in Fair Value of Warrant Liability—Change in fair value of warrant liability was $1.5 million and $0.9 million for the three months ended September 30, 2025 and 2024, respectively.

Income Tax Expense—Income tax expense was $0.6 million for the three months ended September 30, 2025. There was no income tax expense for the three months ended September 30, 2024.

Comparison of the Nine Months Ended September 30, 2025 and 2024

	Nine Months Ended September 30,		Change	
(dollars in thousands)	**2025**	**2024**	**$**	**%**
Revenues				
Product revenue, net	$ 173,041	$ 107,810	$ 65,231	61 %
License, collaboration and other revenue	5,533	5,873	(340)	(6)%
Total revenues	178,574	113,683	64,891	57 %
Cost of goods sold				
Cost of product and other revenue	26,927	15,780	11,147	71 %
Amortization of intangible asset	—	27,032	(27,032)	(100)%
Total cost of goods sold	26,927	42,812	(15,885)	(37)%
Operating expenses				
Research and development	35,711	25,866	9,845	38 %
Selling, general and administrative	81,391	78,870	2,521	3 %
License	2,493	2,242	251	11 %
Restructuring	—	58	(58)	(100)%
Total operating expenses	119,595	107,036	12,559	12 %
Operating income (loss)	32,052	(36,165)	68,217	(189)%
Other expense, net	(19,177)	(11,269)	(7,908)	70 %
Change in fair value of warrant liability	(5,361)	1,345	(6,706)	(499)%
Loss on extinguishment of debt	—	(517)	517	(100)%
Income (loss) before income taxes	7,514	(46,606)	54,120	(116)%
Income tax expense	(615)	—	(615)	*
Net income (loss)	$ 6,899	$ (46,606)	$ 53,505	(115)%

*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 Partner.

Net product revenue was $173.0 million for the nine months ended September 30, 2025, compared to $107.8 million for the nine months ended September 30, 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. We believe the dynamics of Auryxia reimbursement being included in the ESRD bundle could result in a slower revenue decline after the LoE date than in other LoE scenarios. Additionally, since March 2025, our AG Partner has been selling an authorized generic version of Auryxia in the U.S., which may slightly offset a revenue decline following the LoE. However, our ability to continue to generate revenue from sales of Auryxia following LoE 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 by product for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,	
Product	**2025**	**2024**
Vafseo[(1)]	$ 39,635	$ —
Auryxia[(2)]	133,406	107,810
Total product revenues	$ 173,041	$ 107,810

(1) Vafseo entered the U.S. market in January 2025.

(2) Includes the authorized generic version of Auryxia sold and distributed by our AG Partner during the nine months ended September 30, 2025.

License, Collaboration and Other Revenue—License, collaboration and other revenue was $5.5 million for the nine months ended September 30, 2025, compared to $5.9 million for the nine months ended September 30, 2024. The decrease was primarily due to revenue recognized in connection with our supply agreement with MTPC during the nine months ended September 30, 2024.

Cost of Goods Sold—Cost of Product and Other Revenue—Cost of product and other revenue was $26.9 million for the nine months ended September 30, 2025 compared to $15.8 million for the nine months ended September 30, 2024. The increase was primarily due to higher Auryxia volume during the nine months ended September 30, 2025. In addition, cost of product and other revenue for the nine months ended September 30, 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 nine months ended September 30, 2024. We also recorded a charge of $2.1 million related to our firm purchase commitment liability during the nine months ended September 30, 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 $2.4 million for the nine months ended September 30, 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 nine months ended September 30, 2025 was valued at cost, our cost of product and other revenue would have been $4.6 million. As of September 30, 2025, we had $25.4 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 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 $27.0 million in amortization expense for the nine months ended September 30, 2025 and 2024, respectively, related to the developed product rights for Auryxia.

R&D Expenses—R&D expenses were $35.7 million for the nine months ended September 30, 2025, compared to $25.9 million for the nine months ended September 30, 2024. The increase was primarily due to clinical trial activities related to Vafseo and higher headcount related costs.

The following table summarizes our external research and development expenses by program, as well as costs not allocated to programs, for the nine months ended September 30, 2025 and 2024 (in thousands):

	Nine Months Ended September 30,	
	2025	**2024**
Vafseo clinical trial and other external costs	$ 14,914	$ 6,337
External costs for other programs, including feasibility and new processes and methods associated with commercial product	3,985	4,252
Total external R&D expenses	18,899	10,589
Internal personnel, consulting, facilities and other	16,812	15,277
Total R&D expenses	$ 35,711	$ 25,866

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—Selling, general and administrative expenses were $81.4 million for the nine months ended September 30, 2025, compared to $78.9 million for the nine months ended September 30, 2024. The increase was largely due to higher marketing costs in connection with the Vafseo U.S. launch and increased headcount related costs during the nine months ended September 30, 2025.

