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, 2024

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 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, 2024 was 218,181,202.

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 ability to execute a successful commercial launch of Vafseo® (vadadustat), and our plans with respect to commercializing Vafseo and label expansion opportunities currently under evaluation for Vafseo;
- our ability to contract with dialysis organizations in a timely manner, or at all, 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 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 recent 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 intangible asset, 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;
- 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 vadadustat and selling, general and administrative expenses; and
- the timing, outcome and impact of 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 profitable or attain positive cash flows.
- 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.
- 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 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 Agreement for the Provision of a Loan Facility, as amended, or the BlackRock Credit Agreement, with Kreos Capital VII (UK) Limited, or Kreos, which are funds and accounts managed by BlackRock Inc., collectively BlackRock, 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 commercially launch Vafseo, our results of operations and financial condition will be materially harmed.
- If we are unable to maintain or expand, or, with respect to Vafseo, initiate, sales and marketing capabilities or enter into additional 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.
- Conducting clinical trials outside of the U.S., as we have done historically and as we may decide to do in the future, presents additional risks and complexities and, if we decide to conduct a clinical trial outside of the U.S. in the future, we may not complete such trials successfully, in a timely manner, or at all, which could affect our ability to obtain regulatory approvals.
- 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 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.
- 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 if it is determined that any of our activities violates the federal Anti-Kickback Statute.
- Disruptions at the U.S. Food and Drug Administration, regulatory authorities outside the U.S. and other government agencies caused by global health concerns or funding shortages could prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.
- 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.
- 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, Riona and Vafseo and 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 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 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 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.
- We currently rely on third parties in China for the manufacture of raw materials, drug substance and drug product for the commercial supply of Vafseo and for early-stage research services. Our commercialization of Vafseo, or our development of our product candidates could be delayed, prevented or impaired if there are disruptions or delays in obtaining these 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 may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.
- If we fail to attract, retain and motivate senior management and qualified personnel, we may be unable to successfully develop and commercialize Auryxia or Vafseo.
- We may encounter difficulties in managing our growth, including with respect to our employee base, and managing our partnerships and operations successfully.
- We have identified a material weakness in our internal control over financial reporting as of December 31, 2023 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.

Akebia Therapeutics, Inc.
Form 10-Q
For the Quarter Ended September 30, 2024

TABLE OF CONTENTS

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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 34,019	$ 42,925
Inventories	20,493	15,691
Accounts receivable, net	32,170	39,290
Prepaid expenses and other current assets	13,438	20,243
Total current assets	100,120	118,149
Property and equipment, net	2,533	3,629
Operating right-of-use assets	9,300	12,416
Intangible asset, net	9,011	36,042
Goodwill	59,044	59,044
Other long-term assets	27,134	12,423
Total assets	**$ 207,142**	**$ 241,703**
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 13,494	$ 14,635
Accrued expenses and other current liabilities	52,215	67,735
Current portion of long-term debt	—	17,500
Total current liabilities	65,709	99,870
Long-term deferred revenue	—	43,296
Long-term operating lease liabilities	4,937	8,947
Long-term debt, net	38,355	17,183
Liability related to settlement royalties	47,731	—
Liability related to sale of future royalties, net of current portion	52,381	54,013
Working Capital Fund liability	40,203	40,093
Warrant liability	3,501	—
Other long-term liabilities	4,727	8,885
Total liabilities	**257,544**	**272,287**
Commitments and contingencies (Note 10)		
Stockholders' deficit:		
Preferred stock $0.00001 par value, 25,000,000 shares authorized; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock $0.00001 par value; 350,000,000 shares authorized at September 30, 2024 and December 31, 2023; 211,542,122 and 194,582,539 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	2	2
Additional paid-in capital	1,605,146	1,578,358
Accumulated other comprehensive income	6	6
Accumulated deficit	(1,655,556)	(1,608,950)
Total stockholders' deficit	**(50,402)**	**(30,584)**
Total liabilities and stockholders' deficit	**$ 207,142**	**$ 241,703**

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 LOSS

(dollars in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenues				
Product revenue, net	$ 35,592	$ 40,118	$ 107,810	$ 117,068
License, collaboration and other revenue	1,836	1,928	5,873	21,359
Total revenues	37,428	42,046	113,683	138,427
Cost of goods sold				
Cost of product and other revenue	5,150	8,998	15,780	28,452
Amortization of intangible asset	9,011	9,011	27,032	27,032
Total cost of goods sold	14,161	18,009	42,812	55,484
Operating expenses:				
Research and development	8,487	13,330	25,866	53,214
Selling, general and administrative	26,516	22,710	78,870	74,797
License	769	864	2,242	2,381
Restructuring	—	169	58	181
Total operating expenses	35,772	37,073	107,036	130,573
Loss from operations	**(12,505)**	**(13,036)**	**(36,165)**	**(47,630)**
Other income (expense)				
Interest expense	(6,661)	(1,410)	(11,308)	(4,614)
Other (expense) income	(17)	(43)	39	229
Change in fair value of warrant liability	(856)	—	1,345	—
Loss on extinguishment of debt	—	—	(517)	—
Loss on termination of lease	—	—	—	(524)
Net loss before income taxes	**$ (20,039)**	**$ (14,489)**	**$ (46,606)**	**$ (52,539)**
Net loss	**$ (20,039)**	**$ (14,489)**	**$ (46,606)**	**$ (52,539)**
Comprehensive loss	**$ (20,039)**	**$ (14,489)**	**$ (46,606)**	**$ (52,539)**
Net loss per share:				
Basic and diluted	$(0.10)	$(0.08)	$(0.22)	$(0.28)
Weighted average common shares outstanding:				
Basic and diluted	210,348,459	188,306,350	208,343,679	186,643,878

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' Equity (Deficit)
Balance at December 31, 2022	**184,135,714**	**$ 2**	**$ 1,562,247**	**$ 6**	**$ (1,557,025)**	**$ 5,230**
Proceeds from sale of stock under employee stock purchase plan	103,500	—	34	—	—	34
Stock-based compensation expense	—	—	2,489	—	—	2,489
Restricted stock unit vesting	1,596,732	—	—	—	—	—
Net loss	—	—	—	—	(26,876)	(26,876)
Balance at March 31, 2023	**185,835,946**	**$ 2**	**$ 1,564,770**	**$ 6**	**$ (1,583,901)**	**$ (19,123)**
Stock-based compensation expense	—	—	3,490	—	—	3,490
Restricted stock unit vesting	2,292,923	—	—	—	—	—
Net income	—	—	—	—	(11,172)	(11,172)
Balance at June 30, 2023	**188,128,869**	**$ 2**	**$ 1,568,260**	**$ 6**	**$ (1,595,073)**	**$ (26,805)**
Proceeds from sale of stock under employee stock purchase plan	96,694	—	50	—	—	50
Stock-based compensation expense	—	—	1,824	—	—	1,824
Restricted stock unit vesting	88,244	—	—	—	—	—
Net loss	—	—	—	—	(14,489)	(14,489)
Balance at September 30, 2023	**188,313,807**	**$ 2**	**$ 1,570,134**	**$ 6**	**$ (1,609,562)**	**$ (39,420)**

(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)**

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, 2024	2023
Operating Activities:		
Net loss	$ (46,606)	$ (52,539)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,127	1,191
Amortization of intangible asset	27,032	27,032
Change in fair value of warrant liability	(1,345)	—
Non-cash royalty revenue related to sale of future royalties	(1,390)	(1,423)
Non-cash research and development expense	—	782
Non-cash interest expense	7,475	1,318
Non-cash operating lease expense	3,116	(1,221)
Non-cash write-off from termination of lease	—	(825)
Non-cash loss on extinguishment of debt	294	—
Write-down of inventory	2,403	1,327
Change in excess inventory purchase commitments	2,068	—
Stock-based compensation expense	6,078	7,803
Changes in operating assets and liabilities:		
Accounts receivable	7,120	17,692
Inventory	(19,905)	9,238
Prepaid expenses and other current assets	6,805	10,043
Other long-term assets	625	(8,175)
Accounts payable	(3,758)	(9,747)
Accrued expense and other current liabilities	(17,652)	(13,735)
Operating lease liabilities	(3,212)	1,128
Deferred revenue	—	(3,738)
Other long-term liabilities	(6,468)	(7,227)
Net cash used in operating activities	**(36,193)**	**(21,076)**
Investing Activities:		
Purchases of equipment	(31)	—
Net cash used in investing activities	**(31)**	**—**
Financing Activities:		
Proceeds from the issuance of debt	45,000	—
Payments of issuance costs related to BlackRock Credit Agreement	(1,272)	—
Proceeds from issuance of common stock, net of issuance costs	20,402	—
Proceeds from issuance of stock under employee stock purchase plan	153	84
Proceeds from the exercise of stock options	155	—
Repayment of term debt	(37,100)	(24,000)
Net cash provided by (used in) financing activities	**27,338**	**(23,916)**
Decrease in cash, cash equivalents and restricted cash	(8,886)	(44,992)
Cash, cash equivalents and restricted cash — beginning of period	44,579	93,169
Cash, cash equivalents and restricted cash — end of period	**$ 35,693**	**$ 48,177**
Non-cash financing activities		
Issuance of warrants in connection with BlackRock Credit Agreement	$ 4,846	$ —

The accompanying notes are an integral part of these 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 committed to addressing patients' unmet needs. The Company's purpose is to better the life of each person impacted by kidney disease.

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. on March 27, 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. The Company is launching Vafseo in the U.S. 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 will lose 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 providing general and administrative support for these operations. The Company began recording revenue from the U.S. sales of Auryxia and revenue from sublicensing rights to Auryxia in Japan from the Company's Japanese partners, Japan Tobacco, Inc. and its subsidiary Torii Pharmaceutical Co., Ltd., collectively, JT and Torii, in 2018. In addition, the Company continues to explore additional development opportunities to expand its pipeline and portfolio of novel therapeutics.

As of September 30, 2024, the Company had cash and cash equivalents of approximately $34.0 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, 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, 2023, 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 14, 2024, or the 2023 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, 2024 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2024 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, intangible asset 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, 2024, cash and cash equivalents primarily included cash on hand.

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 “other long-term assets” in the consolidated balance sheets.

The following table reconciles cash, cash equivalents and restricted cash reported within the Company's consolidated balance sheets to the total amounts showing in the consolidated statements of cash flows:

(in thousands)	**September 30, 2024**	**December 31, 2023**
Cash and cash equivalents	$ 34,019	$ 42,925
Restricted cash included in other long-term assets	1,674	1,654
Total cash, cash equivalents and restricted cash	$ 35,693	$ 44,579

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 $0.5 million and $1.0 million as of September 30, 2024 and December 31, 2023, respectively.

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

	Nine Months Ended September 30,	
	2024	2023
Beginning balance	$ 1,029	$ 1,106
Provision for bad debts	194	(562)
Recoveries/(write-offs)	(695)	—
Ending balance	$ 528	$ 544

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 product 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 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 active pharmaceutical ingredients and formulated drugs or distribution of finished product to the market.

Recent Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, *Improvements to Reportable Segment Disclosures*. ASU 2023-07 requires disclosure of significant segment expenses that are regularly provided to the chief operating decision maker, or CODM, and included within the segment measure of profit or loss, an amount and description of its composition for other segment items to reconcile to segment profit or loss, and the title and position of the entity's CODM. ASU 2023-07 will be applied retrospectively and is effective for annual reporting periods in fiscal years beginning after December 15, 2023, and interim reporting periods in fiscal years beginning after December 31, 2024. The Company is currently reviewing the impact that the adoption of ASU 2023-07 may have on its consolidated financial statements and disclosure.

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.

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, 2024			
	Level 1	Level 2	Level 3	Total Fair Value
Long-term liability:				
Warrant liability	$ —	$ 3,501	$ —	$ 3,501

	December 31, 2023			
	Level 1	Level 2	Level 3	Total Fair Value
Cash equivalents:				
Money market funds	$ 1,504	$ —	$ —	$ 1,504

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.

Cash equivalents — Money market funds included within cash and cash equivalents are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets. As of September 30, 2024, the Company did not have any money market funds included in cash equivalents.

4. INVENTORIES

Inventories consists of the following (in thousands):

	September 30, 2024	December 31, 2023
Inventories, current:		
Work-in-process	$ 11,861	$ 4,297
Finished goods	8,632	11,394
Inventories, current	$ 20,493	$ 15,691
Long-term inventories included in other long-term assets:		
Raw materials	635	1,143
Work-in-process	23,476	8,260
Finished goods	607	—
Inventories, long-term	24,718	9,403
Total inventories	$ 45,211	$ 25,094

Inventory written down for Auryxia 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 loss totaled approximately $1.3 million and $2.4 million during the three and nine months ended September 30, 2024, respectively, and $0.7 million and $1.3 million during the three and nine months ended September 30, 2023, 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 commercially sell inventory previously written down to zero, its then net realizable value.

Prior to the FDA's approval of Vafseo on March 27, 2024, all costs for the manufacture of product to support clinical development and commercial launch, including pre-launch inventory, were expensed as incurred. Pre-launch inventory manufactured prior to the FDA approval of Vafseo will be used in commercial production until it is depleted. As of September 30, 2024 and December 31, 2023, the Company had cumulatively expensed $28.4 million in pre-launch inventory costs for Vafseo intended for the U.S. launch.

5. INTANGIBLE ASSET AND GOODWILL

Intangible Asset

Intangible asset, net of accumulated amortization, prior impairments and adjustments as of September 30, 2024 and December 31, 2023 consisted of the following (in thousands):

	September 30, 2024			December 31, 2023	
Intangible asset:	Gross Carrying Value	Accumulated Amortization	Net Book Value	Net Book Value	Estimated Useful Life
Developed product rights for Auryxia	$ 214,705	$ (205,694)	$ 9,011	$ 36,042	6 years

The Company recorded $9.0 million in amortization expense for each of the three months ended September 30, 2024 and 2023, and $27.0 million for each of the nine months ended September 30, 2024 and 2023 related to the developed product rights for Auryxia.

Goodwill

As of September 30, 2024 and December 31, 2023, 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, 2024	December 31, 2023
Prepaid manufacturing	$ 7,227	$ 14,489
Other	6,211	5,754
Total prepaid expenses and other current assets	$ 13,438	$ 20,243

Prepaid manufacturing expenses include advance payments to contract manufacturing organizations, or CMOs, for active pharmaceutical ingredient, or API, 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. Prior to receiving regulatory approval for Vafseo, such amounts were expensed to R&D upon the quality release of the batches and transfer of title to the Company from the CMO. See Note 4, *Inventories*, for further information on inventories, including pre-launch inventory.

