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, 2026

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.)
180 Third Avenue, Floor 2 Waltham, MA	**02451**
(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.

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

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

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

The number of shares outstanding of the issuer's common stock as of November 2, 2026 was 277,663,875.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our plans with respect to the timing, investment and associated activities involved in the commercialization of Vafseo® (vadadustat) or any current or future product candidate, as well as potential growth opportunities and our ability to execute thereon, including any potential label expansion opportunities;
- our ability to maintain contracts with dialysis organizations and other customers, including specialty distributors, for the sale of Auryxia® (ferric citrate) and Vafseo in the U.S., including for the post-TDAPA period;
- the potential therapeutic benefits, safety profile, and effectiveness of Vafseo and our product candidates;
- our pipeline and portfolio, including the initiation, timing, progress, results and market potential of our research and development programs, including with respect to ebribafusp (AKB-097), praliciguat and AKB-9090;
- our expectations, projections and estimates regarding our capital requirements, our ability to refinance our existing debt, 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;
- the timing and number of additional generic versions of Auryxia that enter the market following the loss of exclusivity for Auryxia that occurred in March 2025, the amount of generic product available to supply the market, the pricing of generic versions of Auryxia, and the impact of the loss of exclusivity on the product revenue from Auryxia, including the impact on the volume of Auryxia sales;
- the potential indications, demand and market opportunity, potential and acceptance of Auryxia, Vafseo, ebribafusp, praliciguat and our other product candidates, including the size of eligible patient populations and total market size;
- the potential therapeutic applications of the hypoxia inducible factor pathway;
- the entry into therapeutic modalities, such as biologics, that differ significantly from our existing small-molecule expertise, potentially requiring the recruitment of personnel with new technical, regulatory, manufacturing, and commercialization capabilities;
- our competitive position, including estimates, developments and projections relating to our competitors and their products and product candidates, and our industry;
- delivering value broadly to the kidney community, as well as others who may benefit from our medicines, will result in delivering value for stockholders;
- our manufacturing, supply and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences;
- estimates, beliefs and judgments related to the valuation of goodwill, debt and other assets and liabilities, including classification of expenses, assets and liabilities, our impairment analyses and our methodology and assumptions regarding fair value measurements;
- the timing of the availability and disclosure of clinical trial data and results;
- the designs of our studies, and the type of information and data expected from our studies and the expected benefits thereof;
- our and our collaborators' strategy, plans and expectations with respect to the development, manufacturing, supply, commercialization, 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 Vafseo and our ability to complete or otherwise satisfy post-marketing requirements with respect thereto;

- our ability to negotiate, secure and maintain adequate pricing, coverage and reimbursement terms and processes for the post-TDAPA period on a timely basis, or at all, with third-party payors for Auryxia and Vafseo;
- the timing of initiation, enrollment and progress of our clinical trials and plans to conduct preclinical studies and clinical trials in the future;
- the timing and amounts of payments from or to our collaborators and licensees, and the anticipated arrangements and benefits under our collaboration and license agreements, including with respect to milestones and royalties;
- our intellectual property position, including our expectations regarding our ability to obtain and maintain intellectual property protection for our products and product candidates, 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 our approved products and product candidates;
- our ability to maintain adequate inventory levels of Auryxia, Vafseo, ebribafusp, praliciguat and AKB-9090 and any other product candidates to fulfill our contractual obligations with customers and supply our current and future clinical trials;
- 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, commercial strategy, and strategic plans for our business, product candidates and technology, and business development opportunities including potential collaborations, alliances, mergers, acquisitions or licensing of assets;
- additional costs we may incur as we expand our development activities or other operating expenses, including additional costs related to Auryxia, Vafseo, ebribafusp, praliciguat and AKB-9090, and selling, general and administrative expenses; and
- the impact of global economic developments and geopolitical events on our business, operations, strategies and goals, including the imposition of new or revised trade tariffs.

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

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

RISK FACTORS SUMMARY

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

- We have incurred significant losses since our inception, and anticipate that we will continue to incur losses and cannot guarantee when, if ever, we will become and remain profitable.
- We will 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.
- Our obligations, requirements and restrictions in connection with the BlackRock Credit Agreement could adversely affect our financial condition and restrict our operations.
- If we fail to regain compliance 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.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our products and product candidates on unfavorable terms to us.
- We may not be successful in our efforts to identify, acquire, in-license, discover, develop and commercialize additional products or product candidates or our decisions to prioritize the development of certain product candidates over others may not be successful, which could impair our ability to grow.
- We may engage in strategic transactions to acquire assets, businesses, or rights to products, product candidates or technologies or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense.
- Our Royalty Interest Acquisition Agreement contains various covenants and other provisions, which, if violated, could materially adversely affect our financial condition.
- Our business is substantially dependent on the commercial success of Auryxia and Vafseo. If we are unable to continue to successfully commercialize Auryxia and Vafseo, including maintaining contracts with third parties, our results of operations and financial condition will be materially harmed.
- Our, or our partners', failure to obtain or maintain adequate coverage, pricing and reimbursement for Auryxia or Vafseo after the TDAPA period in the United States, or U.S., or for Auryxia and Vafseo outside the U.S., or for 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 our products, and development 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.
- 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.
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent the completion of clinical trials of our products or product candidates, including those that may be in-licensed or acquired.
- 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 current or future product candidates or for any potential label expansion for Vafseo that we may pursue, or we or our collaboration partners may experience significant delays in obtaining required regulatory approvals, which would delay our or their ability to commercialize our products and product candidates, which would materially impair our ability to generate revenue.
- We may not be able to obtain orphan drug exclusivity for praliciguat or any potential future product candidates that we may develop, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

- 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, including applicable "off-label" promotion, anti-kickback, fraud and abuse, and other healthcare laws and regulations, 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.
- Disruptions at the FDA and other government agencies from funding cuts, personnel losses, regulatory reform, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development program and develop and secure approval of our product candidates in a timely manner, which would negatively impact our business.
- Legislative and regulatory healthcare reform may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain for any products that are approved in the U.S. or foreign jurisdictions.
- We depend on collaborations with third parties for the development and commercialization of Auryxia, an authorized generic version of Auryxia, Riona and Vafseo. If these collaborations are not successful or if our collaborators terminate their agreements with us, we may not be able to capitalize on the market potential of Auryxia, Riona and Vafseo, and our business could be materially harmed.
- We rely upon third parties to conduct our clinical trials and certain of our preclinical studies. If they do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain or maintain marketing approval for Auryxia, Vafseo or any of our product candidates, and our business could be substantially harmed.
- Manufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our ebribafusp development program or other product candidates.
- Changes in and uncertainty surrounding U.S. trade policy on tariffs could have a material adverse impact on our business, financial condition and results of operations.
- Changes in the geopolitical environment, including U.S. and international trade policies, particularly with respect to China, Europe or Canada, may adversely impact our business and operating results.
- 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.
- 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 limit Auryxia sales and would likely limit Vafseo sales, either of which would have an adverse impact on our business and results of operations.
- Litigation and administrative proceedings, including third-party claims of intellectual property infringement and opposition/invalidation proceedings against third-party patents, may be costly and time consuming and may delay or harm our drug discovery, development and commercialization efforts.
- Our stock price has been and may continue to be volatile, which could result in substantial losses for holders or future purchasers of our common stock and lawsuits against us and our officers and directors and could result in substantial costs and divert management's attention.

Akebia Therapeutics, Inc.
Form 10-Q
For the Quarter Ended September 30, 2026

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In this Quarterly Report on Form 10-Q, unless otherwise stated or the context otherwise requires, references to "Akebia," "we," "us," "our," "the Company," "our Company" and similar references refer to Akebia Therapeutics, Inc. and, where appropriate, its consolidated subsidiaries.

AURYXIA®, AKEBIA Therapeutics®, Vafseo® and their associated logos are trademarks of Akebia and/or its affiliates. All other trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. Solely for convenience, trademarks, trade names, and service marks referred to in this Quarterly Report on Form 10-Q may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. We do not intend our use or display of other companies' trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other 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, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 159,254	$ 184,844
Inventories	18,702	15,610
Accounts receivable, net	36,440	47,031
Prepaid expenses and other current assets	6,389	5,470
Total current assets	220,785	252,955
Property and equipment, net	2,403	1,222
Operating right-of-use assets	9,673	3,663
Goodwill	59,044	59,044
Other long-term assets	50,222	59,681
Total assets	**$ 342,127**	**$ 376,565**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,612	$ 21,185
Accrued expenses and other current liabilities	102,440	121,716
Current portion of deferred revenue	4,958	2,681
Current portion of long-term debt	37,493	—
Working Capital Fund liability, current portion	9,846	17,356
Total current liabilities	162,349	162,938
Long-term operating lease liabilities	9,291	—
Long-term debt, net of current portion	12,777	48,250
Liability related to settlement royalties, net of current portion	65,096	54,750
Liability related to sale of future royalties, net of current portion	49,558	50,608
Working Capital Fund liability, net of current portion	20,263	22,606
Warrant liability	1,527	2,980
Other long-term liabilities	897	1,823
Total liabilities	**321,758**	**343,955**
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock $0.00001 par value; 25,000,000 shares authorized at September 30, 2026 and December 31, 2025; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock $0.00001 par value; 500,000,000 and 350,000,000 shares authorized at September 30, 2026 and December 31, 2025, respectively; 277,516,290 and 265,424,818 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	3	2
Additional paid-in capital	1,736,381	1,716,307
Accumulated other comprehensive income	6	6
Accumulated deficit	(1,716,021)	(1,683,705)
Total stockholders' equity	**20,369**	**32,610**
Total liabilities and stockholders' equity	**$ 342,127**	**$ 376,565**

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

Akebia Therapeutics, Inc.

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

(dollars in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenues				
Product revenue, net	$ 34,827	$ 56,789	$ 133,584	$ 173,041
License, collaboration and other revenue	2,076	1,977	5,991	5,533
Total revenues	36,903	58,766	139,575	178,574
Cost of goods sold				
Cost of product and other revenue	6,362	9,383	29,076	26,927
Total cost of goods sold	6,362	9,383	29,076	26,927
Operating expenses:				
Research and development	16,183	14,944	45,049	35,711
Selling, general and administrative	23,531	29,094	82,138	81,391
License	946	896	2,508	2,493
Restructuring	1,343	—	3,288	—
Total operating expenses	42,003	44,934	132,983	119,595
Income (loss) from operations	**(11,462)**	**4,449**	**(22,484)**	**32,052**
Other income (expense)				
Interest expense	(3,142)	(4,748)	(10,904)	(19,352)
Other income (expense)	(6)	(10)	(10)	175
Change in fair value of warrant liability	431	1,464	1,453	(5,361)
Income (loss) before income taxes	**(14,179)**	**1,155**	**(31,945)**	**7,514**
Income tax expense	(175)	(615)	(371)	(615)
Net income (loss)	**$ (14,354)**	**$ 540**	**$ (32,316)**	**$ 6,899**
Comprehensive income (loss)	**$ (14,354)**	**$ 540**	**$ (32,316)**	**$ 6,899**
Net income (loss) per share:				
Basic	$(0.05)	$0.00	$(0.12)	$0.03
Diluted	$(0.05)	$0.00	$(0.12)	$0.03
Weighted average shares of common stock outstanding:				
Basic	276,862,564	264,786,432	271,206,644	254,390,502
Diluted	276,862,564	274,372,722	271,206,644	262,680,943

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

(dollars in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2025	**265,424,818**	**$ 2**	**$ 1,716,307**	**$ 6**	**$ (1,683,705)**	**$ 32,610**
Proceeds from sale of stock under employee stock purchase plan	96,347	—	131	—	—	131
Exercise of options	28,424	—	20	—	—	20
Stock-based compensation expense	—	—	3,668	—	—	3,668
Restricted stock unit vesting	2,348,826	—	—	—	—	—
Net loss	—	—	—	—	(9,054)	(9,054)
Balance at March 31, 2026	**267,898,415**	**$ 2**	**$ 1,720,126**	**$ 6**	**$ (1,692,759)**	**$ 27,375**
Issuance of common stock, net of issuance costs	3,138,107	—	3,240	—	—	3,240
Exercise of options	134,550	—	85	—	—	85
Stock-based compensation expense	—	—	3,226	—	—	3,226
Restricted stock unit vesting	571,645	—	—	—	—	—
Net loss	—	—	—	—	(8,908)	(8,908)
Balance at June 30, 2026	**271,742,717**	**$ 2**	**$ 1,726,677**	**$ 6**	**$ (1,701,667)**	**$ 25,018**
Issuance of common stock, net of issuance costs	5,106,588	1	6,570	—	—	6,571
Proceeds from sale of stock under employee stock purchase plan	85,078	—	82	—	—	82
Exercise of options	400,519	—	251	—	—	251
Stock-based compensation expense	—	—	2,801	—	—	2,801
Restricted stock unit vesting	181,388	—	—	—	—	—
Net loss	—	—	—	—	(14,354)	(14,354)
Balance at September 30, 2026	**277,516,290**	**$ 3**	**$ 1,736,381**	**$ 6**	**$ (1,716,021)**	**$ 20,369**

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

Akebia Therapeutics, Inc.

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

Akebia Therapeutics, Inc.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(dollars in thousands)	Nine Months Ended September 30, 2026	2025
Operating Activities:		
Net income (loss)	$ (32,316)	$ 6,899
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	1,014	948
Impairment of fixed assets	50	—
Bad debt expense	296	1,385
Change in fair value of warrant liability	(1,453)	5,361
Non-cash royalty revenue related to sale of future royalties	(1,175)	(1,325)
Non-cash interest expense	10,279	17,056
Non-cash operating lease expense	3,955	3,381
Write-down of inventory	5,797	645
Gain on the sale of property and equipment	—	(172)
Stock-based compensation expense	9,695	8,084
Changes in operating assets and liabilities:		
Accounts receivable	10,295	(33,240)
Inventory	(4,848)	(5,707)
Prepaid expenses and other current assets	(2,618)	6,019
Other long-term assets	(671)	141
Accounts payable	(7,765)	(7,337)
Accrued expense and other current liabilities	(5,104)	34,602
Operating lease liabilities	(2,919)	(4,011)
Deferred revenue	2,277	3,881
Other long-term liabilities	(139)	253
Net cash provided by (used in) operating activities	**(15,350)**	**36,863**
Investing Activities:		
Purchases of equipment	(1,847)	(221)
Proceeds from the sale of property and equipment	—	172
Purchase of IPR&D asset	(4,900)	—
Net cash used in investing activities	**(6,747)**	**(49)**
Financing Activities:		
Proceeds from the issuance of debt and warrants	—	10,000
Payments of issuance costs related to BlackRock Credit Agreement	—	(63)
Proceeds from issuance of common stock, net of issuance costs	9,811	66,449
Proceeds from issuance of stock under employee stock purchase plan	213	230
Proceeds from the exercise of stock options	356	1,621
Repayment of WCF liability	(10,558)	—
Repayment of liability related to settlement royalties	(4,110)	—
Repayment of term debt	—	(462)
Net cash provided by (used in) financing activities	**(4,288)**	**77,775**
Increase (decrease) in cash, cash equivalents and restricted cash	(26,385)	114,589
Cash, cash equivalents and restricted cash — beginning of period	186,543	53,550
Cash, cash equivalents and restricted cash — end of period	**$ 160,158**	**$ 168,139**
Supplemental disclosures of non-cash financing and investing activities		
Purchase of IPR&D asset included in accrued expenses and other current liabilities	100	—
Cashless exercise of warrants in connection with BlackRock Credit Agreement	—	7,494
Right-of-use asset obtained in exchange for lease liabilities	9,965	—
Property and equipment included in accounts payable	398	—

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 focused on developing and commercializing innovative therapeutics.

The Company has two products approved by the Food and Drug Administration, or FDA, in the United States, or U.S. Vafseo® (vadadustat) is an oral hypoxia-inducible factor prolyl hydroxylase, or HIF-PH, inhibitor. Vafseo (vadadustat) Tablets were approved in the U.S. in March 2024 for the treatment of anemia due to chronic kidney disease, or CKD, in adults who have been receiving dialysis for at least three months. Vafseo entered the U.S. market in January 2025. Auryxia® (ferric citrate) is an orally administered medicine approved and marketed in the U.S. for two indications: (i) the control of serum phosphorus levels in adult patients with dialysis dependent chronic kidney disease, or DD-CKD, and (ii) the treatment of iron deficiency anemia, or IDA, in adult patients with non-dialysis dependent chronic kidney disease, or NDD-CKD. Auryxia lost exclusivity in the U.S. in March 2025. On March 11, 2026, Teva Pharmaceuticals USA, Inc., received approval for its Abbreviated New Drug Application for a generic version of Auryxia, which has subsequently entered the market.

Vafseo is also approved for the treatment of symptomatic anemia associated with CKD in the European Economic Area, or EEA, the United Kingdom, or the UK, Switzerland, Australia, South Korea and Taiwan in adult patients on chronic maintenance dialysis and in Japan for adult dialysis-dependent and non-dialysis patients. Vafseo is marketed and sold by the Company's collaboration partners in certain countries.

Ferric citrate is also approved in Japan, and is marketed and sold by the Company's collaboration partner, as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including DD-CKD and NDD-CKD, and for the treatment of adult patients with IDA under the trade name Riona (ferric citrate hydrate).

Since its inception, the Company has devoted most of its resources to research and development, or R&D, including its preclinical and clinical development activities, commercializing Auryxia and Vafseo and providing general and administrative support for these operations. The Company's mid-stage rare kidney disease pipeline assets, praliciguat and ebribafusp, are being evaluated to target areas of unmet need. The Company's early-stage pipeline assets include AKB-9090 and AKB-10108, which are HIF molecules. In addition, the Company continues to explore additional development opportunities to expand its pipeline and portfolio of novel therapeutics through both internal research and external innovation to leverage its fully integrated team.

As of September 30, 2026, the Company had cash and cash equivalents of $159.3 million. Based on its current operating plan, the Company believes that its cash resources and the cash the Company expects to generate from product, royalty, supply and license revenues will be sufficient to fund its current operating plan through at least twelve months from the filing of this Quarterly Report on Form 10-Q, or Form 10-Q. If the Company is unable to refinance its senior secured term loan, or the Company's operating performance deteriorates significantly from the levels expected in the Company's long-term operating plan, including if the Company does not achieve its future anticipated Vafseo revenue projections, it would have an adverse effect on the Company's liquidity and capital resources, and the Company would be required to obtain additional financing to fund its operating plan or 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, 2025, 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 February 26, 2026, or the 2025 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, 2026 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2026 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, a liability related to settlement royalties, revenues, including various rebates, returns and provisions related to product sales, inventories, classification of expenses between cost of goods sold, R&D and selling, general and administrative, long-term assets, including the Company's right-of-use assets and goodwill.

Cash, Cash Equivalents and Restricted Cash

In determining its cash, cash equivalents and restricted cash, the Company considers only those highly liquid investments, readily convertible to cash within 90 days from the date of purchase to be cash equivalents. As of September 30, 2026, cash and cash equivalents primarily included cash on hand and money market funds.

Restricted cash represents amounts required to secure the outstanding letter of credit in connection with the Company’s office and laboratory space in Waltham, Massachusetts, or the Waltham Lease, and the Company’s office and laboratory space in Cambridge, Massachusetts, or the Cambridge Lease as of September 30, 2026 and December 31, 2025, respectively. Restricted cash is included in "other long-term assets" and "prepaid expenses and other current assets" in the consolidated balance sheet as of September 30, 2026 and December 31, 2025, respectively.

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

Reconciliation of cash, cash equivalents and restricted cash (in thousands)	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 159,254	$ 184,844
Restricted cash	904	1,699
Total cash, cash equivalents and restricted cash	$ 160,158	$ 186,543

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 $3.0 million and $2.7 million as of September 30, 2026 and December 31, 2025, respectively.

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

	Nine Months Ended September 30,	
	2026	2025
Beginning balance	$ 2,691	$ 1,212
Provision for bad debts	296	1,385
Ending balance	$ 2,987	$ 2,597

Manufacturing and Distribution Risk

The Company is dependent on third-party manufacturers, logistics companies and distributors to supply products for commercial activities associated with its products and product candidates, as applicable. In particular, the Company relies and expects to continue to rely on a small number of manufacturers to supply it with its requirements for the active pharmaceutical ingredients, or APIs, and formulated drugs related to the Company's product and product candidate activities. These activities, including the commercialization of Auryxia and Vafseo, could be adversely affected by a significant interruption in the supply of APIs and formulated drugs or distribution of finished product to the market.

New Accounting Pronouncements - Recently Adopted

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*. ASU 2025-05 provides a practical expedient that all entities can use when estimating expected credit losses for current accounts receivable and current contract assets arising from transactions accounted for under ASC 606, *Revenue from Contracts with Customers*. Under this practical expedient, an entity is allowed to assume that the current conditions it has applied in determining credit loss allowances for current accounts receivable and current contract assets remain unchanged for the remaining life of those assets in developing reasonable and supportable forecasts. ASU 2025-05 is effective for fiscal years beginning after December 15, 2025, and interim reporting periods in those years. Entities that elect the practical expedient and, if applicable, make the accounting policy election, are required to apply the amendments prospectively. The adoption of this standard did not have a material effect on the Company’s consolidated financial statements and related disclosures.

New Accounting Pronouncements - Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires new tabular disclosures in the notes to consolidated financial statements, disaggregating certain cost and expense categories within relevant captions on the consolidated statements of operations and comprehensive income (loss). The prescribed cost and expense categories requiring disaggregated disclosures include purchases of inventory, employee compensation, depreciation and intangible asset amortization, along with certain other expense disclosures already required by GAAP that would need to be integrated within the new tabular disaggregated expense disclosures. Additionally, the amendments require the disclosure of total selling expenses and an entity's definition of those expenses. ASU 2024-03 will be effective for annual reporting periods in fiscal years beginning after December 15, 2026, and interim reporting periods in fiscal years beginning after

December 31, 2027. Early adoption is permitted and the amendments should be applied on a prospective basis. Retrospective application is permitted. The Company is currently reviewing the impact that the adoption of ASU 2024-03 may have on its expense disclosures in the notes to the consolidated financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software*, which removes all references to prescriptive and sequential software development stages (referred to as "project stages"). An entity will be required to start capitalizing software costs when (i) management has authorized and committed to funding the software project and (ii) it is probable that the project will be completed and the software will be used to perform the function intended (referred to as the "probable-to-complete recognition threshold"). ASU 2025-06 is effective for fiscal years beginning after December 15, 2027, and interim reporting periods within those annual periods. Early adoption is permitted as of the beginning of the annual reporting period. The Company is currently evaluating ASU 2025-06 and does not expect it to have a material effect on the Company's consolidated financial statements.

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements*, to clarify ambiguities and improve consistency across multiple topics in the ASC, or the Update. Key provisions include amendments to Topic 260, *Earnings Per Share*, or EPS, to refine the treatment of anti-dilutive shares in year-to-date diluted EPS calculations when an entity experiences a loss from continuing operations. The amendments in the Update are effective for all entities for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods. Early adoption is permitted in both interim and annual reporting periods in which financial statements have not yet been issued or made available for issuance. If an entity adopts the amendments in the Update in an interim period, it must adopt them as of the beginning of the annual reporting period that includes that interim reporting period. An entity may elect to early adopt the amendments on an issue-by-issue basis. An entity should apply the amendments in the Update (except for the amendments to Topic 260, *Earnings Per Share*) using one of the following transition methods: (i) prospectively to all transactions recognized on or after the date that the entity first applies the amendments, or (ii) retrospectively to the beginning of the earliest comparative period presented. An entity should adjust the opening balance of retained earnings (or other appropriate components of equity or net assets in the statement of financial position) as of the beginning of the earliest comparative period presented. The Company is currently evaluating ASU 2025-12 and does not expect it to have a material effect on the Company's consolidated financial statements.

3. FAIR VALUE MEASUREMENTS

The tables below present certain assets and liabilities measured at fair value categorized by the level of input used in the valuation of each asset and liability (in thousands):

	September 30, 2026			
	Level 1	Level 2	Level 3	Total Fair Value
Cash equivalents:				
Money market funds	$ 138,487	$ —	$ —	$ 138,487
Long-term liability:				
Warrant liability	$ —	$ 1,527	$ —	$ 1,527

	December 31, 2025			
	Level 1	Level 2	Level 3	Total Fair Value
Cash equivalents:				
Money market funds	$ 172,689	$ —	$ —	$ 172,689
Long-term liability:				
Warrant liability	$ —	$ 2,980	$ —	$ 2,980

Cash and cash equivalents — Money market funds included within cash and cash equivalents are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

Warrant liability – The warrant liability is classified within Level 2 of the fair value hierarchy because it is valued using inputs which are observable either directly or indirectly. The fair value was calculated using the Black-Scholes option pricing model using the following key inputs: volatility, risk-free rate, dividend yield and expected term.

The fair value of the Company's senior secured term loan facility approximates its carrying value as of September 30, 2026 and December 31, 2025, as the instrument bears interest at a variable rate that reflects current market rates. See Note 7, *Indebtedness*, for further information.

4. INVENTORIES

Inventories consists of the following (in thousands):

	September 30, 2026	December 31, 2025
Inventories, current:		
Raw materials	$ 50	$ —
Work-in-process	9,394	12,651
Finished goods	9,258	2,959
Inventories, current	$ 18,702	$ 15,610
Long-term inventories included in other long-term assets:		
Raw materials	—	50
Work-in-process	46,848	57,290
Finished goods	2,034	1,789
Inventories, long-term	$ 48,882	$ 59,129
Total inventories	$ 67,584	$ 74,739

Inventory written down as a result of excess, obsolescence, scrap or other reasons charged to cost of product and other revenue in the unaudited condensed consolidated statements of operations and comprehensive income (loss) was $0.9 million and $5.8 million during the three and nine months ended September 30, 2026, respectively, and $0.5 million and $0.6 million during the three and nine months ended September 30, 2025, respectively.

5. GOODWILL

As of each of September 30, 2026 and December 31, 2025, the Company had goodwill of $59.0 million recorded in connection with the December 2018 merger with Keryx Biopharmaceuticals, Inc., pursuant to which Keryx Biopharmaceuticals, Inc. became a wholly owned subsidiary of the Company. 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, 2026	December 31, 2025
Restricted cash	$ —	$ 1,699
Other	6,389	3,771
Total prepaid expenses and other current assets	$ 6,389	$ 5,470

Other prepaid expenses and other current assets, among other things, include capitalized implementation costs, prepaid insurance, prepaid clinical trial costs and prepaid information technology costs.

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

Description	September 30, 2026	December 31, 2025
Long-term inventories	$ 48,882	$ 59,129
Restricted cash	904	—
Other	436	552
Total other long-term assets	$ 50,222	$ 59,681

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

Accrued expenses and other current liabilities are as follows (in thousands):

Description	September 30, 2026	December 31, 2025
Product revenue allowances excluding rebates	$ 2,978	$ 7,916
Product rebates	67,856	64,674
Product return provisions, current portion	2,392	2,375
Clinical trial costs	1,214	1,188
Compensation and related benefits	7,751	11,018
Operating lease liabilities	930	3,548
Royalties due to Panion & BF Biotech, Inc.	3,832	3,924
Professional fees	1,909	1,597
Accrued manufacturing costs	2,550	1,808
Restructuring costs	1,379	—
Liability related to sale of future royalties, current portion	1,515	1,664
Settlement royalties liability, current portion	5,614	12,516
Payments due to Q32 Bio Inc.	100	5,000
Other	2,420	4,488
Total accrued expenses and other current liabilities	$ 102,440	$ 121,716

7. INDEBTEDNESS

Entry into BlackRock Loan Facility

On January 29, 2024, or the Closing Date, the Company entered into the Agreement for the Provision of a Loan Facility, or the BlackRock Credit Agreement, with Kreos Capital VII (UK) Limited, or Kreos, which are funds and accounts managed by BlackRock Inc., collectively, BlackRock, and provides for a senior secured term loan facility in the aggregate principal amount of up to $55.0 million, or the Term Loan Facility. The Term Loan Facility was available in three tranches: (i) Tranche A — $37.0 million was funded on the Closing Date; (ii) Tranche B — $8.0 million was funded on April 19, 2024, or the Tranche B Closing Date; and (iii) Tranche C — $10.0 million was funded on February 3, 2025, or the Tranche C Closing Date.

On February 3, 2025, the Company and Kreos entered into a Second Amendment to the BlackRock Credit Agreement, which, among other things, extended the expiry date of Tranche C from December 31, 2024 to the Tranche C Closing Date, or the Extended Tranche C. Tranche C was available subject to receipt of a certain amount of cumulative gross cash proceeds after the Closing Date in the form of equity or equity linked securities in one or more series of transactions. The terms of the Extended Tranche C are substantially similar to the terms of the original Tranche C, however, interest accrued on the Extended Tranche C as if it was advanced on December 31, 2024.

On the Closing Date, the Company received $34.5 million on Tranche A, after deducting debt issuance costs, fees and expenses. On the Tranche B Closing Date, the Company received $7.5 million, after deducting debt issuance costs, fees and expenses. On the Tranche C Closing Date, the Company received $9.3 million, after deducting debt issuance costs, interest, fees and expenses.

The 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 accrues interest at a floating annual rate equal to the sum of (i) the term Secured Overnight Financing Rate 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, 2026, the Company's interest rate was 11.00%. The Company recognized interest expense related to the BlackRock Credit Agreement of $2.2 million and $6.6 million during the three and nine months ended September 30, 2026, respectively, and $2.1 million and $6.2 million during the three and nine months ended September 30, 2025, respectively.

During the continuance of any payment event of default under the BlackRock Credit Agreement, the interest rate on such overdue sum will automatically increase by an additional 3.0% per annum, and may be subject to an additional late fee of 2.0% of such overdue sum. The Term Loan Facility also includes transaction fees ranging from 1.00% to 1.25% of the draw down amount as well as exit fees of 0.75% of the amount funded to the relevant tranche.

If the Company prepays the outstanding loan prior to maturity, it will be required to pay a prepayment fee ranging from 1.0% to 4.0% of the amount prepaid.

As of September 30, 2026, future principal payments under the BlackRock Credit Agreement are as follows (in thousands):

Years ended December 31,	Principal Payments
2026	$ —
2027	50,558
2028	1,881
Total before unamortized discount and issuance costs	$ 52,439
Less: unamortized discount and issuance costs	(2,169)
Total term loans	$ 50,270

The Term Loan Facility is secured by substantially all of the existing and after-acquired assets of the Company, including intellectual property. The BlackRock Credit Agreement requires the Company to (i) maintain a minimum aggregate cash balance of $15.0 million in one or more controlled accounts or (ii) trailing twelve-month revenue of $150.0 million, both of which are measured monthly. The BlackRock Credit Agreement contains certain representations and warranties, affirmative and negative covenants that limit the Company's ability to engage in specified types of transactions and other provisions typical within a credit agreement. If an event of default occurs and is continuing under the BlackRock Credit Agreement, BlackRock is entitled to take enforcement action, including acceleration of amounts due and it could limit the Company's ability to make certain payments under the Vifor Termination Agreement (as defined below).

On July 10, 2024, in connection with the Termination and Settlement Agreement entered into between the Company and CSL Vifor (as defined below), or the Vifor Termination Agreement, the Company and Kreos entered into a First Amendment to the BlackRock Credit Agreement, which amended certain provisions of the BlackRock Credit Agreement. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for further information on the Vifor Termination Agreement.

Warrants

On the Closing Date, Kreos Capital VII Aggregator SCSp, an affiliate of Kreos, or the Warrant Holder, received a warrant to purchase 3,076,923 shares of the Company’s common stock, at an exercise price per share of $1.30, or the Initial Warrant. On the Tranche C Closing Date, the Company issued the Warrant Holder an additional warrant to purchase 1,153,846 shares of the Company’s common stock at an exercise price per share of $1.30, or the Tranche C Warrant. Each warrant is exercisable for eight years from the date of issuance.

On July 21, 2025, the Warrant Holder exercised its option to purchase 2,115,384 shares of the Company's common stock under the Initial Warrant on a cashless basis at an exercise price per share of $1.30. On July 23, 2025, as a result of the cashless exercise, the Company issued 1,408,588 shares of common stock to the Warrant Holder under the Initial Warrant.

The Initial Warrant and the Tranche C Warrant are liabilities classified under ASC 815, *Derivatives and Hedging*, as they could potentially require net cash settlement outside of the Company’s control. The Initial Warrant and the Tranche C Warrant are measured at fair value each reporting period and when a warrant is exercised, with the changes in fair value presented within the unaudited condensed consolidated statements of operations and comprehensive income (loss). The fair value of the warrant liability was $1.5 million and $3.0 million as of September 30, 2026 and December 31, 2025, respectively. See Note 3, *Fair Value Measurements*, 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.

8. LIABILITY RELATED TO SETTLEMENT ROYALTIES, WORKING CAPITAL FUND LIABILITY AND LIABILITY RELATED TO SALE OF FUTURE ROYALTIES

Vifor License Agreement

Summary of Agreement

In February 2022, the Company entered into a Second Amended and Restated License Agreement, or the Vifor License Agreement, with CSL Vifor, which amended and restated the License Agreement dated as of May 12, 2017, or the Original

License Agreement. The Vifor License Agreement granted CSL Vifor an exclusive license to sell Vafseo to Fresenius Medical Care North America and its affiliates, including Fresenius Kidney Care Group LLC, to certain third-party dialysis organizations approved by the Company, to independent dialysis organizations that are members of certain group purchasing organizations and certain non-retail specialty pharmacies in the U.S. In addition, CSL Vifor made an upfront payment to the Company of $25.0 million in February 2022 in connection with the amendment and restatement of the Vifor License Agreement, which was previously recorded as long-term deferred revenue in the consolidated balance sheets.