License Expenses—License expenses related to royalties due to Panion relating to sales of Riona in Japan were $2.5 million and $2.2 million for the nine months ended September 30, 2025 and 2024, respectively.

Restructuring Expenses—There were no restructuring expenses and $0.1 million of restructuring expenses for the nine months ended September 30, 2025 and 2024, respectively.

Other Expense, Net—Other expense, net, was $19.2 million for the nine months ended September 30, 2025, compared to $11.3 million for the nine months ended September 30, 2024. The increase was primarily due to 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 unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information on our arrangements with CSL Vifor.

Change in Fair Value of Warrant Liability—Change in fair value of warrant liability was $5.4 million and $1.3 million for the nine months ended September 30, 2025 and 2024, respectively.

Loss on Extinguishment of Debt—During the nine months ended September 30, 2024, we recorded a $0.5 million loss on the extinguishment of debt in connection with the repayment of the Pharmakon Term Loans. We did not record any loss on the extinguishment of debt during the nine months ended September 30, 2025.

Income Tax Expense—Income tax expense was $0.6 million for the nine months ended September 30, 2025. There was no income tax expense for the nine months ended September 30, 2024.

Liquidity and Capital Resources

As of September 30, 2025, we had cash and cash equivalents of $166.4 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 September 30, 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 offerings pursuant to our sales agreement with Jefferies LLC 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.

We generated net income of $0.5 million and $6.9 million during the three and nine months ended September 30, 2025, respectively, and incurred net loss of $20.0 million and $46.6 million during the three and nine months ended September 30, 2024, respectively. As of September 30, 2025 and December 31, 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. While we believe the dynamics of Auryxia reimbursement being included in the ESRD bundle could result in a slower revenue decline after the LoE date than in other LoE scenarios, 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. Additionally, since March 2025, our AG Partner has been selling an authorized generic version of Auryxia in the U.S., which may slightly offset the revenue decline following the LoE.

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 the foreseeable future, 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 II, 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 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 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; (ii) Tranche B — $8.0 million was funded on April 19, 2024, and (iii) Tranche C — $10.0 million was funded on February 3, 2025, collectively, the Term Loans. The Term Loan Facility matures on January 29, 2028, or the BlackRock Maturity Date.

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 will accrue 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 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. If prepayment is made during the first year, we are required to pay the amount of otherwise due interest payments for the twelve-month period following pre-payment.

On the Closing Date, the Warrant Holder received a warrant to purchase 3,076,923 shares of our common stock, 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 to the Warrant Holder.

See Note 7, *Indebtedness,* in the accompanying notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q 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 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 a 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, our affiliates or third-party licensees 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 September 30, 2025 was 24.6% which is reflected as interest expense in the unaudited condensed consolidated statements of operations and comprehensive income (loss). The Company recognized interest expense related to the settlement royalties liability of $3.9 million and $14.7 million for the three and nine months ended September 30, 2025, respectively. As of September 30, 2025, $14.3 million and $53.0 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 unaudited condensed consolidated financial statements in Part I, Item 1 of this Form 10-Q for further information.

Working Capital Fund Liability

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 September 30, 2025, $13.0 million and $27.7 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 unaudited condensed consolidated financial statements in Part I, Item 1 of this Form 10-Q 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 MTPC 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 MTPC, or the MTPC 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 September 30, 2025 was 0%. We retain the right to receive all potential future regulatory milestones for Vafseo under the MTPC Agreement. We recorded non-cash royalty revenue of $0.5 million during each of the three months ended September 30, 2025 and 2024, and $1.3 million and $1.4 million during the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, $2.1 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 unaudited condensed consolidated financial statements in Part I, Item 1 of this Form 10-Q for further information.

Off-Balance Sheet Arrangements

Letter of Credit

As of September 30, 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 condensed consolidated balance sheet as of September 30, 2025, while others are considered future obligations. Our material cash requirements as of September 30, 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, and we are currently marketing the furnished office space for sublease.

See Note 9, *Leases*, in the accompanying notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information.

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 unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information.

Cyclerion Agreement

In June 2021, we entered into a license agreement, or the Cyclerion Agreement, with Cyclerion, 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 aggregate of $198.5 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 unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information.

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 unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information.

Amounts Due Under Former Manufacturing and Unconditional Purchase Commitments

On December 22, 2022, we and BioVectra terminated any and all existing agreements for BioVectra to supply us 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 unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information.