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

Description	September 30, 2024	December 31, 2023
Long-term inventories	$ 24,718	$ 9,403
Restricted cash	1,674	1,654
Other	742	1,366
Total other long-term assets	$ 27,134	$ 12,423

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

Cloud Computing Implementation Costs

The Company incurs costs to implement cloud computing arrangements that are hosted by a third-party vendor. In accordance with ASC 350-40, *Goodwill and Other, Internal-Use Software*, for cloud computing arrangements that meet the definition of a service contract, the Company capitalizes qualifying implementation costs incurred during the application development stage as a component of other assets. Capitalization of these costs concludes once the project is substantially complete and the software is ready for the Company's intended use. Once available for its intended use, the capitalized costs are amortized on a straight-line basis over the term of the associated hosting arrangement including periods covered by an option to extend, and are included in selling, general and administrative expenses in the consolidated statements of operations and comprehensive loss. Costs related to data conversion, overhead, general and administrative activities, and training are expensed as incurred. Post-configuration training and maintenance costs will be expensed as incurred.

Prepaid expenses and other current assets and other long-term assets as of September 30, 2024 included approximately $0.2 million and $0.7 million of capitalized implementation costs, respectively. There were no implementation costs capitalized as of December 31, 2023. Amortization expense for the capitalized implementation costs was $0.1 million for the three and nine months ended September 30, 2024. There was no amortization expense for the three and nine months ended September 30, 2023.

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

Description	September 30, 2024	December 31, 2023
Product revenue allowances	$ 15,361	$ 22,940
Product return reserves, current portion	3,380	5,420
Clinical trial costs	573	328
Compensation and related benefits	7,565	8,216
Operating lease liabilities, current portion	5,289	4,491
Royalties due to Panion & BF Biotech, Inc.	2,897	3,989
Professional fees	1,130	1,909
Accrued manufacturing costs	645	5,555
Restructuring costs, current portion	762	737
BioVectra, Inc. termination fees, current portion	9,421	7,500
Liability related to sale of future royalties, current portion	2,235	2,048
Other	2,957	4,602
Total accrued expenses and other current liabilities	$ 52,215	$ 67,735

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 is 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, or the Tranche B Closing Date, and (iii) Tranche C — $10.0 million is available in a single draw through December 31, 2024, collectively the Term Loans. Tranche C is 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.

On the Closing Date, the Company drew $34.5 million on Tranche A, after deducting debt issuance costs, fees and expenses. On the Tranche B Closing Date, the Company drew $7.5 million, after deducting debt issuance costs, 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) 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, 2024, the Company's interest rate was 11.59%. The Company recognized interest expense related to the BlackRock Credit Agreement of $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 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, 2024, future principal payments under the BlackRock Credit Agreement are as follows (in thousands):

	Principal Payments
2024	$ —
2025	—
2026	—
2027	41,363
2028	1,589
Total before unamortized discount and issuance costs	42,952
Less: unamortized discount and issuance costs	(4,597)
Total term loans	$ 38,355

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 Vifor Termination and Settlement Agreement, or the Vifor Termination Agreement, the Company and Kreos entered into a First Amendment to the BlackRock Credit Agreement, or the BlackRock Credit Amendment, which amended certain provisions of the BlackRock Credit Agreement.

Warrant

On the Closing Date, Kreos Capital VII Aggregator SCSp, an affiliate of Kreos, or the Warrant Holder, received a warrant to purchase 3,076,923 shares of the Company's common stock, at an exercise price per share of $1.30, or the Initial Warrant, and upon borrowing of Tranche C, the Company would become obligated to issue to 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. Each warrant shall be exercisable for eight years from the date of issuance.

The Initial Warrant is liability classified under ASC 815, *Derivatives and Hedging*, as it could potentially require net cash settlement outside of the Company's control. The Initial Warrant is measured at fair value each period with changes in fair value presented within the unaudited condensed consolidated statements of operations and comprehensive loss. The fair value of the warrant liability was $3.5 million as of September 30, 2024. See Note 3, *Fair Value of Financial Instruments*, for information on the fair value determination.

Other Agreements Accounted for as Debt

The Company has a liability related to settlement royalties and a Working Capital Fund liability with Vifor (International) Ltd. (now a part of CSL Limited), or CSL Vifor, and a liability related to the sale of future royalties, which are 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, with BioPharma Credit PLC as collateral agent and a lender, or Collateral Agent, and BioPharma Credit Investments V (Master) LP as a lender, and a Guaranty and Security Agreement with the Collateral Agent. BioPharma Credit PLC subsequently transferred its interest in the loans, solely in its capacity as a lender, to its affiliate, BPCR Limited Partnership. The Collateral Agent and the lenders are collectively referred to as Pharmakon. The Pharmakon Loan Agreement, as amended, consisted of a secured term loan facility in an aggregate amount of up to $100.0 million, or Pharmakon Term Loans, which was made available under two tranches: (i) Pharmakon Tranche A - $80.0 million and (ii) Pharmakon Tranche B - $20.0 million. On November 25, 2019, the Company drew $77.3 million on Pharmakon Tranche A, net of fees and expenses of $2.7 million. On December 10, 2020, the Company drew $20.0 million on Pharmakon Tranche B, net of immaterial lender expenses and issuance costs.

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 Pharmakon Term Loans, as amended, bore interest through maturity at a variable rate based on the three month SOFR plus a SOFR adjustment of 0.30% plus 7.50%. The SOFR interest rate was capped at 3.35% through October 31, 2023, the date of the Fourth Amendment to the Pharmakon Loan Agreement, or Fourth Amendment. Interest expense related to the Pharmakon Loan Agreement was immaterial for the three and nine months ended September 30, 2024. The Company recognized $1.4 million and $4.7 million of interest expense related to the Pharmakon Loan Agreement during the three and nine months ended September 30, 2023, respectively.

See Note 7, *Indebtedness*, of the Notes to the Consolidated Financial Statements in the 2023 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 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, or FMCNA, 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, *Deferred Revenue, Refund Liability and Liability Related to Sale of Future Royalties*, of the Notes to the Consolidated Financial Statements in the 2023 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 representing 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 agreement 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 will commence 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 that would be infringed by the making, using, selling or importing of Vafseo in the U.S. or (ii) the expiration of marketing or regulatory exclusivity for Vafseo in the U.S., or the Settlement Royalty Term. Beginning on July 1, 2027 and throughout the Settlement Royalty Term, the Company has the option to make a one-time payment to CSL Vifor, or the Royalty Buy-Down Option, upon which the Settlement Royalty Payments will be adjusted as of the date of exercise of the Royalty Buy-Down Option such that the Company will then only pay CSL Vifor quarterly royalty payments based on a mid-single digit percentage of the Company's net sales of Vafseo up to $450.0 million in the U.S. during a calendar year in lieu of the above Settlement Royalty Payments. If the Company exercises the Royalty Buy-Down Option, the WCF Royalty Payments, as described below, will continue as described above.

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

As a result of the Vifor Termination Agreement, the Company reassessed whether the Vifor License Agreement still met the criteria to be considered a contract within the scope of ASC 606, *Revenue from Contracts with Customers,* and concluded that CSL Vifor no longer met the definition of a customer and, therefore, the arrangement should not be considered a revenue contract with a customer under ASC 606. The Company therefore determined that the consideration received from CSL Vifor of $43.3 million, comprised of the up-front payment of $25.0 million and the premiums paid by CSL Vifor for the 2017 Shares and 2022 Shares of $4.7 million and $13.6 million, respectively, should be classified as debt. Accordingly, the Company recorded the $43.3 million as a liability and is amortizing such amount using the effective interest method over the Settlement Royalty Term. The liability related to settlement royalties and the amortization are based on the Company's current estimates of future royalties expected to be paid over the life of the arrangement. To the extent the Company's estimates of future

royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, the Company will adjust the effective interest rate and recognize 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, 2024 was 41.0% which is reflected as interest expense in the unaudited condensed consolidated statements of operations and comprehensive loss. The Company recognized interest expense of $4.4 million for the three and nine months ended September 30, 2024. As of September 30, 2024, the $47.7 million liability related to settlement royalties is classified as a long-term liability based on the timing of payments.

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 will commence 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 $1.1 million and $2.7 million for the three and nine months ended September 30, 2024, respectively, and $0.7 million and $2.4 million for the three and nine months ended September 30, 2023, respectively. The amortization of the deferred gain was $0.9 million and $2.6 million for the three and nine months ended September 30, 2024, respectively, and $1.0 million and $3.0 million for the three and nine months ended September 30, 2023, respectively.

As of September 30, 2024, the $40.2 million Working Capital Fund liability is classified as a long-term liability based on management's estimated timing of the repayment of the Working Capital Fund liability to CSL Vifor exceeding one-year.

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. 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, 2024 was 0% and, therefore the Company did not recognize any non-cash interest expense in the unaudited condensed consolidated statements of operations and comprehensive 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 loss. See Note 8, *Deferred Revenue, Refund Liability and Liability Related to Sale of Future Royalties*, of the Notes to the Consolidated Financial Statements in the 2023 Form 10-K for a more detailed description of the Royalty Agreement.

The Company paid $0.5 million and $1.4 million of royalties to HCR during the three and nine months ended September 30, 2024, respectively, and $0.5 million and $1.5 million during the three and nine months ended September 30, 2023, respectively. As of September 30, 2024 and December 31, 2023 the balances were as follows (in thousands):

Liability related to sale of future royalties	September 30, 2024	December 31, 2023
Current portion (included in accrued expenses and other current liabilities)	$ 2,235	$ 2,048
Long-term portion	52,381	54,013
Total liability related to sale of future royalties	$ 54,616	$ 56,061

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, 2024, the remaining lease term for the Cambridge Lease was 1.95 years.

Operating lease costs were $1.2 million and $3.7 million for the three and nine months ended September 30, 2024, respectively, and $1.2 million and $4.4 million for the three and nine months ended September 30, 2023, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $1.4 million and $4.3 million for the three and nine months ended September 30, 2024, respectively, and $1.4 million and $4.5 million for the three and nine months ended September 30, 2023, respectively. The security deposit in connection with the Cambridge Lease is $1.7 million in the form of a letter of credit, which is included as restricted cash in other long-term assets in the accompanying unaudited condensed consolidated balance sheets as of September 30, 2024 and December 31, 2023.

Sublease and Former Boston Lease

Previously, the Company leased 27,924 square feet of office space in Boston, Massachusetts, or Boston Lease, under a non-cancelable operating lease that was set to expire in July 2031. The Company subleased the entire Boston Lease, effective October 2019 through February 2023. The Company did not record any rental income for the three and nine months ended September 30, 2024 and recorded no rental income and $0.3 million in rental income as other income in the unaudited condensed consolidated statements of operations and comprehensive loss during the three and nine months ended September 30, 2023, respectively.

In May 2023, pursuant to an Assignment and Assumption of Lease Agreement, or Lease Assignment Agreement, the Company assigned all of its rights, title and interest in, to, and under the Boston Lease to LG Chem Life Sciences Innovation Center, Inc., or LG Chem, and made a payment to LG Chem of $1.3 million. As of May 2023, LG Chem assumed all of the rights and obligations of the Company under the Boston Lease and the Company has no further obligations for rent or other payments under the Boston Lease. In accordance with ASC 842, *Leases*, the Company wrote off the right-of-use asset and lease liability associated with the Boston Lease, and recognized the difference between the right-of-use asset and the lease liability offset

by the $1.3 million payment as a loss on lease termination in the unaudited condensed consolidated statements of operations and comprehensive loss of $0.5 million during the nine months ended September 30, 2023.

Future Lease Commitments

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

	Operating Lease Commitments
Remainder of 2024	$ 1,440
2025	5,819
2026	3,613
Total lease commitments	$ 10,872
Less: present value adjustment	(646)
Current and long-term operating lease liabilities	$ 10,226

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, 2024, the Company is required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $22.3 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 excess firm commitment liability recorded in other long-term liabilities related to the Company's contractual purchase commitments with Siegfried was $3.6 million and $1.5 million as of September 30, 2024 and December 31, 2023, respectively.

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, 2025, 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, 2024, the Company had no minimum commitments with Patheon, however, as estimated global demand fluctuates, the Company may have 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, 2024, the Company has committed to purchase $6.9 million of Vafseo drug substance from WuXi STA through the first half of 2025.

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 will also reimburse 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, 2024, the Company has committed to purchase $1.2 million of Vafseo drug product from WuXi STA 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 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 have 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, 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 $0.4 million and $1.3 million for the three and nine months ended September 30, 2024, respectively, and $0.5 million and $1.4 million for the three and nine months ended September 30, 2023, respectively.

In-Licensing - Panion License Agreement

On April 17, 2019, the Company and Panion & BF Biotech, Inc., or Panion, entered into a second amended and restated license agreement, or Panion Amended License Agreement, which amended and restated in full the license agreement between the Company and Panion. The Panion Amended License Agreement provides the Company with an exclusive license under Panion-owned know-how and patents 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 2023 Form 10-K for a more detailed description of this license agreement.

The Company incurred royalty payments due to Panion of approximately $2.1 million and $6.4 million during the three and nine months ended September 30, 2024, respectively, and $3.1 million and $9.3 million during the three and nine months ended September 30, 2023, respectively, relating to the Company's sales of Auryxia in the U.S. and JT and Torii's net sales of Riona in Japan.

Other Third-Party Contracts

The Company contracts with various organizations to conduct R&D activities with remaining contract costs to the Company of approximately $47.0 million at September 30, 2024. The scope of the services under these R&D contracts can be modified and the contracts cancelled by the Company upon written notice. In some instances, the contracts may be cancelled by the third party upon written notice.

Litigation and Related Matters

The Company is involved from time to time in various legal proceedings arising in the normal course of business. The Company provides disclosure when a loss in excess of any reserve is reasonably possible, and if estimable, the Company discloses the potential loss or range of possible loss. Significant judgment is required to assess the likelihood of various

potential outcomes and the quantification of loss in those scenarios. Changes in the Company's estimates could have a material impact and are recorded as litigation progresses and new information comes to light. Although the outcomes of potential legal proceedings are inherently difficult to predict, the Company does not expect the resolution of current legal proceedings to have a material adverse effect on its financial position, results of operations or cash flows of the Company.