See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, of the Notes to the Consolidated Financial Statements in the 2025 Form 10-K for a more detailed description of the Vifor License Agreement.

Investment Agreements

In May 2017, in connection with the Original License Agreement, the Company sold an aggregate of 3,571,429 shares of its common stock, or 2017 Shares, to CSL Vifor at a price per share of $14.00 for a total of $50.0 million.

In February 2022, in connection with the Vifor License Agreement, the Company sold an aggregate of 4,000,000 shares of its common stock, or 2022 Shares, to CSL Vifor at a price per share of $5.00 for a total of $20.0 million.

The $18.3 million, which represented the premiums over the closing stock price, or $4.7 million for the 2017 Shares and $13.6 million for the 2022 Shares, was previously recorded as long-term deferred revenue in the consolidated balance sheets as it represented consideration related to the Vifor License Agreement.

The 2017 Shares and 2022 Shares are subject to standstill agreements and are subject to voting agreements. The 2017 Shares and 2022 Shares have not been registered pursuant to the Securities Act of 1933, as amended, or the Securities Act, and were issued and sold in reliance upon the exemption from registration contained in Section 4(a)(2) of the Securities Act and Rule 506 promulgated thereunder as the transaction did not involve any public offering within the meaning of Section 4(a)(2) of the Securities Act.

Vifor Termination Agreement

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

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

The WCF Royalty Payments, 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 upfront payment of $25.0 million and the premiums paid by CSL Vifor for the 2017 Shares and 2022 Shares of $4.7 million and $13.6 million, respectively, should be classified as debt. Accordingly, the Company recorded the $43.3 million as a liability and is amortizing such amount using the effective interest method over the Settlement Royalty Term. The liability related to settlement royalties and the amortization are based on the Company's current estimates of future royalties expected to be paid over the life of the arrangement. To the extent the Company's estimates of future royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, the Company will adjust the effective interest rate and recognize the related non-cash interest expense on a prospective basis. On a quarterly basis, the Company reassesses the expected royalty payments.

The annual effective interest rate as of September 30, 2026 was 12.8% which is reflected as interest expense in the unaudited condensed consolidated statements of operations and comprehensive income (loss). The Company recognized interest expense related to the settlement royalties liability of $2.3 million and $7.6 million for the three and nine months ended September 30, 2026, respectively, and $3.9 million and $14.7 million for the three and nine months ended September 30, 2025, respectively. As of September 30, 2026 and December 31, 2025, the balances related to the settlement royalties liability were as follows (in thousands):

Description	September 30, 2026	December 31, 2025
Current portion (included in accrued expenses and other current liabilities)	$ 5,614	$ 12,516
Long-term portion	65,096	54,750
Total settlement royalties liability	$ 70,710	$ 67,266

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 to the Working Capital Fund liability in the condensed consolidated balance sheet.

On May 3, 2024, the Company and CSL Vifor entered into Amendment #1 to the Vifor License Agreement, or the Amendment. Pursuant to the Amendment, and as modified by the Vifor Termination Agreement, the Company and CSL Vifor agreed to modify the method of repayment of the Working Capital Fund such that the Working Capital Fund will be repaid through quarterly tiered royalty payments ranging from 8% to 14% of the Company's net sales of Vafseo in the U.S., or the WCF Royalty Payments. The WCF Royalty Payments commenced on July 1, 2025, and will continue until the earlier of (i) the cumulative total of the WCF Royalty Payments equals $40.0 million, or (ii) May 31, 2028, or the WCF Royalty Term. The WCF Royalty Payments are subject to minimum true-up milestones of $10.0 million, $20.0 million and $40.0 million, or the WCF Royalty True-Up Payments, on each of May 31, 2026, May 31, 2027 and May 31, 2028, respectively, or the WCF Royalty True-Up Dates. If the cumulative total of the WCF Royalty Payments paid to CSL Vifor on any given WCF Royalty True-Up Date is less than the respective WCF Royalty True-Up Payment, the Company will pay CSL Vifor a one-time payment equal to the difference between the WCF Royalty True-Up Payment and the cumulative total of the WCF Royalty Payments paid by the Company through such WCF Royalty True-Up Date. The Company determined that the terms of the Amendment are not substantially different than the terms of the Vifor License Agreement, and therefore the Amendment was accounted for as a modification. The Company concluded that the 15% discount rate remains appropriate. On a quarterly basis, the Company reassesses the effective rate and will adjust the rate prospectively, if needed.

The discount on the Working Capital Fund liability is being amortized to interest expense using the effective interest method over the WCF Royalty Term. The deferred gain is being amortized to interest income on a straight-line basis over the WCF Royalty Term. The amortization of the discount was $0.8 million and $3.2 million for the three and nine months ended September 30, 2026, respectively, and $1.2 million and $3.5 million for the three and nine months ended September 30, 2025, respectively. The amortization of the deferred gain was $0.9 million and $2.5 million for the three and nine months ended September 30, 2026, respectively, and $1.1 million and $3.1 million for the three and nine months ended September 30, 2025, respectively.

As of September 30, 2026 and December 31, 2025, the balances related to the Working Capital Fund liability were as follows (in thousands):

Description	September 30, 2026	December 31, 2025
Current portion	$ 9,846	$ 17,356
Long-term portion	20,263	22,606
Total Working Capital Fund liability	$ 30,109	$ 39,962

Liability Related to Sale of Future Royalties

In February 2021, the Company entered into a royalty interest acquisition agreement, or the Royalty Agreement, with HealthCare Royalty Partners IV, L.P., or HCR, pursuant to which the Company sold to HCR its right to receive royalties and

sales milestones for Vafseo in Japan and certain other Asian countries, such countries collectively, the TPC Territory, and such payments collectively the Royalty Interest Payments, in each case, payable to the Company under the Company's Collaboration Agreement, or the TPC Agreement, with Tanabe Pharma Corporation, formerly Mitsubishi Tanabe Pharma Corporation, or TPC. The Royalty Interest Payments are subject to an annual maximum “cap” of $13.0 million, after which the Company will receive 85% of the Royalty Interest Payments for the remainder of that year. The Royalty Interest Payments are also subject to an aggregate maximum “cap” of $150.0 million, after which the Royalty Interest Payments will revert back to the Company.

The Company retains the right to receive all potential future regulatory milestones for Vafseo under the TPC Agreement. The Royalty Agreement will terminate on the earlier of the date on which HCR has received (i) the last Royalty Interest Payment or (ii) payment by the Company of an amount equal to the Aggregate Cap minus the aggregate amount of all Royalty Interest Payments actually received by HCR.

At the transaction date, the Company recognized the proceeds received from HCR of $44.8 million (net of certain transaction expenses) as a liability and is amortizing it using the effective interest method over the life of the arrangement. The liability related to sale of future royalties and the debt amortization are based on the Company’s current estimates of future royalties expected to be paid over the life of the arrangement. To the extent the Company’s estimates of future royalty payments are greater or less than previous estimates or the estimated timing of such payments is materially different than previous estimates, the Company will adjust the effective interest rate and recognize related non-cash interest expense on a prospective basis. In the event the Company's estimates of future royalties are less than the proceeds from the sale of future royalties, the Company will not recognize related non-cash interest expense. On a quarterly basis, the Company assesses the expected royalty payments. The annual effective interest rate as of September 30, 2026 was 0% and, therefore the Company did not recognize any non-cash interest expense in the unaudited condensed consolidated statements of operations and comprehensive income (loss). As a result of the Company's ongoing involvement in the cash flows related to the royalties and sales milestones in the TPC Territory, the Company will continue to account for the royalties received as non-cash royalty revenue which is reflected within license, collaboration and other revenue in the unaudited condensed consolidated statements of operations and comprehensive income (loss). See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, of the Notes to the Consolidated Financial Statements in the 2025 Form 10-K for a more detailed description of the Royalty Agreement.

The Company paid royalties to HCR of $0.4 million and $1.2 million during the three and nine months ended September 30, 2026, respectively, and $0.5 million and $1.4 million during the three and nine months ended September 30, 2025, respectively. As of September 30, 2026 and December 31, 2025 the balances were as follows (in thousands):

Liability related to sale of future royalties	September 30, 2026	December 31, 2025
Current portion (included in accrued expenses and other current liabilities)	$ 1,515	$ 1,664
Long-term portion	49,558	50,608
Total liability related to sale of future royalties	$ 51,073	$ 52,272

The Royalty Agreement requires the Company to take certain actions, including actions with respect to the Royalty Interest Payments, the TPC Agreement, and the Company's intellectual property. The Royalty Agreement also contains certain representations and warranties, covenants, indemnification obligations, events of default and other provisions that are customary for a royalty monetization transaction of this nature. In addition, the Company granted HCR a precautionary security interest in connection with the Royalty Interest Payments.

9. LEASES

Cambridge Lease

Under the Cambridge Lease, the Company leased approximately 65,167 square feet of office, storage and laboratory space in Cambridge, Massachusetts. In April and September 2026, the Company extended the lease terms for the laboratory space and the office and storage space, respectively, from September 11, 2026 through October 31, 2026.

The Cambridge Lease was non-cancelable and is classified as an operating lease. The Cambridge Lease did not contain residual value guarantees.

The security deposit in connection with the Cambridge Lease was $1.7 million in the form of a letter of credit, which was included as restricted cash in prepaid expenses and other current assets in the accompanying unaudited condensed consolidated balance sheet as of December 31, 2025. No restricted cash related to the Cambridge Lease remained as of September 30, 2026.

Waltham Lease

On January 27, 2026, the Company entered into the Waltham Lease with BP THIRD AVENUE LLC, a Delaware limited liability company, or the Landlord, pursuant to which the Company leases an aggregate of approximately 43,474 square feet, consisting of 28,518 square feet of office space, or the Office Premises, and 14,956 square feet of laboratory space, or the Lab Premises, located in Waltham, Massachusetts. The term of the Waltham Lease expires on August 31, 2033, unless sooner terminated as provided in the Waltham Lease, with one five-year extension option available. The Company relocated its corporate headquarters to Waltham in September 2026.

The Waltham Lease is non-cancelable and is classified as an operating lease. The renewal options with respect to the Office Premises and the Lab Premises were not included in the calculation of the right-of-use asset and operating lease liability as the renewals are not reasonably certain.

The Company's annual rent for the Office Premises began at $0.9 million and will increase by an additional $1.00 per square foot for each successive Rent Year (as defined in the Waltham Lease) until the end of the initial term. The Company's annual rent for the Lab Premises began at $1.0 million and will increase by approximately 3.0% for each successive Rent Year until the end of the initial term. The security deposit in connection with the Waltham Lease is $0.9 million in the form of an irrevocable letter of credit, which is included as restricted cash in other long-term assets in the accompanying unaudited condensed consolidated balance sheet as of September 30, 2026. In addition to rent, the Company is required to pay additional amounts for taxes, insurance, maintenance and other operating expenses.

Future Lease Commitments

Future commitments under the non-cancelable Cambridge Lease and Waltham Lease are as follows (in thousands):

	Operating Lease Commitments
2026	$ 541
2027	1,965
2028	2,025
2029	2,087
Thereafter	8,183
Total lease commitments	$ 14,801
Less: present value adjustment	(4,581)
Current operating lease liabilities	$ 10,220

Total operating lease costs were $1.8 million and $4.4 million for the three and nine months ended September 30, 2026, respectively, and $1.2 million and $3.7 million for the three and nine months ended September 30, 2025, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $1.3 million and $4.2 million for the three and nine months ended September 30, 2026, respectively, and $1.5 million and $4.4 million for the three and nine months ended September 30, 2025, respectively.

The weighted average remaining lease term for the operating leases was 6.89 years and the incremental borrowing rate was 10.98% as of September 30, 2026.

10. COMMITMENTS AND CONTINGENCIES

Manufacturing and Unconditional Purchase Commitment Agreements

Auryxia (Ferric Citrate) Manufacturing

Siegfried

The Company's contractual obligations include a commercial supply agreement with Siegfried Evionnaz SA, or Siegfried, to supply commercial ferric citrate drug substance. The Company and Siegfried entered into a Master Manufacturing Services and Supply Agreement, with the most recent amendment effective in July 2026, or the Siegfried Agreement, under which the Company has agreed to purchase a minimum quantity of ferric citrate drug substance, annually at a predetermined price. As of September 30, 2026, the Company had a minimum total commitment of approximately $7.7 million of ferric citrate drug substance through the end of 2026.

The term of the Siegfried Agreement expires on December 31, 2028. The Siegfried Agreement provides the Company and Siegfried with certain early termination rights.

The Company regularly reviews its estimate of the excess firm purchase commitment liability which relates to the amount of minimum purchase commitments under the Siegfried Agreement that exceeded the then current forecast, including review of assumptions of expected future demand and expiry of inventory. The Company did not have an excess firm purchase commitment liability as of September 30, 2026. The excess firm purchase commitment liability recorded in other long-term liabilities was $0.8 million as of December 31, 2025.

Vafseo (Vadadustat) Manufacturing

Patheon

In March 2020, the Company entered into a Supply Agreement with Patheon Inc., or Patheon, or the Patheon Agreement, under which Patheon agreed to manufacture vadadustat drug product for commercial use under a volume-based pricing structure through June 30, 2023, with the agreement renewing annually unless either party gives the other party eighteen months' prior written notice. Under the Patheon Agreement, the Company agreed to purchase from Patheon a certain percentage of the estimated global demand for vadadustat drug product based on certain quarterly and annual forecasts provided by the Company. As of September 30, 2026, the Company has committed to purchase $1.1 million of vadadustat drug product from Patheon through the end of 2026, however, as estimated global demand fluctuates, the Company may have additional future obligations under the Patheon Agreement.

WuXi STA

In April 2020, the Company entered into a Supply Agreement with STA Pharmaceutical Hong Kong Limited, a subsidiary of WuXi AppTec Co., Ltd., or WuXi STA, or, as amended, the WuXi STA DS Agreement. Under the WuXi STA DS Agreement, WuXi STA will manufacture vadadustat 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 vadadustat drug substance from WuXi STA. As of September 30, 2026, the Company has committed to purchase $69.2 million of vadadustat drug substance from WuXi STA through the end of 2027, however, as estimated global demand fluctuates, the Company may have additional future obligations under the WuXi STA DS Agreement.

Additionally, in February 2021, the Company entered into a Supply Agreement with WuXi STA, with the most recent amendment effective in July 2026, or the WuXi STA DP Agreement, under which WuXi STA will manufacture and supply vadadustat drug product for commercial purposes under a volume-based pricing structure through January 1, 2032. The vadadustat drug product price is reviewed annually by the Company and WuXi STA. The Company also reimburses WuXi STA for certain reasonable expenses. Pursuant to the WuXi STA DP Agreement, the Company has agreed to purchase a certain percentage of global demand for vadadustat 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, 2026, the Company has committed to purchase $1.0 million of vadadustat drug product from WuXi STA through the end of 2026, however, as estimated global demand fluctuates, the Company may have additional future obligations under the WuXi STA DP Agreement.

License Agreements

Panion License Agreement

On April 17, 2019, the Company and Panion & BF Biotech, Inc., or Panion, entered into a second amended and restated license agreement, or the Panion Amended License Agreement, which amended and restated in full the license agreement between the Company and Panion. The Panion Amended License Agreement provides the Company with an exclusive license under Panion-owned know-how and patents covering the rights to sublicense, develop, make, use, sell, offer for sale, import and export ferric citrate worldwide, excluding certain Asian-Pacific countries, or the Licensor Territory. The Panion Amended License Agreement also provides Panion with an exclusive license under Company-owned patents, covering the rights to sublicense (with the Company's written consent), develop, make, use, sell, offer for sale, import and export ferric citrate in certain countries in the Licensor Territory. Under the Panion Amended License Agreement, Panion is eligible to receive from the Company or any sublicensee royalty payments based on a mid-single digit percentage of sales of ferric citrate in the Company's licensed territories. The Company is eligible to receive from Panion or any sublicensee royalty payments based on a mid-single digit percentage of net sales of ferric citrate in Panion's licensed territories. See Note 10, *Commitments and Contingencies*, of the Notes to the Consolidated Financial Statements in the 2025 Form 10-K for a more detailed description of the Panion Amended License Agreement.

The Company incurred royalty payments due to Panion of approximately $1.3 million and $5.2 million during the three and nine months ended September 30, 2026, respectively, and $2.7 million and $8.4 million during the three and nine months

ended September 30, 2025, respectively, relating to the Company's sales of Auryxia in the U.S. and Japan Tobacco, Inc. (succeeded by Shionogi & Co., Ltd.) and its subsidiary Torii Pharmaceutical Co., Ltd., collectively, JT and Torii's, net sales of Riona in Japan.

Cyclerion Agreement

In June 2021, the Company entered into a license agreement, or the Cyclerion Agreement, with Cyclerion Therapeutics Inc. (succeeded by Korsana Biosciences Inc.), or Cyclerion, under which the Company obtained an exclusive global license under certain intellectual property rights to research, develop and commercialize praliciguat, an investigational oral soluble guanylate cyclase stimulator.

Under the terms of the Cyclerion Agreement, the Company made an upfront payment of $3.0 million to Cyclerion, which was paid during the second quarter of 2021. Substantially all of the fair value of the assets acquired in conjunction with the Cyclerion Agreement was concentrated in the acquired license. As a result, the Company accounted for this transaction as an asset acquisition under ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*. The $3.0 million upfront payment was charged to research and development expense at acquisition in June 2021, as it relates to a development stage compound with no alternative future use.

In December 2024, the Company and Cyclerion entered into an amendment to the Cyclerion Agreement, pursuant to which the Company agreed to pay Cyclerion (i) $1.25 million, which was paid in December 2024, and (ii) $0.5 million, which was paid in September 2025. In addition, the parties agreed to the reduction of certain development milestones and the increase of certain royalty rates on net sales and sublicense income. During the year ended December 31, 2024, the Company recorded the $1.25 million payment and $0.5 million payment to research and development expense in accordance with ASC 730, Research and Development, as praliciguat remains a development stage compound with no alternative future use. Furthermore, the only contingency as it related to the $0.5 million payment made in September 2025 was the passage of time.

Under the Cyclerion Agreement, as amended in December 2024, Cyclerion is eligible to receive up to an additional aggregate of $197.5 million from the Company in specified development and regulatory milestone payments on a product-by-product basis. In December 2025, the Company incurred a $1.0 million development milestone in connection with the initiation of a Phase 2 clinical trial for praliciguat in the U.S., which was charged to research and development expense during the year ended December 31, 2025. The $1.0 million development milestone was paid during the nine months ended September 30, 2026. Cyclerion will also be eligible to receive specified commercial milestones as well as tiered royalties ranging from a mid-single-digit percentage to twenty percent of net sales, on a product-by-product basis, and subject to reduction upon expiration of patent rights or the launch of a generic product in the territory.

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

Q32 Agreement

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

Under the terms of the Q32 Purchase Agreement, the Company (i) made an upfront payment of $7.0 million on the APA Closing Date, (ii) made an additional upfront payment of $3.0 million on the six-month anniversary of the APA Closing Date, (iii) made a $1.9 million development milestone payment upon the dosing of the first patient in the Phase 2 clinical trial of ebribafusp in September 2026, (iv) will make certain milestone payments upon the achievement of specified development and regulatory milestone events related to ebribafusp up to an aggregate amount equal to $92.6 million, (v) will make certain milestone payments upon the achievement of specified commercial milestone events with respect to the net sales of ebribafusp up to an aggregate amount equal to $487.5 million, and (vi) will make certain royalty payments based on the net sales of ebribafusp with royalty percentage tiers ranging from the low single digits to mid-teen percentages. The royalties will

expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

The transaction was accounted for as an asset acquisition as the acquired assets did not meet the definition of a business. The Company did not acquire any outputs and there was not an acquired substantive process in place to create outputs. The total purchase consideration of $12.8 million was composed of the $7.0 million upfront payment, the $3.0 million additional upfront payment, the $2.0 million development milestone payment and $0.8 million of direct transaction costs. The only contingency as it relates to the $2.0 million milestone payment upon the earlier of initiation of a Phase 2 clinical trial and December 31, 2026 was the passage of time.

The total purchase consideration was allocated to in process research and development, or IPR&D, assets with no alternative future use for these assets at the closing of the acquisition. As a result, the Company recorded a charge of $12.8 million related to acquired IPR&D expense on the consolidated statements of operations and comprehensive loss during the year ended December 31, 2025. The $0.1 million development milestone payment is included in accrued expenses and other current liabilities in the consolidated balance sheet as of September 30, 2026.

Other Third-Party Contracts

The Company contracts with various organizations to conduct R&D activities with remaining contract costs to the Company of approximately $79.2 million at September 30, 2026. The scope of the services under these R&D contracts can be modified upon mutual agreement of the parties, and the contracts or scope of services can be cancelled by the Company upon written notice. In some instances, the contracts may be cancelled by the third-party upon written notice.

Litigation and Related Matters

The Company is involved from time to time in various legal proceedings arising in the normal course of business. The Company provides disclosure when a loss in excess of any reserve is reasonably possible, and if estimable, the Company discloses the potential loss or range of possible loss. Significant judgment is required to assess the likelihood of various potential outcomes and the quantification of loss in those scenarios. Changes in the Company's estimates could have a material impact and are recorded as litigation progresses and new information comes to light. Although the outcomes of potential legal proceedings are inherently difficult to predict, the Company does not expect the resolution of current legal proceedings to have a material adverse effect on its financial position, results of operations or cash flows of the Company.

Guarantees and Indemnifications

As permitted under Delaware law, the Company may indemnify its officers, directors and employees for certain events or occurrences that happen by reason of their relationship with, or position held at, the Company. The Company may also be subject to indemnification obligations by law with respect to the actions of its employees under certain circumstances and in certain jurisdictions. The Company maintains director and officer liability insurance coverage that is intended to cover a portion of amounts that may be due with respect to indemnification after a deductible is met. Further, the Company is a party to a variety of agreements in the ordinary course of business under which it may be obligated to indemnify third parties with respect to certain matters. For the three and nine months ended September 30, 2026 and 2025, the Company did not experience any losses related to these indemnification obligations, and no claims were outstanding as of September 30, 2026. The Company does not have any claims related to these indemnification obligations and consequently no related accruals were recorded.

11. PRODUCT REVENUE AND PROVISIONS FOR VARIABLE CONSIDERATION

The following table presents net product revenue for Vafseo and Auryxia (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Product	**2026**	**2025**	**2026**	**2025**
Vafseo	$ 14,798	$ 14,322	$ 51,902	$ 39,635
Auryxia[(1)]	20,029	42,467	81,682	133,406
Total product revenues	$ 34,827	$ 56,789	$ 133,584	$ 173,041

(1) Includes the authorized generic version of Auryxia sold and distributed by the Company's authorized generic distribution partner, Mylan Therapeutics, Inc., or AG Distributor, during the three and nine months ended September 30, 2026 and 2025.

The following tables present changes in the Company's contract assets and liabilities related to the Company's sales to its AG Distributor (in thousands):

	Nine Months Ended September 30, 2026			
	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract assets:				
Accounts receivable	$ 194	$ 16,567	$ (14,006)	$ 2,755
Contract liabilities:				
Deferred revenue	$ 2,681	$ 13,865	$ (12,125)	$ 4,421

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

The Company recognized the following revenues related to the Company's sales to its AG Distributor 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:	2026	2025	2026	2025
Deferred revenue — beginning of the period	$ 2,680	$ 2,664	$ 2,681	$ —

Product revenue allowance and provision categories were as follows:

(in thousands)	Chargebacks and Discounts	Rebates, Fees and Other Deductions	Product Returns	Total
Balance at December 31, 2025	$ 1,153	$ 72,589	$ 3,351	$ 77,093
Current provisions related to sales in current year	5,850	51,912	309	58,071
Adjustments related to prior year sales	26	(4,099)	2,638	(1,435)
Credits/payments made	(5,798)	(49,568)	(3,010)	(58,376)
Balance at September 30, 2026	$ 1,231	$ 70,834	$ 3,288	$ 75,353

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

Chargebacks, discounts and estimated product returns are recorded as a reduction of revenue in the period the related product revenue is recognized in the unaudited condensed consolidated statements of operations and comprehensive income (loss). Chargebacks are recorded as a reduction to accounts receivable while discounts, rebates, fees and other deductions are recorded with a corresponding increase to accrued expenses and other current liabilities or accounts payable on the condensed consolidated balance sheets. Estimated product returns on product sales that are not expected to be returned within one year are recorded as other long-term liabilities in the unaudited condensed consolidated balance sheets.

Accounts receivable, net related to product sales, was approximately $29.5 million and $44.4 million as of September 30, 2026 and December 31, 2025, 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**	**2026**	**2025**	**2026**	**2025**
Medice	License and product supply of Vafseo in the EU	$ 77	$ 28	$ 637	$ 52
TPC	Royalties related to the sale of Vafseo in Japan, South Korea and Taiwan	423	455	1,174	1,325
JT and Torii	Royalties related to the sale of Riona in Japan	1,576	1,494	4,180	4,156
Total license and other revenue		$ 2,076	$ 1,977	$ 5,991	$ 5,533

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, 2026			
	Balance at Beginning of Period	**Additions**	**Deductions**	**Balance at End of Period**
Contract asset:				
Accounts receivable[(1)]	$ 2,391	$ 6,519	$ (6,232)	$ 2,678
Contract liability:				
Deferred revenue	$ —	$ 582	$ (44)	$ 538

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

(1) Excludes accounts receivable related to amounts due to the Company from product sales of Auryxia and Vafseo which are included in the accompanying unaudited condensed consolidated balance sheets as of September 30, 2026 and 2025.

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:	**2026**	**2025**	**2026**	**2025**
Deferred revenue — beginning of the period	$ —	$ —	$ —	$ —

During each of the three and nine months ended September 30, 2026 and 2025, the Company recognized no revenue from performance obligations satisfied in previous periods.

Medice License Agreement

On May 24, 2023, or the Medice Effective Date, the Company and MEDICE Arzneimittel Pütter GmbH & Co. KG, or Medice, entered into a License Agreement, or the Medice License Agreement, pursuant to which the Company granted to Medice an exclusive license to develop and commercialize Vafseo for the treatment of anemia in adult patients with CKD in the EEA, the UK, Switzerland and Australia, or collectively, the Medice Territory.

Under the Medice License Agreement, the Company received an upfront 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 upfront payment of $10.0 million, of which the Company received $8.6 million during the quarter ended June 30, 2023. The remaining $1.4 million was withheld by the German Federal Tax Office and was received during the nine months ended September 30, 2025.

Pursuant to the terms of the Medice License Agreement, the upfront 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 upfront payment as license, collaboration and other revenue in the unaudited condensed consolidated statements of operations and comprehensive loss during the year ended December 31, 2023.

In accordance with ASC 606, the Company will recognize sales-based royalties and milestone payments at the later of when the performance obligation is satisfied or the related sales occur. During each of the three and nine months ended September 30, 2026 and 2025, the Company recognized an immaterial amount of revenue and $0.1 million of revenue from Medice royalties, respectively. As of September 30, 2026, there were $0.2 million in contract assets, and no accounts receivable, payables or deferred revenue in connection with the Medice License Agreement.

Supply of Drug Product to Medice

On September 13, 2024, the Company and Medice entered into a supply agreement, or the Medice Supply Agreement, under which the Company supplies Vafseo drug product to Medice for commercial and developmental use in the Medice Territory. The Company recognizes revenue under this arrangement when risk of loss passes to Medice, delivery has occurred, and Medice has accepted the product. The Company recognized an immaterial amount of revenue and $0.5 million of revenue under the Medice Supply Agreement during the three and nine months ended September 30, 2026, respectively. The Company did not recognize any revenue under the Medice Supply Agreement during the three and nine months ended

September 30, 2025. As of September 30, 2026, there were $0.5 million in accounts receivable, immaterial deferred revenue and no contract assets or payables in connection with the Medice Supply Agreement.

Supply of Drug Substance to Medice

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

The Company did not recognize any revenue related to the supply of vadadustat drug substance to Medice during the three and nine months ended September 30, 2026 and 2025.

TPC Collaboration Agreement

On December 11, 2015, the Company and TPC entered into the TPC Agreement, providing TPC with exclusive development and commercialization rights to Vafseo in the TPC Territory, which was amended effective as of December 2, 2022. In addition, the Company supplies Vafseo to TPC for both clinical and commercial use in the TPC Territory. In February 2021, the Company entered into the Royalty Agreement with HCR, whereby the Company sold its right to receive royalties and sales milestones under the TPC Agreement, subject to certain caps and other terms and conditions. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for additional information and Note 12, *License, Collaboration and Other Revenue*, of the Notes to the Consolidated Financial Statements in the 2025 Form 10-K for a more detailed description of the TPC Agreement.

The Company evaluated the elements of the TPC Agreement in accordance with the provisions of ASC 606 and concluded that the contract counterparty, TPC, is a customer. The Company identified two performance obligations in connection with its material promises under the TPC Agreement as follows: (i) *License, Research and Clinical Supply Performance Obligation* and (ii) *Rights to Future Know-How Performance Obligation*.

The transaction price was comprised of: (i) the upfront payment of $20.0 million, (ii) the cost for the Phase 2 studies of $20.5 million, (iii) the cost of all clinical supply provided to TPC for the Phase 3 studies, (iv) $10.0 million in development milestones received, (v) $25.0 million in regulatory milestones received and (vi) $9.8 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, 2026, all development milestones and $25.0 million in regulatory milestones have been achieved. No other regulatory milestones or commercial milestones have been assessed as probable and have been fully constrained until the period in which they are achieved.

The Company allocates the transaction price to each performance obligation based on the Company's best estimate of the relative standalone selling price. The Company developed a best estimate of the standalone selling price for the Rights to Future Know-How Performance Obligation primarily based on the likelihood that additional intellectual property covered by the license conveyed will be developed during the term of the arrangement and determined it is immaterial. As such, the Company did not develop a best estimate of standalone selling price for the License, Research and Clinical Supply Performance Obligation and allocated the entire transaction price to this performance obligation.

Revenue for the License, Research and Clinical Supply Performance Obligation for the TPC Agreement is being recognized using a proportional performance method, for which all deliverables have been completed. The Company recognizes any revenue from TPC royalties in the period in which the sales occur. The Company recognized revenue from TPC royalties of $0.4 million and $1.2 million during the three and nine months ended September 30, 2026, respectively, and $0.5 million and $1.3 million during the three and nine months ended September 30, 2025, respectively. As noted above, in February 2021, the Company entered into the Royalty Agreement, whereby the Company sold its right to receive these royalties and sales milestones under the TPC Agreement, subject to certain caps and other conditions. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for additional information. The revenue is classified as license, collaboration and other revenue in the accompanying unaudited condensed consolidated statements of operations and comprehensive income (loss). As of September 30, 2026, there were no accounts receivable, payables or deferred revenue and $0.4 million in contract assets recorded in connection with the TPC Agreement.

Supply of Drug Product to TPC

On July 15, 2020, the Company and TPC entered into a supply agreement, or the TPC Supply Agreement, under which the Company supplies Vafseo drug product to TPC for commercial use in Japan and certain other Asian countries, as contemplated by the TPC Agreement. See Note 12, *License, Collaboration and Other Revenue*, of the Notes to the Consolidated Financial Statements in the 2025 Form 10-K for a more detailed description of this supply agreement.

The Company does not recognize revenue under this arrangement until risk of loss on the drug product passes to TPC and delivery has occurred and TPC has accepted the product. The Company recognized no revenue under the TPC Supply Agreement during each of the three and nine months ended September 30, 2026 and 2025. As of September 30, 2026, there were no accounts receivable, deferred revenue or other current liabilities relating to the TPC Supply Agreement.

JT and Torii Sublicense Agreement

The Company has an Amended and Restated Sublicense Agreement, which was amended in June 2013, with JT and Torii, or the JT and Torii Sublicense Agreement, under which JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate hydrate in Japan. JT and Torii are responsible for the future development and commercialization costs in Japan. See Note 12, *License, Collaboration and Other Revenue*, of the Notes to the Consolidated Financial Statements in the 2025 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 is immaterial. As such, the Company allocated the entire transaction price to the License and Supply Performance Obligation.

The Company recognized license revenue of $1.6 million and $4.2 million during the three and nine months ended September 30, 2026, respectively, and $1.5 million and $4.2 million during the three and nine months ended September 30, 2025, respectively, related to royalties earned on net sales of Riona in Japan. The Company records the associated mid-single digit percentage of net sales royalty expense due to Panion, the licensor of Riona, in the same period as the royalty revenue from JT and Torii is recorded. As of September 30, 2026, there was $1.5 million in accounts receivable relating to the JT and Torii Sublicense Agreement.

13. CAPITAL STOCK

Authorized and Outstanding Capital Stock

In June 2026, the Company filed a Certificate of Amendment to its Ninth Amended and Restated Certificate of Incorporation, which (i) increased the number of authorized shares of capital stock from 375,000,000 to 525,000,000 and (ii) increased the number of authorized shares of common stock, par value $0.00001 per share, from 350,000,000 to 500,000,000.