Other Third Party Contracts

Unconditional Purchase Commitments

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 $86.8 million as of September 30, 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:

	Nine Months Ended September 30,	
NET CASH PROVIDED BY/(USED IN) (*in thousands*):	**2025**	**2024**
Operating activities	$ 36,863	$ (36,193)
Investing activities	(49)	(31)
Financing activities	77,775	27,338
Increase (decrease) in cash, cash equivalents and restricted cash	$ 114,589	$ (8,886)
Cash, cash equivalents and restricted cash — beginning of period	53,550	44,579
Cash, cash equivalents and restricted cash — end of period	$ 168,139	$ 35,693

Operating Activities

Net cash provided by operating activities was $36.9 million for the nine months ended September 30, 2025. Net cash provided by operating activities for the nine months ended September 30, 2025 consisted of net income of $6.9 million as well as net non-cash adjustments of $35.4 million, including a change in fair value of the warrant liability of $5.4 million, offset by a reduction of $5.4 million in working capital.

Net cash used in operating activities was $36.2 million for the nine months ended September 30, 2024. Net cash used in operating activities consisted of a net loss of $46.6 million and net non-cash adjustments of $46.9 million, including amortization of our intangible asset of $27.0 million, and a reduction of $36.4 million in working capital.

Investing Activities

Immaterial net cash was used in investing activities for each of the nine months ended September 30, 2025 and 2024.

Financing Activities

Net cash provided by financing activities was $77.8 million for the nine months ended September 30, 2025, 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 was $27.3 million for the nine months ended September 30, 2024, which primarily consisted of proceeds of $45.0 million from the issuance of debt under the BlackRock Credit Agreement and net proceeds of $20.4 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, see Note 2, *Summary of Significant Accounting Policies*, of the Notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Critical Accounting Estimates and Significant Judgments

Our management's discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the related disclosure of contingent assets and liabilities in our unaudited condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses, other long-term liabilities, a liability related to settlement royalties, revenues, including various rebates, returns and reserves related to product sales, inventories, classification of expenses between cost of goods sold, R&D and selling, general and administrative, long-term assets, including our right-of-use assets and goodwill. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies.

During the nine months ended September 30, 2025, there were no material changes to our methodologies used for our critical accounting estimates as reported in our 2024 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide information under this item.

Item 4. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, or the Exchange Act, is (i) recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on an evaluation under the supervision and with the participation of our management, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, were not effective as of September 30, 2025 due to the material weakness in internal control over financial reporting described below.

As previously disclosed in our Annual Report on Form 10-K, that was filed with the SEC on March 13, 2025, or 2024 Form 10-K, as of December 31, 2024, our management identified a material weakness in our internal control over financial reporting. Specifically, we did not effectively document controls that operated with a sufficient level of precision to evaluate the completeness, accuracy and reasonableness of the product sales forecast, which is used in the evaluation of excess inventory, including the calculation of excess firm purchase commitments and the classification of current and non-current inventory, or the Remaining Control Deficiencies.

Remediation Efforts of the Material Weakness — Inventories

Our management has taken and plans to continue to take actions to remediate the Remaining Control Deficiencies in our internal control over financial reporting.

We have begun the following remediation plan: 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.

As management continues to evaluate and work to improve our internal control over financial reporting, management may determine it is necessary to take additional measures to address the material weakness. Until the controls have been operating for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively, the material weakness described above will continue to exist.

Changes in Internal Control over Financial Reporting

Except for the ongoing efforts to remediate the material weakness as noted in the preceding paragraphs, there have been no changes in our internal control over financial reporting (as defined by Rule 13a-15(f) or 15d-15(f) under the Exchange Act) during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. 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 November 6, 2024, Sandoz AG filed an opposition against our issued European Patent No. 3007695 covering vadadustat once daily dosing regimen in the European Patent Office. On March 18, 2025, we timely submitted a Patent Proprietor's Reply to the Notice of Opposition. Oral proceedings are scheduled for February 24-25, 2026.

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 the foreseeable future, including to commercialize Vafseo and Auryxia and advance our existing programs. However, we have incurred net losses each year since our inception, and although we generated net income of $0.5 million and $6.9 million for the three and nine months ended September 30, 2025, respectively, we cannot guarantee when, if ever, we will become and remain profitable. As of September 30, 2025, we had an accumulated deficit of $1.7 billion.

In March 2022, we received a complete response letter, or CRL, from the United States, or U.S., Food and Drug Administration, or FDA, regarding our new drug application, or NDA, for vadadustat for the treatment of anemia associated with chronic kidney disease, or CKD. Following a Formal Dispute Resolution Request, or FDRR, to the FDA in 2022 for vadadustat, 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 commercialization of Vafseo was delayed 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 the 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.

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 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' (deficit) equity 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 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 above under Part II, Item 1. 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 September 30, 2025, our cash and cash equivalents were $166.4 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 Auryxia and 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 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 the 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 the foreseeable future, 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 nine months ended September 30, 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.

