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 June 30, 2023

OR

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

For the transition period from _____to_____

Commission File Number 001-36352

AKEBIA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

Registrant's telephone number, including area code: (617) 871-2098
n/a
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

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

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

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of August 25, 2023 was 188,313,807.

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:

- the potential therapeutic benefits, safety profile, and effectiveness of vadadustat;
- our expectations with respect to the development of vadadustat, if any, following our receipt of a complete response letter to and our End of Dispute Type A meeting with the U.S. Food and Drug Administration regarding our new drug application for vadadustat for the treatment of anemia due to chronic kidney disease in adult patients, including the timing of when we expect to resubmit the new drug application for vadadustat and when we expect the Prescription Drug User Fee Act date;
- that 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 pipeline and portfolio, including its potential, and our related research and development activities;
- the timing of or likelihood of regulatory filings and approvals, including with respect to labeling or other restrictions, the potential approval of vadadustat and our outlook related thereto, and potential indications for vadadustat;
- the timing, investment and associated activities involved in continued commercialization of Auryxia® (ferric citrate), its growth opportunities and our ability to execute thereon;
- the potential indications, demand and market opportunity, potential and acceptance of Auryxia and vadadustat, if approved, including the size of eligible patient populations;
- the potential therapeutic applications of the hypoxia inducible factor pathway;
- our competitive position, including estimates, developments and projections relating to our competitors and their products and product candidates, and our industry;
- our expectations, projections and estimates regarding our capital requirements, need for additional capital, financing our future cash needs, costs, expenses, revenues, capital resources, cash flows, financial performance, profitability, tax obligations, liquidity, growth, contractual obligations, 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 direct or indirect impacts of the recent COVID-19 pandemic on our business, operations and the markets and communities in which we and our partners, collaborators, vendors, and customers operate;
- our manufacturing, supply and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences;
- estimates, beliefs and judgments related to the valuation of intangible asset, goodwill, debt and other assets and liabilities, including our impairment analysis and our methodology and assumptions regarding fair value measurements;
- the timing of the availability and disclosure of clinical trial data and results;
- our and our collaborators' strategy, plans and expectations with respect to the development, manufacturing, supply, commercialization, launch, marketing and sale of Auryxia and vadadustat, if approved, and the associated timing thereof;
- our plans with respect to commercializing Vafseo® in Europe;
- the designs of our studies, and the type of information and data expected from our studies and the expected benefits thereof;

- our ability to maintain any marketing authorizations we currently hold or will obtain, including our marketing authorizations for Auryxia and our ability to complete post-marketing requirements with respect thereto;
- our ability to negotiate, secure and maintain adequate pricing, coverage and reimbursement terms and processes on a timely basis, or at all, with third-party payors for Auryxia and vadadustat, if approved;
- the timing of initiation of our clinical trials and plans to conduct preclinical studies and clinical trials in the future;
- the timing and amounts of payments from or to our collaborators and licensees, and the anticipated arrangements and benefits under our collaboration and license agreements, including with respect to milestones and royalties;
- our intellectual property position, including obtaining and maintaining patents, and the timing, outcome and impact of administrative, regulatory, legal and other proceedings relating to our patents and other proprietary and intellectual property rights, patent infringement suits that we have filed or may file, or other actions that we may take against companies, and the timing and resolution thereof;
- expected ongoing reliance on third parties, including with respect to the development, manufacturing, supply and commercialization of Auryxia and vadadustat, if approved;
- accounting standards and estimates, their impact, and their expected timing of completion;
- estimated periods of performance of key contracts;
- our facilities, lease commitments, and future availability of facilities;
- cybersecurity;
- insurance coverage;
- management of personnel, including our management team, and our employees, including employee compensation, employee relations, and our ability to attract, train and retain high quality employees;
- the implementation of our business model, current operating plan, and strategic plans for our business, product candidates and technology, and business development opportunities including potential collaborations, alliances, mergers, acquisitions or licensing of assets;
- our workforce reductions, future charges expected to be incurred in connection therewith and estimated reductions in net cash required for operating activities in connection therewith; and
- the timing, outcome and impact of current and any future legal proceedings.