Guarantees and Indemnifications

As permitted under Delaware law, the Company may indemnify its officers, directors and employees for certain events or occurrences that happen by reason of their relationship with, or position held at, the Company. The Company may also be subject to indemnification obligations by law with respect to the actions of its employees under certain circumstances and in certain jurisdictions. The Company maintains director and officer liability insurance coverage that is intended to cover a portion of amounts that may be due with respect to indemnification after a deductible is met. Further, the Company is a party to a variety of agreements in the ordinary course of business under which it may be obligated to indemnify third parties with respect to certain matters. For the three and nine months ended September 30, 2024 and 2023, the Company did not experience any losses related to these indemnification obligations, and no claims were outstanding as of September 30, 2024. 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

To date, the Company's only source of product revenue has been from the U.S. sales of Auryxia. Total net product revenue was $35.6 million and $107.8 million for the three and nine months ended September 30, 2024, respectively, and $40.1 million and $117.1 million for the three and nine months ended September 30, 2023, respectively. 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, 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

(in thousands)	Chargebacks and Discounts	Rebates, Fees and other Deductions	Product Returns	Total
Balance at December 31, 2022	$ 1,259	$ 26,252	$ 10,923	$ 38,434
Current provisions related to sales in current year	7,485	58,824	3,513	69,822
Adjustments related to prior year sales	92	(1,924)	(56)	(1,888)
Credits/payments made	(7,993)	(59,318)	(9,736)	(77,047)
Balance at September 30, 2023	$ 843	$ 23,834	$ 4,644	$ 29,321

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 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 $30.3 million and $35.9 million as of September 30, 2024 and December 31, 2023, 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**	**2024**	**2023**	**2024**	**2023**
Medice	License and royalties related to the sale of Vafseo in the EU	$ 29	$ —	$ 29	$ 10,000
MTPC	License and Product Supply of Vafseo in Japan	525	487	2,106	5,165
JT and Torii	License and royalties related to the sale of Riona in Japan	1,282	1,441	3,738	3,969
Otsuka	Terminated U.S. and International Agreements	—	—	—	2,225
Total license and other revenue		$ 1,836	$ 1,928	$ 5,873	$ 21,359

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, 2024			
	Balance at Beginning of Period	**Additions**	**Deductions**	**Balance at End of Period**
Contract asset:				
Accounts receivable[1]	$ 3,333	$ 5,873	$ (7,381)	$ 1,825
Contract liability:				
Deferred revenue[2]	$ 43,296	$ —	$ (43,296)	$ —

	Nine Months Ended September 30, 2023			
	Balance at Beginning of Period	**Additions**	**Deductions**	**Balance at End of Period**
Contract assets:				
Accounts receivable[1]	$ 1,901	$ 1,426	$ (2,847)	$ 480
Prepaid expenses and other current assets	$ 781	$ —	$ (781)	$ —
Contract liabilities:				
Deferred revenue	$ 47,034	$ —	$ (3,738)	$ 43,296

(1) Excludes accounts receivable related to amounts due to the Company from product sales of Auryxia which are included in the accompanying unaudited condensed consolidated balance sheets as of September 30, 2024 and 2023.

(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:	**2024**	**2023**	**2024**	**2023**
Deferred revenue — beginning of the period	$ —	$ —	$ —	$ 3,738

During each of the three and nine months ended September 30, 2024 and 2023, the Company recognized no revenue from performance obligations satisfied in previous periods.

Medice License Agreement

On May 24, 2023, or 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 market and sell Vafseo for the treatment of anemia in adult patients with CKD in 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 is included in prepaid expenses and other current assets as of September 30, 2024 and other long-term assets as of December 31, 2023 on the unaudited condensed consolidated balance sheets.

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 nine months ended September 30, 2023.

In accordance with ASC 606, the Company will recognize sales-based royalties and milestone payments at the later of when the performance obligation is satisfied or the related sales occur. During the three and nine months ended September 30, 2024, the Company recognized immaterial revenue from Medice royalties. The Company did not recognize any revenue from Medice royalties during the three and nine months ended September 30, 2023. As of September 30, 2024, there were immaterial contract assets, and no accounts receivable, payables or deferred revenue in connection with the Medice License Agreement.

Medice Letter Agreement

On December 6, 2023, the Company and Medice entered into a letter agreement, or the Medice Letter Agreement, pursuant to which the Company agreed to sell to Medice a partial batch of Vafseo in order to achieve packaging validation for the Medice Territory. The Company previously recognized revenue under this arrangement when risk of loss passed to Medice and delivery occurred. As of September 30, 2024, there were no accounts receivable, contract assets, payables or deferred revenue recorded in connection with the Medice Letter Agreement.

Supply of Drug Product to Medice

On September 13, 2024, the Company and Medice entered into a supply agreement, or the Medice Supply Agreement, under which the Company 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, 2024 or 2023.

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, *Deferred Revenue, Refund 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 2023 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) $6.4 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, 2024, 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, 2024 and 2023 and $1.4 million during each of the nine months ended September 30, 2024 and 2023. 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 loss. As of September 30, 2024, 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 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 2023 Form 10-K for a more detailed description of this supply agreement.

On December 16, 2022, the Company, MTPC and Esteve Química, S.A., or Esteve, executed an Assignment of Supply Agreement, or Esteve Assignment Agreement, pursuant to which the Supply Agreement between the Company and Esteve, or Esteve Agreement was assigned to MTPC. The Esteve Assignment Agreement transferred the rights and obligations of the Company under the Esteve Agreement to MTPC. The Company has no further obligation to take delivery of, or pay for, product delivered by Esteve.

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 and $0.7 million in revenue under the MTPC Supply Agreement during the three and nine months ended September 30, 2024, respectively, and no revenue and $3.7 million in revenue under the MTPC Supply Agreement during the three and nine months ended September 30, 2023, respectively. As of September 30, 2024, there were no accounts receivable, deferred revenue or other current liabilities relating to 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 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 2023 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 $1.3 million and $3.7 million during the three and nine months ended September 30, 2024, respectively, and $1.4 million and $4.0 million during the three and nine months ended September 30, 2023, 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, 2024, the authorized capital stock of the Company included 350,000,000 shares of common stock, $0.00001 par value per share, of which 211,542,122 and 194,582,539 shares were issued and outstanding as of September 30, 2024 and December 31, 2023, 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, 2024 and December 31, 2023.

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. During the three and nine months ended September 30, 2024, the Company sold 1,242,662 shares of its common stock under this program with gross proceeds of $1.7 million ($1.7 million, net of offering expenses).

14. STOCK-BASED COMPENSATION AND BENEFIT PLAN

Stock-Based Compensation and Benefit Plans

The Company incurred stock-based compensation expenses of $1.6 million and $6.1 million for the three and nine months ended September 30, 2024, respectively, and $1.8 million and $7.8 million for the three and nine months ended September 30, 2023, respectively.

Equity Incentive Plans

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

			September 30, 2024		December 31, 2023	
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 RSUs	199,629	—	232,203	—
Akebia Therapeutics, Inc. 2014 Incentive Plan, as amended [2] [3] (the 2014 Plan)	Employees, directors, consultants and advisors	Stock options, RSUs, SARs and performance awards	11,754,663	—	15,311,501	—
Akebia Therapeutics, Inc. 2023 Stock Incentive Plan[3] (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	10,418,117	—	1,712,400	17,382,722

(1) The Keryx Equity Plans consist of the Keryx Biopharmaceuticals, Inc. 1999 Share Option Plan, Keryx Biopharmaceuticals, Inc., as amended, the 2004 Long-Term Incentive Plan, as amended, the Keryx Biopharmaceuticals, Inc. 2007 Incentive Plan, the Keryx Biopharmaceuticals Inc. Amended and Restated 2013 Incentive Plan and the Keryx Biopharmaceuticals, Inc. 2018 Equity Incentive Plan.

(2) New awards are no longer being granted under these plans.

(3) This table includes 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: 1,195,250 options included as outstanding under the 2014 Plan in the table and 2,528,550 options included as outstanding under the 2023 Plan in the table as of September 30, 2024 and 1,616,019 options included as outstanding under the 2014 Plan and 794,000 options included as outstanding under the 2023 Plan in the table as of December 31, 2023.

Common Stock Options and Stock Appreciation Rights

During the nine months ended September 30, 2024, the Company issued 3,432,500 options to employees 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, 2024, the Company granted 1,767,550 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 1,763,550 options remained outstanding as of September 30, 2024.

The Company grants annual service-based stock options to employees and directors and SARs to certain executives under the 2023 and 2014 Plans. 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, 2024, is as follows:

	Stock Options	Weighted Average Exercise Price	Weighted-Average Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	13,312,835	$ 4.20	7.27 years	—
Granted	5,200,050	$ 1.56	—	—
Exercised	(306,464)	$ 0.51	—	—
Expired	(790,326)	$ 9.97		
Canceled and forfeited	(660,270)	$ 3.09	—	—
Outstanding at September 30, 2024	16,755,825	$ 3.22	7.41 years	$ 2,878
Exercisable at September 30, 2024	8,415,196	$ 4.97	5.89 years	

As of September 30, 2024, there was approximately $8.5 million of unrecognized compensation costs related to stock options, which is expected to be recognized over a weighted average period of 2.79 years.

Restricted Stock Units

Generally, restricted stock units, or 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.

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
Outstanding as of December 31, 2023	3,339,869	$ 1.30	603,400	$ 1.48
Granted	—	$ —	3,989,000	$ 1.59
Vested	(1,615,581)	$ 1.60	(343,833)	$ 1.37
Forfeited and canceled	(249,771)	$ 0.92	(106,500)	$ 1.68
Outstanding as of September 30, 2024	1,474,517	$ 1.05	4,142,067	$ 1.59

As of September 30, 2024, there was $6.2 million of unrecognized compensation costs related to time-based RSUs and PSUs, which is expected to be recognized over a weighted-average period of 2.07 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, 2024 and December 31, 2023, a total of 4,448,069 and 4,637,801 shares of the Company's common stock were available for future issuance under the ESPP, respectively. The Company issued 189,732 shares under the ESPP during the nine months ended September 30, 2024.

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	**2024**	**2023**	**2024**	**2023**
Risk-free interest rate	3.60 % - 3.95%	4.08 % - 4.55%	3.60% - 4.66%	3.54% - 4.55%
Expected volatility	111.37 % - 117.40%	102.41 % - 107.01%	109.98% - 118.61%	100.97% - 111.71%
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	$1.17	$1.38	$1.35	$0.69

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Cost of goods sold	$ 115	$ 74	$ 284	$ 214
Research and development	338	403	1,153	1,604
Selling, general and administrative	1,193	1,135	4,603	5,355
Restructuring	—	212	38	630
Total stock-based compensation	$ 1,646	$ 1,824	$ 6,078	$ 7,803

15. NET LOSS PER SHARE

Potentially dilutive securities, warrants, common stock options, RSUs and SARs have been excluded from the calculation of diluted net loss per share as their effects would be anti-dilutive. For periods in which the Company reports a net loss, the weighted average number of shares outstanding used to calculate both basic and diluted net loss per share were the same. The shares in the table below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, due to their anti-dilutive effect:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Warrants[(1)]	3,076,923	—	3,076,923	—
Outstanding common stock options	16,120,512	13,578,800	16,120,512	13,578,800
Unvested RSUs	5,616,584	4,662,596	5,616,584	4,662,596
Stock appreciation rights	635,313	635,313	635,313	635,313
Total	25,449,332	18,876,709	25,449,332	18,876,709

(1) In the event of a drawdown of Tranche C, the Company would become obligated to issue to the Warrant Holder additional warrants to purchase 1,153,846 shares of the common stock which are excluded from this table.

16. 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 disclose of events both recognized in the accompanying unaudited condensed consolidated financial statements as of September 30, 2024, and events which occurred subsequently but were not recognized in the consolidated financial statements. The Company has concluded that no subsequent events have occurred that require disclosure other than the following:

Amendment to WuXi STA DP Agreement

On October 15, 2024, the Company and WuXi STA entered into Amendment #1 to the WuXi STA DP Agreement pursuant to which the parties agreed to extend the term of the WuXi STA DP Agreement until January 1, 2032. In addition, the volume-based pricing structure under the WuXi STA DP Agreement was amended. See Note 10, *Commitments and Contingencies*, for further information on the WuXi STA DP Agreement.

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, 2023 filed with the United States, or U.S., Securities and Exchange Commission, or the SEC, on March 14, 2024, or the 2023 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 commercial-stage biopharmaceutical company committed to addressing patients' unmet needs. We have built a business focused on developing and commercializing innovative therapeutics that we believe serves as a foundation for future growth. Our purpose is to better the life of each person impacted by kidney disease, and we have established ourselves as a leader in the kidney community. We believe our demonstrated ability to deliver value broadly to the kidney community has enabled us to build a sustainable company. Upon this solid foundation and our continued commitment to patients, we believe focusing on all patients who can realize a meaningful benefit from our medicines, will result in delivering value for our stockholders.

Our current portfolio includes:

- ***Vafseo® (vadadustat)*** is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor, approved in 37 countries as a treatment for anemia due to chronic kidney disease, or CKD. On March 27, 2024, the U.S. Food and Drug Administration, or FDA, approved Vafseo (vadadustat) Tablets for the treatment of anemia due to CKD in adults who have been receiving dialysis for at least three months. We are launching Vafseo in the U.S. and expect product availability in January 2025. In October 2024, Centers for Medicare & Medicaid Services, or CMS, determined that Vafseo will be eligible for reimbursement under the Transitional Drug Add-on Payment Adjustment, or TDAPA, starting on January 1, 2025. We also have several lifecycle management and label expansion opportunities currently under evaluation for Vafseo, including the potential for alternative dosing and label expansion for the treatment of adult patients not on dialysis. In May 2023, we entered into a license agreement granting MEDICE Arzneimittel Pütter GmbH & Co. KG, or Medice, the rights to market and sell Vafseo in the European Economic Area, or EEA, the United Kingdom, or UK, Switzerland and Australia, or the Medice Territory, where Vafseo is approved for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis. Vafseo is currently marketed and sold by Medice in certain countries in the Medice Territory. We retain the rights to develop and commercialize Vafseo in Europe for other indications. 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 and South Korea, Vafseo is approved for the treatment of symptomatic anemia due to CKD in adult patients on chronic maintenance dialysis. MTPC plans to commercialize Vafseo in Taiwan.
- ***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. with our well-established, nephrology-focused commercial organization. Our Japanese sublicensee, Japan Tobacco, Inc., and its subsidiary, Torii Pharmaceutical Co., Ltd., collectively, JT and Torii, commercialize ferric citrate hydrate as Riona in Japan. Averoa SAS, or Averoa, has an exclusive license to develop and commercialize ferric citrate in the EEA, Turkey, Switzerland, UK, Turkey, Balkans and certain countries in eastern Europe and the Middle East. In April 2024, Averoa submitted its marketing authorization application, or MAA, for ferric citrate in Europe.
- ***Our HIF-based pipeline assets*** are molecules being evaluated to target areas of unmet needs in acute care settings. The discovery of hypoxia-inducible factor, or HIF, laid the foundation to explore the central role of oxygen sensing in many diseases. As we have seen through the development of vadadustat 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, for use in an acute care setting, potentially for acute kidney disease, or AKI, or acute respiratory distress syndrome, or ARDS, and AKB-10108 for retinopathy of prematurity, or ROP, in neonates.