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 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;
- 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. For example, as a result of receipt of the CRL and implementation of the reductions in workforce, we delayed certain research activities. 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. 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. 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, 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 soluble guanylate cyclase stimulator. 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 have progressed preclinical studies for praliciguat, we needed to do additional work to manufacture product for clinical trials than originally anticipated before we could initiate the trials, and when the clinical trials are started, we may be unsuccessful in developing praliciguat. If any of the assumptions that we made in valuing the transaction, including the costs or timing of development of praliciguat as a result of the additional manufacturing work or otherwise, or the potential benefits of praliciguat, were incorrect, we may not recognize the anticipated benefits of the transaction 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; 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 unaudited condensed consolidated financial statements in Part I, Item 1. Financial Statements of this Form 10-Q 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 MTPC Agreement, with Mitsubishi Tanabe Pharma Corporation, or MTPC, 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 MTPC Agreement, our agreement with MTPC 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 Partner, pursuant to which,

since March 20, 2025, they have been selling an authorized generic version of Auryxia. Currently, no additional generics of Auryxia have entered the market, but the FDA could approve another generic at any time. 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. If Auryxia sales decline faster than we anticipate following LoE, our results of operations and financial condition will be materially harmed.

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. 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. In the quarter ended September 30, 2025, most Vafseo revenue was driven by mid-sized dialysis organizations. If we are unable to increase sales to the large and small 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 by the COVID-19 pandemic since 2021 primarily as the CKD patient populations that we serve experienced both high hospitalization and mortality rates due to COVID-19, and the pandemic had an adverse impact on the phosphate binder market in which Auryxia competes. Labor shortages and costs have also adversely impacted dialysis providers. These impacts have refocused clinical efforts in addressing bone and mineral disorders like hyperphosphatemia to more acute operational issues to ensure patients receive dialysis treatments and still some patients have been rescheduled or missed treatments due to labor shortages. We believe this and potentially other factors, led to the reduction in the phosphate binder market, which has not experienced growth since early 2020. While we are unable to quantify the impact of the COVID-19 pandemic on future Auryxia revenues and revenue growth, ongoing impacts from the COVID-19 pandemic continue to adversely and disproportionately impact CKD patients and the phosphate binder market. Therefore, we expect the impacts from the pandemic to continue to have a negative impact on our Auryxia revenue growth 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. 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 to a greater extent than we already have, 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 Medicare payment for these drugs are no longer available. In addition, dialysis organizations will receive a Transitional Drug Add-on Payment Adjustment, or TDAPA, payment for claims that include phosphate binders for the next two years. 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 at least 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, in the post-TDAPA period, CMS currently expects to increase the single bundled payment base rate paid to the dialysis facility for each dialysis treatment to reflect that bundled drugs will be reimbursed as part of the single bundled payment for Medicare patients. However, 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 at a profit.

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 will be required 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 three and nine months ended September 30, 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 recently also began to ship Vafseo directly to certain dialysis clinics, which requires additional oversight and logistics, and if implementation of this new distribution model is not successful, 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 MTPC in Japan under the trade name Vafseo. Pricing and reimbursement strategy is a key component of MTPC’s commercialization plans for Vafseo in Japan.

If coverage and reimbursement terms change, MTPC 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, Panion & BF Biotech, Inc., or Panion, and, as applicable, Dr. Hsu, 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 Partner, pursuant to which, since March 20, 2025, they have been selling an authorized generic version of Auryxia. Currently, no additional generics of Auryxia have entered the market, but the FDA could approve another generic at any time. 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. If Auryxia sales decline faster than we anticipate following LoE, our results of operations and financial condition will be materially harmed.

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. In October 2023, the FDA approved XPHOZAH® (tenapanor), a phosphate absorption inhibitor that is marketed by Ardelyx and 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 sublicensee, Japan Tobacco International, 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 may 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, GSK's product candidate, and enarodustat, JT's product candidate, 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 the remaining patents 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.