Any or all of these forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be inaccurate. These forward-looking statements involve risks and uncertainties, including those that are discussed below under the heading "Risk Factors Summary", and the risk factors identified further in Part II, Item 1A. "Risk Factors" included in this Quarterly Report on Form 10-Q and elsewhere in this Quarterly Report on Form 10-Q, 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 significant losses and cannot guarantee when, if ever, we will become profitable or attain positive cash flows.
- We will require substantial additional financing to achieve our goals. A failure to obtain this necessary capital when needed, or on acceptable terms, could force us to delay, limit, reduce or terminate our product development or commercialization efforts.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product and product candidates on unfavorable terms to us.
- If we fail to comply with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.
- We may not be successful in our efforts to identify, acquire, in-license, discover, develop and commercialize additional products or product candidates or our decisions to prioritize the development of certain product candidates over others may not be successful, which could impair our ability to grow.
- We may engage in strategic transactions to acquire assets, businesses, or rights to products, product candidates or technologies or form collaborations or make investments in other companies or technologies that could harm our operating results, dilute our stockholders' ownership, increase our debt, or cause us to incur significant expense.
- Our business has been and may continue to be, directly or indirectly, adversely affected by the recent COVID-19 pandemic.
- Our obligations in connection with the loan agreement with Pharmakon and requirements and restrictions in the loan agreement could adversely affect our financial condition and restrict our operations.
- Our Royalty Interest Acquisition Agreement with HealthCare Royalty Partners IV, L.P. contains various covenants and other provisions, which, if violated, could materially adversely affect our financial condition.
- Our business is substantially dependent on the commercial success of Auryxia. If we are unable to continue to successfully commercialize Auryxia, our results or operations and financial condition will be materially harmed.
- If we are unable to maintain or expand, or, if vadadustat is approved, initiate, sales and marketing capabilities or enter into additional agreements with third parties, we may not be successful in commercializing Auryxia, vadadustat, if approved, or any other product candidates that may be approved.
- Our, or our partners', failure to obtain or maintain adequate coverage, pricing and reimbursement for Auryxia, vadadustat, if approved, or any other future approved products, could have a material adverse effect on our or our collaboration partners' ability to sell such approved products profitably and otherwise have a material adverse impact on our business.
- We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.
- The commercialization of Riona® and Vafseo in Japan, Vafseo in Europe and our current and potential future efforts with respect to the development and commercialization of our products and product candidates outside of the United States 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 vadadustat and any other product candidates.
- We may find it difficult to enroll patients in our clinical trials, which could delay or prevent clinical trials of Auryxia, vadadustat or any other product or product candidate, including those that may be in-licensed or acquired.
- Conducting clinical trials outside of the United States, as we have done historically and as we may decide to do in the future, presents additional risks and complexities and, if we decide to conduct a clinical trial outside of the United States in the future, we may not complete such trials successfully, in a timely manner, or at all, which could affect our ability to obtain regulatory approvals.
- Auryxia, vadadustat 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, or successfully commercialize, vadadustat or any other product candidate, or we may experience significant delays in doing so, any of which would materially harm our business.
- Products approved for marketing are subject to extensive post-marketing regulatory requirements 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 any of them is approved.
- We are subject to a complex regulatory scheme that requires significant resources to ensure compliance and our failure to comply with applicable laws could subject us to government scrutiny or enforcement, potentially resulting in costly

investigations, fines, penalties or sanctions, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