As of September 30, 2026 and December 31, 2025, the authorized capital stock of the Company included 500,000,000 and 350,000,000 shares of common stock, respectively, $0.00001 par value per share, of which 277,516,290 and 265,424,818 shares were issued and outstanding as of September 30, 2026 and December 31, 2025, 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, 2026 and December 31, 2025.

At-the-Market Facility

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 an original sales agreement), with Jefferies LLC, as the Company’s sales agent, pursuant to which the Company is able to offer and sell up to $75.0 million of its common stock at current market prices from time to time. Since September 12, 2024 (the date the Company’s shelf registration statement on Form S-3 went effective) through December 31, 2025, the Company sold 23,708,995 shares of its common stock under this program with gross proceeds of $43.0 million ($42.2 million, net of offering expenses). During the nine months ended September 30, 2026, the Company sold 8,244,695 shares of its common stock under this program with gross proceeds of $10.1 million ($9.8 million, net of offering expenses).

Public Offering

On March 19, 2025, the Company entered into an underwriting agreement, or the Underwriting Agreement, with Leerink Partners LLC and Piper Sandler & Co., as representatives of the several underwriters named therein, collectively, the Underwriters, relating to an underwritten public offering, or the Offering, of 25,000,000 shares, or the Shares, of the Company's common stock. The offering price was $2.00 per share, and the Underwriters agreed to purchase the Shares from the Company pursuant to the Underwriting Agreement at a price of $1.88 per share. Under the terms of the Underwriting Agreement, the Company granted the Underwriters a 30-day option to purchase up to 3,750,000 additional shares of

common stock, or the Additional Shares, at the public offering price per share, and the Underwriters partially exercised their option and purchased 850,000 Additional Shares on April 22, 2025.

Net proceeds from the Offering were $46.5 million, after deducting underwriting discounts, commissions and offering expenses and net proceeds from the Offering of the Additional Shares were $1.6 million, after deducting underwriting discounts, commissions and offering expenses.

Unregistered Common Stock

In connection with the Vifor License Agreement, CSL Vifor owns 7,571,429 shares of common stock that are unregistered under the Securities Act. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, for more information.

Warrants to Purchase Common Stock

In connection with the BlackRock Credit Agreement, described in more detail in Note 7, *Indebtedness*, the Company issued a warrant to purchase 3,076,923 shares of the Company's common stock, at an exercise price per share of $1.30, and upon the borrowing of Tranche C in February 2025, the Company issued additional warrants to purchase 1,153,846 shares of the Company's common stock at an exercise price per share of $1.30. Each warrant is exercisable for eight years from the date of issuance. The warrants and the common stock issuable upon the exercise of such warrants were not registered under the Securities Act. Accordingly, the holder thereof may only sell common stock issued upon exercise of such warrants pursuant to an effective registration statement under the Securities Act covering the resale of those shares, an exemption under Rule 144 under the Securities Act or another applicable exemption under the Securities Act.

On July 21, 2025, the Warrant Holder exercised its option to purchase 2,115,384 shares of the Company's common stock under the Initial Warrant on a cashless basis at an exercise price per share of $1.30. On July 23, 2025, as a result of the cashless exercise, the Company issued 1,408,588 shares of common stock to the Warrant Holder under the Initial Warrant.

14. STOCK-BASED COMPENSATION PLANS

Stock-Based Compensation Plans

The Company incurred stock-based compensation expenses of $2.8 million and $9.7 million during the three and nine months ended September 30, 2026, respectively, and $3.2 million and $8.1 million for the three and nine months ended September 30, 2025, respectively.

Equity Incentive Plans

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

			September 30, 2026		December 31, 2025	
Title of Plan	Group Eligible	Type of Award Granted (or to be Granted)	Awards Outstanding	Additional Awards Available for Grant	Awards Outstanding	Additional Awards Available for Grant
Keryx Equity Plans[1][2]	Employees, directors and consultants	Stock options and restricted stock units (RSUs)	49,405	—	148,860	—
Akebia Therapeutics, Inc. 2014 Incentive Plan, as amended [2] [3] (the 2014 Plan)	Employees, directors, consultants and advisors	Stock options, RSUs, stock appreciation rights (SARs) and performance awards	6,832,231	—	8,412,898	—
Akebia Therapeutics, Inc. 2023 Stock Incentive Plan, as amended[3] [4] (the 2023 Plan) *(replaced 2014 Plan)*	Employees, officers, directors, consultants and advisors	Stock options, SARs, restricted stock, unrestricted stock, RSUs, performance awards, other share-based awards and dividend equivalents	21,597,814	17,249,912	15,913,729	24,723,655

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

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

(3) This table includes the following inducement awards that are subject to the terms and conditions of the applicable plan but were granted as inducement awards consistent with Nasdaq Listing Rule 5635(c)(4) and not under the applicable plan: 821,625 options included as outstanding under the 2014 Plan

in the table and 3,544,957 options included as outstanding under the 2023 Plan in the table as of September 30, 2026 and 1,050,525 options included as outstanding under the 2014 Plan and 3,034,085 options included as outstanding under the 2023 Plan in the table as of December 31, 2025.

(4) On June 10, 2025, the 2023 Plan was amended to increase the number of shares of common stock available for issuance thereunder by 18,900,000 shares.

Common Stock Options and Stock Appreciation Rights

During the nine months ended September 30, 2026, the Company granted 4,011,200 options to employees and 536,000 options to directors under the 2023 Plan. Options and SARs granted by the Company generally vest over periods of between 12 and 48 months, subject, in each case, to the individual's continued service through the applicable vesting date. Options and SARs generally vest either 100% on the first anniversary of the grant date or in installments of (i) 25% at the one year anniversary and (ii) 12 equal quarterly installments beginning after the one year anniversary of the grant date, subject to the individual's continuous service with the Company. Options and SARs generally expire ten years after the date of grant.

The Company also maintains an inducement award program with a share pool that is separate from the Company's equity plans under which inducement awards may be granted consistent with Nasdaq Listing Rule 5635(c)(4). During the nine months ended September 30, 2026, the Company granted 1,279,375 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 1,114,275 options remained outstanding as of September 30, 2026.

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

Finally, the Company periodically grants performance-based stock options which generally vest in connection with the achievement of specified commercial, regulatory and corporate milestones. The performance-based stock options also generally feature a time-based vesting component. The expense recognized for these awards is based on the grant date fair value of the Company's common stock multiplied by the number of options granted and recognized over time based on the probability of meeting such commercial, regulatory and corporate milestones.

The combined stock option activity for the nine months ended September 30, 2026, is as follows:

	Stock Options	Weighted Average Exercise Price	Weighted-Average Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	18,152,258	$ 2.85	6.97 years	$ 3,690
Granted	5,826,575	$ 1.38	—	—
Exercised	(563,493)	$ 0.63	—	—
Expired	(1,019,949)	$ 5.24	—	—
Canceled and forfeited	(1,545,933)	$ 1.84	—	—
Outstanding at September 30, 2026	20,849,458	$ 2.46	7.02 years	$ 746
Exercisable at September 30, 2026	11,525,769	$ 3.14	5.62 years	$ 657

As of September 30, 2026, there was approximately $10.9 million of unrecognized compensation costs related to stock options, which is expected to be recognized over a weighted average period of 2.55 years.

Restricted Stock Units

Generally, RSUs granted by the Company vest in one of the following ways: (i) 100% of each RSU grant vests on the first anniversary of the grant date, (ii) one third of each RSU grant vests on the first, second and third anniversaries of the grant date, (iii) 50% of each RSU grant vests on the first anniversary and 25% of each RSU grant vests every six months after the one year anniversary of the grant date, or (iv) one third of each RSU grant vests on the first anniversary of the grant date and the remaining two thirds vests in eight substantially equal quarterly installments beginning after the one year anniversary, subject, in each case, to the individual's continued service through the applicable vesting date. The grant-date fair value of the RSUs is recognized as expense on a straight-line basis. The Company determines the fair value of the RSUs based on the closing price of the common stock on the date of the grants.

The Company also periodically grants performance-based restricted stock units, or PSUs, to employees under the 2023 Plan and previously granted PSUs under the 2014 Plan. The PSUs granted by the Company generally vest in connection with the

achievement of specified commercial, regulatory and corporate milestones. The PSUs also generally feature a time-based vesting component. The expense recognized for these awards is based on the grant date fair value of the Company's common stock multiplied by the number of units granted and recognized over time based on the probability of meeting such commercial, regulatory and corporate milestones.

In addition, the Company has granted PSUs to certain employees under the 2023 Plan with a market condition. The PSUs also generally feature a time-based vesting component. The Company uses a Monte Carlo simulation to determine fair value of the award at the grant date. The expense recognized for these awards is based on the calculated fair value multiplied by the number of the target units granted and is amortized over the service period.

RSU and PSU activity is as follows:

	2014 Plan		2023 Plan	
	Number of Shares	Weighted Average Grant Date Fair Value	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2025	330,622	$ 0.63	5,992,607	$ 2.09
Granted	—	$ —	5,831,100	$ 1.38
Vested	(330,622)	$ 0.63	(2,771,237)	$ 2.17
Forfeited and canceled	—	$ —	(1,422,478)	$ 1.63
Unvested as of September 30, 2026	—	$ —	7,629,992	$ 1.60

As of September 30, 2026, there was $8.3 million of unrecognized compensation costs related to time-based RSUs and PSUs, which is expected to be recognized over a weighted-average period of 1.79 years.

Employee Stock Purchase Plan

On June 6, 2019, the Company's stockholders approved the Amended and Restated 2014 Employee Stock Purchase Plan, or ESPP. Under the ESPP, substantially all employees may voluntarily enroll to purchase shares of the Company's common stock through payroll deductions at a price equal to 85% of the lower of the fair market values of the stock as of the beginning or the end of the six-month offering period. An employee's payroll deductions under the ESPP are limited to 15% of the employee's compensation, and an employee may not purchase more than $25,000 worth of stock during any calendar year. In addition, an employee may not purchase more than 1,500 shares in any six-month offering period. As of September 30, 2026 and December 31, 2025, a total of 4,079,222 and 4,260,647 shares of the Company's common stock were available for future issuance under the ESPP, respectively. The Company issued 181,425 shares under the ESPP during the nine months ended September 30, 2026.

Stock-Based Compensation Expense

The Black-Scholes option pricing model is used to estimate the fair value of the common stock options. The weighted-average assumptions used in calculating the fair values of the rights to acquire stock under the 2023 Plan, the 2014 Plan and inducement awards were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Common Stock Options	2026	2025	2026	2025
Risk-free interest rate	4.49 % - 5.09%	3.79 % - 4.03%	3.61% - 5.09%	3.79% - 4.38%
Expected volatility	108.69 % - 116.07%	111.72 % - 120.16%	96.64% - 119.09%	111.61% - 123.58%
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	$1.05	$2.80	$1.18	$2.18

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Cost of goods sold	$ 106	$ 169	$ 427	$ 491
Research and development	426	677	2,048	1,675
Selling, general and administrative	2,155	2,375	7,042	5,918
Restructuring	114	—	178	—
Total stock-based compensation	$ 2,801	$ 3,221	$ 9,695	$ 8,084

15. NET INCOME (LOSS) PER SHARE

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(Dollars in thousands, except per share amounts)	2026	2025	2026	2025
Numerator				
Net income (loss)	$ (14,354)	$ 540	$ (32,316)	$ 6,899
Denominator				
Denominator for basic net income (loss) per share - weighted average outstanding shares of common stock	276,862,564	264,786,432	271,206,644	254,390,502
Dilutive effect of common stock options and SARs	—	4,416,904	—	3,351,562
Dilutive effect of RSUs	—	3,243,785	—	2,995,205
Dilutive effect of warrants	—	1,924,435	—	1,942,508
Dilutive effect of ESPP	—	1,166	—	1,166
Denominator for diluted net income (loss) per share - weighted average outstanding shares of common stock and assumed conversions	276,862,564	274,372,722	271,206,644	262,680,943
Basic net income (loss) per share	$ (0.05)	$ 0.00	$ (0.12)	$ 0.03
Diluted net income (loss) per share	$ (0.05)	$ 0.00	$ (0.12)	$ 0.03

Potentially dilutive securities including common stock options, RSUs, SARs and warrants have been excluded from the calculation of diluted net loss per share as their effects would be anti-dilutive. For the three and nine months ended September 30, 2026 in which the Company reported a net loss, the weighted average number of shares outstanding used to calculate both basic and diluted net loss per share were the same. The shares in the table below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, due to their anti-dilutive effect:

	Three and Nine Months Ended September 30, 2026
Outstanding common stock options	20,214,145
SARs	635,313
Unvested RSUs	7,629,992
Warrants	2,115,385
Total	30,594,835

16. SEGMENT INFORMATION

The Company operates as one operating segment focused on developing and commercializing innovative therapeutics primarily in the U.S. The accounting policies of the segment are the same as those described in Note 2, *Summary of Significant Accounting Policies*.

The determination of a single business segment is consistent with the consolidated financial information regularly reviewed by the chief executive officer, who is the Company's chief operating decision maker, or CODM, in assessing segment performance and deciding how to allocate resources on a consolidated basis.

The CODM makes decisions on resource allocation, assesses performance of the business, and monitors budget versus actual results using income (loss) from operations. Net income (loss) is also a measure that is considered in monitoring budget versus actual results. The measure of segment assets is reported on the consolidated balance sheets as total consolidated assets.

The following table presents information about reported segment revenues, segment profit or loss and significant segment expenses for the three and nine months ended September 30, 2026 and 2025:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Revenues	$ 36,903	$ 58,766	$ 139,575	$ 178,574
Less:				
Direct cost of product and other revenue	5,027	6,683	23,910	18,569
Panion royalty	1,335	2,700	5,166	8,358
Research and development	16,183	14,944	45,049	35,711
Selling, general and administrative	23,531	29,094	82,138	81,391
License	946	896	2,508	2,493
Restructuring	1,343	—	3,288	—
Income (loss) from operations	(11,462)	4,449	(22,484)	32,052
Other income (expense)				
Interest expense	(3,142)	(4,748)	(10,904)	(19,352)
Other income	(6)	(10)	(10)	175
Change in fair value of warrant liability	431	1,464	1,453	(5,361)
Income (loss) before income taxes	(14,179)	1,155	(31,945)	7,514
Income tax expense	(175)	(615)	(371)	(615)
Net income (loss)	$ (14,354)	$ 540	$ (32,316)	$ 6,899

17. SUBSEQUENT EVENTS

The Company has evaluated events and transactions occurring after the balance sheet date through the filing date of this Form 10-Q with the Securities and Exchange Commission, to ensure that the unaudited condensed consolidated financial statements include appropriate disclosure of events both recognized in the accompanying unaudited condensed consolidated financial statements as of September 30, 2026, 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.

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, 2025 filed with the United States, or U.S., Securities and Exchange Commission, or the SEC, on February 26, 2026, or the 2025 Form 10-K. In addition to historical information, the following discussion and analysis contains forward-looking statements that reflect our plans, estimates, beliefs and explanations that involve significant risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Part II, Item 1A. of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

Business Overview

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

We have established the Company as a leader in the kidney community and believe our cross-organizational expertise in kidney disease positions us for success. Chronic kidney disease, or CKD, is a condition in which the kidneys are progressively damaged to the point that they cannot properly filter the blood circulating in the body. This damage causes waste products to build up in the patient's blood, leading to other health problems, including anemia, cardiovascular disease and bone disease. Our two commercial products address certain complications of kidney disease.

Our current product portfolio includes:

Vafseo® (vadadustat) is an orally administered medicine that was approved by the U.S. Food and Drug Administration, or the FDA, in March 2024 for the treatment of anemia due to CKD in adult patients on dialysis for at least three months. Vafseo is the only oral hypoxia inducible factor, or HIF, based treatment available in the U.S. Vafseo entered the market in January 2025.

Vafseo is approved for use in adults in 37 countries and is marketed in certain countries outside the U.S. by our partners.

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

Today, we market Auryxia in the U.S. Auryxia became part of our portfolio in 2018 and has historically contributed meaningful revenue to the business. In March 2025, Auryxia reached loss of exclusivity, or LoE. On March 11, 2026, Teva Pharmaceuticals USA, Inc., or Teva, received approval for its Abbreviated New Drug Application, or ANDA, for a generic version of Auryxia, which has subsequently entered the market.

Ferric citrate is approved for use and marketed in certain countries outside the U.S. by our partners.

Our development pipeline includes:

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

In November 2025, we entered into an Asset Purchase Agreement, or the Q32 Purchase Agreement, with Q32 Bio Inc. and Q32 Bio Operations Inc., together Q32, pursuant to which we purchased and assumed substantially all assets and liabilities of Q32 and its affiliates related to the research, development, manufacture and commercialization of Q32's clinical-stage development candidate ADX-097, known as ebribafusp (AKB-097), an anti-C3d-Factor H fusion protein complement inhibitor. Ebribafusp is a potential next-generation complement inhibitor, and we believe ebribafusp has applicability across a wide range of complement-mediated rare kidney diseases. Ebribafusp is intended to provide targeted regulation of complement activation at sites of tissue injury while limiting systemic

complement inhibition. In September 2026, we dosed our first patient in a Phase 2 basket study to evaluate ebribafusp in IgA Nephropathy, or IgAN, C3 Glomerulopathy, or C3G, and Lupus Nephritis, or LN.

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

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

Factors Affecting Our Performance and Results of Operations

Financial Components

Product Revenue

We generate product revenue from commercial sales of Auryxia and Vafseo to a limited number of customers, including dialysis organizations, wholesale distributors, certain specialty pharmacy providers and our authorized generic distribution partner for Auryxia, Mylan Therapeutics, Inc., or AG Distributor. Our net product revenue includes many variables, including judgments and estimates of discounts, rebates and product returns, which can fluctuate from quarter-to-quarter and year-over-year.

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 license, collaboration and supply agreements with MEDICE Arzneimittel Pütter GmbH & Co. KG, or Medice, Tanabe Pharma Corporation, or TPC, Japan Tobacco, Inc. (succeeded by Shionogi & Co., Ltd.) and its subsidiary, Torii Pharmaceutical Co., Ltd., collectively, JT and Torii, and any other collaborations into which we have entered or may enter.

Cost of Product and Other Revenue

Cost of product and other revenue includes costs closely correlated or directly related to the costs to manufacture commercial drug substance and drug product, including at our contract development and manufacturing organizations, or CDMOs, 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 a firm purchase commitment liability and royalties due to the licensor of Auryxia related to U.S. and Japan product sales recognized during the period.

Cost of product and other revenue also includes costs to manufacture drug product provided to TPC and Medice for commercial sales of Vafseo in Japan and in the EEA, the UK, Switzerland and Australia, or collectively the Medice Territory, respectively, as well as to our AG Distributor. In addition, cost of product and other revenue includes personnel-related costs, including salaries and bonuses, employee benefits and stock-based compensation attributable to employees in particular functions and associated directly with the manufacturing of our commercial products.

Cost of product and other revenue for a newly launched product does not include the full cost of manufacturing until the initial pre-launch inventory is depleted and additional inventory is manufactured and sold. Until we received regulatory approval for Vafseo in the U.S., we recorded costs incurred to manufacture the U.S. pre-launch inventory, such as raw materials, drug substance and drug product conversion costs as research and development, or R&D, expense.

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 CDMOs;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies associated with our laboratory space as well as our R&D team;
- acquired in process research and development costs associated with the acquisition of Q32's clinical stage development asset known as ebribafusp; and
- costs associated with discovery and development for preclinical, clinical and regulatory activities.

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, 2026, we have incurred $1.8 billion in R&D expenses. We expect to incur significant R&D expenditures for the foreseeable future as we continue the development of Vafseo, praliciguat, ebribafusp, AKB-9090 and any other product or product candidate, including those that may be in-licensed or acquired.

A significant portion of our R&D costs have been external costs, which we track on a program-by-program basis as well as costs related to possible new manufacturing processes and methods associated with our commercial products. These external costs include fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical trials and costs related to acquiring and manufacturing clinical trial materials, including costs paid to CDMOs 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 Vafseo, praliciguat, ebribafusp and AKB-9090 and any other product or product candidate, could result in a significant change in the costs and timing associated with that development.

Selling, General and Administrative Expenses

Selling, general and administrative, or SG&A, expenses consist primarily of compensation for personnel, including stock-based compensation related to commercial, marketing, executive, finance and accounting, information technology, corporate and business development and human resource functions. Other SG&A expenses include costs for marketing initiatives for our commercial products, market research and analysis on our commercial products and potential product candidates, conferences and trade shows, travel expenses, professional services fees (including legal, patent, accounting, audit, tax, and consulting fees), insurance costs, general corporate expenses and allocated facilities-related expenses, including rent and maintenance of facilities.

License Expense

License expense relates to royalties due to Panion & BF Biotech, Inc., or Panion, for sales of Auryxia in the U.S. and Riona in Japan.

Other Income (Expense), Net

Other income (expense), net consists primarily of interest income on our interest-bearing accounts, interest expense related to our term loans and accretion of the debt discount on our term loans. Other income (expense), net, also includes non-cash interest on our liability related to settlement royalties and the amortization of the discount and deferred gain related to our Working Capital Fund (as defined below) liability to Vifor (International) Ltd. (now a part of CSL Limited), or CSL Vifor. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, in the accompanying notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information on our arrangements with CSL Vifor.

Change in Fair Value of Warrant Liability

Change in fair value of warrant liability relates to the change in fair value of our warrant liability related to a warrant agreement with Kreos Capital VII Aggregator SCSp, an affiliate of Kreos Capital VII (UK) Limited, or Kreos. See Note 3, *Fair Value Measurements*, 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

Initiation of Phase 2 Trial in Rare Complement-Mediated Kidney Diseases

In September 2026, we dosed our first patient in a Phase 2 basket trial evaluating ebribafusp for the treatment of rare complement-mediated kidney diseases, including IgAN, LN and C3G. As a result, pursuant to the terms of the Q32 Purchase Agreement, we paid $1.9 million of the $2.0 million development milestone in September 2026 upon such dosing and paid the remaining $0.1 million in October 2026.

Interim Analysis of Vafseo Outcomes In Center Experience (VOICE) Trial

In June 2026, we and U.S. Renal Care, or USRC, Kidney Research announced the results of a planned interim analysis of the VOICE trial and that it met the predefined stopping criteria by establishing non-inferiority and superiority of the primary composite endpoint and the decision by USRC Kidney Research to stop the trial on this basis. The primary investigator made the decision to stop the trial after a recommendation from the Independent Data Monitoring Committee and Trial Steering Committee, based on an interim analysis of data from the trial as of the June 1, 2026 data cutoff date meeting the prescribed stopping criteria.

Increase to Authorized Shares

In June 2026, we filed a Certificate of Amendment to our Ninth Amended and Restated Certificate of Incorporation, which (i) increased the number of authorized shares of capital stock from 375,000,000 to 525,000,000 and (ii) increased the number of authorized shares of common stock, par value $0.00001 per share, from 350,000,000 to 500,000,000.

Cambridge Lease Extension

In April and September 2026, we entered into amendments to our lease for office and laboratory space in Cambridge, Massachusetts, or the Cambridge Lease, to extend the term of the laboratory space and office and storage space, respectively, from September 11, 2026 to October 31, 2026. See Note 9, *Leases*, in the accompanying notes to the consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information on the Cambridge Lease.

Initiation of Phase 1 Trial in CS-AKI

In April 2026, we dosed our first patient in a Phase 1 clinical trial of AKB-9090 for the treatment of CS-AKI.

Waltham Lease

In January 2026, we entered into a lease agreement, or the Waltham Lease, pursuant to which we lease an aggregate of 43,474 square feet, consisting of 28,518 square feet of office space and 14,956 square feet of laboratory space located in Waltham, Massachusetts. We relocated our corporate headquarters to Waltham in September 2026.

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

Results of Operations

Comparison of the Three Months Ended September 30, 2026 and 2025

	Three Months Ended September 30,		Change	
(dollars in thousands)	**2026**	**2025**	**$**	**%**
Revenues				
Product revenue, net	$ 34,827	$ 56,789	$ (21,962)	(39)%
License, collaboration and other revenue	2,076	1,977	99	5 %
Total revenues	36,903	58,766	(21,863)	(37)%
Cost of goods sold				
Cost of product and other revenue	6,362	9,383	(3,021)	(32)%
Total cost of goods sold	6,362	9,383	(3,021)	(32)%
Operating expenses				
Research and development	16,183	14,944	1,239	8 %
Selling, general and administrative	23,531	29,094	(5,563)	(19)%
License	946	896	50	6 %
Restructuring	1,343	—	1,343	100 %
Total operating expenses	42,003	44,934	(2,931)	(7)%
Income (loss) from operations	(11,462)	4,449	(15,911)	(358)%
Other expense, net	(3,148)	(4,758)	1,610	(34)%
Change in fair value of warrant liability	431	1,464	(1,033)	(71)%
Income (loss) before income taxes	(14,179)	1,155	(15,334)	(1328)%
Income tax expense	(175)	(615)	440	(72)%
Net income (loss)	$ (14,354)	$ 540	$ (14,894)	(2758)%

Product Revenue, Net—Net product revenue was $34.8 million for the three months ended September 30, 2026, compared to $56.8 million for the three months ended September 30, 2025. The decrease was primarily due to lower Auryxia revenues. The lower Auryxia revenues are primarily driven by a decrease in net price as well as a decrease in sales volume of Auryxia due to generic competition.

Following LoE for Auryxia in March 2025, our AG Distributor has been selling an authorized generic version of Auryxia in the U.S. On March 11, 2026, Teva received approval for its ANDA for a generic version of Auryxia. As a result of Teva's entry into the market, we have experienced a significant reduction in the volume of Auryxia sales. We expect the ongoing sales of generic versions of Auryxia, including by Teva and our AG Distributor, and of any additional generic versions of Auryxia that may be approved, will continue to have a significant adverse impact on our revenue. However, the extent of the impact on future Auryxia revenues will depend on many factors, including our ability to maintain contracts with dialysis organizations and other customers, including specialty distributors, on favorable terms, or at all, the timing and number of additional generics, the amount of generic product available to supply the market and the pricing of generics and other products on the market that compete with Auryxia.

As a result of changes in the amount of reimbursement dialysis facilities will receive for use of Vafseo when Vafseo transitions from the Transitional Drug Add-on Payment Adjustment, or TDAPA, period to the post-TDAPA period, we believe our customers are likely to reduce inventory levels at the end of 2026. Additionally, when the post-TDAPA period begins in 2027, we expect to price Vafseo within the range of the price for ESAs. ESAs are currently priced significantly lower than Vafseo’s current price. As a result, while we expect to sell a higher unit volume of Vafseo in 2027 as compared to 2026, we expect Vafseo revenues to decrease significantly in 2027 as compared to 2026 due to the expected lower price point.

The following table summarizes our product revenue by product for the three months ended September 30, 2026 and 2025 (in thousands):

Product	Three Months Ended September 30, 2026	2025
Vafseo	$ 14,798	$ 14,322
Auryxia[1]	20,029	42,467
Total product revenues	$ 34,827	$ 56,789

(1) Includes the authorized generic version of Auryxia sold and distributed by our AG Distributor during the three months ended September 30, 2026 and 2025.

License, Collaboration and Other Revenue—License, collaboration and other revenue was $2.1 million for the three months ended September 30, 2026, compared to $2.0 million for the three months ended September 30, 2025.

Cost of Goods Sold—Cost of Product and Other Revenue—Cost of product and other revenue was $6.4 million for the three months ended September 30, 2026 compared to $9.4 million for the three months ended September 30, 2025. The decrease was primarily due to lower Auryxia sales volume during the three months ended September 30, 2026.

We began capitalizing our Vafseo costs in March 2024, in connection with the FDA's approval of Vafseo for the treatment of anemia due to CKD in adult patients on dialysis for at least three months. Prior to the capitalization of Vafseo inventory costs, such costs were recorded as research and development expenses in the period incurred. We recorded a benefit to cost of product and other revenue for Vafseo of $0.3 million for the three months ended September 30, 2026, due to a tariff refund received during the three months ended September 30, 2026, which was offset by manufacturing and overhead costs as the associated inventory costs such as raw materials, drug substance and drug product conversion costs were expensed previously. If Vafseo inventory sold during the three months ended September 30, 2026 was valued at cost, our cost of product and other revenue for Vafseo would have been $2.5 million. As of September 30, 2026, we had $16.3 million of reduced-cost Vafseo inventory. We expect our cost of product and other revenue for Vafseo will increase, reflecting the full cost of manufacturing, subsequent to the utilization of our reduced-cost Vafseo inventory.

R&D Expenses—R&D expenses were $16.2 million for the three months ended September 30, 2026, compared to $14.9 million for the three months ended September 30, 2025. The increase was primarily driven by increased clinical trial activities related to our mid-stage pipeline assets, which include praliciguat and ebribafusp, during the three months ended September 30, 2026.

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, 2026 and 2025 (in thousands):

	Three Months Ended September 30, 2026	2025
Clinical trial and related external costs[1]:		
Vafseo and Auryxia	$ 2,922	$ 4,375
Mid-stage pipeline assets (praliciguat and ebribafusp)	4,253	1,267
Early-stage pipeline assets (AKB-9090 and AKB-10108)	884	1,155
Non-program specific	2,307	1,743
Total external R&D expenses	10,366	8,540
Internal personnel, consulting, facilities and other	5,817	6,404
Total R&D expenses	$ 16,183	$ 14,944

(1) See the section titled "Business Overview" for details on our current product portfolio and development pipeline.

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.

Selling, General and Administrative Expenses—Selling, general and administrative expenses were $23.5 million for the three months ended September 30, 2026, compared to $29.1 million for the three months ended September 30, 2025. The decrease was driven by lower marketing costs and decreased headcount related costs during the three months ended September 30, 2026.

License Expenses—License expenses related to royalties due to Panion for sales of Riona in Japan were $0.9 million for each of the three months ended September 30, 2026 and 2025.

Restructuring Expenses—Restructuring expenses were $1.3 million for the three months ended September 30, 2026. In July 2026, we implemented a reduction in headcount representing approximately 7% of our workforce prior to the reduction in order to improve our operational efficiency to align with our current priorities. There were no restructuring expenses for the three months ended September 30, 2025.

Other Expense, Net—Other expense, net, was $3.1 million for the three months ended September 30, 2026, compared to $4.8 million for the three months ended September 30, 2025. The decrease was primarily due to lower non-cash interest expense related to the settlement royalty liability in connection with the Termination and Settlement Agreement with CSL Vifor, or the Vifor Termination Agreement. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, included in the accompanying notes to the unaudited condensed consolidated financial statements 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 $0.4 million and $1.5 million for the three months ended September 30, 2026 and 2025, respectively.

Income Tax Expense—Income tax expense was $0.2 million and $0.6 million for the three months ended September 30, 2026 and 2025, respectively.

Comparison of the Nine Months Ended September 30, 2026 and 2025

	Nine Months Ended September 30,		Change	
	2026	2025	$	%
Revenues				
Product revenue, net	$ 133,584	$ 173,041	$ (39,457)	(23)%
License, collaboration and other revenue	5,991	5,533	458	8 %
Total revenues	139,575	178,574	(38,999)	(22)%
Cost of goods sold				
Cost of product and other revenue	29,076	26,927	2,149	8 %
Total cost of goods sold	29,076	26,927	2,149	8 %
Operating expenses				
Research and development	45,049	35,711	9,338	26 %
Selling, general and administrative	82,138	81,391	747	1 %
License	2,508	2,493	15	1 %
Restructuring	3,288	—	3,288	100 %
Total operating expenses	132,983	119,595	13,388	11 %
Operating income (loss)	(22,484)	32,052	(54,536)	(170)%
Other expense, net	(10,914)	(19,177)	8,263	(43)%
Change in fair value of warrant liability	1,453	(5,361)	6,814	(127)%
Income (loss) before income taxes	(31,945)	7,514	(39,459)	(525)%
Income tax expense	(371)	(615)	244	(40)%
Net income (loss)	$ (32,316)	$ 6,899	$ (39,215)	(568)%

Product Revenue, Net—Net product revenue was $133.6 million for the nine months ended September 30, 2026, compared to $173.0 million for the nine months ended September 30, 2025. The decrease was primarily due to lower Auryxia revenues, which were partially offset by higher Vafseo revenues. The lower Auryxia revenues are due to a decrease in net price as well as a decrease in sales volume of Auryxia due to generic competition as described in greater detail above. As a result of the foregoing, we expect our Auryxia revenues to continue to be significantly lower for the remainder of 2026 and beyond as compared to 2025 Auryxia revenues.

The following table summarizes our product revenue by product for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,	
Product	**2026**	**2025**
Vafseo	$ 51,902	$ 39,635
Auryxia[(1)]	81,682	133,406
Total product revenues	$ 133,584	$ 173,041

(1) Includes the authorized generic version of Auryxia sold and distributed by our AG Distributor during the nine months ended September 30, 2026 and 2025

License, Collaboration and Other Revenue—License, collaboration and other revenue was $6.0 million for the nine months ended September 30, 2026, compared to $5.5 million for the nine months ended September 30, 2025. The increase was primarily due to revenue recognized in connection with our supply agreement with Medice during the nine months ended September 30, 2026.