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 Highlights

Product revenue was $35.6 million and $107.8 million for the three and nine months ended September 30, 2024, respectively, and $40.1 million and $117.1 million for the three and nine months ended September 30, 2023, respectively.

We have incurred net losses in each year since inception. Our net losses were $20.0 million and $46.6 million for the three and nine months ended September 30, 2024, respectively, and $14.5 million and $52.5 million for the three and nine months ended September 30, 2023, respectively. Substantially all of our net losses resulted from costs incurred in connection with the continued commercialization of Auryxia and development and commercialization efforts relating to Vafseo, including conducting clinical trials of, and seeking regulatory approval for, Vafseo, and providing general and administrative support for these operations and protecting our intellectual property.

Financial Components

Product Revenue

We generate product revenue from commercial sales of Auryxia to a limited number of wholesale distributors as well as certain specialty pharmacy providers. 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 evaluate, at least annually and more frequently, if needed, the price of Auryxia, which will lose exclusivity, or LoE, in March 2025. We expect our product revenue to continue to be generated primarily from our commercial sales of Auryxia until Vafseo's U.S. market entry which is expected in January 2025.

Due to the buying patterns of our customers, we tend to have seasonality from quarter to quarter. In general, our first quarter usually has lower revenues than the preceding fourth quarter, the second and third quarters have higher revenues than the first quarter, and the fourth quarter revenues are the highest in the year. While seasonality may affect quarterly comparisons within a fiscal year, it generally is not material to our annual consolidated financial results. However, absent further legislation or regulation, Auryxia will be included in the end-stage renal disease, or ESRD, bundle starting in January 2025, which we believe will impact the buying patterns of some of our existing customers in the fourth quarter of 2024 and lead to lower inventory levels at certain customers in the fourth quarter of 2024. In addition, based on these changes, and coupled with Auryxia's LoE in March 2025, the buying pattern of certain customers in future years may be different than their historical practices.

We believe CMS's decision to include phosphate binders in the dialysis bundle could potentially lead to higher sales of Auryxia after the LoE date than in other LoE scenarios, and plan to work with payors and providers to seek to continue the use of Auryxia beyond LoE. However, our ability to continue to generate revenue from sales of Auryxia following LoE will depend on many factors, including our ability to successfully contract with dialysis organizations, the timing and number of generics that enter the market 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 for Auryxia, 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.

COGS also includes costs to manufacture drug product provided to MTPC and Medice for commercial sales of Vafseo in Japan and the Medice Territory, respectively, as well as 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 includes 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 and in Europe prior to the European Commission, or EC, approval in April 2023.

R&D costs are expensed as incurred. Advance payments made for goods or services to be received in the future for use in R&D activities are recorded as prepaid expenses and other current assets. The prepaid amounts are expensed as the benefits are consumed. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

We cannot determine with certainty the duration and completion costs of our R&D projects, the costs of related clinical development, or if, when, or to what extent we will generate revenue from the commercialization or sale of any of our product candidates.

From inception through September 30, 2024, 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 product. 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 product 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 relates to royalties due to Panion & BF Biotech, Inc., or Panion, for sales of Auryxia in the U.S. and Riona in Japan.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income on our interest-bearing accounts, interest expense related to our term loans, accretion of the debt discount on our term loans as well as 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 the Company's 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

U.S. Approval and Reimbursement of Vafseo (vadadustat)

In March 2024, we received approval from the FDA for Vafseo (vadadustat) Tablets for the treatment of anemia due to CKD in adults who have been receiving dialysis for at least three months. In June 2024, we applied to designate Vafseo for TDAPA reimbursement from CMS. In October 2024, CMS determined that Vafseo met the criteria for TDAPA in the anemia management ESRD prospective payment system functional category and, as a result, we will be eligible for reimbursement beginning on January 1, 2025. The TDAPA program provides at least two years of reimbursement for Vafseo in addition to the ESRD bundled rate to dialysis organizations. Additionally, we received a Level II Healthcare Common Procedure Coding System code for Vafseo which will be used by dialysis organizations for billing the product for Medicare enrollees.

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. During the three and nine months ended September 30, 2024, we sold 1,242,662 shares of our common stock under this program with gross proceeds of $1.7 million ($1.7 million, net of offering expenses). Including the amount sold during the nine months ended September 30, 2024 through the date of the filing of this form 10-Q, we sold 7,741,616 shares of our common stock under the sales agreement with gross proceeds of $11.6 million ($11.3 million, net of offering expenses).

CSL Vifor Termination and Settlement Agreement

On July 10, 2024, we and CSL Vifor entered into a Termination and Settlement Agreement, or the Vifor Termination Agreement. Pursuant to the Vifor Termination Agreement, we and CSL Vifor agreed, among other things, to terminate, effective immediately, the Second Amended and Restated License Agreement, dated February 18, 2022 and as amended May 3, 2024, or the Vifor License Agreement, pursuant to which we granted to CSL Vifor an exclusive license to sell Vafseo to Fresenius Medical Care North America and its affiliates, including Fresenius Kidney Care Group LLC, to certain third-party dialysis organizations approved by us, to independent dialysis organizations that are members of certain group purchasing organizations, and to certain non-retail specialty pharmacies in the U.S. We and CSL Vifor agreed to terminate the Vifor License Agreement for business reasons.

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 the Vifor Termination Agreement.

Borrowing Under BlackRock Term Loans and Repayment of Pharmakon Term Loans

On January 29, 2024, we entered into a secured term loan facility with Kreos, which are funds and accounts managed by BlackRock Inc., collectively BlackRock, or the BlackRock Credit Agreement, that provides for an aggregate principal amount of up to $55.0 million made available under the following three tranches:

(i) Tranche A — $37.0 million, drawn down on the closing date of the BlackRock Credit Agreement, of which we received $34.5 million, net of debt issuance costs, fees and expenses and was used to repay our senior secured term loans, or the Pharmakon Term Loans, with Pharmakon Advisors LP, or Pharmakon, of $35.0 million,

(ii) Tranche B — $8.0 million, drawn down on April 19, 2024, of which we received $7.5 million, net of debt issuance costs, fees and expenses, and

(iii) Tranche C — $10.0 million available in a single draw through December 31, 2024.

Tranche C is only available subject to receipt of a certain amount of cumulative gross cash proceeds from the sale of common stock.

On January 29, 2024, we also entered into a warrant agreement with Kreos Capital VII Aggregator SCSp, an affiliate of Kreos, pursuant to which we (i) issued a warrant to purchase 3,076,923 shares of our common stock, 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) will issue at the time of drawdown of the Tranche C Loan, if applicable, a warrant to purchase 1,153,846 shares of our common stock, at the Exercise Price. Each warrant shall be exercisable for eight years from the date of issuance.

On July 10, 2024, in connection with the Vifor Termination Agreement, we and Kreos entered into a First Amendment to the Agreement for the Provision of a Loan Facility, which amends certain provisions of the BlackRock Credit Agreement.

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.

Impact of Inflation

We are experiencing rising costs for certain inflation-sensitive operating expenses such as labor and certain service providers that are heavily dependent on labor. We do not believe these impacts were material to our net loss during the three and nine months ended September 30, 2024 or will be going forward. However, significant sustained inflation driven by the macroeconomic environment or other factors could negatively impact our margins, profitability and results of operations in future periods.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

	Three Months Ended September 30,		Change	
(dollars in thousands)	**2024**	**2023**	**$**	**%**
Revenues				
Product revenue, net	$ 35,592	$ 40,118	$ (4,526)	(11)%
License, collaboration and other revenue	1,836	1,928	(92)	(5)%
Total revenues	37,428	42,046	(4,618)	(11)%
Cost of goods sold				
Cost of product and other revenue	5,150	8,998	(3,848)	(43)%
Amortization of intangible asset	9,011	9,011	—	*
Total cost of goods sold	14,161	18,009	(3,848)	(21)%
Operating expenses				
Research and development	8,487	13,330	(4,843)	(36)%
Selling, general and administrative	26,516	22,710	3,806	*
License	769	864	(95)	(11)%
Restructuring	—	169	(169)	*
Total operating expenses	35,772	37,073	(1,301)	(4)%
Loss from operations	(12,505)	(13,036)	531	(4)%
Other expense, net	(6,678)	(1,453)	(5,225)	360 %
Change in fair value of warrant liability	(856)	—	(856)	*
Net loss	$ (20,039)	$ (14,489)	$ (5,550)	38 %

*Percentage change not meaningful.

Product Revenue, Net—Net product revenue is derived only from sales of Auryxia in the U.S. until Vafseo's U.S. market entry, which is expected in January 2025. We distribute Auryxia principally through a limited number of wholesale distributors as well as certain specialty pharmacy providers.

Net product revenue was $35.6 million for the three months ended September 30, 2024, compared to $40.1 million for the three months ended September 30, 2023. The decrease was primarily due to a reduction in volume partially offset by price increases and execution of our contracting strategy with third-party payors.

Auryxia will lose exclusivity in the U.S. in March 2025, which may have a negative impact on revenue. We believe CMS's decision to include phosphate binders in the dialysis bundle could potentially lead to higher sales of Auryxia after the LoE date than in other LoE scenarios, and plan to work with third-party payors and providers to seek to continue the use of Auryxia beyond LoE. However, our ability to continue to generate revenue from sales of Auryxia following LoE will depend on many factors, including our ability to successfully contract with dialysis organizations, the timing and number of generics that enter the market and other products on the market that compete with Auryxia.

License, Collaboration and Other Revenue—License, collaboration and other revenue was $1.8 million for the three months ended September 30, 2024, compared to $1.9 million for the three months ended September 30, 2023. The decrease was primarily due to lower license revenue under our agreement with JT and Torii.

Cost of Goods Sold—Cost of Product and Other Revenue—Cost of product and other revenue was $5.2 million for the three months ended September 30, 2024 compared to $9.0 million for the three months ended September 30, 2023. The decrease was primarily due to a $3.7 million benefit that we recorded during the three months ended September 30, 2024 due to our ability to commercially sell inventory previously written-down as excess inventory and lower year-over-year sales volume.

Cost of Goods Sold—Amortization of Intangible Asset—Amortization of intangible asset relates to the acquired developed product rights for Auryxia, which is being amortized using a straight-line method over its estimated useful life of approximately six years. Amortization of intangible asset during each of the three months ended September 30, 2024 and 2023 was $9.0 million and will continue through the end of 2024.

R&D Expenses—R&D expenses were $8.5 million for the three months ended September 30, 2024, compared to $13.3 million for the three months ended September 30, 2023. The decrease was largely due to the completion of activities related to certain clinical trials, lower headcount related costs and decreased professional service and consulting expenses. Additionally, during the three months ended September 30, 2023, prior to receiving regulatory approval for Vafseo in the U.S., we recorded costs incurred to manufacture the U.S. pre-launch inventory as R&D expenses. The decrease in R&D expense was partially offset by increased costs related to the start-up of an outcomes study for Vafseo.

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, 2024 and 2023 (in thousands):

	Three Months Ended September 30,	
	2024	2023
Vafseo clinical trial and other external costs	$ 3,046	$ 2,224
Vafseo pre-launch inventory	—	73
External costs for other programs, including feasibility and new processes and methods associated with commercial product	1,462	2,769
Total external R&D expenses	4,508	5,066
Internal personnel, consulting, facilities and other	3,979	8,264
Total R&D expenses	$ 8,487	$ 13,330

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 $26.5 million for the three months ended September 30, 2024, compared to $22.7 million for the three months ended September 30, 2023. The increase was primarily due to higher headcount related costs and marketing costs in connection with the Vafseo launch expected in January 2025, as well as increased promotional expenses and registration and filing fees.

License Expenses—License expenses related to royalties due to Panion relating to sales of Riona in Japan were $0.8 million and $0.9 million for the three months ended September 30, 2024 and 2023, respectively.

Restructuring Expenses—There were no restructuring expenses and $0.2 million of restructuring expenses for the three months ended September 30, 2024 and 2023, respectively.

Other Expense, Net—Other expense, net, was $6.7 million for the three months ended September 30, 2024, compared to $1.5 million for the three months ended September 30, 2023. The increase was primarily due to non-cash interest expense related to the settlement royalty liability in connection with the Vifor Termination Agreement. 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.

Change in Fair Value of Warrant Liability—Change in fair value of warrant liability was $0.9 million for the three months ended September 30, 2024. There was no change in fair value of warrant liability for the three months ended September 30, 2023 since the warrant agreement was entered into in January 2024.

Comparison of the Nine Months Ended September 30, 2024 and 2023

(dollars in thousands)	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023	Change $	Change %
Revenues				
Product revenue, net	$ 107,810	$ 117,068	$ (9,258)	(8)%
License, collaboration and other revenue	5,873	21,359	(15,486)	(73)%
Total revenues	113,683	138,427	(24,744)	(18)%
Cost of goods sold				
Cost of product and other revenue	15,780	28,452	(12,672)	(45)%
Amortization of intangible asset	27,032	27,032	—	— %
Total cost of goods sold	42,812	55,484	(12,672)	(23)%
Operating expenses				
Research and development	25,866	53,214	(27,348)	(51)%
Selling, general and administrative	78,870	74,797	4,073	5 %
License	2,242	2,381	(139)	(6)%
Restructuring	58	181	(123)	(68)%
Total operating expenses	107,036	130,573	(23,537)	(18)%
Operating loss	(36,165)	(47,630)	11,465	(24)%
Other expense, net	(11,269)	(4,385)	(6,884)	157 %
Change in fair value of warrant liability	1,345	—	1,345	100 %
Loss on extinguishment of debt	(517)	—	(517)	*
Loss on termination of lease	—	(524)	524	*
Net loss	$ (46,606)	$ (52,539)	$ 5,933	(11)%

*Percentage change not meaningful.