- We will incur significant liability if it is determined that we are promoting any “off-label” use of Auryxia or any other product we may develop, in-license or acquire or if it is determined that any of our activities violates the federal Anti-Kickback Statute.
- Disruptions in the FDA, regulatory authorities outside the U.S. and other government agencies caused by global health concerns or funding shortages could prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.
- Compliance with privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.
- Legislative and regulatory healthcare reform may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain for any products that are approved in the United States or foreign jurisdictions.
- We depend on collaborations with third parties for the development and commercialization of Auryxia, Riona, Vafseo and vadadustat and if these collaborations are not successful or if our collaborators terminate their agreements with us, we may not be able to capitalize on the market potential of Auryxia, Riona, Vafseo and vadadustat, and our business could be materially harmed.
- We may seek to establish additional collaborations and, if we are not able to establish them on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans.
- We rely upon third parties to conduct all aspects of our product manufacturing, and in many instances only have a single supplier, and the loss of these manufacturers, their failure to supply us on a timely basis, or at all, or their failure to successfully carry out their contractual duties or comply with regulatory requirements, cGMP requirements, or guidance could cause delays in or disruptions to our supply chain and substantially harm our business.
- We rely upon third parties to conduct our clinical trials and certain of our preclinical studies. If they do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain or maintain marketing approval for Auryxia, vadadustat or any of our product candidates, and our business could be substantially harmed.
- If the licensor of certain intellectual property relating to Auryxia terminates, modifies or threatens to terminate existing contracts or relationships with us, our business may be materially harmed.
- If we are unable to adequately protect our intellectual property, third parties may be able to use our intellectual property, which could adversely affect our ability to compete in the market.
- We may not be able to protect our intellectual property rights throughout the world.
- The intellectual property that we own or have licensed and related non-patent exclusivity relating to our current and future products is, and may be, limited, which could adversely affect our ability to compete in the market and adversely affect the value of Auryxia.
- The market entry of one or more generic competitors or any third party’s attempt to challenge our intellectual property rights will likely limit Auryxia sales and have an adverse impact on our business and results of operation.
- Litigation and administrative proceedings, including third party claims of intellectual property infringement and opposition/invalidation proceedings against third party patents, may be costly and time consuming and may delay or harm our drug discovery, development and commercialization efforts.
- We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.
- If we fail to attract, retain and motivate senior management and qualified personnel, we may be unable to successfully develop, obtain and/or maintain marketing approval of and commercialize vadadustat or commercialize Auryxia.
- Our cost savings plan and the associated workforce reductions implemented in April, May and November 2022 may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.
- We may encounter difficulties in managing our growth, including with respect to our employee base, and managing our partnerships and operations successfully.
- We have identified a material weakness in our internal control over financial reporting as of December 31, 2022 relating to our product return reserves that resulted in a revision of our financial statements for the years ended December 31, 2022, 2021 and 2020. If we are not able to remediate this material weakness, or if we experience additional material weaknesses or other deficiencies in our internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.
- We are currently subject to legal proceedings that could result in substantial costs and divert management's attention, and we could be subject to additional legal proceedings.
- 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.