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. 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 MTPC exclusive rights to commercialize Vafseo, which has been approved and is being marketed by MTPC 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. 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, 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 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 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 $INNO_2VATE$ program; however, while Vafseo achieved the primary and key secondary efficacy endpoints in each of the two PRO_2TECT studies, the PRO_2TECT 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 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. After a recent Type C meeting with the FDA, we determined that, while we have not yet received final minutes from the meeting, based on the FDA feedback, we have not come to 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. As a result, we do not plan to initiate the VALOR clinical trial, and therefore do not expect to pursue a broad label for Vafseo for adult patients with NDD-CKD. Based on the Type C meeting, we expect to continue to maintain a dialogue with the FDA around a potential smaller subgroup of CKD non-dialysis dependent patients where there may be potential to align on a clinical design and path forward. However, we will 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. 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. 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 adult 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 plan to request 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 continue conducting certain of our clinical trials globally. 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$_2$VATE 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$_2$TECT 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 MTPC. 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 additional indications, 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, after a recent Type C meeting with the FDA, while we have not yet received final minutes from the meeting, based on the FDA feedback, we have not come to 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. As a result, we do not plan to initiate the VALOR clinical trial, and therefore do not expect to pursue a broad label for Vafseo for adult patients with NDD-CKD. Based on the Type C meeting, we expect to continue to maintain a dialogue with the FDA around a potential smaller subgroup of CKD non-dialysis patients where there may be potential to align on a clinical design and 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 European Commission, or EC, to approve Averoa's marketing authorization, and the EC granted marketing authorization 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.

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 European Commission in November 2020. The European Commission'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. This proposal will now be the subject of additional negotiations and technical meetings, with the objective of reaching agreement on issues such as the regulatory data protection framework and the access and supply obligations. At this point, it appears that the period of market exclusivity for innovator products may be reduced from two years to one, exclusions from patent infringement for studies and trials will likely expand, and there will be a new obligation to ensure sufficient supply of medicines.

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 pediatric studies of Auryxia and Vafseo under the Pediatric Research Equity Act of 2003, or PREA. 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 plan to request 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. These and 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 truthful, non-misleading, factual, and unbiased and includes 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 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 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. There are also ongoing deliberations within the administration and Congress over potentially substantial proposed cuts to the overall budget for HHS and funding of the FDA for the 2026 federal fiscal year.

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 as of November 7, 2025 it has not reopened. 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 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 or have already passed comprehensive privacy laws during the 2024 legislative sessions that will go into effect in 2025 and beyond. 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-only ESRD-related drugs without injectable or intravenous equivalents, including Auryxia and other phosphate lowering medications, are included in the ESRD bundle and separate 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. There can be no assurances that any increase in the Medicare bundled payment will be sufficient to adequately reimburse dialysis facilities for the costs of Auryxia or Vafseo at an amount that allows us to continue to sell our products at a profit.

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.

More recently, 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.

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."

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, on October 10, 2025, another pharmaceutical company, AstraZeneca, announced that it too had reached an agreement with the administration to lower prices for "eligible patients with prescriptions for chronic diseases" in the U.S. and that it will participate in the TrumpRx direct-to-patient marketing website.

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 Partner, pursuant to which, since March 2025, our AG Partner has been selling an authorized generic version of Auryxia. We will be relying on our AG Partner for the commercialization of this authorized generic. If competition, including from generics other than our AG Partner, 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 Partner, and if there are problems in 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 MTPC 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. 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 other product candidates. For example, following the termination of our collaboration agreements with Otsuka in 2022, we incurred additional expenses in connection with the development 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 MTPC 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 MTPC 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 MTPC 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 MTPC 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 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 a single source supplier for Auryxia drug substance and drug product, including for our authorized generic, and commercial supply from other suppliers is not readily available. We have also engaged Cardinal Health, Inc., as the exclusive third-party logistics distribution agent 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, development, commercialization, or obtaining and maintaining marketing approvals, 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
- any of our third-party distributors fail to perform or encounter any damage or other disruption at their facilities.

If we, or any of our third-party manufacturers or distributors 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 development of Vafseo or 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, 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. In addition, 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.

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.

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.

There are a limited number of manufacturers that are capable of manufacturing Auryxia and Vafseo for us and complying 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 into the manufacturing processes of our third-party manufacturers, we do not ultimately control such manufacturing processes of, and have little 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 have little control over the ability of our third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. 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.

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 in Japan, or to commercialize Vafseo in Europe and other countries, or to develop, obtain marketing approval for or market Vafseo our other product candidates, if approved.

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.

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 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 a third party, Panion, 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 unaudited condensed consolidated financial statements in Part I, Item 1. Financial Statements of this Form 10-Q 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.

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 has 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 framework 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 45% 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.

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 will likely 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. For example, in February 2024, U.S. lawmakers called for investigations into and the imposition of possible economic sanctions against Chinese biotechnology companies WuXi AppTec and WuXi Biologics, or collectively WuXi, over alleged ties to the Chinese military. In addition, the U.S. Department of Commerce's Bureau of Industry and Security, or BIS, recently published an interim final rule, 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. 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, in 2024, the U.S. Congress considered legislation widely referred to as the BIOSECURE Act . If this legislation had been enacted into law, it would have prohibited, subject to limited exceptions, the direct or indirect use of U.S. federal government contract, grant, and loan funds for purchasing biotechnology equipment and services from certain Chinese biotechnology companies, possibly including WuXi entities. On October 9, 2025, the U.S. Senate passed a revised version of the BIOSECURE legislation as part of its National Defense Authorization Act for FY 2026. Instead of specifying particular Chinese entities for restrictions, the Senate bill would initially target biotechnology companies that have been identified on the so-called 1260H List by the U.S. Department of Defense as Chinese Military Companies Operating in the United States. 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 would allow for other biotechnology companies, possibly including WuXi entities, to be added to the federal funding prohibitions at a later time. The U.S. House of Representatives has passed a version of the bill that does not contain similar biotechnology provisions, so it is not currently known whether the House or Senate language or other language or neither will become law.