Product Revenue, Net—Net product revenue is derived only from sales of Auryxia in the U.S. until Vafseo's U.S. market entry, which is expected in January 2025. We distribute Auryxia principally through a limited number of wholesale distributors as well as certain specialty pharmacy providers.

Net product revenue was $107.8 million for the nine months ended September 30, 2024, compared to $117.1 million for the nine months ended September 30, 2023. The decrease was primarily due to a reduction in volume partially offset by price increases and execution of our contracting strategy with third-party payors.

Auryxia will lose exclusivity in the U.S. in March 2025, which may have a negative impact on revenue. We believe CMS's decision to include phosphate binders in the dialysis bundle could potentially lead to higher sales of Auryxia after the LoE date than in other LoE scenarios, and plan to work with third-party payors and providers to seek to continue the use of Auryxia beyond LoE. However, our ability to continue to generate revenue from sales of Auryxia following LoE will depend on many factors, including our ability to successfully contract with dialysis organizations, the timing and number of generics that enter the market and other products on the market that compete with Auryxia.

License, Collaboration and Other Revenue—License, collaboration and other revenue was $5.9 million for the nine months ended September 30, 2024, compared to $21.4 million for the nine months ended September 30, 2023. The decrease was primarily due to a one-time $10.0 million upfront payment recognized in connection with the Medice License Agreement during the nine months ended September 30, 2023 as well as a reduction in revenue under our supply agreement with MTPC as a result of the assignment of our supply agreement with Esteve Química, S.A. to MTPC in December 2022. We also recognized $2.2 million in revenue in connection with the Packaging Validation Transfer Agreement we entered into with Otsuka during the nine months ended September 30, 2023.

Cost of Goods Sold—Cost of Product and Other Revenue—Cost of product and other revenue was $15.8 million for the nine months ended September 30, 2024 compared to $28.5 million for the nine months ended September 30, 2023. The decrease was primarily due to a $12.3 million benefit that we recorded during the nine months ended September 30, 2024 due to our

ability to commercially sell inventory previously written-down as excess inventory and lower year-over-year sales volume, which was partially offset by a $2.1 million charge related to our firm purchase commitment liability.

See Note 10, *Commitments and Contingencies*, for further information on our firm purchase commitment liability.

Cost of Goods Sold—Amortization of Intangible Asset—Amortization of intangible asset relates to the acquired developed product rights for Auryxia, which is being amortized using a straight-line method over its estimated useful life of approximately six years. Amortization of intangible asset during each of the nine months ended September 30, 2024 and 2023 was $27.0 million and will continue through the end of 2024.

R&D Expenses—R&D expenses were $25.9 million for the nine months ended September 30, 2024, compared to $53.2 million for the three months ended September 30, 2023. The decrease was largely due to the completion of activities related to certain clinical trials, a reduction in consulting expenses associated with pursuing Vafseo regulatory approval in the Medice Territory in 2023, lower headcount related costs, including stock-based compensation, and decreased professional service expenses. Additionally, during the nine months ended September 30, 2023, prior to receiving regulatory approval for Vafseo in the U.S., we recorded costs incurred to manufacture the U.S. pre-launch inventory as R&D expenses.

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, 2024 and 2023 (in thousands):

	Nine Months Ended September 30,	
	2024	**2023**
Vafseo clinical trial and other external costs	$ 6,337	$ 12,843
Vafseo pre-launch inventory	—	3,311
External costs for other programs, including feasibility and new processes and methods associated with commercial product	4,252	8,668
Total external R&D expenses	10,589	24,822
Internal personnel, consulting, facilities and other	15,277	28,392
Total R&D expenses	$ 25,866	$ 53,214

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 $78.9 million for the nine months ended September 30, 2024, compared to $74.8 million for the nine months ended September 30, 2023. The increase was primarily due to higher headcount related costs and marketing costs in connection with the Vafseo launch expected in January 2025, as well as increased promotional expenses and registration and filing fees.

License Expenses—License expenses related to royalties due to Panion relating to sales of Riona in Japan were $2.2 million and $2.4 million for the nine months ended September 30, 2024 and 2023, respectively.

Restructuring Expenses—Restructuring expenses were $0.1 million and $0.2 million for the nine months ended September 30, 2024 and 2023, respectively.

Other Expense, Net—Other expense, net, was $11.3 million for the nine months ended September 30, 2024, compared to $4.4 million for the nine months ended September 30, 2023. The increase was primarily due to non-cash interest expense related to the settlement royalty liability in connection with the Vifor Termination Agreement and a decrease in sublease income due to the assignment of our lease for office space in Boston, Massachusetts, or the Boston Lease. 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.

Change in Fair Value of Warrant Liability—Change in fair value of warrant liability was $1.3 million for the nine months ended September 30, 2024. There was no change in fair value of warrant liability for the nine months ended September 30, 2023 since the warrant agreement was entered into in January 2024.

Loss on Extinguishment of Debt—During the nine months ended September 30, 2024, we recorded $0.5 million loss on the extinguishment of debt in connection with the repayment of the Pharmakon Term Loans.

Loss on Lease Termination—On May 26, 2023 we incurred a loss on lease termination of $0.5 million in connection with the assignment of our Boston Lease. In accordance with ASC 842, *Leases*, we wrote off the right-of-use asset and lease liability

associated with the Boston Lease, and recognized the difference between the right-of-use asset and the lease liability offset by the $1.3 million payment we made to LG Chem Life Sciences Innovation Center, Inc. in connection with the assignment.

Liquidity and Capital Resources

As of September 30, 2024, we had cash and cash equivalents of $34.0 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, 2024, we raised approximately $840.6 million of net proceeds from the sale of equity, including $519.8 million from various underwritten public offerings, $250.8 million from at-the-market offerings pursuant to our current sales agreement with Jefferies LLC and prior sales agreements with Jefferies LLC and Cantor Fitzgerald & Co., and $70.0 million from the sale of 7,571,429 shares of common stock to CSL Vifor.

We have incurred recurring losses and negative cash flow from operations in each year since inception and anticipate net losses and negative operating cash flows for the near future. We incurred net operating losses of $20.0 million and $46.6 million during the three and nine months ended September 30, 2024, respectively, and $14.5 million and $52.5 million during the three and nine months ended September 30, 2023, respectively. As of September 30, 2024 and December 31, 2023, we had an accumulated deficit of $1.7 billion and $1.6 billion, respectively.

We currently have exclusive rights under a series of patents and patent applications to commercialize Auryxia in the U.S. that protect us from generic drug competition until March 2025. Following LoE in the U.S. in March 2025, we may not be able to realize enough product revenue from sales of Auryxia to realize net profits from product sales. While we believe CMS's decision to include phosphate binders in the dialysis bundle could potentially lead to higher sales of Auryxia after the LoE date than in other LoE scenarios, and plan to work with payors and providers to seek to continue the use of Auryxia beyond LoE, Auryxia product sales have not generated, and may not generate, now or following LoE in the U.S., sufficient product revenue to realize net profits from product sales to cover our current or long-term operating costs. Our ability to continue to generate revenue from sales of Auryxia following LoE will depend on many factors, including our ability to successfully contract with dialysis organizations, the timing and number of generics that enter the market and other products on the market that compete with Auryxia.

We believe our existing cash resources and the cash we expect to generate from product, royalty, supply and license revenues are sufficient to fund our current operating plan for at least twenty-four months. However, if our operating performance deteriorates significantly from the levels expected in our operating plan, it would have an adverse effect on our liquidity and capital resources and could affect our ability to 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 up to $55.0 million, or the Term Loan Facility. The Term Loan Facility is 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 is available in a single draw through December 31, 2024, collectively, the Term Loans. Tranche C is 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 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.

On the Closing Date, Kreos Capital VII Aggregator SCSp, an affiliate of Kreos, or the Warrant Holder, received a warrant to purchase 3,076,923 shares of our common stock, at an exercise price per share of $1.30, and upon borrowing of Tranche C, we will become obligated to issue additional warrants to purchase 1,153,846 shares of our common stock at an exercise price per share of $1.30. Each warrant shall be exercisable for eight years from the date of issuance.

In connection with the entry into the BlackRock Credit Agreement, on the Closing Date, we terminated the Pharmakon Loan Agreement, all obligations thereunder were paid in full and discharged and Pharmakon's security interests in our assets and property were released. 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.

On July 10, 2024, in connection with the Vifor Termination Agreement, we and Kreos entered into a First Amendment to the Agreement for the Provision of a Loan Facility, which amends 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*, 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

Pursuant to the terms of the Vifor Termination Agreement, we will pay CSL Vifor decreasing quarterly tiered royalty payments ranging from a high single-digit percentage of our net sales of Vafseo up to $450.0 million to mid-single digit percentage of our net sales of Vafseo above $450.0 million, in each case, in the U.S. during a calendar year, or the Settlement Royalty Payments. The Settlement Royalty Payments will commence upon the first sale of Vafseo by us, 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 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 above.

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

As a result of the Vifor Termination Agreement, 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 agreement 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, 2024 was 41.0% which is reflected as interest expense in the unaudited condensed consolidated statements of operations and comprehensive loss. The Company recognized interest expense of $4.4 million for the three and nine months ended September 30, 2024. As of September 30, 2024, the $47.7 million liability related to settlement royalties is classified as a long-term liability based on the timing of payments.

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 (Previously Referred to as Refund Liability to Customer)

In February 2022, we amended our agreement with CSL Vifor and they contributed $40.0 million to a working capital fund, or the Working Capital Fund, established to partially fund our costs of purchasing Vafseo from our contract manufacturers.

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, 2024, the $40.2 million Working Capital Fund liability is classified as a long-term liability based on management's estimated timing of the repayment of the Working Capital Fund liability to CSL Vifor exceeding one-year.

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 will commence 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.

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 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, 2024 was 0%. We retain the right to receive all potential future regulatory milestones for Vafseo under the MTPC Agreement. We recorded $0.5 million and $1.4 million of non-cash royalty revenue during each of the three and nine months ended September 30, 2024 and 2023, 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, 2024, 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, 2024, while others are considered future obligations. Our material cash requirements as of September 30, 2024, include contractual obligations and commitments arising in the normal course of business, including leases, license agreements, manufacturing agreements and unconditional purchase commitments which are described in more detail below.

Cambridge Lease

We lease approximately 65,167 square feet of office, storage and laboratory space in Cambridge, Massachusetts under non-cancelable operating leases, collectively the Cambridge Lease. The office, storage and lab lease expires on September 11, 2026.

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

License Agreements

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.

In June 2021, we entered into a license agreement, or Cyclerion Agreement, with Cyclerion Therapeutics Inc. 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. We may be obligated to pay up to an aggregate of $222.0 million in specified development and regulatory milestone payments, certain specified commercial milestones and tiered royalties ranging from a low-single-digit to mid-double-digit percentage 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. We may terminate the Cyclerion Agreement in its entirety or only with respect to a particular licensed compound or product upon 180 days' prior written notice to Cyclerion. 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.

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. 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.

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 $47.0 million as of September 30, 2024. The scope of the services under these R&D contracts can be modified and the contracts 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*):	**2024**	**2023**
Operating activities	$ (36,193)	$ (21,076)
Investing activities	(31)	—
Financing activities	27,338	(23,916)
Decrease in cash, cash equivalents and restricted cash	$ (8,886)	$ (44,992)
Cash, cash equivalents and restricted cash — beginning of period	44,579	93,169
Cash, cash equivalents and restricted cash — end of period	$ 35,693	$ 48,177

Operating Activities

Net cash used in operating activities was $36.2 million for the nine months ended September 30, 2024. Net cash used in operating activities for the nine months ended September 30, 2024 consisted of a net loss of $46.6 million reduced by net non-cash adjustments of $46.9 million, including amortization of our intangible asset of $27.0 million, a change in excess inventory purchase commitments of $2.1 million and a change in fair value of the warrant liability of $1.3 million, offset by a reduction of $36.4 million in working capital.

Net cash used in operating activities was $21.1 million for the nine months ended September 30, 2023. Net cash used in operating activities consisted of a net loss of $52.5 million reduced by net non-cash adjustments of $36.0 million, including amortization of our intangible asset of $27.0 million and a noncash write-off of $0.8 million related to the termination of our Boston Lease, offset by a reduction of $4.5 million in working capital.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2024 was immaterial. No net cash was used in investing activities for the nine months ended September 30, 2023.

Financing Activities

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.

Net cash used in financing activities was $23.9 million for the nine months ended September 30, 2023, which primarily consisted of principal payments of debt related to the Pharmakon Term Loans.

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, product 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, intangible asset 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, 2024, there were no material changes to our methodologies used for our critical accounting estimates as reported in our 2023 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, 2024 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 14, 2024, or 2023 Form 10-K, as of December 31, 2023, our management identified a material weakness in our internal control over financial reporting. Specifically, we did not maintain effective controls related to (i) the review of inventory reconciliations, (ii) the validation of the inventory costing, (iii) the classification of inventory within the balance sheet and cost of product and other revenue related costs in the statement of operations, (iv) the calculation of estimated excess firm purchase commitment liability and (v) the verification that the existence of all inventories subject to physical inventory counts were accurately counted.

Remediation Efforts of the Material Weakness — Inventories

Our management has taken and plans to continue to take actions to remediate the deficiency in our internal control over financial reporting and has implemented new processes, procedures and controls designed to address the underlying causes associated with the material weakness.

For example, we are in the process of: (i) implementing and documenting new processes and controls to help ensure the completeness and accuracy of our inventory reconciliations, (ii) engaging additional third-party subject matter experts and accounting personnel with U.S. GAAP experience specific to inventory accounting, (iii) enhancing the accuracy of key reports used to calculate the firm purchase commitment liability; and (iv) establishing effective monitoring and oversight controls to help to ensure the completeness and accuracy of inventory included in our financial statements and related disclosures.

As our management continues to evaluate and work to improve our internal control over financial reporting, our 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 our 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. Defending such proceedings is costly and can impose a significant burden on management and employees. The results of any current or future litigation cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on

us because of defense and settlement costs, diversion of management resources and other factors. We are not presently a party to any litigation the outcome of which, if determined adversely to us, would in our estimation, have a material adverse effect on our business, operating results, cash flows or financial condition.

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 profitable or attain positive cash flows.