Akebia Therapeutics, Inc.
Form 10-Q
For the Quarter Ended June 30, 2023

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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," and similar references refer to Akebia Therapeutics, Inc. and, where appropriate, its consolidated subsidiaries. On December 12, 2018, in connection with the consummation of the merger (Merger) with Keryx Biopharmaceuticals, Inc. (Keryx), Keryx became a wholly owned subsidiary of the Company.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Akebia Therapeutics, Inc.
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(dollars in thousands, except per share amounts)	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 53,572	$ 90,466
Inventories	20,905	21,568
Accounts receivable, net	19,572	40,284
Prepaid expenses and other current assets	24,398	32,864
Total current assets	118,447	185,182
Property and equipment, net	4,419	5,214
Operating right-of-use assets	14,391	29,158
Intangible asset, net	54,063	72,084
Goodwill	59,044	59,044
Other long-term assets	3,348	5,372
Total assets	**$ 253,712**	**$ 356,054**
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable	$ 11,776	$ 18,021
Accrued expenses and other current liabilities	56,408	75,777
Short-term deferred revenue	—	3,738
Current portion of long-term debt	24,000	32,000
Total current liabilities	92,184	129,536
Deferred revenue, net of current portion	43,296	43,296
Long-term operating lease liabilities	11,480	28,961
Embedded debt derivative	760	760
Long-term debt, net	18,486	34,078
Liability related to sale of future royalties	56,548	57,484
Refund liability to customer	40,623	40,992
Other long-term liabilities	17,142	15,717
Total liabilities	**280,519**	**350,824**
Commitments and contingencies (Note 13)		
Stockholders' (deficit) equity:		
Preferred stock $0.00001 par value, 25,000,000 shares authorized; no shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock $0.00001 par value; 350,000,000 shares authorized at June 30, 2023 and December 31, 2022; 188,128,869 and 184,135,714 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	2	2
Additional paid-in capital	1,568,260	1,562,247
Accumulated other comprehensive income	6	6
Accumulated deficit	(1,595,075)	(1,557,025)
Total stockholders' (deficit) equity	**(26,807)**	**5,230**
Total liabilities and stockholders' (deficit) equity	**$ 253,712**	**$ 356,054**

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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenues				
Product revenue, net	$ 42,244	$ 43,309	$ 76,950	$ 84,681
License, collaboration and other revenue	14,132	83,056	19,431	103,307
Total revenues	56,376	126,365	96,381	187,988
Cost of goods sold				
Product	8,273	9,589	19,452	32,694
Amortization of intangible asset	9,011	9,011	18,021	18,021
Total cost of goods sold	17,284	18,600	37,473	50,715
Operating expenses:				
Research and development	20,197	26,027	39,883	69,860
Selling, general and administrative	27,036	32,240	52,090	76,806
License expense	949	892	1,517	1,580
Restructuring	(94)	14,531	12	14,531
Total operating expenses	48,088	73,690	93,502	162,777
Operating (loss) income	**(8,996)**	**34,075**	**(34,594)**	**(25,504)**
Other income (expense)				
Interest expense	(1,642)	(5,037)	(3,204)	(10,099)
Other (expense) income	(10)	411	272	1,545
Loss on lease termination	(524)	—	(524)	—
Net (loss) income	**$ (11,172)**	**$ 29,449**	**$ (38,050)**	**$ (34,058)**
Comprehensive (loss) income	**$ (11,172)**	**$ 29,449**	**$ (38,050)**	**$ (34,058)**
Net (loss) income per share:				
Basic	$(0.06)	$0.16	$(0.20)	$(0.19)
Diluted	$(0.06)	$0.15	$(0.20)	$(0.19)
Weighted average common shares outstanding:				
Basic	186,817,431	183,597,766	185,798,865	181,609,452
Diluted	186,817,431	190,375,317	185,798,865	181,609,452

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

Akebia Therapeutics, Inc.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' (DEFICIT) EQUITY

(dollars in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2021	**177,000,963**	**$ 1**	**$ 1,536,800**	**$ 6**	**$ (1,462,799)**	**$ 74,008**
Issuance of common stock, net of issuance costs	4,404,600	1	7,177	—	—	7,178
Proceeds from sale of stock under employee stock purchase plan	191,146	—	367	—	—	367
Stock-based compensation expense	—	—	4,536	—	—	4,536
Restricted stock unit vesting	1,789,326	—	—	—	—	—
Net loss	—	—	—	—	(63,509)	(63,509)
Balance at March 31, 2022	**183,386,035**	**$ 2**	**$ 1,548,880**	**$ 6**	**$ (1,526,308)**	**$ 22,580**
Stock-based compensation expense	—	—	6,841	—	—	6,841
Exercise of options	142,440	—	67	—	—	67
Restricted stock unit vesting	176,179	—	—	—	—	—
Net income	—	—	—	—	29,449	29,449
Balance at June 30, 2022	**183,704,654**	**$ 2**	**$ 1,555,788**	**$ 6**	**$ (1,496,859)**	**$ 58,937**