Cost of Goods Sold—Cost of Product and Other Revenue—Cost of product and other revenue was $29.1 million for the nine months ended September 30, 2026 compared to $26.9 million for the nine months ended September 30, 2025. The increase was primarily due to an increase in inventory write-downs as a result of excess, obsolescence, scrap or other reasons during the nine months ended September 30, 2026.

We began capitalizing our Vafseo costs in March 2024, in connection with the FDA's approval of Vafseo for the treatment of anemia due to CKD in adult patients on dialysis for at least three months. Prior to the capitalization of Vafseo inventory costs, such costs were recorded as research and development expenses in the period incurred. Cost of product and other revenue for Vafseo was $2.2 million for the nine months ended September 30, 2026, comprised of manufacturing and overhead costs as the associated inventory costs such as raw materials, drug substance and drug product conversion costs were expensed previously. If Vafseo inventory sold during the nine months ended September 30, 2026 was valued at cost, our cost of product and other revenue for Vafseo would have been $12.0 million. As of September 30, 2026, we had $16.3 million of reduced-cost Vafseo inventory. We expect our cost of product and other revenue for Vafseo will increase, reflecting the full cost of manufacturing, subsequent to the utilization of our reduced-cost Vafseo inventory.

R&D Expenses—R&D expenses were $45.0 million for the nine months ended September 30, 2026, compared to $35.7 million for the nine months ended September 30, 2025. The increase was primarily driven by increased clinical trial activities related to Vafseo and our mid-stage pipeline assets, which include praliciguat and ebribafusp, as well as higher headcount related costs during the nine months ended September 30, 2026.

The following table summarizes our external research and development expenses by program, as well as costs not allocated to programs, for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,	
	2026	**2025**
Clinical trial and related external costs[(1)]:		
Vafseo and Auryxia	$ 9,349	$ 9,251
Mid-stage pipeline assets (praliciguat and ebribafusp)	8,664	1,505
Early-stage pipeline assets (AKB-9090 and AKB-10108)	2,503	3,432
Non-program specific	5,492	4,711
Total external R&D expenses	26,008	18,899
Internal personnel, consulting, facilities and other	19,041	16,812
Total R&D expenses	$ 45,049	$ 35,711

(1) See the section titled "Business Overview" for details on our current product portfolio and development pipeline.

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.

Selling, General and Administrative Expenses—Selling, general and administrative expenses were $82.1 million for the nine months ended September 30, 2026, compared to $81.4 million for the nine months ended September 30, 2025.

License Expenses—License expenses related to royalties due to Panion for sales of Riona in Japan were $2.5 million for each of the nine months ended September 30, 2026 and 2025.

Restructuring Expenses—Restructuring expenses were $3.3 million for the nine months ended September 30, 2026 due to our commercial reorganization implemented in June 2026 and the reduction in headcount implemented in July 2026. There were no restructuring expenses for the nine months ended September 30, 2025.

Other Expense, Net—Other expense, net, was $10.9 million for the nine months ended September 30, 2026, compared to $19.2 million for the nine months ended September 30, 2025. The decrease was primarily due to lower non-cash interest expense related to the settlement royalty liability in connection with the Vifor Termination Agreement, as well as higher interest income related to our money market funds. See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, included in the accompanying notes to the unaudited condensed consolidated financial statements 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 $1.5 million and $5.4 million for the nine months ended September 30, 2026 and 2025, respectively.

Income Tax Expense—Income tax expense was $0.4 million and $0.6 million for the nine months ended September 30, 2026 and 2025, respectively.

Liquidity and Capital Resources

As of September 30, 2026, we had cash and cash equivalents of $159.3 million and restricted cash of $0.9 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 and a royalty transaction. From inception through September 30, 2026, we raised approximately $938.9 million of net proceeds from the sale of equity, including $567.9 million from various underwritten public offerings, $301.0 million from at-the-market, or ATM, offerings, pursuant to our sales agreement with Jefferies LLC, or Jefferies, and prior sales agreements with Cantor Fitzgerald & Co., and $70.0 million from the sale of 7,571,429 shares of common stock to CSL Vifor. During the nine months ended September 30, 2026, we sold 8,244,695 shares of our common stock under the ATM offering with Jefferies with gross proceeds of $10.1 million ($9.8 million, net of offering expenses).

We incurred a net loss of $14.4 million and $32.3 million during the three and nine months ended September 30, 2026, respectively, and generated net income of $0.5 million and $6.9 million during the three and nine months ended September 30, 2025, respectively. As of September 30, 2026 and December 31, 2025, we had an accumulated deficit of $1.7 billion.

We had exclusive rights under a series of patents and patent applications to commercialize Auryxia in the U.S. that protected us from generic drug competition until March 2025. Following LoE, our AG Distributor has been selling an authorized generic version of Auryxia in the U.S. On March 11, 2026, Teva received approval for its ANDA for a generic version of Auryxia. As a result of Teva's entry into the market, we have experienced a significant reduction in the volume of Auryxia sales. We expect the ongoing sales of generic versions of Auryxia, including by Teva and our AG Distributor, and of any additional generic versions of Auryxia that may be approved, will continue to have a significant adverse impact on our revenue. However, the extent of impact on future Auryxia revenues will depend on many factors, including our ability to maintain contracts with dialysis organizations and other customers, including specialty distributors, the timing and number of additional generics that enter the market, the amount of generic product available to supply the market and the pricing of generics and other products on the market that compete with Auryxia.

We believe our existing cash resources and the cash we expect to generate from product, royalty, supply and license revenues are sufficient to fund our current operating plan for at least two years. This estimate is contingent upon us refinancing our outstanding debt under our senior secured term loan facility to defer the payment of principal, which would otherwise commence on January 1, 2027. 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 our senior secured term loan facility. If we are unable to execute such refinancing on favorable terms or at all, we believe that our existing cash resources and the cash we expect to generate from product, royalty, supply and license revenues will be sufficient to enable us to fund our current operating plan for at least 12 months from the filing of this Quarterly Report on Form 10-Q.

If we are unable to refinance our senior secured term loan, or our operating performance deteriorates significantly from the levels expected in our long-term operating plan, including if we do not achieve our future anticipated revenue projections from Vafseo, it would have an adverse effect on our liquidity and capital resources, and we would be required to obtain additional financing to fund our operating plan or continue as a going concern in the future. In addition, we may also seek to sell additional private or public equity, enter into new debt transactions, explore potential strategic transactions or a combination of these approaches or other strategic alternatives. If we raise additional funds by issuing equity securities, our shareholders would experience dilution. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Additional financing may not be available to us in amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital in sufficient amounts when needed or on attractive terms, we may not be able to pursue development and commercial activities related to 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 Agreement for the Provision of a Loan Facility, as amended, or the BlackRock Credit Agreement, with Kreos Capital VII (UK) Limited, or Kreos, which are funds and accounts managed by BlackRock Inc., collectively, BlackRock. The BlackRock Credit Agreement provides for a senior secured term loan facility, in the aggregate principal amount of up to $55.0 million, or the Term Loan Facility. The Term Loan Facility was available in three tranches (i) Tranche A — $37.0 million was funded on the Closing Date; (ii) Tranche B — $8.0 million was funded on April 19, 2024; and (iii) Tranche C — $10.0 million was funded on February 3, 2025, or the Tranche C Closing Date, collectively, the Term Loans. The Term Loan Facility matures on January 29, 2028, or the BlackRock Maturity Date.

On February 3, 2025, we and Kreos entered into a Second Amendment to the BlackRock Credit Agreement, which, among other things, extended the expiry date of Tranche C from December 31, 2024 to the Tranche C Closing Date, or the Extended Tranche C. Tranche C was available subject to receipt of a certain amount of cumulative gross cash proceeds after the Closing Date in the form of equity or equity linked securities in one or more series of transactions. The terms of the Extended Tranche C are substantially similar to the terms of the original Tranche C, however, interest accrued on the Extended Tranche C as if it was advanced on December 31, 2024.

We are required to make interest-only payments until December 31, 2026 after which, we will begin making equal monthly principal payments. In the event of certain prespecified events, the repayment schedule will be accelerated.

The Term Loan Facility accrues interest at a floating annual rate equal to the sum of (i) term Secured Overnight Financing Rate 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, or the Initial Warrant, at an exercise price per share of $1.30, and upon the borrowing of Tranche C in February 2025, we issued additional warrants to purchase 1,153,846 shares of our common stock at an exercise price per share of $1.30. Each warrant is exercisable for eight years from the date of issuance.

On July 21, 2025, the Warrant Holder exercised its option to purchase 2,115,384 shares of our common stock under the Initial Warrant on a cashless basis at an exercise price per share of $1.30. On July 23, 2025, as a result of the cashless exercise, we issued 1,408,588 shares of our common stock to the Warrant Holder.

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

Liability Related to Settlement Royalties

On July 10, 2024, we and CSL Vifor entered into the Vifor Termination Agreement. Pursuant to the terms of the Vifor Termination Agreement, we pay CSL Vifor decreasing quarterly tiered royalty payments ranging from a high single-digit percentage of our net sales of Vafseo up to $450.0 million to a mid-single digit percentage of our net sales of Vafseo above $450.0 million, in each case, in the U.S. during a calendar year, or the Settlement Royalty Payments. The Settlement Royalty Payments commenced upon the first sale of Vafseo by us to a third-party for use in the U.S., and will continue until the later of the (i) expiration of the last-to-expire valid claim listed in the FDA Orange Book that would be infringed by the making, using, selling or importing of Vafseo in the U.S. or (ii) the expiration of marketing or regulatory exclusivity for Vafseo in the U.S., or the Settlement Royalty Term. Beginning on July 1, 2027 and throughout the Settlement Royalty Term, we have the option to make a one-time payment to CSL Vifor, or the Royalty Buy-Down Option, upon which the Settlement Royalty Payments will be adjusted as of the date of exercise of the Royalty Buy-Down Option such that we will then only pay CSL Vifor quarterly royalty payments based on a mid-single digit percentage of our net sales of Vafseo up to $450.0 million in the U.S. during a calendar year in lieu of the above Settlement Royalty Payments. If we exercise the Royalty Buy-Down Option, the WCF Royalty Payments will continue as described below.

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

As a result of the Vifor Termination Agreement, we concluded that CSL Vifor no longer met the definition of a customer and, therefore, the arrangement should not be considered a revenue contract with a customer under ASC 606, *Revenue from Contracts with Customers.* We therefore determined that the $43.3 million received from CSL Vifor in connection with the Vifor License Agreement and related investment agreements should be classified as debt and we are amortizing such amount using the effective interest method over the Settlement Royalty Term. The liability related to settlement royalties and the amortization are based on our current estimates of future royalties expected to be paid over the life of the arrangement. The annual effective interest rate as of September 30, 2026 was 12.8% which is reflected as interest expense in the unaudited condensed consolidated statements of operations and comprehensive income (loss). We recognized interest expense related to the liability related to settlement royalties of $2.3 million and $7.6 million for the three and nine months ended September 30, 2026, respectively, and $3.9 million and $14.7 million during the three and nine months ended September 30, 2025, respectively. As of September 30, 2026, $5.6 million and $65.1 million of the liability related to settlement royalties is classified as a current and non-current liability, respectively.

See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, in the accompanying notes to the unaudited condensed consolidated financial statements in Part I, Item 1 of this Form 10-Q for further information.

Working Capital Fund Liability

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

Pursuant to the terms of the Vifor Termination Agreement, and generally consistent with the terms of the Vifor License Agreement, we agreed to repay the Working Capital Fund to CSL Vifor through quarterly tiered royalty payments ranging from 8% to 14% of our net sales of Vafseo in the U.S., or the WCF Royalty Payments. The WCF Royalty Payments commenced on July 1, 2025, and will continue until the earlier of (i) the cumulative total of the WCF Royalty Payments equals $40.0 million, or (ii) May 31, 2028. The WCF Royalty Payments are subject to certain minimum true-up milestones.

The Working Capital Fund is considered a debt arrangement with zero coupon interest, and we impute interest on the Working Capital Fund liability at a rate of 15.0% per annum. As of September 30, 2026, $9.8 million and $20.3 million of the Working Capital Fund liability is classified as a current and non-current liability, respectively, based on management's estimated timing of the repayment of the Working Capital Fund liability to CSL Vifor.

See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, in the accompanying notes to the unaudited condensed consolidated financial statements in Part I, Item 1 of this Form 10-Q for further information.

Liability Related to Sale of Future Royalties

In February 2021, we sold to HealthCare Royalty Partners IV L.P., or HCR, our right to receive royalties and sales milestones for Vafseo in Japan and certain other Asian countries, such countries collectively, the TPC Territory, such payments collectively the Royalty Interest Payments, in each case, payable to us under the Collaboration Agreement dated December 11, 2015, between us and TPC, or the TPC Agreement. The Royalty Interest Payments are subject to an annual maximum "cap" of $13.0 million, after which we will receive 85% of the Royalty Interest Payments for the remainder of that year. The Royalty Interest Payments are also subject to an aggregate maximum "cap" of $150.0 million, after which the Royalty Interest Payments will revert back to us.

We received $44.8 million from HCR, net of certain transaction expenses, which we recorded as a liability at the transaction date. We amortize the liability related to the sale of future royalties using the effective interest method over the life of the arrangement. The annual effective interest rate as of September 30, 2026 was 0%. We retain the right to receive all potential future regulatory milestones for Vafseo under the TPC Agreement. We recorded non-cash royalty revenue of $0.4 million and $1.2 million during the three and nine months ended September 30, 2026, respectively, and $0.5 million and $1.3 million during the three and nine months ended September 30, 2025, respectively. As of September 30, 2026, $1.5 million and $49.6 million of the liability related to the sale of future royalties is classified as a current and non-current liability, respectively.

See Note 8, *Liability Related to Settlement Royalties, Working Capital Fund Liability and Liability Related to Sale of Future Royalties*, in the accompanying notes to the unaudited condensed consolidated financial statements in Part I, Item 1 of this Form 10-Q for further information.

Off-Balance Sheet Arrangements

Letter of Credit

As of September 30, 2026, in connection with the Waltham Lease, we had $0.9 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 unaudited condensed consolidated balance sheet as of September 30, 2026, while others are considered future obligations. Our material cash requirements as of September 30, 2026, 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 leased 65,167 square feet of office, storage and laboratory space under the Cambridge Lease, which expired on October 31, 2026.

Waltham Lease

We lease 43,474 square feet of office space and laboratory space under the Waltham Lease. We relocated our corporate headquarters to Waltham in September 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 on the Cambridge Lease and Waltham Lease.

License Agreements

Panion License Agreement

We have a license agreement with Panion, under which we are required to pay royalties related to the sale of Auryxia. The royalty payment obligations are contingent upon generating product revenue, and the amount and timing of such payments are not known. See Note 10, *Commitments and Contingencies*, in the accompanying notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information.

Cyclerion Agreement

In June 2021, we entered into a license agreement, or the Cyclerion Agreement, with Cyclerion, as amended in December 2024, under which we obtained an exclusive global license under certain intellectual property rights to research, develop and commercialize praliciguat, an investigational oral soluble guanylate cyclase stimulator.

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

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

Q32 Purchase Agreement

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

Under the terms of the Q32 Purchase Agreement, we (i) made an upfront payment of $7.0 million on the APA Closing Date, (ii) made an additional upfront payment of $3.0 million on the six-month anniversary of the APA Closing Date, (iii) paid $1.9 million of the $2.0 million development milestone in September 2026 in connection with the dosing of the first patient in the Phase 2 clinical trial of ebribafusp and paid the remaining $0.1 million in October 2026, (iv) will make certain milestone payments upon the achievement of specified development and regulatory milestone events related to ebribafusp up to an aggregate amount equal to $92.6 million, (v) will make certain milestone payments upon the achievement of specified commercial milestone events with respect to the net sales of ebribafusp up to an aggregate amount equal to $487.5 million, and (vi) will make certain royalty payments based on the net sales of ebribafusp with royalty percentage tiers ranging from the low single digits to mid-teen percentages. The royalties will expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

See Note 10, *Commitments and Contingencies*, in the accompanying notes to the consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information on the Q32 Purchase Agreement.

Manufacturing Agreements

We have various supply arrangements to which we are a party, and we are obligated to pay for drug substance and drug product for commercial use. We are 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.

Other Third-Party Contracts

We enter into agreements in the normal course of business with various vendors, which are generally cancellable upon notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of service providers, up to the date of cancellation. In addition, we contract with various organizations to conduct R&D activities with remaining contract costs to us of approximately $79.2 million as of September 30, 2026. The

scope of the services under these R&D contracts can be modified upon mutual agreement of the parties, and the contracts or scope of services can be cancelled by us upon written notice. In some instances, the contracts may be cancelled by the third-party upon written notice.

Cash Flows

The following table provides a summary of cash flow data for each applicable period:

	Nine Months Ended September 30,	
NET CASH PROVIDED BY/(USED IN) (*in thousands*):	**2026**	**2025**
Operating activities	$ (15,350)	$ 36,863
Investing activities	(6,747)	(49)
Financing activities	(4,288)	77,775
Increase (decrease) in cash, cash equivalents and restricted cash	$ (26,385)	$ 114,589
Cash, cash equivalents and restricted cash — beginning of period	186,543	53,550
Cash, cash equivalents and restricted cash — end of period	$ 160,158	$ 168,139

Operating Activities

Net cash used in operating activities was $15.4 million for the nine months ended September 30, 2026 and consisted of a net loss of $32.3 million and net non-cash adjustments of $28.5 million, including a change in fair value of the warrant liability of $1.5 million, and a reduction of $11.5 million in working capital.

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

Investing Activities

Net cash used in investing activities was $6.7 million for the nine months ended September 30, 2026 and was comprised of the additional upfront payment of $4.9 million paid to Q32 as well as purchases of equipment.

Net cash used in investing activities for the nine months ended September 30, 2025 was immaterial.

Financing Activities

Net cash used in financing activities was $4.3 million for the nine months ended September 30, 2026, which primarily consisted of payments to CSL Vifor of $10.6 million and $4.1 million related to the Working Capital Fund liability and liability related to settlement royalties, respectively, which were partially offset by net proceeds of $9.8 million from the sale of common stock under our ATM facility.

Net cash provided by financing activities was $77.8 million for the nine months ended September 30, 2025, which primarily consisted of proceeds of $10.0 million from the issuance of debt under the BlackRock Credit Agreement and net proceeds of $66.4 million from the sale of common stock from our March 2025 underwritten public offering and under our ATM facility.

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 Policies and Significant Judgments and Estimates

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, including the current or long-term classification of such assets, liabilities and expenses, classification of the expenses and the related disclosure of contingent assets and liabilities. We monitor our estimates on an ongoing basis for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate. In making estimates and judgments, management employs critical accounting policies.

During the nine months ended September 30, 2026, there were no material changes to our methodologies used for our critical accounting estimates as reported in our 2025 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Risk

We had cash, cash equivalents and short-term marketable securities of $159.3 million and $184.8 million at September 30, 2026 and December 31, 2025, respectively, which consisted of cash and money market funds. Interest income is sensitive to changes in the general level of interest rates. However, due to the nature of these investments, a change in market interest rates of 1% would not be expected to have a material impact on our financial condition or results of operations for either period.

Foreign Exchange Risk

We are exposed to market risk related to exchange rates. The majority of our revenues for the three and nine months ended September 30, 2026 and 2025 was received in U.S. dollars, including revenues we received from royalty payments converted to U.S. dollars based on the net sales of Riona® and Vafseo™, in Japanese yen and the Euro, respectively. Our exchange rate risk arises from such foreign currency net sales. As a result, we are exposed to movements in the exchange rates of the Japanese yen and the Euro against the U.S. dollar. During the three and nine months ended September 30, 2026 and 2025, the impact of foreign currency exposure was immaterial and thus did not have a significant impact on our consolidated financial statements.

Item 4. Controls and Procedures.

Management's Evaluation of our 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.

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our management, with the participation of our principal executive officer and principal financial officer, carried out an evaluation of our disclosure controls and procedures as of September 30, 2026. Based upon their evaluation, our principal executive officer and principal financial officer concluded that as of September 30, 2026, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising from the normal course of business activities.

Opposition Proceedings Against Akebia

In September 2018, Dr. Reddy's Laboratories Limited filed an opposition to our issued Indian Patent No. 287720 covering the composition of matter of vadadustat in the Indian Patent Office. In response to a preliminary opinion, we requested to amend the claims, and the amended claims were published on May 9, 2025. On December 19, 2025, we attended an oral hearing conducted on the basis of the amended claims. We filed our written submission on July 2, 2026 and are awaiting the decision from the Indian Patent Office. However, the decision in this opposition is not material to our business.

Item 1A. Risk Factors.

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

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

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

Investment in pharmaceutical product development and commercialization is highly speculative because it requires upfront capital expenditures and significant research and development, or R&D, expenses. Despite the investment in assets and R&D, there is significant risk that a product candidate will fail to gain marketing approval or that an approved product will not be commercially viable. Since our inception, we have devoted most of our resources to R&D, including our preclinical and clinical development activities, commercializing our two approved products, Auryxia and Vafseo, and providing general and administrative support for these operations. We have funded our operations principally through product sales, payments received from our collaboration and licensing partners, borrowings under term loans, sales of our common stock, including through our employee stock purchase plan, a working capital payment from Vifor (International) Ltd. (now a part of CSL Limited), or CSL Vifor, and a royalty transaction. Prior to our 2018 merger, or the Keryx Merger, with Keryx Biopharmaceuticals, Inc., or Keryx, whereby Keryx became our wholly owned subsidiary, we had no products approved for commercial sale and had not generated any revenue from the sale of products. We currently have two commercial products and believe that our existing cash resources and the cash we expect to generate from product, royalty, supply and license revenues are sufficient to fund our current operating plan for at least two years. This estimate is contingent upon us refinancing the outstanding debt under our senior secured term loan facility to defer the payment of principal, which would otherwise commence on January 1, 2027. See Note 7, *Indebtedness*, to our unaudited condensed consolidated financial statements in Part I, Item 1. Financial Statements of this Quarterly Report on Form 10-Q, or Form 10-Q, for additional information regarding our obligations under our senior secured term loan facility. However, there can be no assurance that we will be able to refinance our senior secured term loan facility on favorable terms or at all. If we are unable to execute such refinancing on favorable terms or at all, we believe that our existing cash resources and the cash we expect to generate from product, royalty, supply and license revenues will be sufficient to enable us to fund our current operating plan for at least 12 months from the filing of this Form 10-Q. Since inception, we have incurred net losses each year, including a net loss of $14.4 million and $32.3 million for the three and nine months ended September 30, 2026, respectively, and we cannot guarantee when, if ever, we will become and remain profitable. As of September 30, 2026, we had an accumulated deficit of $1.7 billion.

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

Additionally, in March 2026, Teva Pharmaceuticals USA, Inc., or Teva, received approval for its Abbreviated New Drug Application, or ANDA, for a generic version of Auryxia. As a result of Teva's entry into the market, we have experienced a significant reduction in the volume of Auryxia sales. We expect the ongoing sales of generic versions of Auryxia, including by Teva and our authorized generic distribution partner, Mylan Therapeutics, Inc., or AG Distributor, and of any additional generic versions of Auryxia that may be approved, will continue to have a significant adverse impact on our revenue.

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

- obtaining and maintaining adequate or favorable pricing and reimbursement from private and governmental payors for Auryxia, Vafseo and any other product or product candidate that may be approved, including those that may be in-licensed or acquired;
- the extent that we, or our collaboration partners, are able to obtain and maintain market acceptance of Auryxia, the authorized generic version of Auryxia, Vafseo and any of our other product candidate that may be approved, including those that may be in-licensed or acquired;
- the size of any market for our approved products or any product candidates that may be approved, and the extent to which we or our collaboration partners are able to obtain and maintain adequate market share in those markets;
- maintaining marketing approvals for Auryxia, Vafseo and any other product candidate that may be approved, including those that may be in-licensed or acquired;
- obtaining regulatory approval for any potential label expansion for Vafseo, including the timing and scope thereof;
- our ability to maintain contracts with dialysis organizations and other customers, including specialty distributors, for the sale of Auryxia and Vafseo in the U.S. on favorable terms, or at all;

- actual or perceived advantages or disadvantages of our products or product candidates as compared to alternative treatments, including their respective safety, tolerability and efficacy profiles, the potential convenience and ease of administration and cost;
- maintaining an acceptable safety and tolerability profile of our approved products, including the frequency and severity of any side effects;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, based, in part, on their perception of our clinical trial data and/or the actual or perceived safety, tolerability and efficacy profile;
- patients' adherence or non-adherence to the prescribed treatment regimen;
- the timing and scope of marketing approvals for any product candidate, if approved, including those that may be in-licensed or acquired;
- the timing and number of additional generic versions of Auryxia that enter the market following loss of exclusivity, or LoE, for Auryxia that occurred in March 2025, the availability and pricing of generic versions of Auryxia, the impact of LoE on the product revenue from Auryxia, including the impact on the price of Auryxia;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate supplies of products that are compliant with good manufacturing practices to support the clinical development and the market demand for Auryxia, Vafseo and any other product and product candidate, including those that may be in-licensed or acquired;
- maintaining adequate inventory levels of Auryxia, Vafseo and any other products or product candidates;
- the extent of the impact of geopolitical pressures, including tariffs and global trade policies, or the Biosecure provisions 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 marketing, promotion, manufacturing and distribution strategies and operations;
- competing effectively with any products for the same or similar indications as our products (including generics); and
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents and trade secrets.

Our license, collaboration and other revenue also depends on our partners' ability to successfully market and sell Vafseo and Auryxia in the territories in which they have licensed our products. For example, in May 2023, we entered into a license agreement with MEDICE Arzneimittel Pütter GmbH & Co. KG, or Medice, pursuant to which we granted Medice an exclusive license to develop and commercialize Vafseo for the treatment of anemia in patients with CKD in the European Economic Area, or the EEA, the United Kingdom, or the UK, Switzerland and Australia, or collectively, the Medice Territory. Vafseo is currently marketed and sold by Medice in certain countries in the Medice Territory. Previously, Medice's launch of Vafseo in certain countries in the Medice Territory was later than anticipated due to required prerequisite activities. If Medice's launch of Vafseo in certain countries in the Medice Territory is further 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, and as a result, we regained our rights to sell Vafseo to Fresenius Kidney Care North America and its affiliates and certain other third-party dialysis organizations in the U.S.

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

WCF Royalty Payments paid by us through such WCF Royalty True-Up Date. If we are not successful in commercializing Vafseo, including maintaining contracts with dialysis organizations on favorable terms, or at all, our expected revenue related to Vafseo would be adversely impacted, and we may be unable to repay all or part of the WCF Royalty Payments, which could have a material adverse impact on our consolidated financial statements and our ability to achieve and maintain profitability.

In addition, on November 28, 2025, or the APA Closing Date, we entered into an Asset Purchase Agreement, or the Q32 Purchase Agreement, with Q32 Bio Inc. and Q32 Bio Operations Inc., together, Q32, pursuant to which we purchased and assumed from Q32 substantially all assets and liabilities of Q32 and its affiliates related to the research, development, manufacture, and commercialization of Q32's clinical-stage development candidate ADX-097, known as ebribafusp (AKB-097) worldwide for the treatment, prevention or diagnosis of any disease or condition in humans. Under the terms of the Q32 Purchase Agreement, we (i) made an upfront payment in an amount equal to $7.0 million on the APA Closing Date, (ii) made an additional upfront payment in an amount equal to $3.0 million on the sixth-month anniversary of the APA Closing Date, (iii) paid $1.9 million of the $2.0 million development milestone in September 2026 in connection with the dosing of the first patient in the Phase 2 clinical trial of ebribafusp and paid the remaining $0.1 million in October 2026, (iv) will make certain milestone payments upon the achievement of additional specified development and regulatory milestone events related to ebribafusp up to an aggregate amount equal to $92.6 million as of September 30, 2026, (v) will make certain milestone payments upon the achievement of specified commercial milestone events with respect to the net sales of ebribafusp up to an aggregate amount equal to $487.5 million, and (vi) will make certain royalty payments based on the net sales of ebribafusp with royalty percentage tiers ranging from the low single digits to mid-teen percentages. The royalties will expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

Our ability to achieve and maintain profitability also depends on our ability to manage our expenses. We expect to continue to incur substantial additional operating expenses, including additional R&D expenses related to our pipeline, including ebribafusp, praliciguat and AKB-9090, and additional R&D and selling, general and administrative expenses for ongoing development, post-marketing requirements and commercialization of Auryxia and Vafseo and any other products, including those that may be in-licensed or acquired, which could lead to operating losses for the foreseeable future. Our prior losses have had, and expected future losses will continue to have, an adverse effect on our stockholders' equity (deficit) and working capital.

In addition to any further costs not currently contemplated in our operating plan, our ability to achieve and maintain profitability and our financial position will depend, in part, on the rate of our future expenditures, the timing of our product, license, collaboration 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 or to refinance our senior secured term loan facility on favorable terms or at all, if and when needed. In addition, we expect to continue to incur significant expenses if and as we:

- continue our commercialization activities for 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 clinical trials for praliciguat, ebribafusp and AKB-9090, and post-marketing studies or any other clinical trials for Vafseo or any other product or product candidate, including those that may be in-licensed or acquired;
- seek marketing approval for any product candidate, including those that may be in-licensed or acquired;
- maintain marketing approvals for Auryxia, Vafseo and any other product, including those that may be in-licensed or acquired;
- manufacture Auryxia, Vafseo and any other product or product candidate, including those that may be in-licensed or acquired, for commercial sale and clinical trials;
- secure and validate manufacturing facilities for any of our products and product candidates;
- conduct discovery and development activities for our products and product candidates or platforms that may lead to the discovery of additional product candidates;
- engage in transactions, including strategic, merger, collaboration, acquisition and licensing transactions, pursuant to which we would market and develop commercial products, or develop and commercialize other product candidates and technologies;
- repay, and pay any associated pre-payment penalties, if applicable, the term loans under the senior secured term loan facility pursuant to the BlackRock Credit Agreement;

- make royalty, milestone or other payments under our current and any future in-licensing agreements, the Q32 Purchase Agreement and the Vifor Termination Agreement;
- maintain, protect and expand our intellectual property portfolio; and
- experience any delays or encounter issues with any of the above.

We have expended and may in the future expend significant resources on our legal proceedings, as described above under Part II, Item 1. Legal Proceedings, including any legal proceedings that may be brought by or against us in the future.

Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency, or the EMA, or other regulatory or governmental authorities, or if we otherwise believe it is necessary or advisable, to change our manufacturing processes or assays, to bring on additional manufacturers, to relocate the manufacturing of our products or starting materials, to amend or replace our study protocols, to perform studies different from, larger than or in additional jurisdictions to 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 our product candidates, or if there are any delays in completing any of these activities.

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

In addition, our ability to generate revenue has been and will continue to be negatively affected if certain dialysis organizations are unwilling to include or maintain Auryxia or its authorized generic or Vafseo in their formulary, the size of our addressable patient population is not as significant as we estimate, 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, its authorized generic and Vafseo in the U.S. and royalties from Riona (ferric citrate hydrate) and Vafseo in Japan, and Vafseo in Europe and other territories where it is approved, and may generate revenue and royalties from the sale of any products that may be approved in the future, including those that may be in-licensed or acquired, we may never generate revenue and royalties that are significant enough for us to become and remain profitable, and we will need to obtain additional financing to continue to fund our operating plan.

We will 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, 2026, our cash and cash equivalents were $159.3 million. We expect to continue to expend substantial amounts of cash for the foreseeable future as we continue to manufacture Auryxia for sale in the U.S.; develop and commercialize Vafseo in the U.S.; develop our product candidates; and commercialize any product candidate that may be approved, including those that may be in-licensed or acquired. These expenditures will include costs associated with R&D, manufacturing, potentially obtaining marketing approvals and marketing products approved for sale. In addition, other unanticipated costs may arise. Because the outcomes of our current and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of funding necessary to successfully complete clinical development for any current or future product candidates or to complete post-marketing studies for Vafseo. Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of conducting clinical trials or any post-marketing requirements or any other clinical trials for Vafseo, praliciguat, ebribafusp, AKB-9090, 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;
- our ability to refinance our senior secured term loan under the BlackRock Credit Agreement on favorable terms, or at all;
- the results of our meetings with the FDA, the EMA and other regulatory authorities with respect to our approved products and product candidates and any consequential effects, including on timing of and ability to obtain and maintain marketing approval, any label expansion that we may pursue, study design, study size and resulting operating costs;

- any difficulties or delays in conducting or enrolling patients in our ongoing or future clinical trials for Vafseo, praliciguat, ebribafusp, AKB-9090 or any other product candidates;
- the outcome of our efforts to obtain marketing approval for any product candidates, including those that may be in-licensed or acquired, including any additional clinical trials or post-approval commitments imposed by regulatory authorities;
- the timing of, and the costs involved in obtaining, any marketing approvals for any product candidate, including those that may be in-licensed or acquired, including to fund the preparation, filing and prosecution of regulatory submissions;
- the costs of maintaining marketing approvals for Auryxia, Vafseo or any other product, including those that may be in-licensed or acquired;
- the timing and number of additional generic versions of Auryxia that enter the market following LoE for Auryxia, the availability and pricing of generic versions of Auryxia, the impact of LoE on product revenue from Auryxia, including the impact on the price of Auryxia;
- the cost of securing and validating manufacturing facilities for any of our products and product candidates, including those that may be in-licensed or acquired, and maintaining our manufacturing arrangements for Auryxia and Vafseo or any other product or product candidate, including those that may be in-licensed or acquired, or securing and validating additional arrangements;
- the costs involved in preparing, filing and prosecuting patent applications and maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of such litigation;
- the costs involved in any legal proceedings to which we are a party;
- our status as a publicly traded company on the Nasdaq Capital Market;
- our decisions with respect to personnel;
- our decisions with respect to infrastructure; and
- the extent to which we engage in transactions, including strategic, merger, collaboration, acquisition and licensing transactions, pursuant to which we could develop and market commercial products, or develop other product candidates and technologies.