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 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 are not currently profitable, and we have incurred net losses each year since our inception, including a net loss of $20.0 million for the three months ended September 30, 2024. As of September 30, 2024, we had an accumulated deficit of $1.7 billion. We cannot guarantee when, if ever, we will become profitable.

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 and the commercialization of Vafseo was delayed, which had and could continue to have an adverse effect on our business.

Our ability to generate product revenue and achieve 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 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;
- the timing and scope of marketing approvals for Vafseo and any other product candidate, if approved, including those that may be in-licensed or acquired;
- maintaining marketing approvals for Auryxia, Vafseo and any other product, including those that may be in-licensed or acquired;
- our ability to successfully contract 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;

- 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;
- the potential impact of geopolitical pressures 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;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents and trade secrets; and
- the adverse impact of the recent COVID-19 pandemic on CKD patients and the phosphate binder market in which we compete.

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 market and sell 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 Medice Territory. Vafseo is currently marketed and sold by Medice in certain countries in the Medice Territory. If Medice's launch of Vafseo 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. If we are not successful in contracting with dialysis organizations and commercializing Vafseo in a timely manner, or at all, our expected revenue related to Vafseo would be adversely impacted.

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 will commence 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 contracting with dialysis organizations and commercializing Vafseo in a timely manner, 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.

Our ability to achieve 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, additional R&D and selling, general and administrative expenses for ongoing development and commercialization of Auryxia and Vafseo, which could lead to operating losses for the foreseeable future. We will continue to incur substantial expenditures relating to continued commercialization and post-marketing requirements for Auryxia, Vafseo and any other products, including those that may be in-licensed or acquired, as well as costs relating to the R&D of Vafseo and any other product candidate, including those that may be in-licensed or acquired. Our prior losses have had, and expected future losses will continue to have, an adverse effect on our stockholders' deficit and working capital.

In addition to any further costs not currently contemplated in our operating plan, our ability to achieve 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;
- 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;
- conduct discovery and development activities for additional 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 up to $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;
- 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, 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 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. The net losses we incur may 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 royalties from Riona and Vafseo in Japan, may generate royalties from Vafseo in Europe and other territories where it is approved, may generate product and collaboration revenue from Vafseo in the U.S., 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, 2024, our cash and cash equivalents were $34.0 million. We expect to continue to expend substantial amounts of cash for the foreseeable future as we continue to commercialize Auryxia; 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, 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 number of generic versions of Auryxia that enter the market following loss of exclusivity, or LoE, for Auryxia in March 2025, and the timing of, and the magnitude of, the impact on the product revenue from Auryxia, including the impact on the price of Auryxia;
- the cost of securing and validating commercial manufacturing for any of our product candidates, including those that may be in-licensed or acquired, and maintaining our manufacturing arrangements for Auryxia and Vafseo or any other product, 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 or any future commercialization efforts.

We believe our existing cash resources and the cash we expect to generate from product, royalty, supply and license revenues are sufficient to fund our current operating plan for at least twenty-four months. However, if our operating performance deteriorates significantly from the levels expected in our operating plan, it would have an adverse effect on our liquidity and capital resources and could affect our ability to 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 rising inflation, increasing interest rates, slower economic growth or recession, global supply chain disruptions, the Russia-Ukraine war, Israel-Hamas war and the war in the Middle East and tensions between China and Taiwan, 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. 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.

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.

On May 9, 2023, we received a letter from Nasdaq stating that we had not regained compliance with the minimum bid price rule during the compliance period and were subject to delisting. On May 22, 2023, we received a letter from the Office of General Counsel of Nasdaq informing us that Nasdaq confirmed that we had regained compliance with the $1.00 per share minimum bid price requirement.

On August 11, 2023, we received a notification letter from Nasdaq informing us that since we had not yet filed our Quarterly Report on Form 10-Q for the three months ended June 30, 2023, we were not in compliance with Nasdaq's listing rule requiring timely filing of all required periodic financial reports with the U.S. Securities and Exchange Commission, or the SEC. On August 30, 2023, we received a letter from the Office of General Counsel of Nasdaq informing us that Nasdaq confirmed that we had regained compliance with Nasdaq's listing rule requiring timely filing of all required periodic financial reports with the SEC.

Although the minimum bid price deficiency and Nasdaq periodic reporting requirement matters are now closed, there can be no assurance that we will be able to continue to comply with the Nasdaq continued listing requirements.

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, 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. Although we have progressed preclinical studies for praliciguat, we need to do additional work to manufacture product for clinical trials than originally anticipated before we can 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, such as the Auryxia intangible asset impairment in the second quarter of 2020 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 up to $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, and an additional amount of $8.0 million, or the Tranche B Loan, was drawn on April 19, 2024. An additional $10.0 million is available under the Term Loan Facility in a single draw through December 31, 2024, 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 Tranche C Loan is subject to various conditions precedent, including (x) the absence of any defaults or events of default and our continued compliance with the terms and provisions of the BlackRock Credit Agreement and (y) 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 Term Loan Facility had an initial maturity date of March 31, 2025, which was automatically extended to January 29, 2028, or the Maturity Date, since we received FDA approval for Vafseo prior to June 30, 2024.

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, 2025 (which was extended to December 31, 2026 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 commercially launch 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 execute and/or maintain contracts with dialysis organizations and other customers for the sale of Auryxia and Vafseo on favorable terms, in a timely manner, 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.

Given the concentration of dialysis clinics in large networks, with DaVita, Inc., or DaVita, and Fresenius Kidney Care Group LLC, 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. If dialysis organizations do not add Vafseo to their medical protocols in a timely manner, or at all, our operations could be materially adversely affected.

If oral-only phosphate binders, including Auryxia, are included in the end-stage renal disease, or ESRD, Prospective Payment System, or PPS, bundle payment, beginning in January 2025 as we currently anticipate, it will take time for dialysis organizations to implement internal mechanisms to dispense phosphate binders which could divert their attention from focusing on other therapeutic areas such as anemia management, which in turn could negatively impact the market for phosphate binders, including Auryxia. 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.

In addition, we currently have exclusive rights under a series of patents and patent applications to commercialize Auryxia in the U.S. that protect us from generic drug competition until March 2025. Following LoE, in March 2025, the number of generic versions of Auryxia that enter the market will affect our revenue from Auryxia. We believe the Centers for Medicare & Medicaid Services', or CMS, decision to include phosphate binders in the dialysis bundle could potentially lead to higher sales of Auryxia after the LoE date than in other LoE scenarios, and plan to work with dialysis organizations, other customers and providers to seek to continue the use of Auryxia beyond LoE. However, our ability to continue to generate revenue from sales of Auryxia following LoE will depend on many factors, including our ability to successfully contract with dialysis organizations, the timing and number of generics that enter the market and other products on the market that compete with Auryxia. If we

are unable to maintain sales of Auryxia following LoE, our results of operations and financial condition will be materially harmed.

We believe our revenue growth has been negatively impacted by the recent 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 recent COVID-19 pandemic on future revenues and revenue growth, the recent COVID-19 pandemic and the ongoing impacts from the recent 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 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. 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;
- the availability of discounts and rebates to dialysis organizations to facilitate access for patients;
- the safety and efficacy of the product, as demonstrated in clinical trials and in the post-marketing setting;
- 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;
- use at dialysis organizations and their willingness to include Auryxia or Vafseo in their formulary or protocols starting in 2025;
- 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;
- 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 judgement 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, our business could be harmed.

Several healthcare facilities, including DaVita, have previously restricted access for non-patients as a result of the recent COVID-19 pandemic, resulting in restricted access for certain members of our sales force. As a result, we continue to engage with some healthcare providers and other customers virtually where possible. The restrictions on our customer-facing employees' in-person interactions with healthcare providers have, and could continue to, negatively impact our access to healthcare providers and ultimately our sales, including with respect to Vafseo. Such precautionary measures have since been relaxed at certain healthcare facilities and, as a result, members of our sales force have resumed in person interactions with those customers. Nevertheless, some restrictions remain, and more restrictions may be put in place again due to a resurgence in COVID-19 cases, including those involving new variants of COVID-19, which may be more contagious and more severe than prior strains of the virus. Given this uncertain environment and the disproportionate impact of the recent COVID-19 pandemic on CKD patients, we are actively monitoring the demand in the U.S. for Auryxia and Vafseo, including the potential for further declines or changes in prescription trends and customer orders, which could have a material adverse effect on our business, results of operations, and financial condition.

If we are unable to maintain or expand, or, with respect to Vafseo, initiate, sales and marketing capabilities or enter into additional 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, which we believe that we can leverage in the U.S. for Vafseo as well, with incremental additional hires in our sales force. 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. 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 of such product candidate or distract the current sales force from promoting Auryxia. We may underestimate the size of the sales force required for a successful product launch, and we may need to expand our sales force to a greater extent or earlier than we currently plan and at a higher cost 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, especially as a result of the delay in the approval of Vafseo following receipt of the CRL; 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, depends 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. CMS, local Medicare administrative contractors, Medicare Part D plans and/or PBMs operating on behalf of Medicare Part D 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 is covered by Medicare under Part D 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. The inclusion of oral medications without injectable or intravenous equivalents such as Auryxia in the bundled payment was initially delayed by CMS until January 1, 2014, and through several subsequent legislative actions has been delayed until January 1, 2025.

Absent further legislation or regulation on this matter, beginning in January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including Auryxia and all other phosphate lowering medications, will be included in the ESRD bundle and separate Medicare payment for these drugs will no longer be available, as is the case today under Medicare Part D. ESRD facilities may nonetheless receive a Transitional Drug Add-on Payment Adjustment, or TDAPA, for new renal dialysis drugs and biological products that meet certain criteria for a period of at least two years. The TDAPA will provide 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. In July 2023, the U.S. House of Representatives introduced the Kidney Patient Access to Technologically Innovative and Essential Nephrology Treatments (PATIENT) Act (H.R. 5074), or the Patient Act, and the Senate advanced a similar bill (S. 4510), which legislation, if passed and enacted into law prior to January 1, 2025, would delay the inclusion of phosphorus lowering drugs in the bundled payment. In addition, 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 2008. In October 2024, Ardelyx filed 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. The court has not scheduled a date for oral argument on these motions and, instead, indicated that it may address these motions on the papers alone. If the Patient Act is passed and enacted into law prior to January 1, 2025 or Ardelyx is successful in its claims, oral-only phosphate lowering therapies, including Auryxia, may not be included in the ESRD bundle in 2025 or at all, which could reduce anticipated revenue for Auryxia. Even if Auryxia is included in the ESRD bundle, the TDAPA reimbursement amount for Auryxia may be lower than anticipated or revenue for sales of Auryxia could be significantly less in the TDAPA period than anticipated or than it would be if Auryxia is not bundled into the ESRD PPS, which would have an adverse impact on our revenue. 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 oral only phosphate lowering 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 addition, in September 2018, CMS decided that Auryxia would no longer be covered by Medicare for the treatment of iron deficiency anemia, or IDA, in adult patients not on dialysis, or NDD-CKD. While this decision does not impact CMS coverage for the control of serum phosphorus levels in adult patients with anemia due to CKD in patients on dialysis, or DD-CKD, or the Hyperphosphatemia Indication, it requires Part D Plan sponsors to impose prior authorization or other steps to ensure that

Auryxia is reimbursed only for the Hyperphosphatemia Indication. We decided beginning in 2022 to terminate certain Part D contracts, as patients no longer had the access benefit given the prior authorization requirement. Now patients must go through a medical exemption process, which is very similar to a prior authorization review. While we believe this had, and may continue to have, a negative impact on our overall sales volume, we believe it had a significant positive impact on our net selling price. However, if we experience additional negative impacts on our sales volume as a result of this change, it could have a negative impact on our product revenue.

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. Four distributors, Fresenius Medical Care Rx, McKesson Corporation, Cardinal Health, Inc. and Cencora, Inc., formerly known as AmerisourceBergen Drug Corporation, in the aggregate, accounted for a significant percentage of our gross revenue during the three and nine months ended September 30, 2024 and the year ended December 31, 2023. If we are not able to maintain our arrangements with these key distributors on favorable terms, on a timely basis or at all, or if there is any adverse change in one or more of these distributors' business practices or financial condition, it would adversely impact the market opportunity for Auryxia, our product revenues and operating results.

Vafseo will be included in the bundled reimbursement model for Medicare beneficiaries and, in October 2024, CMS determined that Vafseo will receive a TDAPA for at least two years starting on January 1, 2025. However, if there are updates to the TDAPA rule that decrease the basis for reimbursement or if the TDAPA is eliminated, then our profitability may be adversely affected. For example, the Medicare Payment Advisory Commission, an independent legislative branch advisory body to Congress on issues related to the Medicare program, has recommended that TDAPA not be provided to newly approved drug products considered to fall within "functional categories" for which costs are already accounted for in the bundled reimbursement model, such as for anemia management drugs.

Further, Vafseo will be included in the fixed reimbursement model for a bundle of dialysis services, which will require us to enter into contracts to supply Vafseo to specific dialysis providers, instead of through distributors, which we believe could be challenging. The dialysis market is unique and is dominated by two providers: DaVita and Fresenius Medical Care, which account for a vast majority of the dialysis population in the U.S. Under the Vifor Termination Agreement, we have regained our rights 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 group purchasing organizations, and to certain non-retail specialty pharmacies in the U.S. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, to our unaudited condensed consolidated financial statements in Part I, Item 1. Financial Statements of this Form 10-Q for additional information regarding the Vifor Termination Agreement. If we are not able to enter into supply agreements with dialysis organizations for the sale of Vafseo on favorable terms, in a timely matter or at all, our business may be materially harmed.

Similar to how payor coverage may affect the sales of a product, formulary status within dialysis organizations may affect what products are prescribed within that specific organization. Therefore, if a product is not on a formulary, the prescribers within that organization may be less likely to prescribe that product or may have a difficult time prescribing that product, resulting in less sales. Further, one dialysis organization's determination to add a product to their formulary does not assure that other dialysis organizations will also add the product to theirs. There is always a risk a dialysis organization will not contract with a drug manufacturer for a specific product, resulting in that product not being on that organization's formulary. If any dialysis organization does not add Vafseo to 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 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 our ability to obtain reimbursement in another jurisdiction. In addition, we plan to rely on a partner 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 anemia due to CKD in DD-CKD patients. 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 Vafseo in certain countries in Europe and is working on securing pricing and reimbursement for Vafseo in 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 commercially launch 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.