If these bills become law, or similar laws are passed, they would 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.

In addition, 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. This proposal will now be the subject of additional negotiations and technical meetings, with the objective of reaching agreement on issues such as the regulatory data protection framework and the access and supply obligations. At this point, it appears that the period of market exclusivity for innovator products may be reduced from two years to one, exclusions from patent infringement for studies and trials will likely expand, and there will be a new obligation to ensure sufficient supply of medicines.

We cannot assure you that Auryxia, Vafseo or any of our potential future products will obtain such pediatric exclusivity, NCE 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.

While we expect that the availability of the authorized generic version of Auryxia and any additional generic versions of Auryxia will negatively impact our net product revenue for Auryxia and our results of operations, it is difficult to estimate the impact of generics on Auryxia net product revenue, and if the impact is greater than we currently anticipate, it may materially adversely impact our business and results of operations. Generic competition for Auryxia 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, MTPC, 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, MTPC, 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 and the European 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. Specifically, following receipt of the CRL, we implemented a reduction of our workforce in April and May 2022 by approximately 42% across all areas of our Company (47% inclusive of the closing of the majority of open positions), including several members of management. In November 2022, we

also implemented a reduction of our workforce, by approximately 14% consisting of individuals within our commercial organization as a result of our decision to shift to a strategic account management focused model for our commercial efforts. 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, MTPC, 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 MTPC 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, if and as we increase our development activities, we expect to expand 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. If we are unable to successfully grow and integrate these 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 have 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. If we are not able to remediate this material weakness, or if we experience additional material weaknesses or other deficiencies in our internal control over financial reporting 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.

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.

As previously disclosed in our 2024 Form 10-K, we identified a material weakness in our internal control over financial reporting as of December 31, 2024. A material weakness is a deficiency, or combination of deficiencies, in 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. Our management concluded that we did not design and maintain effective controls over inventory. Specifically, we did not maintain effective review controls that operated with a sufficient level of precision to evaluate the completeness, accuracy and reasonableness of the product sales forecast, which is used in the evaluation of excess inventory, including the calculation of excess firm purchase commitments and the classification of current and non-current inventory. For further discussion of the material weakness, see Part I, Item 4, "Controls and Procedures."

We have taken and plan to continue to take actions to remediate this material weakness: 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. However, we cannot provide assurance that we will be able to correct this material weakness in a timely manner or that our remediation efforts will be adequate to allow us to conclude that our internal control over financial reporting will be effective in the future. Even if this material weakness is remediated in the future, we could identify additional material weaknesses or deficiencies in our internal control over financial reporting that could require correction or remediation. For example, we previously identified a material weakness in our internal control over financial reporting as of December 31, 2022 relating to our product return reserves that resulted in a revision of our financial statements for the years ended December 31, 2022, 2021 and 2020.

In addition, our conclusion that we have a material weakness could give rise to increased scrutiny, review, audit and investigation over our accounting controls and procedures, which could then lead to additional areas of deficiency or errors in our financial statements.

We will need to continue to dedicate internal resources, engage outside consultants and maintain a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to remediate the material weakness relating to our accounting for inventory and inventory related transactions described above and any future control deficiencies or material weaknesses, and improve control processes as appropriate, validate through testing that controls are functioning as documented and maintain a continuous reporting and improvement process for internal control over financial reporting. If we are not able to correct material weaknesses or deficiencies in internal controls in a timely manner or otherwise comply with the requirements of Section 404 in a timely manner, our ability to record, process, summarize and report financial information accurately and within applicable time periods may be adversely affected, and we could be subject to sanctions or investigations by the Securities Exchange Commission, or 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, 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, 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. 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. 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, 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. 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. Security breaches, whether through physical or electronic break-ins, computer viruses, ransomware, impersonation of authorized users, attacks by hackers or other means, can create system disruptions or shutdowns that impact our business operations or 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 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 the use of artificial intelligence

to generate sophisticated spoofed emails and deep fake voice and video, 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;
- 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 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 have 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 September 30, 2025, we had approximately $59.0 million of goodwill from the Merger, $1.5 million of property and equipment and $4.8 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 unaudited condensed consolidated financial statements in Part I, Item 1. Financial Statements and Supplementary Data of this Form 10-Q. 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-Q 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 September 30, 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 5.7% of our outstanding shares of common stock and the Vanguard Group, or Vanguard, beneficially owned approximately 4.8% of our outstanding shares of common stock. By selling a large number of shares of common stock, BlackRock or Vanguard could cause the price of our common stock to decline. In addition, as of September 30, 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, an affiliate of Kreos, or the Warrant Holder, 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 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 September 30, 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Sales of Unregistered Securities