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

We believe our existing cash resources and the cash we expect to generate from product, royalty, supply and license revenues are sufficient to fund our current operating plan for at least two years. This estimate is contingent upon us refinancing our outstanding debt under the senior secured term loan facility to defer the payment of principal, which would otherwise commence on January 1, 2027. If we are unable to refinance our senior secured term loan, or our operating performance deteriorates significantly from the levels expected in our long-term operating plan, including if we do not achieve our future anticipated revenue projections from Vafseo, it would have an adverse effect on our liquidity and capital resources, and we would be required to obtain additional financing to fund our operating plan or continue as a going concern in the future. Our forecast of the period of time through which our financial resources will be adequate to support our operating plan 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 or may be unable to refinance our senior secured term loan facility on favorable terms, or at all. 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 execute on our development and commercialization plans for our approved products and product candidates, including those that may be in-licensed or acquired. Also, additional funds may not be available to us in sufficient amounts or on acceptable terms or at all. In addition, raising funds in the current economic environment may present additional challenges. For example, any sustained disruption in the capital markets from adverse macroeconomic conditions and an uncertain geopolitical environment, such as tariffs, rising inflation, increasing interest rates, slower economic growth or recession, global trade policies, global supply chain disruptions, ongoing conflicts including the Russia-

Ukraine war, hostilities between Israel and Hamas, instability in the Middle East, including the current conflict with Iran, tensions between China and Taiwan and other emerging geopolitical crises, could negatively impact our ability to raise capital, and we cannot predict the extent or duration of such macroeconomic disruptions. If we are unable to raise additional capital in sufficient amounts when needed or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development and/or commercialization of Auryxia, Vafseo and any other products or product candidates, including those that may be in-licensed or acquired. Any of these events could significantly harm our business, financial condition and prospects.

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

We expect to finance future cash needs through product revenue and royalty and license revenue, and we may seek to sell public or private equity, enter into new debt transactions, explore potential strategic transactions or a combination of these approaches or other strategic alternatives. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, our fixed payment obligations may increase, any such securities may have rights senior to those of our common stock, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect the rights of our common stockholders. For example, from September 12, 2024 (the date our shelf registration statement on Form S-3 went effective) through December 31, 2025, we sold 23,708,995 shares of our common stock in an at-the-market offering with gross proceeds of $43.0 million, and during the nine months ended September 30, 2026, we sold 8,244,695 shares of our common stock under this program, resulting in gross proceeds of $10.1 million ($9.8 million, net of offering expenses), respectively. 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 products and product candidates, future revenue streams or research programs or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds when needed, we may not be able to pursue planned development and commercialization activities and we may need to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

Although we continue to focus a substantial amount of our efforts to develop and commercialize Vafseo and commercialize Auryxia, a key element of our long-term growth strategy is to develop additional product candidates and acquire, in-license, develop and/or market additional products and product candidates. For example, on November 28, 2025, we acquired ebribafusp, a clinical-stage development candidate with the potential to treat rare kidney diseases. In addition, in January 2026, we announced that the first patient was dosed in a Phase 2 clinical trial of praliciguat, in April 2026, we announced that the first patient was dosed in a Phase 1 clinical trial of AKB-9090, and in September 2026, we announced that we dosed the first patient in a Phase 2 basket trial of ebribafusp.

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

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

- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- a product candidate may not be accepted as safe and effective by patients, the medical community, or third-party payors, if applicable.

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

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

Because our internal research capabilities are limited, we may be dependent upon other pharmaceutical and biotechnology companies, academic scientists and institutions, and other researchers to sell or license product candidates, products or technology to us. As a result, our rights to these product candidates may be limited or we may be required to make future payments to such third parties if we are successful in developing such product candidates. For example, under the terms of the Q32 Purchase Agreement, we (i) paid $1.9 million of the $2.0 million development milestone in September 2026 in connection with the dosing of the first patient in the Phase 2 clinical trial of ebribafusp and paid the remaining $0.1 million in October 2026, (ii) will make certain milestone payments upon the achievement of additional specified development and regulatory milestone events related to ebribafusp up to an aggregate amount equal to $92.6 million as of September 30, 2026, (iii) will make certain milestone payments upon the achievement of specified commercial milestone events with respect to the net sales of ebribafusp up to an aggregate amount equal to $487.5 million, and (iv) will make certain royalty payments based on the net sales of ebribafusp with royalty percentage tiers ranging from the low single digits to mid-teen percentages. The success of this strategy depends partly upon our ability to identify, select, and acquire promising product candidates and products. The process of identifying, selecting, negotiating and implementing a license or acquisition of a product candidate or an approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of a product candidate or an approved product. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses, and technologies and integrate them into our current infrastructure.

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

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

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

As part of our business strategy, we may engage in additional strategic transactions to expand and diversify our portfolio, including through the merger, acquisition or in-license of assets, businesses, or rights to products, product candidates or technologies or through strategic alliances or collaborations, similar to the Keryx Merger or the acquisition of ebribafusp from Q32, 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, require the assumption and management of third-party manufacturing relationships for clinical and commercial supply, which could be more expensive or time intensive than we originally anticipate, and require management resources that would otherwise focus on developing our existing business. Even if we are able to achieve the long-term benefits of a strategic transaction, our expenses and short-term costs may increase materially and adversely affect our liquidity. Any of the foregoing could have a detrimental effect on our business, results of operations and financial condition. For example, the acquisition of ebribafusp in November 2025 and the initiation of a Phase 2 basket trial of ebribafusp in August 2026 have increased and are expected to continue to increase research and development expenses and have required and will continue to require significant management attention for development, which could divert resources from other priorities, raise short-term costs, and adversely affect our liquidity. In addition, pursuant to our amended license agreement with Cyclerion Therapeutics Inc. (succeeded by Korsana Biosciences, Inc.), we were granted an exclusive global license under certain intellectual property rights to research, develop and commercialize praliciguat, and we currently control all clinical and commercial manufacturing of praliciguat, which will be conducted by a third-party manufacturer. Although we performed additional work to manufacture product for clinical trials than originally anticipated before we could initiate the trial for praliciguat, in January 2026, we announced that the first patient was dosed in a Phase 2 clinical trial in the U.S. However, even though the clinical trial has started, we may be unsuccessful in developing praliciguat. If any of the assumptions that we made in valuing the transactions, including the costs or timing of development of ebribafusp or praliciguat, or the potential benefits of ebribafusp or praliciguat, were incorrect, we may not recognize the anticipated benefits of the transactions and our business could be harmed.

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

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

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

Risks Related to our Financial Arrangements

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

We entered into the BlackRock Credit Agreement, which provides for a senior secured term loan facility, in the aggregate principal amount of $55.0 million, or the Term Loan Facility. The initial tranche of $37.0 million closed on January 29, 2024, an additional amount of $8.0 million was drawn on April 19, 2024, and an additional $10.0 million was drawn on February 3, 2025. See Note 7, Indebtedness, to our unaudited condensed consolidated financial statements in Part I, Item 1. Financial Statements of this Form 10-Q for additional information regarding our obligations under the BlackRock Credit Agreement. The Term Loan Facility has a maturity date of January 29, 2028, or the Maturity Date.

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

The Term Loan Facility accrues 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 January 29, 2024 and ending on December 31, 2026, 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. We are currently pursuing options to refinance the outstanding debt under the Term Loan Facility, including to defer the timing of payment of principal; however, there can be no assurance that we will be successful in refinancing the Term Loan Facility in a timely manner, on favorable terms, or at all, which could have an adverse impact on our business, financial condition and results of operations.

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

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

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

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

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

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

Risks Related to Commercialization

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

Our business and our ability to generate product revenue largely depend on our, and our collaborators', ability to successfully commercialize Auryxia and Vafseo. Our ability to generate revenue depends on our ability to execute on our development and commercialization plans, and the size of the market for, and the level of market acceptance of, Auryxia, Vafseo and any other product or product candidate, including those that may be in-licensed or acquired. If we are not able to maintain contracts with dialysis organizations and other customers, including specialty distributors, for the sale of Auryxia and Vafseo on favorable terms, or at all, or our products do not achieve the level of market acceptance at such dialysis organizations as we anticipate, 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 has affected and may continue to affect the level of market acceptance of Vafseo.

We had exclusive rights under a series of patents and patent applications to commercialize Auryxia in the U.S. that protected us from generic drug competition until March 20, 2025. Following LoE, the number of generic versions of Auryxia that enter the market, and the timing thereof, have and will continue to adversely affect our revenue from Auryxia. On February 5, 2025, we entered into an Authorized Generic Distribution and Supply Agreement with our AG Distributor, as amended in September 2025, pursuant to which, since March 20, 2025, our AG Distributor has been selling an authorized generic version of Auryxia. On March 11, 2026, Teva received approval for its ANDA for a generic version of Auryxia. As a result of Teva's entry into the market, we have experienced a significant reduction in the volume of Auryxia sales. We expect the ongoing sales of generic versions of Auryxia, including by Teva and our AG Distributor, and of any additional generic versions of Auryxia that may be approved, will continue to have a significant adverse impact on our revenue. However, the extent of the impact on future Auryxia revenues will depend on many factors, including our ability to maintain contracts with dialysis organizations and other customers, including specialty distributors, on favorable terms, or at all, the timing and number of additional generics, the amount of generic product available to supply the market and the pricing of generics and other products on the market that compete with Auryxia.

DaVita, Inc., or DaVita, Fresenius Kidney Care Group LLC, or Fresenius, and U.S. Renal Care, or USRC, account for a vast majority of the dialysis population in the U.S. As a result of this concentration of dialysis facilities in large networks, treatment is usually driven by medical protocols that are implemented across the entire network of clinics. Dialysis organizations require large data sets to adopt medical protocols and often have lengthy processes to implement and operationalize the protocol and make the new therapy available for patients. For example, to date, Fresenius does not have a medical protocol in place for Vafseo but may allow for its use through a medical exception process. If Fresenius does not add Vafseo to its medical protocol or if the protocol services smaller populations than the current label, Vafseo may not become standard of care nor achieve the level of market acceptance we anticipate. In addition, some dialysis organizations have medical protocols that require specific steps once Vafseo is prescribed that lengthen the time before the patient starts treatment, delaying initial adoption. Once a dialysis organization has added a new therapy to its medical protocol, implementation in dialysis clinics requires changes to these dialysis organizations' formularies, administration methods and operational practices, as well as gaining acceptance from healthcare professionals. If dialysis organizations do not add Vafseo to their medical protocol or if dialysis organizations that currently have a protocol in place do not keep Vafseo on their medical protocols, or maintain protocols that delay treatment initiation by requiring additional steps, or if the protocols service smaller populations than the current label, or if the average dose per patient is lower than we expect due to patient compliance or other factors, our results of operations could be materially adversely affected and Vafseo may not achieve standard of care. For example, although Vafseo has been added to most dialysis organizations' protocols, physicians initiating and, in some cases, maintaining, patients on therapy within the highly protocolized dialysis environment has been taking longer than we expected. Additionally, in the third quarter of 2026, our Vafseo revenue was lower than anticipated. This decrease was primarily due to customers reducing their inventory levels to align with their assessment of future inventory needs, based on the average dose per patient and patients' compliance with their dialysis sessions being lower than expected, and in anticipation of the Transitional Drug Add-on Payment Adjustment, or TDAPA, period ending as of January 1, 2027. In 2025 and in the nine months ended September 30, 2026, most Vafseo revenue was driven by mid-sized dialysis organizations. If we are unable to increase or maintain sales to the large dialysis organizations and other medium-sized dialysis organizations, our results of operations will be negatively impacted. Furthermore, as a result of changes in the amount of reimbursement dialysis facilities will receive for use of Vafseo when Vafseo transitions from the TDAPA period to the post-TDAPA period, we expect our customers to further reduce inventory levels at the end of 2026. Additionally, when the post-TDAPA period begins in January 2027, we expect to price Vafseo within the range of the price for erythropoiesis stimulating agents, or ESAs. ESAs are currently priced significantly lower than Vafseo's current price. As a result, while we expect to sell a higher unit volume of Vafseo in 2027 as compared to 2026, we expect Vafseo revenues to decrease significantly in 2027 as compared to 2026 due to

the expected lower price point. Further, we believe competition has increased pricing pressures for ESAs, which may negatively impact the price of, and the market for, Vafseo in the post-TDAPA period. For more information, see the risk factor entitled "*Our, or our partners', failure to obtain or maintain adequate coverage, pricing and reimbursement for Auryxia or Vafseo after the TDAPA period in the U.S., or for Auryxia and Vafseo outside the U.S., or for 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.*"

Oral-only phosphate binders, including Auryxia, are included in the end-stage renal disease, or ESRD, Prospective Payment System, or PPS, bundle payment, as of January 2025. Dialysis organizations may choose lower cost binders over Auryxia or generic versions of Auryxia, or treatments that may have features or benefits more aligned with the dialysis organization's operational activities. In addition, we have experienced and expect to continue to experience a decrease in net price under our customer contracts as a result of government reimbursement levels, as well as a decrease in sales volume due to generic competition. As a result of the foregoing, our Auryxia revenues have been significantly lower in 2026, and we expect them to continue to be lower through the remainder of 2026 and beyond as compared to 2025 Auryxia revenues.

Market acceptance and maintaining favorable pricing 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 does not achieve or maintain market acceptance to the extent that we expect or market acceptance decreases, including as a result of generic competition, we may not be able to generate significant product revenue and our business would be materially harmed. For example, an unexpected number of patients initially prescribed Vafseo discontinued treatment. While we continue to work with dialysis organizations to improve adherence, if a higher than expected number of patient discontinuations persists, or increases, this could negatively impact the market acceptance of Vafseo and could adversely affect our financial results. Obtaining and maintaining market acceptance of Auryxia, Vafseo or any other approved product depends on a number of factors, including:

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

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

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

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

For example, certain restrictions on access for members of our commercial field team to dialysis organizations have negatively impacted, and may continue to negatively impact, our ability to market Vafseo to healthcare providers, which has affected and could continue to affect our sales of Vafseo. Furthermore, additional restrictions on access to healthcare providers could be imposed in the future, including as a result of outbreaks of infectious diseases. Such restrictions could result in slower adoption of Vafseo, declines or changes in prescription trends and customer orders, and could have a material adverse effect on our business, results of operations, and financial condition. In addition, we may continue to evaluate and adapt our strategy in response to the marketplace, including reevaluating the structure, focus and size of the commercial field team required to successfully commercialize Vafseo. For example, in June 2026, we modified our commercial approach with the goal of increasing the efficiency and effectiveness of our commercial field team based on the stage of our Vafseo launch and implemented a commercial reorganization. However, there can be no assurance that our commercial strategy will be successful and increase sales of Vafseo, which may require us to, among other things, further adjust our commercialization strategy and plans.

Additionally, training a commercial field team is expensive and time consuming and could delay any commercial launch or market acceptance of such product. For example, we have trained and will continue to train our commercial field team to effectively perform their new role following the change in our commercial strategy for Vafseo in June 2026. If we are unsuccessful in this training, it could have an adverse effect on our field team's effectiveness and the commercialization and market acceptance of Vafseo.

We devote significant effort to recruiting individuals with experience in the marketing and promotion of pharmaceutical products. Competition for personnel with these skills is significant, particularly in the nephrology space, and retaining qualified personnel with experience in our industry is difficult. If key commercial field 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 marketing and promotion capabilities, including the following:

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

If we are unable to maintain our own marketing and promotion capabilities, we will not be successful in commercializing 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 marketing and promotion, if we are unsuccessful in entering into additional arrangements with third parties to market and promote our products or if 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 or Vafseo after the TDAPA period in the U.S., or for Auryxia and Vafseo outside the U.S., or for any other future approved products,

could have a material adverse effect on our or our collaboration partners' ability to sell such approved products profitably and otherwise have a material adverse impact on our business.

Market acceptance and sales of any approved products, including Auryxia and Vafseo, depend significantly on the availability of adequate coverage and reimbursement from third-party payors and may be affected by existing and future healthcare reform measures, and in the case of Auryxia, the entry of generics to the market. 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 Procedure Coding System, which codes are assigned on a quarterly basis. Within Medicare, for oral drugs dispensed by pharmacies and also administered in facilities, coverage and reimbursement may vary depending on the setting. Centers for Medicare & Medicaid Services, or CMS, local Medicare administrative contractors, Medicare Advantage and/or Part D plans and/or PBMs operating on behalf of such plans, may have some responsibility for determining the medical necessity of such drugs, and therefore coverage, for different patients. Different reimbursement methodologies may apply, and CMS may have some discretion in interpreting their application in certain settings.

As of January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including Auryxia and all other phosphate lowering medications, are included in the ESRD PPS bundled payment 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. However, from January 1, 2025 through December 31, 2026, dialysis organizations receive a TDAPA payment for claims that include phosphate binders. After the TDAPA period for Auryxia and other oral-only phosphorus lowering medications, CMS will make a permanent adjustment increasing the single bundled payment base rate paid to the dialysis facility for each Medicare dialysis treatment to account for the cost of these drugs. After the TDAPA period, dialysis organizations will not receive any additional payment for use of Auryxia outside the bundled rate. The adjustment will be calculated by CMS based on the weighted average cost of all phosphate lowering medications, including Auryxia. However, based on the final CY2027 ESRD Prospective Payment System Rule issued by CMS on October 28, 2026, or the 2027 ESRD Rule, such increase in the single bundled payment base rate may be inadequate for dialysis facilities to elect to make Auryxia available to patients, which would have a negative impact on our revenue from Auryxia.

Vafseo, which we began selling in January 2025, is also reimbursed under the ESRD PPS. For a period of two years starting on January 1, 2025 and continuing through December 31, 2026, ESRD dialysis facilities will receive a payment adjustment under TDAPA for Vafseo as a new renal dialysis drug meeting certain criteria. The payment adjustment under TDAPA is based on Vafseo's Average Sales Price, or ASP, and is a separate payment in addition to the base rate paid to dialysis facilities to facilitate the adoption of innovative therapies. After the TDAPA period, for a period of three years, dialysis facilities will receive an additional payment based on current utilization and pricing per dialysis treatment, regardless of Vafseo use. As a result, dialysis organizations will receive no additional payment for their use of Vafseo. The calculation of the post-TDAPA add-on payment adjustment was expected to be determined and published by CMS on an annual basis. However, pursuant to the 2027 ESRD Rule, CMS plans to adjust this calculation on a quarterly basis, which may create uncertainty in reimbursement amounts. As a result of the method used by CMS to calculate and apply the post-TDAPA add-on payment adjustment, there will be a significant decline in the level of reimbursement provided to dialysis facilities for use of Vafseo. After the TDAPA period, we anticipate pricing Vafseo within the range of the price for ESAs. ESAs are priced significantly lower than Vafseo's current price. As a result, while we expect to sell a higher unit volume of Vafseo in 2027 as compared to 2026, we expect Vafseo revenues to decrease significantly in 2027 as compared to 2026 due to the expected lower price point. Further, we

believe competition has increased pricing pressures for ESAs, which may negatively impact the price of, and the market for, Vafseo after the TDAPA period. The post-TDAPA add-on adjustment to the bundled rate will be effective as of January 1, 2027. There can be no assurance that the level of reimbursement determined by CMS in the post-TDAPA period will improve. Such reduced reimbursement amounts or reimbursement uncertainty could limit provider adoption of Vafseo, restrict patient access and have a negative effect on the demand for, and the price of, Vafseo, which would adversely impact our revenue.

In late 2025, the Kidney Care Access Protection Act, or KCAPA, was introduced in the U.S. Congress, which seeks to maintain patient access to innovative kidney care treatments, including Vafseo, by improving reimbursement following TDAPA expiration. Although the KCAPA may have the potential to improve post-TDAPA reimbursement if enacted, there can be no assurance that such legislation will be enacted before the TDAPA period for Vafseo expires on December 31, 2026, or that it will be enacted with the provisions as currently proposed, or at all.

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

Additionally, we have entered into and may continue to enter into, or amend contracts with dialysis organizations, group purchasing organizations, or GPOs, third-party payors and/or PBMs offering rebates or discounts on our products in order to obtain favorable formulary status, and we may not be able to agree upon commercially reasonable terms with such dialysis organizations, GPOs, third-party payors or PBMs, or provide data sufficient to obtain favorable coverage and reimbursement for many reasons, including that we may be at a competitive disadvantage relative to companies with more extensive product lines. In addition, dialysis organizations, GPOs, third-party payors, PBMs and/or other entities that purchase our products may impose restrictions on our ability to raise prices for our products over time without incurring additional costs. Three dialysis organizations have accounted for a significant percentage of our gross revenue from Auryxia and Vafseo. For example, during the three months ended September 30, 2026, DaVita and USRC accounted for a significant percentage of our gross revenue, and, during the nine months ended September 30, 2026, DaVita, Fresenius Medical Care Rx, and USRC accounted for a significant percentage of our gross revenue. If we are not able to maintain supply agreements with these, and other, dialysis organizations for the sale of Vafseo and Auryxia on favorable terms, on a timely basis or at all, our business may be materially harmed.

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

Formulary status within dialysis organizations may also affect what products are prescribed within that specific organization. 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 fewer 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 their formulary. There is always a risk a dialysis organization will not contract with a drug manufacturer for a specific product, or will terminate their contract, resulting in that product not being on that organization’s formulary. If any large or medium-sized dialysis organization does not add Vafseo, or removes Auryxia or Vafseo, from its formulary, our business may be materially harmed.

In addition, we may be unable to sell Auryxia or Vafseo to dialysis organizations on a profitable basis if CMS significantly reduces the level of reimbursement for dialysis services, including as currently contemplated in the post-TDAPA period under the 2027 ESRD Rule, and dialysis providers choose to use alternative therapies, including generics, or look to re-negotiate or amend their contracts with us. Our revenues may also be affected if the price dialysis organizations pay for our products declines faster than anticipated or if our costs of production exceed reimbursement levels. Adequate coverage and reimbursement of our products by government and private insurance plans, including Medicare Advantage plans, are central to patient and provider acceptance of any products for which we receive marketing approval. Existing competitive products

may enter into sole source agreements with dialysis providers that impact the ability for new product innovations and new competitors may face price pressure based on existing contracts with dialysis providers.

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

However, the failure to obtain reimbursement in one jurisdiction may negatively impact the ability to obtain reimbursement in another jurisdiction. In addition, we plan to rely on partners to obtain approval by reimbursement authorities outside the U.S. Our partners may not be able to obtain such reimbursement approvals on a timely basis, if at all, and favorable pricing in certain countries depends on a number of factors, some of which are outside of our partners' control. For example, Vafseo was approved in Japan for the treatment of adult patients with anemia due to CKD and is being marketed by TPC in Japan under the trade name Vafseo. Pricing and reimbursement strategy is a key component of TPC's commercialization plans for Vafseo in Japan. If coverage and reimbursement terms change, TPC may not be able to, or may decide not to, continue commercialization of Vafseo in Japan. Furthermore, Vafseo was approved in Europe and Australia for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis. In Europe, reimbursement is obtained on a country-by-country basis and it is a time consuming process. Additionally, pursuant to our license agreement with Medice, Medice launched and has received pricing and reimbursement for Vafseo in certain countries in Europe and is working on launching and securing pricing and reimbursement for Vafseo in other markets across Europe. There is no guarantee of the timing or extent of reimbursement that they will receive in each country, if at all. If Medice is not able to obtain favorable pricing in the Medice Territory, or if such approvals are delayed, it will affect Medice's sales of Vafseo in the Medice Territory, we may not receive the revenue that we expect from Medice on the timing anticipated, or at all, 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 Vafseo and any other product or product candidate, including those that may be in-licensed or acquired, as well as the extent to which we are able to maintain market share of Auryxia following LoE. Our objective is to successfully commercialize Auryxia and Vafseo and develop and commercialize new products with clinically proven efficacy, convenience, tolerability and/or safety. In many cases, any approved products that we commercialize will compete with existing, market-leading products. If existing or new competitors of Auryxia or Vafseo take market share from us, it could have an adverse impact on our revenue and our business.

We had exclusive rights under a series of patents and patent applications to commercialize Auryxia in the U.S. that protected us from generic drug competition until March 20, 2025. Following LoE, the number of additional generic versions of Auryxia that enter the market, and the timing thereof, have and will continue to adversely affect our revenue from Auryxia. We and our licensors entered into settlement agreements with all of the third parties who submitted Paragraph IV certification notice letters regarding ANDAs submitted to the FDA, pursuant to which we granted licenses to market a generic version of Auryxia in the U.S. beginning on March 20, 2025 (subject to FDA approval). In addition, pursuant to the Authorized Generic Distribution and Supply Agreement with our AG Distributor, our AG Distributor has been selling an authorized generic version of Auryxia since March 20, 2025. On March 11, 2026, Teva received approval for its ANDA for a generic version of Auryxia. As a result of Teva's entry into the market, we have experienced a significant reduction in the volume of Auryxia sales. We expect the ongoing sales of generic versions of Auryxia, including by Teva and our AG Distributor, and of any additional generic versions of Auryxia that may be approved, will continue to have a significant adverse impact on our revenue. However, the extent of the impact on future Auryxia revenues will depend on many factors, including our ability to maintain contracts with dialysis organizations and other customers, including specialty distributors, the timing and number of additional generics, the amount of generic product available to supply the market and the pricing of generics and other products on the market that compete with Auryxia.

In addition to the generic version of Auryxia, Auryxia is competing in the hyperphosphatemia market in the U.S. with other FDA-approved phosphate binders such as Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate), both marketed by Sanofi, generic versions of calcium acetate, previously marketed as PhosLo® by Fresenius Medical Care North America, Fosrenol® (lanthanum carbonate), marketed by Takeda Pharmaceuticals U.S.A., Inc., 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 these phosphate binders listed above are now also available in generic forms. In addition, other agents are in development, including Unicycive's

oxylanthanum carbonate (formerly RENAZORB™or lanthanum dioxycarbonate), that could otherwise enter the market that may impact the market for Auryxia. XPHOZAH® (tenapanor), a phosphate absorption inhibitor that is marketed by Ardelyx, Inc., is indicated to reduce serum phosphorus in adults with CKD on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy, which may adversely impact the market for Auryxia.

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

In Japan, our Japanese sublicensees, Japan Tobacco International (succeeded by Shionogi & Co., Ltd.), or JT, and its subsidiary, Torii Pharmaceutical Co., Ltd., or Torii, commercialize Riona. In the hyperphosphatemia market, Riona competes with Fosrenol® (lanthanum carbonate hydrate) marketed by Bayer Yakuhin Ltd., generic lanthanum carbonate hydrate products, and Phozevel® (tenapanor 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 additional generic versions of Auryxia enter the market.

Drugs that compete with Vafseo include Epogen® (epoetin alfa) and Aranesp® (darbepoetin alfa), both commercialized by Amgen in the U.S. and Europe, Procrit® (epoetin alfa) and Eprex® (epoetin alfa), commercialized by Johnson & Johnson in the U.S. and Europe, respectively, Mircera® (methoxy PEG-epoetin beta), commercialized by CSL Vifor in the U.S. and Roche Holding Ltd., or Roche, outside of the U.S., Evrenzo® (roxadustat) in Europe commercialized by Astellas Pharma Inc., or Astellas, Eporatio® (epoetin theta) in Europe commercialized by Teva Pharmaceutical Industries 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 Group AG, and NeoRecormon® (epoetin beta) in Europe commercialized by Roche. We believe competition has increased pricing pressures for ESAs, which may negatively impact the price of, and the market for, Vafseo after the TDAPA period.

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

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

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

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

With respect to praliciguat, there are a number of treatments to address focal segmental glomerulosclerosis, or FSGS in development, and in April 2026, the FDA approved FILSPARI® (sparsentan), the first FDA-approved therapy for FSGS, indicated to reduce proteinuria in adult and pediatric patients aged eight years and older with FSGS without nephrotic syndrome. FILSPARI is a dual endothelin and angiotensin II receptor antagonist, which is being commercialized in the U.S. by Travere® Therapeutics Inc. In addition, current treatment includes glucocorticoid steroids, calcineurin inhibitors, other immunosuppressives such as rituximab, and antihypertensives such as angiotensin-converting enzyme inhibitors, such as enalapril, and angiotensin II receptor blockers, such as losartan. These treatments may slow kidney failure progression in some patients with FSGS. There are a number of treatments to address FSGS in development, including DMX-200 (repagermanium), in Phase 3 development by Dimerix Limited; MZE829 (APOL1 inhibitor) in Phase 2 development by Maze Therapeutics, Inc., Vanrafia® (atrasentan), in Phase 2 development by Novartis AG; and WAL0921 (a monoclonal antibody that binds soluble urokinase plasminogen activator receptor) in Phase 2 development by Walden Biosciences, Inc. and other investigational treatments in Phase 3 or Phase 2 development by companies including Boehringer Ingelheim, Sanofi, Vera Therapeutics, Inc., or Vera, and Vertex Pharmaceuticals Incorporated, or Vertex. Since FSGS is heterogeneous in nature, we expect a number of therapies will be needed to fully address the needs of the FSGS patient population. Additionally, a combination of therapies may also provide a beneficial impact for some patients.

We are developing ebribafusp for potential treatment of IgA Nephropathy, or IgAN; C3 Glomerulopathy, or C3G; and Lupus Nephritis, or LN. There are other complement inhibitors and medications in development or approved for treatment of these rare kidney diseases. FABHALTA® (iptacopan) is FDA-approved and marketed by Novartis AG for reduction of proteinuria in adults with primary IgAN. FILSPARI® (sparsentan) is FDA-approved, indicated to slow kidney function decline in adults with primary IgAN. Both FABHALTA and FILSPARI labeling includes a REMS. TARPEYO® (budesonide), an FDA-approved medicine used to reduce the loss of kidney function in adults with primary IgAN, is marketed in the U.S. by Calliditas Therapeutics AB, or Calliditas (acquired by Asahi Kasei Corporation). VANRAFIA™ (atrasentan), marketed by Novartis, is an endothelin receptor antagonist indicated to reduce proteinuria in adults with primary IgAN. In November 2025, the FDA approved VOYXACT® (sibeprenlimab-szsi) to reduce proteinuria in adults with primary IgAN. VOYXACT is a humanized monoclonal antibody that binds to and blocks A PRoliferation-Inducing Ligand, or APRIL.

In July 2026, Vera received accelerated approval from the FDA for TRUTAKNA™ (atacicept) for the treatment of IgAN. TRUTAKNA is a recombinant fusion protein that binds to B-cell Activating Factor, or BAFF, and APRIL cytokines. Vertex submitted a BLA for povetacicept, a dual antagonist of the BAFF and APRIL cytokines, for the treatment of IgAN, which was accepted by the FDA for accelerated approval and assigned a November 30, 2026 Prescription Drug User Fee Act target action date. A number of complement inhibitors are in development for the treatment of IgAN by companies including Alexion Pharmaceuticals, Inc. (ULTOMIRIS, ravulizumab, C5 inhibitor, Phase 3), Apellis Pharmaceuticals, Inc., or Apellis (acquired by Biogen, Inc.) (EMPAVELI, pegcetacoplan, C3 inhibitor, Phase 2), Roche and Ionis Pharmaceuticals, Inc. (sefaxersen, complement Factor B antisense therapy, Phase 3, with positive interim proteinuria data reported in September 2026), Biogen (felzartamab, CD38-directed antibody, Phase 3), Novartis (zigakibart, anti-APRIL antibody, Phase 3), and Arrowhead Pharmaceuticals, or Arrowhead (ARO-C3, C3 inhibitor, in Phase 1/2).

There are two FDA-approved complement-inhibitor therapies to reduce proteinuria in C3G patients: FABHALTA® (Novartis, iptacopan, Factor B inhibitor) and EMPAVELI® (Biogen, following its acquisition of Apellis, pegcetacoplan, C3 inhibitor). Both FABHALTA and EMPAVELI labeling includes a REMS. Other complement inhibitors are in development by Kira Pharmaceuticals, with KP104 (C5 inhibitor fused to Factor H) in Phase 2, Arrowhead with ARO-C3 (C3 inhibitor) in Phase 1/2, NovelMed Therapeutics Inc., with NM8074 (ruxoprubart, Bb inhibitor) in Phase 1b, and Novo Nordisk, with zaltenibart (MASP-3 inhibitor) in Phase 2, and One04 Therapeutics, with CPV-104 (recombinant Factor H) in Phase1.