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

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

have product candidates in various stages of preclinical or clinical development to treat diseases and complications of the diseases for which we are marketing Auryxia. In addition, we and our licensors, Panion & BF Biotech, Inc., or Panion, and, as applicable, Dr. Hsu, entered into settlement agreements with all but one 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 in March 2025 (subject to FDA approval), or earlier under certain circumstances customary for settlement agreements of this nature. While we expect that the availability of 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.

Drugs that may compete with Vafseo include Epogen® (epoetin alfa) and Aranesp® (darbepoetin alfa), both commercialized by Amgen, Procrit® (epoetin alfa) and Eprex® (epoetin alfa), commercialized by Johnson & Johnson in the U.S. and Europe, respectively, 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., 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 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. For example, FibroGen filed an NDA for its product candidate, roxadustat, with the FDA, to which the FDA issued a complete response letter indicating the FDA will not approve the NDA in its present form and requested that an additional clinical trial for roxadustat be conducted prior to resubmission of the NDA or additional response to the FDA's complete response letter. In Europe however, roxadustat is approved for the treatment of anemia in patients with CKD. If roxadustat is approved by the FDA, then roxadustat will compete with Vafseo.

Furthermore, certain companies are developing potential new therapies for 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 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 if we are able to commercially launch 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. 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.

In 2023, the marketing authorization for Vafseo was granted by the EMA, the United Kingdom Medicines and Healthcare Products Regulatory Agency, the Swiss Agency for Therapeutic Products, or Swissmedic, and the Australian Therapeutic Goods Administration, or TGA. 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, Swissmedic and Australia to Medice. 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 exchange rates between the Japanese yen 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 the Japanese yen depreciates 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 label expansion for Vafseo or 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 INNO2VATE program; however, while Vafseo achieved the primary and key secondary efficacy endpoint in each of the two PRO2TECT studies, the PRO2TECT 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 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 and the commercialization of Vafseo was delayed, which had and could continue to have an adverse effect on our business.

We have several lifecycle management and label expansion opportunities currently under evaluation for Vafseo, one of which is the potential for alternative dosing, and another of which is label expansion for the treatment of adult patients with NDD-CKD. However, we will be required to complete additional clinical trials before seeking approval for label expansion for the treatment of adult patients with NDD-CKD 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 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. 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 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 change or expand 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 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 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. 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 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. 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.

Conducting clinical trials outside of the U.S., as we have done historically and as we may decide to do in the future, presents additional risks and complexities and, if we decide to conduct a clinical trial outside of the U.S. in the future, we may not complete such trials successfully, in a timely manner, or at all, which could affect our ability to obtain regulatory approvals.

Our ability to successfully initiate, enroll and complete a clinical trial in any country outside of the U.S. is subject to numerous additional risks unique to conducting business in jurisdictions outside the U.S., including:

- difficulty in establishing or managing relationships with qualified CROs, physicians and clinical trial sites;
- difficulty in complying with different local standards for the conduct of clinical trials;
- difficulty in complying with various and complex import laws and regulations when shipping drug to certain countries; and
- the potential burden of complying with a variety of laws, medical standards and regulatory requirements, including the regulation of pharmaceutical and biotechnology products and treatments.

Data obtained from studies conducted in the U.S. may not be accepted by the EMA, the PMDA and other regulatory authorities outside of the U.S. Also, certain jurisdictions require data from studies conducted in their country in order to obtain approval in that country. Further, when a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP, including undergoing review and receiving approval by an independent ethics committee, and seeking and receiving informed consent from subjects. Thus, to the extent that we rely on data from foreign clinical trials that are not the subject of an IND but are used to support of an NDA, there is a risk that FDA may not review such data in connection with its review of the NDA.

If we or our collaboration partners have difficulty conducting future clinical trials in jurisdictions outside the U.S. as planned, we may need to delay, limit or terminate such clinical trials, any of which could have an adverse effect on our business.

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;
- 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; and
- 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 the projected patient populations that will be treated with 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 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 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, as 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 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 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 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 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 several lifecycle management and label expansion opportunities currently under evaluation for Vafseo, one of which is the potential for alternative dosing, and another of which is 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.

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 and the application is still under review.

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.

Changes in or the enactment of additional statutes, promulgation of regulations or issuance of guidance during preclinical or clinical development, or comparable changes in the regulatory review process for each submitted product application, may cause delays in the approval or rejection of an application. For example, in December 2022, with the passage of 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. 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.

Further, on January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 became applicable in the EU and replaced the prior Clinical Trials Directive 2001/20/EC. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the EU. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one EU Member State will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU Member States and the public. We have not previously secured authorization to conduct clinical studies in the EU pursuant to this new regulation and, accordingly, there is a risk that we may be delayed in commencing such studies.

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 the 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 due to the recent COVID-19 pandemic or otherwise;
- 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.

Finally, 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. 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.

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 is ongoing and actively recruiting patients, but the final report for the trial was due in April 2024, so the trial is considered delayed. With regard to Auryxia for the treatment of IDA in adult NDD-CKD patients, or IDA Indication, we initially committed to completing the post-approval pediatric study and submitting a final report to the FDA by January 2023. We did not meet a required milestone relating to this post-approval pediatric study of Auryxia in a timely manner and received a notification from the FDA. Subsequently, the FDA agreed to extend the pediatric clinical trial timelines for the IDA Indication and required that the final report be submitted in August 2024. We subsequently communicated to the FDA that we would be delaying the start of the clinical trial in the IDA Indication while we work to produce smaller size tablets. In response, the FDA issued a partial clinical hold until we manufacture the smaller tablets and provide the FDA with relevant information regarding the smaller sized tablets for review. The FDA lifted the partial clinical hold in June 2022, and we continued to conduct feasibility, however, we have not commenced start-up of this study. In February 2024, we requested an extension for the submission of the final report and such request was denied by the FDA in April 2024. In October 2024, we received a letter from the FDA regarding our non-compliance with PREA due to our failure to complete the IDA post-approval pediatric study, and we submitted our response, including a proposal to waive the PMR with regard to the IDA Indication, to the FDA on November 1, 2024. If the FDA denies our waiver of the PMR with regard to the IDA Indication, or we are unable to complete these studies successfully or have further delays in completing these studies, we will need to inform the FDA, have

further discussions and, if the FDA finds that we failed to comply with pediatric study requirements, 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. 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, 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 involves substantial costs and requires 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.

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 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 FDA acted within its statutory authority under the Administrative Procedure Act, or 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. 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.

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 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 the IDA Indication, 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 October 2023, the FDA published draft guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. 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 data 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.

In addition, if a company's activities are determined to have violated the federal Anti-Kickback Statute, this can 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, regulatory authorities outside the U.S. and other government agencies caused by global health concerns or funding shortages could prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

The ability of the FDA and regulatory authorities outside the U.S. to review and approve new products can be affected by a variety of factors, including global health concerns, government budget and funding levels, staffing shortages, statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's or other regulatory authorities' ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result of certain of these factors. In addition, government funding of other government agencies that fund R&D activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may increase the time necessary for new drugs to be reviewed or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our, or our collaboration partners', regulatory submissions, which could have a material adverse effect on our business.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 already 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 in order 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.

New 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 2023 legislative sessions that will go into effect in 2025 and beyond, including New Hampshire and New Jersey. Other states will be considering these 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, Washington state passed a health privacy law in 2023 that regulates the collection and sharing of health information, 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 additional states (including Vermont) are considering such legislation for 2024. 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.

A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with current and any future federal and state laws regarding privacy and security of personal information could expose us to fines and penalties. We also face a threat of potential consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and 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.

In the U.S. and some foreign jurisdictions, there have been a number of 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.

For example, the former administration issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, CMS issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

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 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. Florida now 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.

Further, on July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The Order directs HHS to create a plan within 45 days to combat "excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging." On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

On August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The new 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.

As an oral drug, Auryxia is covered by Medicare under Part D. 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. The inclusion of oral medications without injectable or intravenous equivalents such as Auryxia in the bundled payment was initially delayed by CMS until January 1, 2014, and through several subsequent legislative actions has been delayed until January 1, 2025.

Absent further legislation or regulation on this matter, beginning in January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including Auryxia and all other phosphate lowering medications, will be included in the ESRD bundle and separate Medicare payment for these drugs will no longer be available, as is the case today under Medicare Part D. ESRD facilities may nonetheless receive a TDAPA for new renal dialysis drugs and biological products that meet certain criteria for a period of at least two years. The TDAPA will provide separate payment based on the drug's ASP that will be in addition to the base rate in order to facilitate the adoption of innovative therapies. In July 2023, the U.S. House of Representatives introduced the Patient Act and the Senate advanced a similar bill, which legislation, if passed and enacted into law prior to January 1, 2025, would delay the inclusion of phosphorus lowering drugs in the bundled payment. In addition, 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 2008. In October 2024, Ardelyx filed 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. The court has not scheduled a date for oral argument on these motions and, instead, indicated that it may address these motions on the papers alone. If the Patient Act is passed and enacted into law prior to January 1, 2025 or Ardelyx is successful in its claims, oral-only phosphate lowering therapies, including Auryxia, may not be included in the ESRD bundle in 2025 or at all, which could reduce anticipated revenue for Auryxia. Even if Auryxia is included in the ESRD bundle, the TDAPA reimbursement amount for Auryxia may be lower than anticipated or revenue for sales of Auryxia could be significantly less in the TDAPA period than anticipated or than it would be if Auryxia is not bundled into the ESRD PPS, which would have an adverse impact on our revenue. 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 oral only phosphate lowering 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 sell Auryxia at a profit.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. 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. On October 2, 2024, in final guidance, CMS indicated that it will announce the selection of up to 15 additional drugs covered by Part D for the second cycle of negotiations by February 1, 2025. 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.

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 new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

On June 6, 2023, Merck & Co. Inc. filed a lawsuit against HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, 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 and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. HHS has generally won the substantive disputes in these cases, and various federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. Certain of these cases are now on appeal and oral arguments were held on October 30, 2024. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results. Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

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 addition, 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, a number of 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 a number of 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, former 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 in order 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, Riona and Vafseo and 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 sublicensed the rights to commercialize Riona to JT and Torii in Japan. We also entered into a collaboration agreement with MTPC to develop and commercialize Vafseo in Japan and certain other Asian countries. In addition, we granted to Averoa an exclusive license to develop and commercialize ferric citrate in the Averoa Territory. Furthermore, in May 2023, we entered into a 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. We may form or seek other strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our and our partners' commercialization efforts with respect to Auryxia, Riona, Vafseo and any other product candidates. 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 with them, 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. For example, 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 the 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.

In addition, 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, 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, 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 for the development and commercialization of Auryxia, Vafseo or our 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, including wholesale distributors and certain specialty pharmacy providers, and we will utilize third parties for the commercial distribution of Vafseo. 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 each of Auryxia drug substance and drug product and Vafseo drug substance and drug product, and alternate sources of supply may not be readily available. We have also engaged Cardinal Health, Inc. as the exclusive third-party logistics distribution agent for commercial sales of Auryxia. 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;
- we are unsuccessful in validating new sites;
- our commercial supply arrangements for Auryxia or Vafseo are terminated;
- any of our third party manufacturers are unable to fulfill the terms of their agreements with us due to technical issues, natural disasters or other reasons, including with respect to quality and quantity, or are unable or unwilling to continue to manufacture 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 catastrophic events, including pandemics, terrorist attacks, wars or other armed conflicts, geopolitical tensions 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 commercialization of Auryxia and/or Vafseo or may experience delays in the development of our products or product candidates, which could materially and adversely impact our business and results of operation. For example, one of our manufacturers has notified us that it will be discontinuing operations at one site at a future date and then we will only be able to manufacture at their other site. In some cases, there may be a limited number of qualified replacement manufacturers, or the technical skills or equipment required to manufacture a product or product candidate may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party, or a feasible alternative may not exist. These factors would increase our reliance on our current manufacturers or require us to obtain necessary regulatory approvals and licenses in order to have another third party manufacture Auryxia or Vafseo. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays and costs associated with the qualification of a new manufacturer and validation of manufacturing processes would negatively affect our ability to supply clinical trials, obtain and maintain marketing approval, or commercialize or satisfy patient demand for Auryxia and Vafseo, where approved, in a timely manner, within budget, or at all.

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 and technology transfer and 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, a production-related issue resulted in an interruption in the supply of Auryxia in the third and fourth quarters of 2016. This supply interruption negatively impacted our revenues in 2016. This supply interruption was resolved, and we have taken and continue to take actions designed to prevent future interruptions in the supply of Auryxia. However, we had experienced issues in manufacturing Auryxia, 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. In addition, before we can manufacture product at a new site, we must 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 quality or quantity based, for Auryxia or Vafseo where approved, would 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 regulatory authorities. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation, which occur in addition to our own quality assurance releases. 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, and the facilities and processes used by our third party manufacturers to manufacture Vafseo will be inspected by the FDA, the EMA and other regulatory authorities prior to or after we submit our marketing applications. Although we have general visibility 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, during the year ended December 31, 2022, we had higher write-downs to inventory reserves related to Auryxia drug substance that will not be forward processed into drug product. If we have additional write-downs to inventory reserves in the future, it could negatively impact our ability to supply Auryxia, 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 or 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 Japan, 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. These and 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 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.

We currently rely on third parties in China for the manufacture of raw materials, drug substance and drug product for the commercial supply of Vafseo and for early-stage research services. Our commercialization of Vafseo, or our development of our product candidates could be delayed, prevented or impaired if there are disruptions or delays in obtaining these products or services.

The manufacturing of our drug substance and drug product for commercial supply of Vafseo takes place in China through a third-party manufacturer. Currently, we rely on a third-party contract manufacturer in China, STA Pharmaceutical Hong Kong Limited, a subsidiary of WuXi AppTec, or WuXi STA, for the manufacture of Vafseo drug substance and drug product for commercial use and will likely continue to rely on foreign CMOs in the future. 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. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs or to perform research services, whether as a result of changes in the regulatory framework in the U.S. or China, trade war, political unrest or unstable economic conditions in China, or other causes could impair our ability to commercialize Vafseo or to develop our product candidates.

For example, in January 2024, the U.S. House of Representatives introduced the BIOSECURE Act (H.R. 7085) and the Senate advanced a substantially similar bill (S.3558), which legislation, if passed and enacted into law, would have the potential to restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products related to biological materials from, or otherwise collaborate with, certain Chinese biotechnology companies "of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. It is possible some of our contractual counterparties, including WuXi STA, could be impacted by this legislation, which, depending on the scope of the final legislation if enacted, could adversely affect our business.