During the quarter ended September 30, 2025, we did not have any sales of unregistered securities, other than pursuant to transactions previously disclosed in our Current Reports on Form 8-K.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. 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.

The following table describes, for the third quarter of 2025, each trading arrangement for the sale or purchase of Company securities adopted or terminated by our directors and officers that is either (1) a contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) (a "Rule 10b5-1 trading arrangement") or (2) a "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K):

Name (Title)	Action Taken (Date of Action)	Type of Trading Arrangement	Nature of Trading Arrangement	Duration of Trading Arrangement	Aggregate Number of Securities
John P. Butler (President and Chief Executive Officer)	August 19, 2025	Rule 10b5-1 Non-Discretionary Option Exercise and Stock Sale Plan	Sale	Until November 16, 2026	Up to an aggregate of 702,562 shares
John P. Butler (President and Chief Executive Officer)	September 8, 2025	Durable Rule 10b5-1 trading arrangement for sell-to-cover transactions relating to all equity awards that have or may be granted	Sale	Until final settlement of any restricted stock units, or RSUs	Indeterminable (1)
Erik J. Ostrowski (Senior Vice President, Chief Financial Officer, Chief Business Officer and Treasurer)	September 8, 2025	Durable Rule 10b5-1 trading arrangement for sell-to-cover transactions relating to all equity awards that have or may be granted	Sale	Until final settlement of any RSUs	Indeterminable (1)
Nicholas P. Grund (Senior Vice President, Chief Commercial Officer)	September 9, 2025	Durable Rule 10b5-1 trading arrangement for sell-to-cover transactions relating to all equity awards that have or may be granted	Sale	Until final settlement of any RSUs	Indeterminable (1)
Richard C. Malabre (Senior Vice President, Chief Accounting Officer)	September 8, 2025	Durable Rule 10b5-1 trading arrangement for sell-to-cover transactions relating to all equity awards that have or may be granted	Sale	Until final settlement of any RSUs	Indeterminable (1)

(1) The number of shares subject to RSUs that will be sold to satisfy applicable tax withholding obligations upon vesting is unknown as the number will vary based on the extent to which vesting conditions are satisfied, the market price of the Company's common stock at the time of settlement and the potential future grant of additional RSUs subject to this arrangement. This trading arrangement, which applies to RSUs whether vesting is based on the passage of time and/or the achievement of performance goals, provides for the automatic sale of shares that would otherwise be issuable on each settlement date of a RSU in an amount sufficient to satisfy the applicable tax withholding obligation, with the proceeds of the sale delivered to the Company in satisfaction of the applicable tax withholding obligation.

Item 6. Exhibits.

Exhibits

3.1	Ninth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (001-36352), filed on March 28, 2014).
3.2	Certificate of Amendment of Ninth Amended and Restated Certificate of Incorporation of Akebia Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (001-36352), filed on June 9, 2020).
3.3	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (001-36352), filed on April 28, 2023).
10.1!*	Amendment #3 to the Supply Agreement by and between the Company and STA Pharmaceutical Hong Kong Limited dated August 15, 2025.
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.
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 portions of the exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K

SIGNATURES

Pursuant to the requirements 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: November 10, 2025

By: /s/ John P. Butler
John P. Butler
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 10, 2025

By: /s/ Erik J. Ostrowski
Erik J. Ostrowski
Senior Vice President, Chief Financial Officer, Chief Business Officer and Treasurer
(Principal Financial Officer)

Date: November 10, 2025

By: /s/ Richard C. Malabre
Richard C. Malabre
Senior Vice President, Chief Accounting Officer (Principal Accounting Officer)

Exhibit 10.1

AMENDMENT #3 TO SUPPLY AGREEMENT

This Amendment #3 (the "Amendment") to the Supply Agreement by and between **Akebia Therapeutics, Inc.** ("Akebia") and **STA Pharmaceutical Hong Kong Limited** ("STA") is effective as of August 15, 2025 (the "Amendment Effective Date"). Akebia and STA are each referenced individually herein as a "Party" and together as the "Parties".