There are three FDA-approved therapies for LN: BENLYSTA (belimumab, GSK), LUPKYNIS® (voclosporin, Aurinia Pharmaceuticals Inc.) and GAZYVA (obinutuzumab, Genentech, a member of the Roche Group). Additionally, there are several companies with products and product candidates in development for LN, including Novartis AG, with ianalumab in Phase 3, AstraZeneca, with Saphnelo (anifrolumab) in Phase 3, Cabaletta Bio, Inc., with CABA-201 (CD19-CAR T cell therapy) in Phase 1/2, and Bristol Myers Squibb Company, with CC-97540 (BMS-986353)(CD19-targeted autologous CAR T-cell therapy) in Phase 2.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products. Large and established companies such as Amgen Inc., Roche and GSK plc, among others, compete in the market for drug products to treat kidney disease. In particular, these companies have greater experience and expertise in conducting preclinical testing and clinical trials, obtaining marketing approvals, manufacturing such products on a broad scale and marketing approved products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates

that we are developing obsolete. Smaller and other early-stage companies may also prove to be significant competitors. In addition, a number of large pharmaceutical companies and small to mid-sized and specialty biotechnology companies have marketed and are developing treatments for rare kidney diseases, including indications we are pursuing with our mid-stage rare kidney disease pipeline. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval, or discovering, developing and commercializing competitive products, before, or more effectively than, we do. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

The commercialization of our products, and development of our products and product candidates, outside of the U.S., subject us to a variety of risks associated with international operations, which could materially adversely affect our business

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

In addition, we have conducted, currently conduct for ebribafusp and AKB-9090, and in the future may conduct, clinical trials outside of the U.S. for any product or product candidate that may be in-licensed or acquired. As a result of these and other activities, we are or may become subject to additional risks in developing and commercializing Auryxia and Vafseo and our product candidates outside the U.S., including, among others:

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

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

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

Risks Related to Product Development

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

The risk of failure in drug development is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates, including praliciguat, ebribafusp and AKB-9090, 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 Vafseo and our product candidates or to successfully obtain approval of any potential label expansion for Vafseo or approval of our product candidates, if the results of those trials and studies are not positive or are only modestly positive, or if there are concerns with the product profile due to efficacy or safety. Further, the results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials; interim, preliminary, or topline results of a clinical trial do not necessarily predict final results and remain subject to final verification that may result in the final data being materially different from the initial data previously published. Additionally, results of Phase 3 clinical trials for one indication may not be predictive of results of Phase 3 clinical trials for another indication. For example, we announced positive results from the INNO$_2$VATE program; however, while Vafseo achieved the primary and key secondary efficacy endpoints in each of the two PRO$_2$TECT studies, the PRO$_2$TECT program did not meet the primary major adverse cardiovascular event, or MACE, safety endpoint. Many companies in the biopharmaceutical industry have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development, and we may face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. For example, in March 2022, we received the CRL for Vafseo indicating that the FDA had determined that it could not approve the NDA in its present form, thus delaying any potential approval of Vafseo. Following submission of the Formal Dispute Resolution Request, or FDRR, to the FDA in 2022, we filed a resubmission to our NDA for vadadustat for the treatment of anemia due to CKD only in adult DD-CKD patients in 2023. In March 2024, the FDA approved our NDA for vadadustat under the trade name of Vafseo for the treatment of anemia due to CKD in adults who have been receiving dialysis for at least three months. However, we expended significant additional resources to obtain the approval of Vafseo, the approved indication is limited to the treatment of anemia due to CKD in adults who have been receiving dialysis for at least three months and the commercialization of Vafseo was delayed, which had and could continue to have an adverse effect on our business. 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 have had, and in the future may have, lifecycle management and label expansion opportunities under evaluation for Vafseo, including label expansion for the treatment of adult patients with NDD-CKD and for alternative dosing. However, if we pursue such opportunities, the FDA may not agree with our study design or may determine that our results are not sufficient to support a label expansion and may require us to conduct additional trials, or we may not successfully demonstrate safety and/or efficacy needed to obtain regulatory approval. For example, previously, we considered label expansion for the treatment of adult patients with NDD-CKD. However, following a Type C meeting with the FDA in October 2025, we believed that, based on the FDA feedback, regulatory alignment on a path forward for the design of the VALOR clinical trial for the use of vadadustat to treat anemia in patients with late-stage NDD-CKD would require a significantly larger number of patients than proposed, and accordingly would require meaningfully more time and cost to complete than we anticipated. As a result, we did not initiate the VALOR trial, and therefore did not pursue a broader label for Vafseo for adult patients with NDD-CKD. Further, based on additional communications with the FDA regarding smaller subpopulations, we do not expect to pursue approval for potential subgroups of CKD non-dialysis dependent patients. If we pursue any potential label expansion opportunities for Vafseo and do not obtain FDA approval of such label expansion, it could have an adverse effect on our ability to commercialize and generate revenues for Vafseo.

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 for or commercialize our product candidates. We may be required to complete additional clinical trials for Vafseo and any other product or product candidate, including those that may be in-licensed or acquired, in order to obtain or maintain required regulatory approvals. Our preclinical studies and clinical trials may take longer to complete than currently anticipated, or may be delayed,

suspended, required to be repeated, prematurely terminated or may not successfully demonstrate safety and/or efficacy needed to obtain or maintain regulatory approval for a variety of other reasons, such as:

- the costs may be greater than we anticipate;
- the number of patients required for clinical trials may be larger than we anticipate;
- enrollment in our clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, such as our contract research organizations, or CROs, may fail to comply with regulatory requirements, perform effectively, or meet their contractual obligations to us in a timely manner, or at all, or we may fail to communicate effectively or provide the appropriate level of oversight of such third-party contractors;
- the supply or quality of our starting materials, drug substance and drug product necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators, independent data monitoring committees, institutional review boards, safety committees, or ethics committees, may require that we suspend or terminate our clinical trials for various reasons, including noncompliance with regulatory requirements, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using our product candidate, or a finding that the participants are being exposed to unacceptable health risks;
- clinical trials of our product candidates may produce negative or inconclusive results or results that may be interpreted in a manner different than we interpret them, and we may decide, or regulators may require us, to conduct additional clinical trials, repeat a clinical trial or abandon product development programs;
- lack of adequate funding to continue a clinical trial, including unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials or repeat a clinical trial and increased expenses associated with the services of our CROs and other third parties;
- we may fail to initiate, delay or fail to complete a clinical trial as a result of an Investigational New Drug application, or IND, being placed on clinical hold by the FDA, the EMA, the PMDA, or other regulatory authorities, or for other reasons, such as failure to recruit or enroll suitable patients or patients' failure to return for post-treatment follow up;
- we may determine to expand or otherwise change a clinical trial, including after it has begun;
- clinical trial sites and investigators deviating from the clinical protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial, or failure by us or our CROs to communicate effectively or provide the appropriate level of oversight of such clinical sites and investigators;
- there may be an inability, delay, or failure in identifying, initiating, and maintaining a sufficient number of clinical trial sites, many of which may already be engaged in other clinical programs;
- there may be a delay or failure in reaching agreement with the FDA, the EMA, the PMDA or other regulatory authorities on a clinical trial design upon which we are able to execute;
- there may be a delay or failure in obtaining authorization to commence a clinical trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- there may be delays in reaching, or failure to reach, agreement on acceptable terms with prospective clinical trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- the FDA, the EMA, the PMDA or other regulatory authorities may require us to submit additional data or impose further requirements before permitting us to initiate a clinical trial or during an ongoing clinical trial;
- the FDA, the EMA, the PMDA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials;
- third parties with which we work may fail to comply with good practice quality guidelines and regulations, or GxP, including good laboratory practice, good clinical practice, or GCP, and current good manufacturing practice, or cGMP; or
- there may be changes in governmental regulations or administrative actions.

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

- regulators may require that we change our study designs, 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 other risk management plan imposed by FDA or other regulatory authority that uses 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 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 the completion of clinical trials of our products or product candidates, 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, including for our clinical trials of ebribafusp, praliciguat, and AKB-9090. Ebribafusp and praliciguat are being studied for rare diseases with small patient populations and many of those patients are treated with other therapies or products. Also, there are only a limited number of specialist physicians that regularly treat patients with these rare diseases and major clinical centers that support such treatment are concentrated in a few geographic regions globally. In addition, other companies are conducting, or have announced plans for, clinical trials that are seeking, or are likely to seek, to enroll patients with these rare diseases. These patients are generally only able to enroll in a single trial at a time. The small population of patients, competition for these patients, the nature of the disease and limited trial sites have made it and in the future may make it difficult for us to initiate and enroll enough patients to complete our clinical trials of praliciguat and ebribafusp, or other product candidates, on the timelines we anticipate and in a cost-effective manner. Patients may also 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 or that includes a placebo arm. Additionally, it is often more difficult to enroll special or particular subpopulations of patients, such as pediatric or elderly patients, due to a number of factors including parental or other caregiver considerations, concerns and burdens. For example, we began enrolling sites in a post-approval pediatric study for the control of serum phosphorus levels in patients with DD-CKD, or the Hyperphosphatemia Indication, of Auryxia in the second quarter of 2022, which began patient recruitment in the third quarter of 2022, but enrollment of eligible pediatric patients in study sites continued to be very slow despite efforts to do so. We informed the FDA of the enrollment and retention challenges in the trial, and in late August 2025, the FDA recommended that we halt enrollment in the trial until we have further discussions with the FDA. As a result, we halted enrollment and plan to submit to the FDA the data from those patients who completed the study.

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, location 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 approved and investigational therapies and clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product or product candidate being studied in relation to available therapies or other product candidates in development;
- efforts to facilitate timely enrollment in clinical trials;
- participation length and demands on patients and caregivers;
- site staffing shortages and turnover;
- clinical trial sites and investigators failing to perform effectively; and
- patient referral practices of physicians.

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

Further, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of the Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan, or DAP, for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. However, given actions taken by the Trump Administration and ongoing litigation, there is considerable uncertainty surrounding how the FDA will consider diversity action plans in connection with its review of marketing applications. For more information, see the section entitled "*Business - Government Regulation and Product Approvals - Human Clinical Trials in Support of an NDA"* included in our Annual Report on Form 10-K for the year ended December 31, 2025.

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

We have conducted and currently conduct certain of our clinical trials outside of the U.S. The acceptance by the FDA or other regulatory authorities of data from clinical trials conducted outside their jurisdiction may be subject to certain conditions, or such data may not be accepted at all.

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

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

- additional foreign legal and regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- diminished protection of intellectual property in some countries;
- increased protection of personal data, such as GDPR in the EU; and
- interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism.

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

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

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

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

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

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

With respect to the global INNO$_2$VATE Phase 3 program, the incidence of treatment emergent adverse events, or TEAEs, during the Correction and Conversion study in Vafseo-treated patients was 83.8% and 85.5% in darbepoetin alfa treated patients. During the study, the most common TEAEs reported in Vafseo/darbepoetin alfa treated patients were hypertension

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

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

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

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

In addition, the post-marketing clinical trials that we are conducting for Vafseo, and any post-marketing clinical trials that we may conduct for any other product for which we receive marketing approval, if successful, may expand the patient populations treated with such product within or outside of their current indications or patient populations, which could result in the identification of previously unknown undesirable effects, increased frequency or severity of known undesirable effects, or result in the identification of unexpected safety signals. In addition, Vafseo and any other products we commercialize 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 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 current or future product candidates or for any potential label expansion for Vafseo that we may pursue, or we or our collaboration partners may experience significant delays in obtaining required regulatory approvals, which would delay our or their ability to commercialize our products and product candidates, which would materially impair our ability to generate revenue.

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 of our current or future product candidates, including those that may be in-licensed or acquired, or for any potential label expansion for Vafseo that we may pursue. Further, any product candidate may not receive marketing approval in the U.S. even if it is approved in other countries. Each regulatory authority makes their own assessment as to the safety and efficacy of a drug, and the FDA's concern about the safety or efficacy of any product candidate could impact the regulatory authority's decision in another country.

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

Vafseo is currently approved as a treatment for anemia due to CKD for dialysis dependent patients in the U.S., European Union, United Kingdom, Switzerland and Australia. In Japan, Vafseo is approved as a treatment for anemia due to CKD in both dialysis dependent and non-dialysis dependent patients and is marketed and sold by our collaborator TPC. In Taiwan and South Korea, Vafseo is approved for the treatment of symptomatic anemia due to CKD in adult patients on chronic maintenance dialysis. We are not permitted to market Vafseo in any additional jurisdictions or other indications until the requisite approval from regulatory authorities in such jurisdiction is received. As a condition to receiving marketing approval for Vafseo in additional territories or for other indications, we may be required by regulatory authorities to conduct additional preclinical studies or clinical trials, which are time consuming and expensive. For example, previously, we had considered pursuing label expansion for the treatment of adult patients with NDD-CKD, because we believe there are compelling data supporting a positive benefit-risk profile for the use of Vafseo broadly in U.S. patients with CKD. However, following a Type C meeting with the FDA in October 2025, we believed that, based on the FDA feedback, regulatory alignment on a path forward for the design of the VALOR trial for the use of vadadustat to treat anemia in patients with late-stage NDD-CKD would require a significantly larger number of patients than proposed, and accordingly would require meaningfully more time and cost to complete than we anticipated. As a result, we do not plan to initiate the VALOR trial, and therefore will not pursue a broad label for Vafseo for adult patients with NDD-CKD. Further, based on additional communications with the FDA regarding smaller subpopulations, we do not expect to pursue approval for potential subgroups of CKD non-dialysis dependent patients.

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. For example, the FDA reviews an application to determine, among other things, whether the product is safe and whether it is effective for its intended use(s), with the latter determination being made on the basis of substantial evidence. The FDA has traditionally interpreted this evidentiary standard to require at least two adequate and well-controlled clinical investigations to establish effectiveness of a new product. In February 2026, FDA leadership declared that, in most cases, the new default requirement for FDA approval of a new product will be one adequate and well-controlled pivotal clinical trial plus confirmatory evidence, rather than two pivotal clinical trials. In the event that we submit an application on the basis of one clinical trial and confirmatory evidence, the FDA could determine that such information is not sufficient to support approval of the application and the agency could require us to conduct an additional trial in support of approval.

Furthermore, approval of a drug does not ensure successful commercialization. In April 2024, Averoa submitted its marketing authorization application for ferric citrate in Europe. In March 2025, the Committee for Medicinal Products for Human Use of the EMA adopted a positive opinion recommending the European Commission, or EC, approve Averoa’s marketing authorization, which the EC granted in June 2025. In November 2025, the MHRA granted Averoa's UK marketing authorization. However, Averoa has not yet obtained pricing authorization nor commenced sales of ferric citrate in Europe or the UK.

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

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

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

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

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

We plan to rely on orphan drug exclusivity for praliciguat and may rely on orphan drug exclusivity for potential future product candidates that we may develop. However, we cannot assure you that we will receive orphan drug designation for praliciguat or any of our potential future product candidates; and further, that we will be able to maintain orphan designation at the time of marketing approval in the U.S., EU, or other jurisdictions. For the FDA to grant orphan drug exclusivity to one of our products, at the time of marketing approval, the FDA must find that the prevalence of the disease for which the product is indicated is still fewer than 200,000 in the U.S., the approved indication matches the designation obtained during development, and that the drug is a new orphan drug, or clinically superior to an already approved drug that is considered "the same" as our drug. The FDA may conclude that the condition or disease for which orphan drug exclusivity is sought does not meet this standard. Exclusivity attaches only to the approved indication and the specific drug product. For the EMA, during marketing application review, submission of updated data on the prevalence of the disease and a justification of significant benefit will be required to maintain an EU orphan designation. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of the patients with the rare disease or condition.

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

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

Additionally, we and our partners could face heightened risks with respect to obtaining or maintaining marketing authorizations in the UK as a result of the withdrawal of the UK from the EU, commonly referred to as Brexit. The UK is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the MHRA is responsible for approving all medicinal products destined for the United Kingdom market (i.e., Great Britain and Northern Ireland). On October 1, 2025, the MHRA updated its guidance for clinical trials to address, among other things, research transparency requirements for clinical trials, the approvals process, Research Ethics Committee review of clinical trials, simplified arrangements for consent in clinical trials and pharmacovigilance.

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

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the EC in November 2020. On December 11, 2025, the European Parliament and the Council of the European Union, or the Council, reached a provisional political agreement on the legislation. The Council formally adopted these new rules on September 28, 2026. The new provisions were considered by the European Parliament in October 2026 and are expected to enter into force by December 2026 and to become applicable in law 2028 following a 24-month transition period. In this time interval, all EU member states, or EU Member States, will need to update their national laws to align with the new rules. The revisions may have a significant impact on the pharmaceutical industry and our business. The new Pharma Package would, among other things, shorten marketing authorization times from 210 to 180 days, and set a baseline period of eight years of data exclusivity and one year of market exclusivity with possible extensions for new indications up to a maximum of 11 years total.

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

regulatory requirements or if we experience unanticipated problems with our products, or product candidates, when and if approved.

Marketing approvals may be subject to limitations on the approved indicated uses for which the product may be marketed, other conditions of approval, or contain requirements or commitments for potentially costly post-marketing studies and surveillance to monitor the safety and efficacy of the product, including REMS, or Risk Management Plans in the EU, or registries or observational studies. For example, in connection with the FDA approvals of Auryxia and Vafseo, we committed to the FDA to conduct certain post-approval studies, including pediatric studies of Auryxia and Vafseo under the Pediatric Research Equity Act of 2003, or PREA, and observational studies of Vafseo related to safety, malignancy and pregnancy. Under PREA, an NDA or supplement to an NDA for certain drug products must contain data to assess the safety and effectiveness of the drug product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, and a waiver may be granted in pediatric sub-populations in which the disease is not yet present or in which it is impracticable to study the drug. Regarding 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. The FDA has since released us 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 FDA denied this request in August 2023. The PMR trial had been actively recruiting patients, but the final report for the trial was due in April 2024, so the trial is considered delayed. We informed the FDA of the enrollment and retention challenges in the trial and requested a release from the PMR, and in late August 2025, the FDA recommended that we halt further enrollment in the trial until we have further interactions with the FDA. As a result, we halted trial enrollment and plan to submit to the FDA the data from those patients who completed the study. If the FDA does not grant the release from the PMR, we would be required to restart the trial or conduct a separate trial, which would be time consuming and expensive. In addition, if the FDA finds that we failed to comply with the pediatric study requirement with regard to the Hyperphosphatemia Indication, in violation of applicable law, it could institute enforcement proceedings to seize or enjoin the sale of Auryxia, seek civil penalties or other adverse consequences, which would have a material adverse impact on our ability to commercialize Auryxia and our ability to generate revenues from Auryxia.

In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for Auryxia, Vafseo and any other product for which we receive regulatory approval will be subject to extensive and ongoing regulatory oversight, requirements, and guidance. If we, our contract development and manufacturing organizations, or CDMOs, 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;
- voluntary or compelled withdrawal of the product from the market, or product recalls;
- restrictions on the labeling or marketing of a product;
- fines, restitution or disgorgement of profits or revenues;
- warning or untitled letters or clinical holds;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- REMS; and
- injunctions or the imposition of civil or criminal penalties.

For example, we previously had three limited, voluntary recalls of Auryxia. Any other recalls or any supply, quality or manufacturing issues in the future related to Auryxia or Vafseo could result in significant negative consequences, including reputational harm, loss of customer confidence, and a negative impact on our financials, any of which could have a material adverse effect on our business and results of operations, and may impact our ability to supply Auryxia in the U.S. or Europe and Vafseo in the U.S., Japan, Europe or in other countries, for commercial and clinical use.

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

The FDA's policies and those of other regulatory authorities may change, and additional government regulations may be enacted. We cannot predict the likelihood, nature or extent of government regulations that may arise from future legislation or administrative action, either in the U.S. or in other jurisdictions. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or unable 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 data protection laws in force from time to time, the retained EU law version of the General Data Protection Regulation as saved into United Kingdom law by virtue of section 3 of the United Kingdom's European Union (Withdrawal) Act 2018;
- federal and state laws requiring the submission of accurate product prices and notifications of price increases;
- federal and state securities laws;
- environmental, health and safety laws and regulations; and
- international trade laws, which are laws that regulate the sale, purchase, import, export, re-export, transfer and shipment of goods, products, materials, services and technology.

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

- the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, which among other things, strictly regulates drug product marketing and promotion and prohibits manufacturers from marketing such products for off-label use;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs, and laws requiring notification of price increases;
- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal

government, with potential liability including mandatory treble damages and significant per-claim penalties, and violations of the FDCA, the federal government pricing laws, and the federal Anti-Kickback Statute trigger liability under the federal False Claims Act;

- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by 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. For example, there has been 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. In addition, recent healthcare reforms have strengthened these laws. For example, the ACA (as defined below), 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 ACA also amended the False Claims Act, such that violations of the Anti-Kickback Statute are now deemed violations of the False Claims Act.

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

Efforts to ensure that our business complies with applicable healthcare laws and regulations involve substantial costs and require us to expend significant resources. One of the potential areas for governmental scrutiny involves federal and state requirements for pharmaceutical manufacturers to submit accurate price reports to the government. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, or potential qui tam complaints, and it is possible that such reviews could result in changes, recalculations, or defense costs that may have adverse legal or financial consequences. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, any of which could materially adversely affect our business and would result in increased costs and diversion of management attention and could negatively impact the development, regulatory approval and commercialization of Auryxia or Vafseo, any of which could have a material adverse effect on our business. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government funded healthcare programs.

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

Physicians are permitted to prescribe drug products for uses that differ from those approved by the FDA or other applicable regulatory agencies. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict manufacturer communications regarding unapproved uses of an approved drug. Companies are not permitted to promote drugs for unapproved uses or in a manner that is inconsistent with the FDA-approved labeling. There are also restrictions about making comparative or superiority claims based on safety or efficacy that are not supported by substantial evidence. Accordingly, we may not promote Auryxia in the U.S. for use in any indications other than the Hyperphosphatemia Indication and for the treatment of IDA in adult NDD-CKD patients, and we may not promote Vafseo in the U.S. for use in any indication other than as a once-daily 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. A company that is found to have improperly promoted off-label uses or to have otherwise engaged in false or misleading promotion or improper distribution of drugs will be subject to significant liability, potentially including civil and administrative remedies as well as criminal sanctions. It may also be subject to exclusion and debarment from federal healthcare reimbursement programs.

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

Further, we will need to ensure full compliance with the administration's recently announced enforcement position on direct-to-consumer, or DTC, prescription drug advertising and related promotional activities. On September 9, 2025, the President issued a Memorandum directing HHS to ensure transparency and accuracy in direct-to-consumer prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements. The same day, the Make America Healthy Again Commission released a report declaring that the FDA, HHS, FTC and DOJ will increase oversight and enforcement under current authorities for violations of DTC prescription drug advertising laws. To that end, the FDA announced that it is initiating a rulemaking process to eliminate the adequate provision loophole that allows pharmaceutical advertisements to address safety information by placing it in another format or location. In this context, the FDA declared that it will no longer tolerate what it characterized as deceptive practices in prescription drug advertising and that the agency would aggressively deploy its available enforcement tools, with heightened scrutiny of fair balance and disclosures in social media promotions. The FDA also issued a generic notice letter to a substantial number of companies, including us, directing such companies to remove any noncompliant advertising and bring all promotional communications into compliance. We believe that we maintain a robust compliance program and processes designed to ensure that all promotional advertising activities are performed in a legal and compliant manner. However, given the administration's enforcement position on these issues, we may be at increased risk that the FDA, DOJ or FTC will find our promotional advertising and other digital campaigns, including social media activities, are not in compliance with fair balance requirements and anticipated rule changes at the FDA and possibly other agencies.

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

The FDA and comparable regulatory agencies in foreign jurisdictions, such as the EMA and the Committee for Medicinal Products for Human Use of the EMA, play an important role in the development of our product candidates by providing guidance on our clinical development programs and reviewing our regulatory submissions, including INDs, requests for special designations and marketing applications. If these oversight and review activities are disrupted due to funding cuts, personnel losses, reductions in force, regulatory reform or government shutdown, it could lead to delays in FDA guidance on our clinical development programs, or review, processing and approval of our regulatory submissions for our products and product candidates, then correspondingly our ability to develop and secure timely approval of our regulatory submissions for our products and product candidates could be impacted in a negative manner, which could negatively impact our business.

There is also substantial uncertainty as to how regulatory reform measures being implemented by the Trump Administration across the government will impact the FDA and other federal agencies with jurisdiction over our activities. For example, since taking office, President Trump has issued several executive orders that could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. If these or other orders or executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Similarly, actions by the U.S. government have significantly disrupted the operations of U.S. government agencies such as the National Institutes of Health, National Science Foundation, Centers for Disease Control and Prevention and FDA, which have traditionally provided funding for basic research, R&D, and clinical testing. These U.S. government actions could, directly or indirectly, significantly disrupt, delay, prevent, or increase the costs of our research and product commercialization programs, including our ability to develop new product candidates, conduct clinical trials, implement research collaborations with other companies or institutions, and obtain approvals to market and sell new products.

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

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, including in the conduct of our clinical trials, 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.

Complying with the GDPR's requirements, as well as the requirements of the UK Data Protection Act 2018, 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 or the UK. 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. We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement (depending on the nature of the alleged violations). If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements.

Laws also are being considered at both the state and federal levels. For example, in California, the CCPA, as amended by the CPRA, incorporates GDPR-like provisions and creates similar risks and obligations as those created by GDPR, 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 such laws, 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, a number of 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. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

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

If we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

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

financial condition. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

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

In the U.S. and some foreign jurisdictions, there have been several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of any product candidate, restrict or regulate post-approval activities and affect our or our collaborators' ability to profitably sell Auryxia and Vafseo or any other product candidate for which we, or they, obtain marketing approval. 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. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

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. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress, which led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which will remain in effect for six months into fiscal year 2032.

The American Taxpayer Relief Act of 2012, 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. These laws and 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 any of our approved products or product candidates for which we may obtain regulatory approval, or the frequency with which such products are 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.

As of January 2025, oral ESRD-related drugs without injectable or intravenous equivalents, including Auryxia and all other phosphate lowering medications, are included in the ESRD bundle. However, ESRD facilities receive a payment adjustment under TDAPA for Auryxia for a period of two years starting on January 1, 2025 based on ASP. After the TDAPA period for Auryxia and other oral-only phosphorus lowering drugs, a permanent adjustment increasing the single bundled payment base rate paid to the dialysis clinic for each Medicare dialysis treatment will be made by CMS to account for the cost of these drugs. However, CMS calculates the adjustment based on the weighted average cost of all phosphate lowering medications, including Auryxia. After the TDAPA period, dialysis organizations will not receive any additional payment for use of Auryxia outside the bundled rate. Furthermore, based on the 2027 ESRD Rule, such increase in the single bundled payment base rate may be inadequate for dialysis facilities to elect to make Auryxia available to patients, which would have a negative impact on our revenue from Auryxia.

Vafseo, which we began selling in January 2025, is also reimbursed under the ESRD PPS. ESRD facilities receive a payment adjustment under TDAPA for Vafseo as a new renal dialysis drug meeting certain criteria for a period of no more than two years starting on January 1, 2025 and continuing through December 31, 2026. The payment adjustment under TDAPA is based on Vafseo’s ASP and is a separate payment that is in addition to the base rate paid to dialysis facilities in order to facilitate the adoption of innovative therapies. After the TDAPA period, for a period of three years, dialysis facilities will receive an additional payment based on current utilization and pricing per dialysis treatment, regardless of Vafseo use. As a result, dialysis organizations will receive no additional payment for their use of Vafseo after the TDAPA period. The calculation of the post-TDAPA add-on payment adjustment was expected to be determined and published by CMS on an annual basis; however, pursuant to the 2027 ESRD Rule, CMS plans to adjust this calculation on a quarterly basis, which may create uncertainty in reimbursement amounts. As a result of the method used by CMS to calculate and apply the post-TDAPA add-on payment adjustment, we expect a significant decline in the level of reimbursement provided to dialysis facilities for use of Vafseo. After the TDAPA period, we anticipate pricing Vafseo within the range of the price for ESAs. ESAs are priced significantly lower than

Vafseo's current price. As a result, while we expect to sell a higher unit volume of Vafseo in 2027 as compared to 2026, we expect Vafseo revenues to decrease significantly in 2027 as compared to 2026 due to the expected lower price point. Further, we believe competition has increased pricing pressures for ESAs, which may negatively impact the price of, and the market for, Vafseo after the TDAPA period. The 2027 post-TDAPA add-on adjustment will be effective as of January 1, 2027. There can be no assurance that the level of reimbursement determined by CMS in the post-TDAPA period will improve. Such reduced reimbursement amounts or reimbursement uncertainty could limit provider adoption of Vafseo, restrict patient access and have a negative effect on the demand for, and the price of, Vafseo, which would adversely impact our revenue.

In late 2025, KCAPA, which seeks to maintain patient access to innovative kidney care treatment, including Vafseo, by improving reimbursement following TDAPA expiration, was introduced in the U.S. Congress. Although the KCAPA has the potential to improve post-TDAPA reimbursement if enacted, there can be no assurance that such legislation will be enacted before the TDAPA period for Vafseo expires on December 31, 2026, or that it will be enacted with the provisions as currently proposed, or at all.

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

Since adoption of the IRA, the Trump Administration has taken a number of actions to reduce the costs of pharmaceutical products. On April 15, 2025, President Trump issued an Executive Order which directs HHS to take steps to reduce the prices of pharmaceutical products.

Further, on May 12, 2025, President Trump issued an additional Executive Order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the United States. The Order directs the Secretary of HHS to communicate most-favored-nation, or MFN, price targets to pharmaceutical manufacturers to bring prices in line with comparably developed nations. The Executive Order further provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes MFN pricing in the United States.

Thereafter, on July 31, 2025, President Trump issued letters to 17 pharmaceutical companies reiterating the requirements of the May 12, 2025, Executive Order and demanding that such companies extend MFN pricing to Medicaid patients. Virtually all of these pharmaceutical companies have entered into agreements with the administration to provide for lower prices on certain pharmaceuticals. On February 5, 2026, the President launched TrumpRx.gov, a website that directs individuals to pharmaceutical manufacturer websites that are offering price discounts based on the administration's pricing agreements with pharmaceutical manufacturers. At the same time, U.S. federal and state governments continue to pursue legislative and regulatory initiatives designed to reduce prescription drug spending, including the Medicare Drug Price Negotiation Program, Medicare inflation rebate requirements and demonstration programs administer by CMS, through its Center for Medicare and Medicaid Innovation, or CMMI, which has broad authority to develop and test payment and reimbursement models intended to reduce federal spending on prescription drugs. For example, on September 30, 2026, CMS issued a final rule for the Global Benchmark for Efficient Drug Pricing Model, or GLOBE Model, a Medicare Part B demonstration program that may require manufacturers of certain covered drugs to pay additional rebates when U.S. prices exceed specified international pricing benchmarks. CMS has also proposed additional models that could apply similar concepts to other federal healthcare programs, such as the Guarding U.S. Medicare Against Rising Drug Costs, a Medicare Part D demonstration program.

On October 7, 2026, the Pharmaceutical Research and Manufacturers of America filed a lawsuit in the U.S. District Court for the District of Columbia challenging CMS' final GLOBE Model and seeking declaratory and injunctive relief. The complaint asserts that CMS exceeded its authority under Section 1115A of the Social Security Act by using the CMMI's demonstration authority to impose a mandatory manufacturer rebate regime tied to international reference prices.

Although we cannot predict whether, when, or to what extent any of our product candidates, if approved, would become subject to these or future pricing and reimbursement programs, such measures could reduce reimbursement for pharmaceutical products, place downward pressure on pricing, increase rebate, discount, or other payment obligations, limit commercial flexibility, and adversely affect demand for pharmaceutical products. These initiatives could adversely affect the market opportunity, pricing expectations, reimbursement levels, commercial potential, and profitability of our product candidates, and may influence our development, commercialization, partnering, and investment strategies. Because many of these initiatives are relatively new, continue to evolve through rulemaking, guidance, and implementation activities, or may be expanded through future legislation, regulation, or demonstration programs, their ultimate scope, implementation, legal viability, and financial impact remain uncertain. The adoption, expansion, or modification of these initiatives could make it

more difficult for us to establish favorable pricing and reimbursement following any future product approval, achieve broad market acceptance, attract collaborators or commercial partners, accurately forecast future revenues, and achieve profitability.

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

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

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

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

Furthermore, in some countries, including EU Member States, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take a significant amount of time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States and parallel distribution, or arbitrage between low-priced and high-priced EU Member States, can further reduce prices, and in certain instances render commercialization in certain markets infeasible or disadvantageous from a financial perspective. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product and/or our product candidates to other available products in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or government authorities may lead to further pressure on the prices or reimbursement levels. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, the commercial launch of our product and/or product candidates could be delayed, possibly for lengthy periods of time, we or our collaborators may not launch at all in a particular country, we may not be able to recoup our investment in one or more product candidates, and there could be a material adverse effect on our business.

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

As a condition of reimbursement by various federal and state health insurance programs, we are required to calculate and report certain pricing information to federal and state agencies. The regulations governing the calculations, price reporting and payment obligations are complex and subject to interpretation by various government and regulatory agencies, as well as the courts. Reasonable assumptions have been made where there is lack of regulations or clear guidance and such

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

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

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

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

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

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

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

In December 2019, President Trump signed legislation intended to facilitate the development of generic and biosimilar products. The bill, previously known as the CREATES Act, authorizes sponsors of ANDAs, 505(b)(2) NDAs or biosimilar product applications to file lawsuits against companies holding NDAs or BLAs that decline to provide sufficient quantities of an approved reference drug or biological product on commercially reasonable, market-based terms. Drug or biological products on the 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.