The biopharmaceutical industry in China is strictly regulated by the Chinese government. Changes to Chinese regulations or government policies affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our service providers in China, which could have an adverse effect on our business, financial condition, results of operations and prospects. Evolving changes in China's public health, economic, political, and social conditions and the uncertainty around China's relationship with other governments, such as the United States and the UK, could also negatively impact our ability to manufacture Vafseo or other product candidates or have an adverse effect on our ability to secure government funding, which could adversely affect our financial condition and cause us to delay the commercialization of Vafseo or other product candidates.

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 Vafseo and other 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 Vafseo or any other future 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). 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.

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 Orange Book-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 allow such ANDA filers to market a generic version of Auryxia in the U.S. beginning on 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. 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 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 an opposition proceeding in the Indian Patent Office. The proceeding may be ongoing for a number of years and may involve substantial expense and diversion of employee resources from 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 or Vafseo.

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 members of our commercial organization. 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. In addition, uncertainty related to the outcome of regulatory decisions, could increase attrition. Losing members of management and other key personnel subjects 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 any product candidates. Our future financial performance and our ability to develop and commercialize Auryxia and Vafseo 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. Over the last several years, the challenges in recruiting and retaining employees across the pharmaceutical and biotechnology industries have increased substantially due to current industry job market dynamics.

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.

Our cost savings plan and the associated workforce reductions implemented in April, May and November 2022 may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

Following receipt of the CRL we implemented a reduction in workforce in April and May 2022 by approximately 42% across all areas of our Company, 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. The reductions in workforce reflected our determination to refocus our strategic priorities around our commercial product, Auryxia, and our development portfolio, and were steps in a broader cost savings plan to significantly reduce our operating expense profile. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. We recorded a restructuring charge of approximately $0.2 million and $15.9 million in the years ended December 31, 2023 and 2022, respectively, primarily related to contractual termination benefits including severance, non-cash stock-based compensation expense, healthcare and related benefits. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. We also cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future. Furthermore, our cost savings plan may be disruptive to our operations, including our commercialization of Auryxia and Vafseo, which could affect our ability to generate product revenue. In addition, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or disruptions in our day-to-day operations. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, manufacturing and sales and marketing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully commercializing Auryxia and Vafseo, and from successfully developing and commercializing our product candidates in the future. We will need to hire additional employees to support the commercialization of Vafseo in the U.S., and if we are unsuccessful or delayed in doing so, the potential launch of Vafseo could be delayed.

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 or will be 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, Auryxia in Europe, Vafseo in Japan, Europe, the U.S. and other territories where it is approved for commercial and clinical use to MTPC, Medice and Averoa, 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 where approved, and to compete effectively 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. For example, we recently transitioned to a new enterprise resource planning system and if we encounter any difficulties or issues with the new system it could affect our ability to close our books and complete our financial reporting in a timely manner. 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, we may need to further 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, 2023 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 2023 Form 10-K, we identified a material weakness in our internal control over financial reporting as of December 31, 2023. 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. Specifically, our management concluded that we did not design and maintain effective controls over the completeness and accuracy of accounting for inventory and inventory related transactions, including inventory reconciliations, calculation of overheads, presentation of inventory in our balance sheet between short-term and long-term and our liabilities related to the calculation of firm purchase commitments. 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, including (i) implementing and documenting new processes and controls to help ensure the completeness and accuracy of our inventory reconciliations, (ii) engaging additional third-party subject matter experts and accounting personnel with U.S. GAAP experience specific to inventory accounting, (iii) enhancing the accuracy of key reports used to calculate the firm purchase commitment liability and (iv) establishing effective monitoring and oversight controls to help to ensure the completeness and accuracy of inventory included in our financial statements and related disclosures. 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 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 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, 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. 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 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 or the unauthorized disclosure of confidential information.

Although we believe our collaborators, vendors and service providers, such as our CROs, take steps to manage 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 hold a marketing authorization for Vafseo from the TGA, and 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 and an intangible asset as a result of the Merger. The intangible asset has become impaired and could become further impaired in the future under certain conditions. In addition, 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, goodwill or intangible asset may significantly impact our results of operations and financial condition.

As of September 30, 2024, we had approximately $68.1 million in the aggregate of goodwill and a definite lived intangible asset from the Merger, $2.5 million of property and equipment and $9.3 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 and intangible asset. 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 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 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, including if Auryxia does not meet its current forecasted projections, additional impairment charges related to plant and equipment, right-of-use assets, goodwill or our intangible asset could be recorded in the future and additional corresponding adjustments may need to be made to the estimated useful life of the developed product rights for Auryxia, 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.

We face an inherent risk of product liability as a result of the clinical and commercial use of Auryxia and Vafseo. For example, we may be sued if Auryxia or Vafseo allegedly causes injury or is found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. 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. 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 or Vafseo;
- 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 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 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. In addition, the Tax Cuts and Jobs Act, including amendments made by the CARES Act, includes changes to U.S. federal tax rates and the rules governing net operating loss carryforwards that may significantly impact our ability to utilize our net operating losses to fully offset taxable income in the future. Future changes in our stock ownership, many of which are outside of our control, could result in an additional ownership change under Section 382. 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 net operating losses 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. Since our initial public offering in March 2014, the price of our common stock as reported on The Nasdaq Stock Market has ranged from a low of $0.24 on October 24, 2022 to a high of $31.00 on June 20, 2014. The daily closing market price for our common stock varied between a high price of $1.55 on August 26, 2024 and August 30, 2024 and a low price of $0.94 on July 5, 2024 in the three-month period ending on September 30, 2024. During that time, the price of our common stock ranged from an intra-day low of $0.91 per share to an intra-day high of $1.58 per share. 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, 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 including as a result of our reductions in workforce, 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. See Part I, Item 3. Legal Proceedings of the 2023 Form 10-K for information concerning securities class action initiated against Keryx and certain current and former directors and officers of ours and Keryx's. 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.

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 stockholders intend to sell such shares, could reduce the market price of our common stock.

As of September 30, 2024, and based on the amounts reported in the most recent filing made by BlackRock under Section 13(g) of the Exchange Act, BlackRock beneficially owned approximately 7.2% of our outstanding shares of common stock. By selling a large number of shares of common stock, BlackRock could cause the price of our common stock to decline. The shares beneficially owned by CSL Vifor 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.

In addition, 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, 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) if we drawdown the Tranche C Loan, at that time we will issue 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.

We have a significant number of shares that are subject to outstanding options and restricted stock units, and in the future we may issue additional options, restricted stock units, or other derivative securities convertible into our common stock. The exercise or vesting of any such options, restricted stock units, or other derivative 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.

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, 2024, 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, 2024, we did not have any sales of unregistered securities.

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.

None of the Company's directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as each term is defined in Item 408(c) of Regulation S-K) during the quarterly period covered by this report.

Item 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!	Termination and Settlement Agreement, dated July 10, 2024, by and between the Company and Vifor (International) Ltd. (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q (001-36352), filed on August 8, 2024).
10.2!	Amendment #1 to Agreement for the Provision of a Loan Facility, dated July 10, 2024, by and between the Company and Kreos Capital VII (UK) Limited (incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q (001-36352), filed on August 8, 2024).
10.3	Amended and Restated Open Market Sale Agreement, dated September 3, 2024, by and between the Company and Jefferies LLC (incorporated by reference to Exhibit 1.2 to the Company's Registration Statement on Form S-3 (333-281903) filed on September 3, 2024).
10.4*	Amendment #1 to License Agreement, dated August 30, 2024, by and among Akebia Therapeutics, Inc., Keryx Biopharmaceuticals, Inc. and Averoa SAS.
10.5*!	Amendment #1 to Supply Agreement, dated October 15, 2024, by and between the Company and STA Pharmaceutical Hong Kong Limited.
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 7, 2024

By: /s/ John P. Butler

John P. Butler

President and Chief Executive Officer
(Principal Executive Officer)

Date: November 7, 2024

By: /s/ Erik J. Ostrowski

Erik J. Ostrowski

Senior Vice President, Chief Financial Officer, Chief Business Officer and Treasurer
(Principal Financial Officer)

Date: November 7, 2024

By: /s/ Richard C. Malabre

Richard C. Malabre

Senior Vice President, Chief Accounting Officer (Principal Accounting Officer)

Exhibit 10.4

AMENDMENT #1 TO LICENSE AGREEMENT

This Amendment #1 (the "**Amendment**") to the License Agreement (the "**License Agreement**") dated December 22, 2022 by and between **Akebia Therapeutics, Inc.,** a Delaware corporation with its principal place of business at 245 First Street, Cambridge, MA 02142 and its Subsidiary, **Keryx Biopharmaceuticals, Inc.** ("**Keryx,**" and collectively, "**Akebia**"), and **Averoa SAS,** a French corporation, having a place of business at 11 avenue Paul Verlaine, 38100 Grenoble, France, ("**Licensee**") is effective as of **August 30, 2024** (the "**Amendment Effective Date**"). Akebia and Licensee are each referenced individually herein as a "Party" and together as the "Parties".

WHEREAS, the Parties desire to amend the License Agreement to expand the definition of the Territory of the License Agreement to include the State of Israel and certain other eastern European countries as set forth below in this Amendment;

NOW, THEREFORE the Parties agree as follows:

1. Section 1.128 (Definition of Territory) of the Agreement is hereby deleted in its entirety and replaced with the following:

   1.128. "**Territory**" means the European Economic Area, Turkey, Switzerland, the United Kingdom, Serbia, Albania, Bosnia-Herzegovina, Kosovo, Montenegro, North Macedonia, Belarus, Moldova, and Israel.

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

3. Except as otherwise provided herein, all provisions of the Agreement, as amended shall remain in full force and effect.

4. This Amendment #1 may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Counterparts may be delivered via electronic mail, including Adobe™ Portable Document Format (PDF) or any electronic signature complying with the U.S. Federal ESIGN Act of 2000, and any counterpart so delivered will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Amendment #1.

IN WITNESS WHEREOF, the Parties have executed this Amendment #1 to the License Agreement effective as of the Amendment Effective Date written above.

AKEBIA THERAPEUTICS, INC.	**AVEROA SAS**
By: /s/ Erik Ostrowski	By: /s/ Luc-André GRANIER
Print Name: Erik Ostrowski	Print Name: Luc-André GRANIER
Title: SVP, Chief Financial Officer & Chief Business Officer	Title: CEO

Exhibit 10.5

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

AMENDMENT #1 TO SUPPLY AGREEMENT

This Amendment #1 (the "Amendment") to the Supply Agreement dated February 10, 2021, by and between **Akebia Therapeutics, Inc.** ("Akebia") and **STA Pharmaceutical Hong Kong Limited** ("STA") is effective as of October 15, 2024 (the "Amendment Effective Date"). Akebia and STA are each referenced individually herein as a "Party" and together as the "Parties".

WITNESSETH:

WHEREAS, STA and Akebia entered into a Supply Agreement dated February 10, 2021 (the "Supply Agreement") under which STA manufactures Product for purchase by Akebia; and

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

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, STA and Akebia hereby agree to amend the Supply Agreement as follows:

1. Section 3.2 is hereby deleted in its entirety and replaced with the following:

   3.2. Throughout the Term, in accordance with the Minimum Order Quantity and Purchase Order Lead Time, Akebia shall submit to STA a Purchase Order to facilitate payment to STA which shall be consistent with the Rolling Forecast. Upon provision of a Purchase Order by Akebia to STA, STA shall provide acceptance of such Purchase Order within [**] upon receipt of the same. Failure by STA to provide notice of any acceptance or rejection of any such Purchase Order will be considered acceptance of the Purchase Order. STA agrees that it shall not [**] fail to accept any Purchase Order provided by Akebia. Should Akebia issue a Purchase Order [**] *as set forth in Exhibit A*. If there is a contradiction between a provision of this Agreement and a Purchase Order, then the provision in this Agreement will take precedence.

2. Section 3.3 of the Supply Agreement is hereby deleted in its entirety and replaced with the following:

   3.3. Events of [**] any product containing the Product in a market (e.g. delay in or withdrawal of market approval from regulatory agencies, etc.) which then [**] purchasing an amount of Product corresponding to an accepted Purchase Order, shall [**] the Parties. *In such event, Akebia shall pay for any Services already performed, any expenses already incurred or irrevocably committed [**] in connection with the cancelled or delayed Purchase Order; provided, however, that STA should exercise its commercially reasonable efforts to use the Components purchased by STA for the cancelled or delayed Purchase Order in any open Purchase Orders.*

3. Section 7.2 of the Supply Agreement is hereby deleted in its entirety and replaced with the following:

7.2. 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*.

4. Section 7.4 of the Supply Agreement is hereby deleted in its entirety and replaced with the following:

7.4 Storage. Prior to delivery, all Product at the Facility will be stored in a clean, secured, segregated area. 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 by the Parties. *Upon placement of any Product into storage at STA's Facility (including any free storage period), the Products shall be deemed to have been delivered and title, control and risk of loss thereto shall transfer to Akebia. The Parties shall use their good faith efforts to enter into a storage agreement with regards to any stored Product.*

5. Section 14.1 of the Supply Agreement is hereby deleted in its entirety and replaced with the following:

14.1 Term. *Subject to Section 14.2, the Term of this Agreement shall expire on January 1, 2032. Notwithstanding any termination as described in Sections 14.2, 14.3, 14.4 or 14.5, it is the intent of the Parties that any renewal or extension of the Term will be agreed to in writing between the Parties, no later than eighteen (18) calendar months prior to its expiration.*

6. Exhibit A – Product Price, Lead Time and Minimum Order Quantity of the Supply Agreement is deleted in its entirety and replaced by the new Exhibit A attached hereto.

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

8. All terms and conditions of the Supply Agreement not expressly amended by this Amendment remain in full force and effect.

9. 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.

Signature Page to Follow

IN WITNESS WHEREOF, this Amendment has been executed by the parties hereto through their duly authorized officers on the date(s) set forth below.

AKEBIA THERAPEUTICS, INC.

By: /s/ Kim Garko

Print Name: Kim Garko

Title: SVP, CTO

Date: October 15, 2024

STA PHARMACEUTICAL HONG KONG LIMITED

By: /s/ Jinling Chen

Print Name: Jinling Chen

Title: SVP and Head of Pharmaceutical Development and Manufacturing Services, STA

Date: September 27, 2024

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 7, 2024

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 7, 2024

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, 2024 (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 7, 2024

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

Date: November 7, 2024

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