WHEREAS, STA and Akebia entered into a Supply Agreement dated April 2, 2020, as amended on April 15, 2021, and April 15, 2024 (collectively, the "Supply Agreement"), under which STA manufactures vadadustat drug substance for purchase by Akebia; and

WHEREAS, the Parties desire to amend the Supply Agreement as set forth in this Amendment;

NOW, THEREFORE the Parties agree as follows:

1. The second paragraph of Section 5.7 is hereby deleted and replaced with the following:

   Safety Stock shall be maintained by STA in quantities, at any given time, as mutually agreed by the Parties in writing during the Term of this Agreement. Akebia shall promptly submit to STA a Purchase Order for the quantity of Safety Stock of the Product mutually agreed by the Parties. Upon expiration or termination of the Agreement, and contingent upon [**] held by STA.

2. Section 6.2 is hereby deleted in its entirety and replaced with the following:

   6.2. **Akebia Quality Release**. No delivery of Product by STA will occur without prior Akebia Release. Akebia's certificate of lot disposition must be received by STA prior to delivery of Product. For such purpose, Akebia's quality department will review the documentation provided by STA for any Batch of Product and will provide STA with the certificate of lot disposition or, otherwise, with its justified objections to issuing the certificate of lot disposition in accordance with the Quality Agreement, in each case, within [**] of receipt of the documentation.

3. Section 6.4 is hereby deleted in its entirety and replaced with the following:

   6.4 **Storage**. Prior to delivery, all Product at the Facility will be stored in a clean, secured, segregated area. If after Akebia's release of the Product pursuant to Section 6.2 and the agreed delivery date, Akebia requests that STA store the Product at STA's facilities and STA accepts, or [**] pursuant to Section 15.1 or places a purchase order to use such Product in the manufacture of a drug product incorporating such Product within [**] of Akebia's release of the Product, (i) such Product in storage at STA's facilities shall be deemed to have been accepted by Akebia and delivered to Akebia and title to, control of and risk of loss thereto shall transfer to Akebia, and (ii) the Parties shall promptly enter into a mutually agreeable storage agreement with regards to storage of such Product. Except for Safety Stock, for any Product that has been stored for more than [**] after Akebia Release STA will charge Akebia storage fees at a [**], unless different rates are otherwise agreed in writing by the Parties. The storage fees are subject to periodic review and adjustment by STA; provided that storage fees shall not be adjusted more than [**] in any [**] period. Akebia agrees that it is responsible to insure its

Products in storage at STA's facilities against damage or loss and shall purchase appropriate insurance to cover such Products.

4. Section 15.1 is hereby deleted in its entirety and replaced with the following:

15.1 All materials, as the case may be, to be provided by STA to Akebia will be delivered [**], including Product, returned Akebia Materials, Raw Materials, returned Batch Records and returned Confidential Information. For the avoidance of doubt, [**]. Title to, control of and risk of loss of such material (if not already vested in Akebia) shall transfer from STA to Akebia upon delivery. Notwithstanding the foregoing, the material (other than the Product) shall be deemed to have been delivered to Akebia if [**] within [**] after STA notifies Akebia that such material is ready for delivery.

5. Exhibit A of the Supply Agreement is hereby deleted in its entirety and replaced with the following:

Exhibit A—Product Price, Lead Time and Minimum Order Quantity

[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**
[**]	**[**]**

[**].

6. All capitalized terms not defined herein shall have meaning set forth in the Supply Agreement.

7. Except as otherwise provided herein, all provisions of the Supply Agreement, not expressed amended by this Amendment shall remain in full force and effect.

8. This Amendment may be executed by electronic means (including .PDF) and in any number of counterparts, each of which when executed and delivered, shall constitute an original, but all of which together shall constitute one agreement binding on all parties, notwithstanding that all parties are not signatories to the same counterpart.

IN WITNESS WHEREOF, the Parties have executed this Amendment to the Supply Agreement effective as of the Amendment Effective Date written above.

AKEBIA THERAPEUTICS, INC.

By: /s/ Kimberly Garko

Print Name: Kimberly Garko

Title: Senior Vice President, Chief Technical Officer

Date: August 20, 2025

STA PHARMACEUTICAL HONG KONG LIMITED

By: /s/ Xiaoyong Fu

Print Name: Xiaoyong Fu

Title: Executive Vice President, Head of STA

Date: 2025-08-20

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 Quarterly Report on Form 10-Q 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: November 10, 2025

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 Quarterly Report on Form 10-Q 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: November 10, 2025

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 Quarterly Report of Akebia Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2025 (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, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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: November 10, 2025

By: /s/ John P. Butler
John P. Butler
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 10, 2025

By: /s/ Erik J. Ostrowski
Erik J. Ostrowski
Senior Vice President, Chief Financial Officer, Chief Business Officer and Treasurer
(Principal Financial Officer)