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

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

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

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

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

Risks Related to our Reliance on Third Parties

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

With respect to Auryxia, we sublicensed the rights to commercialize Riona to JT and Torii in Japan. In addition, we granted Averoa an exclusive license to develop and commercialize ferric citrate in the Averoa Territory. In February 2025, in advance of the market entry of generic competition to our branded Auryxia following LoE, we entered into an Authorized Generic Distribution and Supply Agreement with our AG Distributor, pursuant to which, since March 2025, our AG Distributor has been selling an authorized generic version of Auryxia. We will be relying on our AG Distributor for the commercialization of this authorized generic, which currently competes with both Auryxia and Teva's generic version of Auryxia which received approval in March 2026. In addition, we are responsible for supplying product to our AG Distributor, and if there are challenges within the supply chain, we could be subject to certain penalties, which could be substantial.

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

Our ability to generate revenues from these existing and future arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements and our ability to maintain our collaborations for development and commercialization. We cannot predict the success of any collaboration that we enter into. For example, although Averoa has received marketing authorization for ferric citrate in the EU and the UK, it has not yet obtained pricing authorization nor commenced sales of ferric citrate in Europe or the UK. Additionally, Medice's launch of Vafseo in certain countries in the Medice Territory was later than anticipated due to required prerequisite activities. If we are unable to maintain our collaborations, or our collaboration partners are unable to successfully perform their obligations under the agreements on the timelines anticipated or at all, we may not be able to capitalize on the market potential of our products or product candidates, and our business could be materially harmed.

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

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

If any of these events occur, the market potential of Auryxia, including our authorized generic, Riona or Vafseo, where approved, and any other products or product candidates, could be reduced, and our business could be materially harmed. Collaborations may also divert resources, including the attention of management and other employees, from other parts of our business, which could have an adverse effect on other parts of our business, and we cannot be certain that the benefits of the collaboration will outweigh the potential risks.

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

We may seek additional collaborations, strategic alliances, or joint ventures, or enter into additional licensing arrangements with third parties that we believe will complement or augment our and our partners' development and/or commercialization efforts with respect to Auryxia, Vafseo or any other products or product candidates both within and outside of the U.S. Additionally, our product development and research programs and the potential commercialization of any product candidates we may develop will require substantial additional cash to fund expenses. For certain product candidates we may develop, we may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. 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 our 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.

We may not be able to negotiate and enter into future collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to delay or curtail the development of the product candidates for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay their potential commercialization, 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 commercialize Auryxia or develop or commercialize Vafseo or our product candidates.

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

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

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

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

We rely upon third parties to conduct all aspects of our product manufacturing and commercial distribution, and in many instances only have a single supplier or distributor, and the loss of these manufacturers or distributors, their failure to supply us on a timely basis, or at all, or their failure to meet our demand, scale production or 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. Additionally, we may also face significant time, cost and regulatory challenges in qualifying and transitioning to alternative manufacturers or distributors, which could adversely affect our ability to manufacture, develop and commercialize our products and product candidates.

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

our demand, including as a result of quality issues such as batch failures or recalls, it could delay, prevent or impair our and our partners' development or commercialization efforts.

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

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

If we, or any of our third-party manufacturers or our 3PL cannot or do not perform as agreed or expected, or any of the third-parties on which we rely were to experience shutdowns, delays or other business disruptions, including as a result of resource constraints, catastrophic events, including pandemics, terrorist attacks, wars or other armed conflicts, geopolitical tensions, tariffs, trade agreement disputes, or natural disasters, or 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, our supply chain may be disrupted, which would limit our ability to manufacture our product candidates for our clinical trials and research and development operations and our products for commercialization, and to fulfill our requirements under our supply contracts. In such event, we may be forced to 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. Additionally, these third-party manufacturers may be unable to meet our demand or scale production, may experience quality issues such as batch failures or recalls, and depend on limited suppliers for raw materials, any of which could further disrupt supply. If any of these events occur, especially with respect to one of our sole source suppliers, we may not have sufficient quantities of product for the commercial distribution of Auryxia, our authorized generic of Auryxia, or Vafseo or the development of our product candidates, which could delay our clinical trials and materially and adversely impact our business and results of operation. In addition, if we do not have sufficient quantities of Auryxia, including our authorized generic, or Vafseo, including vadadustat drug substance, to satisfy the requirements of our customer and supply contracts, including inventory levels, we have incurred with respect to Auryxia, and may in the future incur with respect to Auryxia, including our authorized generic, or Vafseo, contractual penalties, which could be substantial.

In some cases, there may be a limited number of qualified replacement manufacturers, or the technical skills or equipment required to manufacture a product or product candidate may be unique or proprietary to the original manufacturer, and we may have difficulty transferring such skills or technology to another third-party, or a feasible alternative may not exist. In addition, Auryxia, Vafseo and our product candidates may compete with other products and product candidates for access to third-party manufacturing facilities, and certain 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, which would limit our ability to engage such manufacturers as a replacement or secondary source supplier. 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, Vafseo or our drug products. If we are required to change manufacturers for any reason, including as may be necessary to relocate the manufacturing of our products or starting materials, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays and costs associated with the qualification of a new manufacturer and validation of manufacturing processes would negatively affect our ability to supply clinical trials, obtain and maintain marketing approval, or commercialize or satisfy patient demand for Auryxia and Vafseo, where approved, in a timely manner, within budget, or at all.

Moreover, issues that may arise in any scale-up, technology transfer, or continued commercial scale manufacture of our products may lead to significant delays in our development, marketing approval and commercial timelines for new products

or affect commercial supply of Auryxia or Vafseo and negatively impact our financial performance. For example, in the past, we have experienced issues in manufacturing Auryxia, including capacity constraints, which have impacted inventory levels, and if we experience manufacturing issues going forward, or incur additional costs, or our actions to prevent future interruptions are not successful, we may experience additional supply issues, which could have an adverse impact on our business. In addition, before we can manufacture product at a new site, we need to validate the process at that site. If the process validation is unsuccessful, or takes longer than we anticipate, we may have to expend additional resources and could experience a supply interruption or delay in product development. Any future supply interruptions, whether related to inventory levels, capacity, quality or quantity, for Auryxia or our authorized generic, or Vafseo where approved, or for our product candidates, may negatively and materially impact our development timelines, our business, reputation and financial condition.

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

In addition, the cost of obtaining Auryxia and Vafseo is subject to adjustment based on our third-party manufacturers' costs of obtaining raw materials and producing the product, and the impact of tariffs, as discussed below under the heading "*Changes in and uncertainty surrounding U.S. trade policy on tariffs could have a material adverse impact on our business, financial condition and results of operations*." 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 expect increases in the cost to import Auryxia and Vafseo as a result of tariffs. Any significant increase in the cost of obtaining our products could materially adversely affect our revenue for Auryxia and Vafseo.

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

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

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

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

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

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

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

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

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

Any of these events could cause our preclinical studies and clinical trials, including post-approval clinical trials, to be extended, delayed, suspended, required to be repeated or terminated, or we may receive untitled or 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 or increase the cost of, 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 applicable 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 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 trials and preclinical studies 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 to distribute to our clinical trial sites. Any performance failure on the part of our storage or distribution partners could delay clinical development, marketing approval or commercialization, resulting in additional costs and depriving us of potential product revenue.

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

We do not own all of the rights to our product, Auryxia. We have licensed and sublicensed certain rights, patent and otherwise, to Auryxia from Panion & BF Biotech, Inc., or Panion, a third-party, who in turn licenses certain rights to Auryxia from one of the inventors of Auryxia. The license agreement with Panion, or the Panion License Agreement, required us to meet development milestones and imposed 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 where the manufacture, use or sale of Auryxia would, but for the license granted, infringe a licensed patent of the licensed technologies, 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. 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 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 obligations thereunder, 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 License Agreement, or force us to negotiate a revised or new license agreement on terms less favorable than the original. In addition, in the event that the owners and/or licensors of the rights we license were to enter into bankruptcy or similar proceedings, we could potentially lose our rights to Auryxia or our rights could otherwise be adversely affected, which could prevent us from continuing to commercialize Auryxia.

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

The manufacturing of biologics is highly complex, and we may experience production issues or interruptions in supply for our ebribafusp development program or other product candidates. These challenges may include variability in raw materials, equipment performance issues, process scale-up difficulties, and the need to maintain consistent product quality across batches. In addition, risks related to product characterization and analytical testing—such as limitations in assay sensitivity or specificity, incomplete understanding of critical quality attributes, difficulties in method development, qualification or validation, and potential discrepancies between analytical methods—may impact our ability to fully characterize the product and ensure comparability. Failures or delays in analytical testing, including stability testing, impurity profiling, or potency assessment, could further delay release, regulatory submissions, or approval timelines. Collectively, these issues may result in increased costs, supply interruptions, or delays in clinical development and regulatory approval.

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

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

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

Our CDMOs are subject to routine or for-cause inspections of the facilities that manufacture, test, and/or store our product candidates. Deficiencies identified during these inspections may require remediation potentially impacting or delaying the development or approval of ebribafusp or other product candidates and thereby delaying our clinical trials or the commercial approval of ebribafusp. Additionally, remediation of deficiencies poses the risk of lost product or significant financial impact which also may result in delays to our clinical trials or commercial approval and could materially harm our business.

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

In 2025, the Trump Administration initiated a series of tariff-related actions against U.S. trading partners. In February 2026, the U.S. Supreme Court held that the International Emergency Economic Powers Act of 1977, or the IEEPA, does not authorize the president to impose tariffs, invalidating both the “reciprocal” tariffs and certain country-specific tariffs previously imposed by executive orders. Following this decision, the U.S. Customs and Border Protection began refunding previously collected IEEPA duties through a phased administrative process; we have received a refund of the IEEPA duties paid for Vafseo. Separately, in April 2025, the U.S. Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 into the impact on U.S. national security of the imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. Then, on April 2, 2026, President Trump issued a Proclamation invoking Section 232 of the Trade Expansion Act of 1962 to impose tariffs on imports of patented pharmaceuticals, biologics, and associated ingredients into the U.S. The action affects pharmaceutical manufacturers, importers, and supply chain participants. Specifically, for companies like ours that are not listed in the annexes to the proclamation (i.e., those that have not concluded qualifying onshoring plans and MFN pharmaceutical pricing agreements with the U.S. government), as of September 29, 2026, a 100% tariff went into effect for imports of pharmaceutical articles that are subject to a valid, unexpired U.S. patent and are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), including Auryxia and Vafseo, or are listed in the FDA’s Lists of Licensed Biological Products (the Purple Book). The 100% tariff also applies to active pharmaceutical ingredients, or APIs and key starting materials for such articles. Preferential tariff rates are provided for imports of covered pharmaceuticals from Japan, the EU, Korea, Switzerland, Liechtenstein and the UK. Certain categories of products are exempt from these tariffs, but the exemptions do not currently apply to our products.

We primarily manufacture our Vafseo drug substance and drug product in China and conduct certain research activities in China, and we manufacture our Auryxia drug substance in France. Although we do not currently expect the 100% Section 232 tariff to have a significant impact on our cost of goods or revenue for Vafseo in 2027 and 2028 due to our current inventory of Vafseo in the U.S., we could use our inventory sooner than we expect and the application of these tariffs to our imports of drug substance and drug product in the future could significantly increase our costs of goods, which could have a material adverse effect on our business, financial condition and results of operations. Additionally, sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S.-based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on CDMOs and other service providers that operate in China, including our current Vafseo manufacturers.

U.S. trade policy has been subject to numerous changes and remains subject to significant uncertainty, and accordingly, a host of other U.S. tariff actions remain possible.

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

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

Many of our manufacturers and suppliers for Auryxia and Vafseo are located in China, Europe and Canada, and we may continue to rely on foreign CDMOs in the future. Our primary third-party manufacturer of our drug substance and drug product for commercial supply of Vafseo, STA Pharmaceutical Hong Kong Limited, or WuXi STA, a subsidiary of WuXi AppTec

Co., Ltd., or WuXi AppTec, is located in China. We also have a third-party manufacturer of our drug product for commercial use of both Auryxia and Vafseo, Patheon, Inc., or Patheon, that is located in Canada. We also have third-party manufacturers of drug substance for commercial use of both Auryxia and Vafseo in France and Spain, respectively. We also rely on third parties in China for the supply of raw materials used in the manufacture of Vafseo and for certain early-stage research services. Trade tensions and conflicts between the U.S. and China, Europe, Canada or other countries have recently been escalating and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the U.S., China, Europe, Canada or other countries, trade agreement disputes or due to geopolitical unrest and unstable economic conditions. In addition, certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. In addition, the U.S. Department of Commerce's Bureau of Industry and Security, or BIS, published an interim final rule in September 2025, referred to as the "Affiliates Rule," which expands the scope of BIS export restrictions to include entities with 50% or greater ownership, in the aggregate, by one or more entities listed on the BIS entity list. The Affiliates Rule has been suspended until November 10, 2026 as part of the U.S.-China tentative framework agreement, and the U.S. Treasury Secretary publicly stated in September 2026 that the parties had agreed to extend that agreement until January 10, 2027, which a U.S. government official has indicated will also extend the suspension of the Affiliates Rule, although BIS has not yet published a notice in the Federal Register formally extending the suspension. Escalating tensions between the United States and China may prevent or hinder the export of materials or technical information between us and our CDMO and third parties, such as pharmaceutical manufacturers. These third parties may voluntarily require compliance or supply chain requirements that go above and beyond potential legislation to address perceived risk of "pass through," which would make it difficult for us to operate our business.

In addition, on December 18, 2025, President Trump signed into law the National Defense Authorization Act for Fiscal Year 2026, including its Section 851 (the Biosecure provisions). These provisions limit U.S. government procurement from and grants to biotechnology companies of concern, or BCCs. Under the Biosecure provisions, U.S. government agencies cannot (i) buy or obtain biotechnology equipment or services provided by a BCC; (ii) enter into, extend, or renew a contract with any entity using biotechnology equipment or services provided by a BCC to perform a government contract; or (iii) expend loan or grant funds for biotechnology equipment or services provided by a BCC. The Biosecure provisions do not name specific companies as BCCs but provide that the Office of Management and Budget (OMB) will establish a list of BCCs no later than December 2026, which will include any company on the U.S. Department of Defense, or the Department of Defense, 1260H list of Chinese Military Companies as a BCC. On June 8, 2026, the Department of Defense published an updated list, which included WuXi AppTec. Since WuXi AppTec was just added to the list, it will be covered under a five-year grandfather clause that allows any contracts signed before the effective date of the ban to be protected through 2031. Nonetheless, on June 11, 2026, WuXi AppTec filed a legal challenge to its designation as a Chinese Military Company, and on August 7, 2026, the U.S. District Court for the District of Columbia granted WuXi AppTec a preliminary injunction enjoining the Department of Defense from enforcing the designation. On September 18, 2026, the Department of Defense filed its answer to WuXi AppTec's complaint and the litigation is ongoing. It is currently unclear whether such designation would apply to WuXi STA, as a subsidiary of WuXi AppTec, and the outcome of the pending litigation is unknown. Accordingly, the implications of this action remain unclear, and we are continuing to assess the potential impact on our business and operations. If the Department of Defense adds WuXi STA to the 1260H list, or it is determined that WuXi STA is included in the designation of a Chinese Military Company as a subsidiary of WuXi AppTec, it could have an adverse effect on our business.

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

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

Risks Related to our Intellectual Property

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

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

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. The issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. 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. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. 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. Although our agreements require employees to acknowledge ownership by us of inventions conceived as a result of employment from the point of conception and, to the extent necessary, perfect such ownership by assignment, and we require employees, consultants, advisors and third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, or otherwise have a duty of confidentiality to us, we cannot be certain that our trade secrets, proprietary know-how and other confidential information and technology will not be subject to unauthorized disclosure, use, or misappropriation or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how and other information and technology. 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.

In addition, many countries, including some where we plan to conduct clinical trials, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries also limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and financial condition may be adversely affected.

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. In *Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.* (2026), the Supreme Court held that proving active inducement requires showing “affirmative steps to bring about the desired result” of infringement, and that vague statements combined with speculation about how others may act are insufficient to state an inducement claim. 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. Additionally, under the *Hikma v. Amarin* decision, a generic manufacturer’s use of a skinny label, compliance with FDA labeling requirements, and standard industry practices such as describing a drug as a “generic equivalent” may not constitute active inducement, further limiting our ability to enforce our method-of-use patents against generic competitors.

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

In addition to patent rights in the U.S., we may seek non-patent exclusivity for any approved or future products under other provisions of the FDCA such as new chemical entity, or NCE, exclusivity, Reference Product Exclusivity, or RPE, for a new use or new formulation, but there is no guarantee that any products will receive such exclusivity. The FDCA provides a five-year period of non-patent exclusivity within the U.S. to the first sponsor to gain approval of an NDA for an NCE. The Biologics Price Competition and Innovation Act of 2009 provides a twelve-year period of non-patent exclusivity within the U.S. for a biological product that is a reference product from the date of first licensure. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which consists of the molecule(s) or ion(s) responsible for the action of the drug substance (but not including those portions of the molecule that cause it to be a salt or ester or which are not bound to the molecule by covalent or similar bonds). Vafseo was granted NCE status following its approval in March 2024 and received a five-year NCE exclusivity. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the sponsor does not own or have a legal right of reference to all the data required for approval. In December 2025, the FDA denied our petition for reconsideration regarding the claim of 5-year NCE exclusivity for Auryxia.

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 the FDA final approval of an ANDA runs from the date on which the sponsor of the reference listed drug receives notice of a Paragraph IV certification from the ANDA sponsor.

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

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

We cannot assure you that Auryxia, Vafseo, praliciguat, ebribafusp, AKB-9090 or any of our other potential future products will obtain such pediatric exclusivity, NCE exclusivity, RPE, orphan drug exclusivity or any other market exclusivity in the U.S., EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any non-patent exclusivity protection. We also cannot assure you that 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 limit Auryxia sales and would likely limit Vafseo sales, either of which would have an adverse impact on our business and results of operations.

Although the composition and use of Auryxia is currently claimed by 2 issued patents that are listed in the FDA's Orange Book, or OB, and the composition and use of Vafseo is currently claimed by 14 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 additional generic equivalents of Auryxia or generic equivalents of Vafseo or any of our potential future products. Our patents covering certain aspects of our products or the use thereof could be delisted from the OB because of challenges by third parties before the FDA or the courts. If our OB-listed patents are successfully challenged, narrowed or delisted by a third-party and additional generic versions of Auryxia or a generic version of Vafseo is approved and launched sooner than we anticipate, revenue from Auryxia or Vafseo, respectively, could decline significantly, which would have a material adverse effect on our sales, results of operations and financial condition.

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

On March 11, 2026, Teva received approval for its ANDA for a generic version of Auryxia, which subsequently entered the market. As a result of Teva's entry into the market, we have experienced a significant reduction in volume of Auryxia sales. We expect the ongoing sales of generic versions of Auryxia, including by Teva and our AG Distributor, and of any additional generic versions of Auryxia that may be approved, will continue to have a significant adverse impact on our revenue.

Further, third parties may challenge our patent listings in the OB by asserting that the listed patents do not claim the approved drug product or an approved method of using the drug product. Such challenges may be made by ANDA or 505(b)(2) applicants, or by third parties through a citizen petition or other administrative or judicial proceeding. If a third-party is successful in challenging the propriety of our OB patent listings, the relevant patents could be delisted from the OB, which could enable generic or other competitors to obtain FDA approval of their products without the delays associated with patent certification procedures and without triggering the 30-month stay of FDA approval that applies when an ANDA or 505(b)(2) applicant makes a Paragraph IV certification. This could result in generic competition earlier than we anticipate.

Additional generic competition for Auryxia and generic competition for Vafseo or any of our potential future products could have a material adverse effect on our sales, results of operations and financial condition.

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

We may be forced to initiate litigation to enforce our contractual and intellectual property rights, or we may be sued by third parties asserting claims based on contract, tort or intellectual property infringement. Competitors may infringe our patents or misappropriate our trade secrets or confidential information. We may not be able to prevent infringement of our patents or misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S. In addition, third parties may have or may obtain patents in the future and claim that our products or other technologies infringe their patents. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims, or the expiration of relevant patents are complete, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary to commercialization of our products in any jurisdiction. 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 products and product candidates. As the pharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

While our product candidates are in preclinical studies and clinical trials, we believe that the use of our product candidates in these preclinical studies and clinical trials in the U.S. falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e), which provides that it shall not be an act of infringement to make, use, offer to sell, or sell within the U.S. or import into the U.S. a patented invention solely for uses reasonably related to the development and submission of information to the FDA. There is an increased possibility of a patent infringement claim against us with respect to commercial products. Our portfolio includes two commercial products: Auryxia and Vafseo. We attempt to ensure that our products and product candidates and the methods we employ to manufacture them, as well as the methods for their use which we intend to promote, do not infringe other parties' patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

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

Third parties, including FibroGen, may in the future claim that our products and product candidates and other technologies infringe upon their patents and may challenge our ability to commercialize Auryxia and Vafseo. Parties making claims against

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

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

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

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

We are currently involved in opposition proceedings in the Indian Patent Office. The proceedings may be ongoing for a number of years, may be resolved in a manner adverse to us and may involve substantial expense and diversion of employee resources from our business, which could have an adverse effect on our business. In addition, we may become involved in additional opposition proceedings or other legal or administrative proceedings in the future. For more information, see the other risk factors under "Risks Related to our Intellectual Property".

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and some administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure during discovery. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from potential collaborators, prospective licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. We may also be subject to claims that former employees, collaborators or other third parties have an ownership

interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to our Business and Managing Growth

If we fail to attract, retain and motivate senior management and qualified personnel, we may be unable to successfully develop and commercialize our approved products or any of our product candidates.

Recruiting and retaining qualified personnel is critical to our success. We are highly dependent on our executives, certain members of our senior management and certain key personnel. The loss of the services of our executives, senior managers or other employees could impede the achievement of our research, development, regulatory and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Losing members of management and other key personnel could subject us to a number of risks, including the failure to coordinate responsibilities and tasks, the necessity to create new management systems and processes, the impact on corporate culture, and the loss of historical knowledge.

For example, on October 7, 2026, Nicholas Grund, our Senior Vice President and Chief Commercial Officer, notified us of his resignation, effective November 6, 2026. Although we have entered into a consulting agreement with Mr. Grund pursuant to which he has agreed to provide consulting and advisory services through April 30, 2027 to assist with the transition, if we are unable to effectively transition Mr. Grund's responsibilities or retain other key members of our commercial leadership team, our ability to commercialize our products could be adversely affected. This leadership transition, and any future changes in our senior management or key personnel, could disrupt our operations or execution of our commercialization strategy, divert management attention and resources, result in the loss of institutional knowledge and key relationships, or adversely affect employee morale and our ability to retain other key personnel.

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 our approved products and develop our product candidates. Our future financial performance and our ability to commercialize our approved products and develop our product candidates and to compete effectively depends, in part, on our ability to identify, hire, train, integrate, and retain qualified personnel with sufficient experience. We may be unable to hire, train, retain or motivate these personnel on acceptable terms given the intense competition for our personnel from our competitors and other companies throughout our industry, particularly in our geographic region. The pharmaceutical and biotechnology industries continue to face challenges in recruiting and retaining qualified employees.

In addition, we rely on contractors, consultants and advisors, including scientific and clinical advisors, to assist us in formulating and executing our R&D and commercialization strategy. Our contractors, consultants and advisors may become employed by companies other than ours and may have commitments with other entities that may limit their availability to us. If additional members of management or other personnel leave, or we are unable to continue to attract and retain high quality personnel, our ability to grow and pursue our business strategy will be limited.

We may encounter difficulties in managing our growth, including with respect to our employee base, and managing our partnerships and operations successfully.

In our day-to-day operations, we may encounter difficulties in managing the size of our operations as well as challenges associated with managing our business. We have strategic collaborations for the commercialization of Riona in Japan, the development and commercialization of ferric citrate in Europe, and the development and commercialization of Vafseo by our collaboration partner, TPC, in Japan and potentially other Asian countries and our collaboration partner, Medice, in the Medice Territory. As our operations continue, we expect that we will need to manage our current relationships and enter into new relationships with various strategic collaborators, consultants, vendors, suppliers and other third parties. These relationships are complex and create numerous risks as we deal with issues that arise.

For example, we supply or have agreed to supply, as applicable, ferric citrate in Europe to Averoa and Vafseo in Japan, Europe and other territories where it is approved for commercial use to TPC and Medice, which will require us to successfully manage our limited financial and managerial resources. In addition, we may not be able to obtain the raw materials or product that we need, or the cost of the raw materials or product may be higher than expected. If we are unable to successfully manage our supply obligations, our ability to commercialize our products or supply such products to our partners could have a material adverse effect on our relationships with our partners and our results of operations.

Our future financial performance and our ability to commercialize Auryxia and Vafseo and to compete effectively and to continue to develop our products and product candidates on the timelines we anticipate, or at all, will depend, in part, on our ability to manage any future growth effectively. This future growth will impose significant added responsibilities on the business and members of management. To manage any future growth, we must continue to implement and improve our managerial, operational and financial systems, procedures and processes. We may not be able to implement these improvements in an efficient or timely manner and may discover deficiencies in existing systems, procedures and processes. Moreover, the systems, procedures and processes currently in place or to be implemented may not be adequate for any such growth. Any expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully managing the company and, as applicable, our growth.

In addition, as we expand our development activities, we expect to grow the teams, infrastructure, and processes necessary to support these efforts. Scaling our development activities will require recruiting, training, and integrating new personnel, as well as enhancing cross-functional coordination, which may introduce additional operational complexity. For example, integrating and developing ebribafusp, which we acquired on November 28, 2025, has required, and will continue to require, significant management attention, which could divert resources from other priorities. If we are unable to successfully integrate our teams or adapt our processes to meet the demands of increased development activity, our ability to advance our product candidates and achieve our strategic objectives could be adversely affected.

Furthermore, we may need to adjust the structure and size of our workforce as a result of changes to our expectations and priorities 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. For example, in June 2026, we modified our commercial approach with the goal of increasing the efficiency and effectiveness of our commercial field team based on the stage of our Vafseo launch and implemented a commercial reorganization, which resulted in a reduction in headcount representing approximately 13% of our workforce prior to the reduction. However, there can be no assurance that this change to our commercial strategy will be successful and increase sales of Vafseo. In addition, in July 2026, we implemented a reduction in headcount representing approximately 7% of our workforce prior to the reduction in order to improve our operational efficiency to align with our current priorities. We may have to undertake additional workforce reductions or restructuring activities in the future if we are unable to realize the expected operational and strategic efficiencies and cost savings. Additionally, such reductions in headcount could be disruptive to our operations, or could yield unanticipated consequences, such as attrition beyond planned staff reductions, or disruptions in our day-to-day operations. Such reductions could also harm our ability to attract and retain qualified personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully commercializing our approved products and developing and, if approved, commercializing our product candidates. 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.

If we fail to develop or maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in us and the trading price of our common stock may decline.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and effectively prevent fraud and operate successfully as a public company. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If our internal control over financial reporting is not effective, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting could also restrict our future access to the capital markets.

A material weakness in internal control over financial reporting has in the past and could in the future lead to deficiencies in the preparation of financial statements. Deficiencies in the preparation of financial statements could lead to litigation claims against us. The defense of any such claims may cause the diversion of management's attention and resources, and we may be required to pay damages if any such claims or proceedings are not resolved in our favor. Any litigation, even if resolved in our favor, could cause us to incur significant legal and other expenses. Such events could also affect our ability to raise capital to fund future business initiatives.

Security breaches and unauthorized use of our information technology systems and information, or the information technology systems or information in the possession of our collaborators, contractors and other third parties, including those arising from the malicious use of artificial intelligence tools to penetrate systems, manipulate data or generate convincing fraudulent communications, could damage the integrity of our clinical trials, impact our regulatory filings, compromise our ability to protect our intellectual property, and subject us to regulatory actions that could result in significant fines or other penalties.

We, our collaborators, contractors and other third parties rely significantly upon information technology, including in certain instances artificial intelligence-enabled software, and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our business. In addition, we and our collaborators, contractors and other third parties rely on information technology networks and systems, including the Internet and artificial intelligence-enabled software, to process, transmit and store clinical trial data, patient information, and other electronic information, and manage or support a variety of business processes, including operational and financial transactions and records, personal identifying information, payroll data and workforce scheduling information. While these artificial intelligence-enabled systems can enhance efficiency and analytical capabilities, they may also introduce new vulnerabilities such as algorithmic manipulation, data poisoning, or exploitation of artificial intelligence models to gain unauthorized access or use information in ways that harm our business. We purchase our information technology from vendors or service providers, on whom our systems depend. We rely on commercially available systems, software, tools and monitoring to provide security for the processing, transmission and storage of company and customer information. We may have limited visibility into whether and how third-party providers deploy or integrate artificial intelligence in products and services on which we rely, and contractual, technical or operational safeguards may not fully prevent inappropriate processing, retention, disclosure or use of our information.

In the ordinary course of our business, we and our third-party contractors collect, store and transmit personal, confidential and other sensitive data on our and their respective networks, including our intellectual property and proprietary or confidential business information relating to our business and that of our clinical trial patients and business partners. In particular, we rely on CROs and other third parties to store and manage information from our clinical trials, including patient information. We also rely on third parties to manage patient information for Auryxia and Vafseo.

Additionally, artificial intelligence-based software is increasingly being used by us and in the biopharmaceutical industry generally. Use of artificial intelligence based software may lead to the release of confidential proprietary information, and adversarial artificial intelligence techniques could be used to reverse-engineer proprietary algorithms, infer sensitive clinical data from anonymized datasets, or bypass existing security controls, which may impact our ability to realize the benefit of our intellectual property. The secure maintenance of this sensitive information is critical to our business and reputation.

Companies and other entities and individuals have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access to systems and information that could impact our business operations, including our clinical trials. These threats can come from a variety of sources, ranging in sophistication from individual hackers to state-sponsored attacks. Attackers have used artificial intelligence and machine learning to launch more automated, targeted and coordinated attacks against targets, including deepfake audio or video impersonations of executives, artificial intelligence-generated spear-phishing campaigns, and automated vulnerability scanning that can rapidly exploit weaknesses before detection. Cyber threats may be broadly targeted, or they may be custom-crafted against our information systems or those of our vendors or third-party service providers. A security incident, cyber attack or other unauthorized access to our systems, could affect our ability to operate our business or the ability of our vendors or third-party service providers to provide services pursuant to their contractual obligations. A security breach, cyberattack or unauthorized access of our clinical data or other data could damage the integrity of our clinical trials, impact our regulatory filings, cause significant risk to our business, compromise our ability to protect our intellectual property, and subject us to regulatory actions, including under the GDPR and CCPA discussed elsewhere in these risk factors and the privacy or security rules under federal, state, or other local laws outside of the U.S. protecting confidential or personal information, that could be expensive to defend and could result in significant fines or other penalties. Cyberattacks can include malware, computer viruses, hacking, social engineering, zero day vulnerabilities or other unauthorized access or other significant compromise of our computer, communications and related systems. Although we take steps to manage and avoid these risks and to be prepared to respond to attacks, our preventive and any remedial actions may not be successful and no such measures can eliminate the possibility of the systems' improper functioning or the improper access or disclosure of confidential or personally identifiable information such as in the event of cyberattacks. Artificial intelligence-driven attacks can adapt in real time to bypass conventional cybersecurity measures, making detection and response significantly more challenging. Security breaches, whether through physical or electronic break-ins, computer viruses, ransomware, impersonation of authorized users, attacks by hackers, artificial intelligence-generated fraudulent communications or other means, can create system disruptions or shutdowns that impact our business operations or cause the unauthorized disclosure of confidential information.

Although we believe our collaborators, vendors and service providers, such as our CROs, take steps to manage, mitigate and avoid information security risks and respond to attacks, we may be adversely affected by attacks against our collaborators, vendors or service providers, and we may not have adequate contractual remedies against such collaborators, vendors and service providers to remedy any harm to our business caused by such event. Additionally, outside parties may attempt to fraudulently induce employees, collaborators, or other contractors to disclose sensitive information or take other actions, including making fraudulent payments or downloading malware, by using "spoofing" and "phishing" emails, artificial intelligence-generated deep fake communications or other types of attacks. Our employees may be targeted by such fraudulent activities. Outside parties may also subject us to distributed denial of services attacks or introduce viruses or other malware through "trojan horse" programs to our users' computers in order to gain access to our systems and the data stored therein. Cyber-attacks have become more prevalent and much harder to detect and defend against. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and continuously become more sophisticated, including through the use of artificial intelligence to generate sophisticated spoofed emails, deep fake voice and video, and synthetic identities, and often are not recognized until launched against a target and may be difficult to detect for a long time, we may be unable to anticipate these techniques or to implement adequate preventive or detective measures, and we might not immediately detect such incidents and the damage caused by such incidents. Although we do maintain cyber liability insurance, our insurance coverages may not be sufficient in type or amount to cover us against any such losses, claims, or liabilities related to security breaches, cyber-attacks, cyber intrusion, or other related breaches or disruptions.

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 and Vafseo patients and others;
- damage the integrity of our studies or delay their completion, disrupt our development programs, our business operations and commercialization efforts;
- compromise our ability to protect our trade secrets and proprietary information;
- result in manipulation or falsification of clinical trial data through artificial intelligence-generated synthetic data or altered records, undermining regulatory submissions and scientific validity;
- damage our reputation and deter business partners from working with us; or
- divert the attention of our management and key information technology resources.

Any failure to maintain proper functionality and security of our internal computer and information systems, including failures arising from vulnerabilities in artificial intelligence models or artificial intelligence-enabled systems, could result in a loss of, or damage to, our data or marketing applications or inappropriate disclosure of confidential or proprietary information, interrupt our operations, damage our reputation, subject us to liability claims or regulatory penalties, under a variety of federal, state or other applicable privacy laws, such as HIPAA, the GDPR, or state data protection laws including the CCPA, harm our competitive position and delay the further development and commercialization of our products and product candidates, or impact our relationships with customers and patients.

Our employees, independent contractors, principal investigators, CROs, CDMOs, 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, CDMOs, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate applicable laws, including the following:

- FDA and other healthcare authorities' regulations, including those laws that require the reporting of true, complete and accurate information to regulatory authorities, and those prohibiting the promotion of unapproved drugs or approved drugs for an unapproved use;
- quality standards, including GxP;
- federal and state healthcare fraud and abuse laws and regulations and their non-U.S. equivalents;

- anti-bribery and anti-corruption laws, such as the FCPA and the UK Bribery Act or country-specific anti-bribery or anti-corruption laws, as well as various import and export laws and regulations;
- laws that require the reporting of true and accurate financial information and data; and
- U.S. state and federal securities laws and regulations and their non-U.S. equivalents, including those related to insider trading.

We conducted our global clinical trials for Vafseo, and may in the future conduct additional trials, in countries where corruption is prevalent, and violations of any of these laws by our personnel or by any of our vendors or agents, such as our CROs or CDMOs, 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 CDMOs, from making improper payments to foreign government officials for the purpose of obtaining or keeping business or obtaining any kind of advantage for the company. The FCPA also requires companies to keep accurate books and records and maintain adequate accounting controls. A number of past and recent FCPA investigations by the Department of Justice and the SEC have focused on the life sciences sector.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. Some of the countries in which we have conducted clinical trials and in which we had CDMOs 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, CDMOs, 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, CDMOs, vendors or principal investigators, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and

future earnings, curtailment of our operations, disclosure of our confidential information and imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

Our financial statements include long-lived assets, including goodwill as a result of the Keryx Merger. Other long-lived assets, including property and equipment, right-of-use assets or goodwill, could become impaired in the future under certain conditions. Any potential future impairment of property and equipment, our right-of-use assets or goodwill may significantly impact our results of operations and financial condition.

As of September 30, 2026, we had approximately $59.0 million of goodwill from the Keryx Merger, $2.4 million of property and equipment and $9.7 million right-of-use assets. In accordance with ASC 350, *Goodwill and Other*, we are required annually for goodwill, or more frequently upon certain indicators of impairment, to review our estimates and assumptions underlying the fair value of our goodwill. In addition, under ASC 360, *Property, Plant and Equipment*, we are required to review our property and equipment and right-of-use assets whenever events or changes in circumstances indicate that the carrying amount of an asset or asset group may not be recoverable. Events giving rise to impairment of long-lived assets are an inherent risk in the pharmaceutical industry and often cannot be predicted.

Conditions that could indicate impairment and necessitate such a review include, but are not limited to, Auryxia's and Vafseo's commercial performance, our inability to execute on our strategic initiatives, the deterioration of our market capitalization such that it is significantly below our net book value, a significant adverse change in legal factors, unexpected adverse business conditions, and an adverse action or assessment by a regulator. To the extent we conclude our long-lived assets have become impaired, we may be required to incur material write-offs relating to such impairment and any such write-offs could have a material impact on our future operating results and financial position. The estimates, judgments and assumptions used in our impairment analyses, and the results of our analyses, are discussed in Note 2, *Summary of Significant Accounting Policies*, to our unaudited condensed consolidated financial statements in Part I, Item 1. Financial Statements of this Form 10-Q. If these estimates, judgments and assumptions change in the future, additional impairment charges related to plant and equipment, and right-of-use assets or goodwill could be recorded in the future, which could materially impact our financial position, certain of our material agreements, and our future operating results.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Auryxia or Vafseo or affect the development of our product candidates.

We face an inherent risk of product liability as a result of the clinical and commercial use of Auryxia and Vafseo and our product candidates. For example, we may be sued if Auryxia, Vafseo or our product candidates allegedly causes injury or is found to be otherwise unsuitable during clinical trials or commercial use. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product or product candidate, negligence, strict liability and breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of Auryxia or Vafseo or affect the development of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for Auryxia or Vafseo;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- delay or termination of clinical trials;
- our inability to continue to develop Vafseo or our product candidates;
- significant costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to study subjects or patients;
- product recalls or withdrawals, or labeling, marketing or promotional restrictions;
-
- loss of revenue;
- the inability to commercialize Auryxia or Vafseo; and
- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the development of our product candidates or commercialization of products we develop. We currently carry product liability insurance that we believe is appropriate for our Company. Although we maintain

product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have insufficient or no coverage. If we have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, we may not have, or be able to obtain, sufficient capital to pay such amounts. In addition, insurance coverage is becoming increasingly expensive, and we may not be able to maintain insurance coverage at a reasonable cost. We also may not be able to obtain additional insurance coverage that will be adequate to cover additional product liability risks that may arise. Consequently, a product liability claim may result in losses that could be material to our business.

We will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we operate in a demanding regulatory environment, and we have and will continue to incur significant legal, accounting, auditing, directors and officers insurance and other expenses. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and certain corporate governance practices. In particular, our compliance with Section 404 of the Sarbanes-Oxley Act has required and will continue to require that we incur substantial accounting-related expenses and expend significant management efforts. Our testing, or the testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls that we would be required to remediate in a timely manner. If we are not able to comply with the requirements of the Sarbanes-Oxley Act, we could be subject to sanctions or investigations by the SEC, Nasdaq 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, 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 Keryx Merger, which we believe has resulted in an ownership change under Section 382. Future changes in our stock ownership, many of which are outside of our control, could result in an additional ownership change under Section 382. In addition, the deduction for NOLs arising in taxable years beginning after December 31, 2017 is limited to 80% of current-year taxable income. As a result, if we generate taxable income, our ability to use our pre-change NOL carryforwards to offset federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. At the state level, state NOLs generated in one state cannot be used to offset income generated in another state and there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. taxable income. As described above under "—Risks Related to our Financial Position, Need for Additional Capital and Growth Strategy," we have incurred significant net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future; thus, we do not know whether or when we will generate the U.S. taxable income necessary to utilize our NOLs.

Our Charter designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our Charter provides that, subject to limited exceptions, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the DGCL, our Charter or our Bylaws, or (iv) any other action asserting a claim against us, our directors, officers or other employees that is governed by the internal affairs doctrine. Under our Charter, this exclusive forum provision will not apply to claims that are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Charter described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our Charter inapplicable to, or unenforceable with respect to, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

Risks Related to our Common Stock

Our stock price has been and may continue to be volatile, which could result in substantial losses for holders or future purchasers of our common stock and lawsuits against us and our officers and directors and could result in substantial costs and divert management's attention.

Our stock price has been and will likely continue to be volatile. The stock market in general and the market for similarly situated biopharmaceutical companies specifically have experienced extreme volatility that has often been unrelated to the operating performance of particular companies, such as rising inflation and increasing interest rates. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, including, among others, developments related to and results of our research or clinical trials, developments related to our regulatory submissions and meetings with regulatory authorities, commercialization of Auryxia, Vafseo, and any other product candidates, announcements by us or our competitors of significant transactions or strategic collaborations, market entry of additional generic competition to Auryxia, negative publicity around Auryxia or Vafseo, regulatory or legal developments in the U.S. and other countries, developments or disputes concerning our intellectual property, the recruitment or departure of key personnel, actual or anticipated changes in estimates as to financial results, changes in the structure of healthcare payment systems, market conditions in the biopharmaceutical sector, potential delisting from the Nasdaq Capital Market and other factors beyond our control. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price at which they purchased it.

In addition, securities class actions, shareholder derivative lawsuits and other legal proceedings are often brought against companies for any of the risks described in this Form 10-Q following a decline or volatility in the market price of their securities. We could be the target of such litigation or other legal proceedings in the future. Class actions, shareholder derivative lawsuits and other legal proceedings, whether successful or not, could result in substantial costs, damage or settlement awards and such costs and any related settlements or judgments may not be covered by insurance. Monetary damages or any other adverse judgment would have a material adverse effect on our business and financial position. In addition, if other resolution or actions taken as a result of legal proceedings were to restrain our ability to operate or market our products and services, our consolidated financial position, results of operations or cash flows could be materially adversely affected. We could also suffer an adverse impact on our reputation, negative publicity and a diversion of management's attention and resources, which could have a material adverse effect on our business.

If we fail to regain compliance 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.

On October 21, 2026, we received a deficiency letter from the Listing Qualifications Department, or the Nasdaq Staff, of Nasdaq notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below $1.00 per share, which is the minimum bid price required to maintain continued listing on The Nasdaq Capital Market, pursuant to Nasdaq Listing Rules referred to as the minimum bid price requirement. In accordance with Nasdaq Listing Rules, we have an initial period of 180 calendar days, or until April 19, 2027, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days at any time before April 19, 2027, at which time the Nasdaq Staff will provide written notification to us that we have regained compliance with the minimum bid price requirement, unless the Nasdaq Staff exercises its discretion to extend this 10-day period pursuant to the Nasdaq Listing Rules.

If we do not regain compliance with the minimum bid price requirement by April 19, 2027, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the minimum bid price requirement. In addition, we would need to provide written notice to the Nasdaq Staff of our intention to cure the deficiency during the additional compliance period by effecting a reverse stock split, if necessary. As part of its review process, the Nasdaq Staff will make a determination of whether it believes the Company will be able to cure this deficiency.

If we do not qualify for the second compliance period, or if the Nasdaq Staff grants a second compliance period, but we do not regain compliance with the minimum bid price requirement by the end of the second compliance period, the Staff will provide written notice to us that our securities are subject to delisting. Upon receipt of any delisting notice, we may appeal the Nasdaq Staff's delisting determination to a Nasdaq Hearings Panel (the "Panel"). However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by the Nasdaq Staff to the Panel, such appeal would be successful.

We intend to monitor the closing bid price of our common stock and will evaluate available options to regain compliance with the minimum bid price requirement, which could include seeking to effect a reverse stock split. However, there can be no assurance that we will be able to regain compliance with the minimum bid price requirement or maintain compliance with the other listing requirements of Nasdaq.

If we are unable to regain compliance with applicable Nasdaq listing standards, shares of our common stock would be subject to delisting, which could have a material adverse effect on the market for, and the liquidity and price of, our common stock and would adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from Nasdaq could also have other negative results, including, without limitation, the potential loss of confidence by investors, customers and employees and fewer business development opportunities. Any delisting of our common stock from Nasdaq would also make it more difficult for our stockholders to sell their shares of our common stock in the public market.

The issuance of additional shares of our common stock or the sale of shares of our common stock by any of our directors, officers or significant stockholders will dilute our stockholders' ownership interest in Akebia and may cause the market price of our common stock to decline.

Most of our outstanding common stock can be traded without restriction at any time. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell such shares, could reduce the market price of our common stock.

As of September 30, 2026 and based on the amounts reported in the most recent filings made under Section 13(g) of the Exchange Act, BlackRock, Inc. beneficially owned approximately 6.9% of our outstanding shares of common stock, and State

Street Corporation beneficially owned approximately 4.2% of our outstanding shares of common stock. By selling a large number of shares of common stock, BlackRock, Inc. or State Street Corporation could cause the price of our common stock to decline. In addition, as of September 30, 2026, CSL Vifor beneficially owned 7,571,429 shares of common stock, which 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, but if they are registered in the future, those shares would become freely tradable and, if a large portion of such shares are sold, could cause the price of our common stock to decline.

Further, we entered into a warrant agreement with Kreos Capital VII Aggregator SCSp, or the Warrant Holder, an affiliate of Kreos Capital VII (UK) Limited, pursuant to which (i) we issued a warrant to the Warrant Holder to purchase 3,076,923 shares of our common stock, or the Initial Warrant, at an exercise price per share of $1.30 (subject to standard adjustments for stock splits, stock dividends, rights offerings and pro rata distributions), or the Exercise Price, and (ii) we issued a warrant to the Warrant Holder to purchase 1,153,846 shares of our common stock, at an exercise price per share equal to the Exercise Price. Each warrant is exercisable for eight years from the date of issuance. On July 21, 2025, the Warrant Holder exercised its option to purchase 2,115,384 shares of our common stock under the Initial Warrant on a cashless basis at the Exercise Price. As a result of the cashless exercise, we issued 1,408,588 shares of our common stock to the Warrant Holder under the Initial Warrant. If any or all of the outstanding warrants are exercised, our stockholders could suffer further dilution and the value of their shares could decrease.

We have a significant number of shares that are subject to outstanding options, restricted stock units and other securities convertible into our common stock, and in the future we may issue additional options, restricted stock units, or other securities convertible into our common stock. The exercise or vesting of any such options, restricted stock units, or other securities, and the subsequent sale of the underlying common stock, could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. Such sales of our common stock could result in higher than average trading volume and may cause the market price for our common stock to decline.

In addition, we currently have on file with the SEC a shelf registration statement on Form S-3, which allows us to offer and sell up to $250.0 million in registered securities, such as common stock, preferred stock, debt securities, warrants and units, from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale, including a sales agreement prospectus that covers the offering, issuance and sale by us of up to a maximum aggregate offering price of up to $75.0 million of our common stock that may be issued and sold from time to time under a sales agreement with Jefferies LLC, of which $21.8 million remains available for future issuance and sale as of September 30, 2026.

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, 2026, 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 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 proposals 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 stock 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, 2026, 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	Certificate of Amendment of Ninth Amended and Restated Certificate of Incorporation of Akebia Therapeutics, Inc. (incorporated by reference to Exhibit 3.3 to the Company's Quarterly Report on Form 10-Q (001-36352), filed on August 5, 2026).
3.4	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*	Second Amendment to Amended and Restated Sublicense Agreement, dated May 20, 2026, by and between Keryx Pharmaceuticals, Inc. and Shionogi & Co., Ltd. (successor to Japan Tobacco Inc.) and Torii Pharmaceuticals Co., Ltd.
10.2*!	Amendment # 5, effective as of July 24, 2026, to Supply Agreement, dated as of April 2, 2020, by and between Akebia Therapeutics, Inc. and STA Pharmaceutical Hong Kong Limited.
10.3*!	Amendment # 3, effective as of July 24, 2026, to Supply Agreement, dated as of February 10, 2021, by and between Akebia Therapeutics, Inc. and STA Pharmaceutical Hong Kong Limited.
10.4*!	Amendment No. 6 to Master Manufacturing Services and Supply Agreement, effective July 29, 2026, by and between Siegfried Evionnaz SA and Keryx Biopharmaceuticals, Inc.
10.5*	Ninth Amendment to Lease between CLPF-Cambridge Science Center, LLC and Akebia Therapeutics, Inc., dated September 23, 2026.
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 5, 2026

By: /s/ John P. Butler

John P. Butler

President and Chief Executive Officer
(Principal Executive Officer)

Date: November 5, 2026

By: /s/ Erik J. Ostrowski

Erik J. Ostrowski

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

Date: November 5, 2026

By: /s/ Richard C. Malabre

Richard C. Malabre

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

SECOND AMENDMENT TO AMENDED AND RESTATED SUBLICENSE AGREEMENT

THIS SECOND AMENDMENT TO AMENDED AND RESTATED SUBLICENSE AGREEMENT (this "Amendment"), effective this 20th day of May, 2026 ("Amendment Effective Date"), is by and between KERYX BIOPHARMACEUTICALS, INC., with offices at 245 First St Cambridge, MA 02142, U.S.A. ("Keryx" or "Sublicensor") and Shionogi & Co., Ltd., with offices at 1-8, Doshomachi 3-chome Chuo-ku, Osaka 541-0045, Japan ("Shionogi") and TORII PHARMACEUTICAL CO., LTD., with offices at Torii Nihonbashi Bldg., 4-1, Nihonbashi-Honcho 3-Chome, Chuo-ku, Tokyo 103-8439, Japan ("TORII")(Shionogi and TORII are collectively referred to herein as "Sublicensee");

WHEREAS, Sublicensor, Japan Tobacco Inc ("JT") and TORII entered into that certain AMENDED AND RESTATED SUBLICENSE AGREEMENT dated the 8th day of June, 2009 as amended by the FIRST AMENDMENT TO AMENDED AND RESTATED SULICENSE AGREEMENT dated 12th June 2013 (collectively the "Amended and Restated Agreement"), pursuant to which the Sublicensor granted certain rights and licenses to JT and TORII; and

WHEREAS, Shionogi succeeded JT's pharmaceutical business, including its rights and obligations under the Amended and Restated Agreement, as of December 1, 2025, through a company simplified absorption-type split.

WHEREAS, Sublicensor and Sublicensee, in order to avoid potential disputes or confusion regarding certain aspects of the rights and licenses granted pursuant to the Amended and Restated Agreement, desire to amend the Amended and Restated Agreement as set forth in this Amendment.

NOW THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants set forth herein and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree as follows:

ARTICLE 1. DEFINITIONS

Capitalized terms used but not defined herein shall have the meaning ascribed to them in the Amended and Restated Agreement.

ARTICLE 2. AMENDMENT

2.1 Amendment of Section 10.2.3(b). Section 10.2.3(b) of the Amended and Restated Agreement is hereby deleted in its entirety and is replaced by the following text:

"10.2.3 (b) Sublicensor grants Sublicensee and its sublicensees the non-exclusive right, without any restrictions, to manufacture (and have manufactured) the active pharmaceutical ingredient for purposes of developing and supplying the same solely in the Sublicensee Territory, provided that Sublicensee and its sublicensees shall bear all costs associated with such production."

ARTICLE 3. CONFIRMATION OF TERMS

3.1 Confirmation of Terms. Except as expressly set forth in this Amendment, the Amended and Restated Agreement shall continue in full force and effect in accordance with its terms.

3.2 Effect of Amendment. This Amendment is entered into by the parties in accordance with Article 29 of the Amended and Restated Agreement, and is part of the Amended and Restated Agreement, as the same is amended hereby.

3.3 This Amendment shall be governed by and construed in accordance with the laws of the State of New York, exclusive of choice-of-law rules.

3.4 The Amended and Restated Agreement, as amended by this Amendment, constitutes the entire agreement and understanding of the parties and supersedes any prior agreements or understandings relating to the subject matter hereof. In the event of any conflict between the provisions of the Amended and Restated Agreement and this Amendment, the provisions of this Amendment shall govern and control.

3.5 This Amendment may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on the parties notwithstanding that each of the parties may have signed different counterparts. The parties agree that this Amendment may be electronically signed by one or more parties (including through DocuSign). Any electronic signature used by a party to sign this Amendment shall be treated the same as handwritten signatures for the purposes of validity, enforceability and admissibility. Without limiting the foregoing, nothing in this Amendment shall be construed to require a party to sign this Amendment by electronic signature.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS HEREOF, the parties have executed this Amendment as of the Amendment Effective Date set forth above.

KERYX BIOPHARMACEUTICALS, INC.

By: /s/ John P. Butler

Name: John P. Butler

Title: President and CEO

SHIONOGI & CO., LTD.

By: /s/ Takayuki Yamaguchi

Name: Takayuki Yamaguchi

Title: Senior Vice President, Development Business Division

TORII PHARMACEUTICALS CO., LTD.

By: /s/ Gen Matsuo

Name: Gen Matsuo

Title: Executive Officer, Head of Innovation Group

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 omission.

AMENDMENT #5 TO SUPPLY AGREEMENT

This Amendment #5 (the "Amendment") to the Supply Agreement by and between **Akebia Therapeutics, Inc.** ("Akebia") and **STA Pharmaceutical Hong Kong Limited** ("STA") is effective as of July 24, 2026 (the "Amendment Effective Date"). Akebia and STA are each referenced individually herein as a "Party" and together as the "Parties".

WHEREAS, Akebia and STA entered into a Supply Agreement dated April 2, 2020, as amended on April 15, 2021, April 15, 2024, August 15, 2025, and April 28, 2026 (collectively, the "Agreement"), under which STA manufactures vadadustat drug substance for purchase by Akebia; and

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

NOW, THEREFORE the Parties agree as follows:

1. The Agreement is hereby amended to add to the Agreement, as a new "Exhibit B," the Appendix 1 attached to this Amendment.

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, not expressed amended by this Amendment shall remain in full force and effect.

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

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

AKEBIA THERAPEUTICS, INC.

By: /s/ Justin McCue

Print Name: Justin McCue

Title: CTO

Date: October 6, 2026

STA PHARMACEUTICAL HONG KONG LIMITED

By: /s/ Xiaoyong Fu

Print Name: Xiaoyong Fu

Title: EVP

Date: October 2, 2026

Appendix 1

Exhibit B

Mandatory Government Contractor Clauses

[**]

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 omission.

AMENDMENT #3 TO SUPPLY AGREEMENT

This Amendment #3 (the "Amendment") to the Supply Agreement by and between **Akebia Therapeutics, Inc.** ("Akebia") and **STA Pharmaceutical Hong Kong Limited** ("STA") is effective as of July 24, 2026 (the "Amendment Effective Date"). Akebia and STA are each referenced individually herein as a "Party" and together as the "Parties".

WHEREAS, Akebia and STA entered into a Supply Agreement dated February 10, 2021, as amended on April 15, 2024 and November 25, 2025 (collectively, the "Agreement"), under which STA manufactures vadadustat drug product for purchase by Akebia; and

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

NOW, THEREFORE the Parties agree as follows:

1. The Agreement is hereby amended to add to the Agreement, as a new "Exhibit B," the Appendix 1 attached to this Amendment.

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, not expressed amended by this Amendment shall remain in full force and effect.

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

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

AKEBIA THERAPEUTICS, INC.

By: /s/ Justin McCue

Print Name: Justin McCue

Title: CTO

Date: October 6, 2026

STA PHARMACEUTICAL HONG KONG LIMITED

By: /s/ Xiaoyong Fu

Print Name: Xiaoyong Fu

Title: EVP

Date: October 2, 2026

Exhibit B

Mandatory Government Contractor Clauses

[**]

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 omission.

AMENDMENT NO. 6 TO MASTER MANUFACTURING SERVICES AND SUPPLY AGREEMENT

This Amendment No. 6 to the Master Manufacturing Services and Supply Agreement ("Amendment No. 6") is entered into and made effective as of July 29, 2026 (the "Amendment No. 6 Effective Date") by and between **Keryx Biopharmaceuticals, Inc.**, with its offices at 245 First Street, Cambridge, Massachusetts 02142, USA ("Keryx") and **Siegfried AG**, with principal offices located at Untere Brühlstrasse 4, 4800 Zofingen, Switzerland (together with its Affiliates and subsidiaries "Vendor") as transferred from Siegfried Evionnaz SA on January 01, 2024 ("Vendor").

Keryx and Vendor are each referenced individually herein as a "Party" and together as the "Parties".

WHEREAS, Vendor and Keryx entered into a Master Manufacturing Services and Supply Agreement dated December 20, 2017, as amended on December 21, 2020, January 29, 2021, February 11, 2021, December 17, 2021, February 28, 2023 and December 5, 2024 ("Agreement") under which Vendor manufactures Product for purchase by Keryx;

WHEREAS, on December 12, 2018, Keryx merged with Akebia Therapeutics, Inc. ("Akebia") and, pursuant to such merger, Akebia assumed all of Keryx's rights and obligations under the Agreement. Keryx continues to operate as a wholly owned subsidiary of Akebia, and Akebia is an Affiliate of Keryx; and

WHEREAS, the Parties desire to amend the Agreement as set forth in this Amendment No. 6.

NOW, THEREFORE the Parties agree as follows:

1. For the purpose of this Amendment No. 6, the defined terms used herein shall have the same meanings as those used in the Agreement, unless otherwise specified in this Amendment No. 6.

2. Effective as of the Amendment No. 6 Effective Date, the following new subsection 3.4.6 is hereby added to the Agreement:

   3.4.6 at Keryx' sole option, up to [**], upon receipt of which Vendor shall within [**] confirm its acceptance in writing and, in accordance with Section 3.8 provide a delivery schedule mutually acceptable for both Parties that set out delivery dates for specified quantities of Product.

3. Effective as of the Amendment No. 6 Effective Date, section 16.1 is hereby deleted in its entirety and replaced with the following new Section 16.1.

   16.1 The term of this Agreement (the "Term") shall commence as of the Agreement Date and, subject to earlier termination in accordance with the provisions of this Section 16, shall end on December 31, 2028 unless otherwise agreed by the Parties. Notwithstanding the foregoing, Keryx may elect to extend the Term through December 31, 2031 with written notice sent at least twelve (12) months prior to the expiry of the Term, in accordance with Section 22 herein. For the avoidance of doubt, expiration of the Term in accordance with this Section 16.1.1 shall not relieve Keryx of its responsibilities to pay any undisputed invoices issued by Vendor for Product or other Services performed in accordance with Section 3 of the Agreement.

4. Effective as of the Amendment No. 6 Effective Date, Attachment B of the Agreement is hereby deleted in its entirety and replaced with the Attachment B as set forth in Exhibit 1 of this Amendment No. 6.

5. Effective as of the Amendment No. 6 Effective Date, a new Attachment H as set forth in Exhibit 2 of this Amendment No. 6 is hereby added to the Agreement.

6. Except as otherwise provided herein, all provisions of the Agreement, not expressed amended by this Amendment shall remain in full force and effect. In the event there is a conflict among this Amendment and the Agreement, the terms of this Amendment shall govern.

7. 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.

8. The governing law and jurisdiction applicable to the Agreement shall apply to this Amendment No. 6.

IN WITNESS WHEREOF, the Parties have caused this Amendment No. 6 to be executed by their duly authorized representatives as of the date first above written.

KERYX BIOPHARMACEUTICALS, INC.

By: /s/ Justin McCue

Print Name: Justin McCue

Title: CTO

Date: September 24, 2026

SIEGFRIED AG

By: /s/ Peter Freisler

Print Name: Peter Freisler

Title: Chief Business Officer

Date: September 13, 2026

SIEGFRIED AG

By: /s/ Klaus Stingl

Print Name: Klaus Stingl

Title: SVP, Global Head BD & Sales Drug Substance

Date: September 12, 2026

EXHIBIT 1

ATTACHMENT B – PRODUCT PRICE AND MINIMUM ANNUAL PURCHASE OBLIGATION

[**]

EXHIBIT 2

Attachment H

Mandatory Government Contractor Clauses

[**]

NINTH AMENDMENT TO LEASE

This NINTH AMENDMENT TO LEASE (this "**Amendment**") is entered into as of September 23, 2026 (the "**Effective Date**"), by and between CLPF-CAMBRIDGE SCIENCE CENTER, LLC, a Delaware limited liability company ("**Landlord**"), and AKEBIA THERAPEUTICS, INC., a Delaware corporation ("**Tenant**").

RECITALS

A. MA-Riverview/245 First Street, L.L.C., a Delaware limited liability company, (the "**Original Landlord**") and Tenant entered into that certain Office Lease Agreement dated as of December 3, 2013 (the "**Original Lease**"), as amended by that certain First Amendment to Lease dated December 15, 2014, that certain Second Amendment to Lease dated November 23, 2015, that certain Third Amendment to Lease dated July 25, 2016, that certain Fourth Amendment to Lease dated May 1, 2017, that certain Fifth Amendment to Lease dated April 9, 2018, that certain Sixth Amendment to Lease dated November 30, 2020, that certain Seventh Amendment to Lease dated May 6, 2024 and that certain Eighth Amendment to Lease dated April 9, 2026 (collectively, the "**Lease**"), respecting certain premises consisting of approximately 59,216 rentable square feet on the 11th, 12th and 14th floors of the office building (the "**Office Building Premises**") and approximately 5,951 rentable square feet on the 1st floor of the adjacent lab building (the "**First Floor Premises**") (collectively, the "**Premises**"), which buildings are located at 245 First Street, Cambridge, Massachusetts and together comprise the Cambridge Science Center.

B. Landlord is the successor in interest to the Original Landlord.

C. The Term of the Office Building Premises (the "**Office Building Term**") is scheduled to expire on September 11, 2026 pursuant to the terms of the Lease.

D. Landlord and Tenant wish to enter into this Amendment to (i) extend the Office Building Term and (ii) amend certain other terms and conditions of the Lease.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby amend the Lease as follows:

1. Recitals; Capitalized Terms. All of the foregoing recitals are true and correct. Unless otherwise defined herein, all capitalized terms used in this Amendment shall have the meaning ascribed to them in the Lease, and all references to the Lease or "this Lease" or "herein" or "hereunder" or similar terms or to any sections thereof shall mean the Lease, or such section thereof, as amended by this Amendment.

2. Term Extension. The Office Building Term is hereby extended for an additional period commencing on September 12, 2026 and expiring on October 31, 2026 (the "**Office Building Extension Term**") on the terms and conditions set forth below. All terms and provisions of the Lease, as amended hereby, shall apply to Tenant's leasing of the Office Building Premises and during the Office Building Extension Term, except to the extent expressly provided otherwise in this Amendment.

3. Rent for the Office Building Extension Term.

a. Commencing on September 12, 2026 and continuing through the Office Building Extension Term, Tenant shall no longer be responsible for paying Base Rent or Additional Rent with respect to the Office Building Premises.

b. Tenant shall continue to pay Base Rent, Additional Rent and the Tank Fee with respect to the First Floor Premises through the Office Building Extension Term in accordance with the terms of the Lease.

4. Brokerage. Each party represents to the other that it has not dealt with any broker in connection with this Amendment. Tenant shall indemnify and hold Landlord harmless from and against any claim or claims for brokerage or other commissions relating to this Amendment asserted by any broker, agent or finder engaged by Tenant or with whom Tenant has dealt. Landlord shall indemnify and hold Tenant harmless from and against any claim or claims for brokerage or other commissions relating to this Amendment asserted by any broker, agent or finder engaged by Landlord or with whom Landlord has dealt.

5. Ratification. Except as expressly modified by this Amendment, the Lease shall remain in full force and effect, and as further modified by this Amendment, is expressly ratified and confirmed by the parties hereto. This Amendment shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, subject to the provisions of the Lease regarding assignment and subletting.

6. Governing Law; Interpretation and Partial Invalidity. This Amendment shall be governed and construed in accordance with the laws of the Commonwealth of Massachusetts. If any term of this Amendment, or the application thereof to any person or circumstances, shall to any extent be invalid or unenforceable, the remainder of this Amendment, or the application of such term to persons or circumstances other than those as to which it is invalid or unenforceable, shall not be affected thereby, and each term of this Amendment shall be valid and enforceable to the fullest extent permitted by law. The titles for the paragraphs are for convenience only and are not to be considered in construing this Amendment. This Amendment contains all of the agreements of the parties with respect to the subject matter hereof, and supersedes all prior dealings between them with respect to such subject matter. No delay or omission on the part of either party to this Amendment in requiring performance by the other party or exercising any right hereunder shall operate as a waiver of any provision hereof or any rights hereunder, and no waiver, omission or delay in requiring performance or exercising any right hereunder on any one occasion shall be construed as a bar to or waiver of such performance or right on any future occasion.

7. Successors. This Amendment shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns.

8. Counterparts and Authority. This Amendment may be executed in multiple counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same document. Landlord and Tenant each warrant to the other that the person or persons executing this Amendment on its behalf has or have authority to do so and that such execution has fully obligated and bound such party to all terms and provisions of this Amendment.

[Signature Pages Follow]

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment as of the day and year first above written.

LANDLORD:

CLPF-CAMBRIDGE SCIENCE CENTER, LLC,
a Delaware limited liability company

By: CLPF – MA REIT, LLC,
a Delaware limited liability company,
its sole member

By: Clarion Lion Properties Fund Holdings, L.P.,
a Delaware limited partnership,
its Sole Member

By: CLPF-Holdings, LLC,
a Delaware limited liability company,
its General Partner

By: Clarion Lion Properties Fund Holdings REIT, LLC,
a Delaware limited liability company,
its Sole Member

By: Clarion Lion Properties Fund, LP,
a Delaware limited partnership,
its Managing Member

By: Clarion Partners LPF GP, LLC,
a Delaware limited liability company,
its General Partner

By: Clarion Partners, LLC,
a New York limited liability company,
its Sole Member

By: /s/ Rachel Astle
Name: Rachel Astle
Title: Authorized Signatory

TENANT:

AKEBIA THERAPEUTICS, INC.,
a Delaware corporation

By: /s/ Erik Ostrowski
Name: Erik Ostrowski
Title: Chief Financial Officer

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 5, 2026

By: /s/ John P. Butler

John P. Butler
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Erik J. Ostrowski, certify that:

1. I have reviewed this 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 5, 2026

By: /s/ Erik J. Ostrowski

Erik J. Ostrowski

Senior Vice President, Chief Financial Officer, Chief Business Officer and Treasurer

(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002 (18 U.S.C. Section 1350)

In connection with the accompanying Quarterly Report of Akebia Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2026 (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 5, 2026

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

Date: November 5, 2026

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