(dollars in thousands)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2022	**184,135,714**	**$ 2**	**$ 1,562,247**	**$ 6**	**$ (1,557,025)**	**$ 5,230**
Proceeds from sale of stock under employee stock purchase plan	103,500	—	34	—	—	34
Stock-based compensation expense	—	—	2,489	—	—	2,489
Restricted stock unit vesting	1,596,732	—	—	—	—	—
Net loss	—	—	—	—	(26,878)	(26,878)
Balance at March 31, 2023	**185,835,946**	**$ 2**	**$ 1,564,770**	**$ 6**	**$ (1,583,903)**	**$ (19,125)**
Stock-based compensation expense	—	—	3,490	—	—	3,490
Restricted stock unit vesting	2,292,923	—	—	—	—	—
Net loss	—	—	—	—	(11,172)	(11,172)
Balance at June 30, 2023	**188,128,869**	**$ 2**	**$ 1,568,260**	**$ 6**	**$ (1,595,075)**	**$ (26,807)**

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

Akebia Therapeutics, Inc.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(dollars in thousands)	Six Months Ended June 30, 2023	2022
Operating Activities:		
Net loss	$ (38,050)	$ (34,058)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	795	833
Amortization of intangible asset	18,021	18,021
Non-cash interest expense related to sale of future royalties	—	4,428
Non-cash royalty revenue related to sale of future royalties	(936)	(764)
Non-cash collaboration revenue	—	(9,550)
Non-cash research and development expense	782	—
Non-cash interest expense	983	916
Non-cash operating lease expense	(955)	(1,198)
Non-cash write-off from termination of lease	(825)	—
Write-down of inventory	612	7,430
Change in excess inventory purchase commitments	—	4,854
Stock-based compensation expense	5,979	11,453
Change in fair value of embedded debt derivative	—	(710)
Changes in operating assets and liabilities:		
Accounts receivable	20,712	(30,421)
Inventory	10,828	(4,362)
Prepaid expenses and other current assets	7,684	561
Other long-term assets	(5,876)	10,012
Accounts payable	(12,058)	(8,807)
Accrued expense and other current liabilities	(19,382)	(19,464)
Operating lease liabilities	1,034	1,205
Deferred revenue	(3,738)	5,963
Other long-term liabilities	481	(8,622)
Net cash used in operating activities	**(13,909)**	**(52,280)**
Investing Activities:		
Purchases of equipment	—	(114)
Net cash used in investing activities	**—**	**(114)**
Financing Activities:		
Proceeds from refund liabilities to customers	—	40,000
Proceeds from issuance of common stock, net of issuance costs	—	7,102
Proceeds from issuances of stock under employee stock purchase plan	34	367
Proceeds from the exercise of stock options	—	67
Repayments of term debt	(24,000)	—
Net cash (used in) provided by financing activities	**(23,966)**	**47,536**
Decrease in cash, cash equivalents and restricted cash	(37,875)	(4,858)
Cash, cash equivalents and restricted cash — beginning of period	93,169	151,839
Cash, cash equivalents and restricted cash — end of period	**$ 55,294**	**$ 146,981**

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

1. NATURE OF BUSINESS

Akebia Therapeutics, Inc., referred to as Akebia or the Company, was incorporated in the State of Delaware in 2007. Akebia is a fully integrated biopharmaceutical company with the purpose of bettering the lives of people impacted by kidney disease. The Company has one commercial product, Auryxia® (ferric citrate), which is approved by the U.S. Food and Drug Administration (FDA), and marketed for two indications in the United States: the control of serum phosphorus levels in adult patients with chronic kidney disease (CKD) on dialysis (DD-CKD), and the treatment of iron deficiency anemia (IDA) in adult patients with CKD not on dialysis (NDD-CKD). Ferric citrate is also approved and marketed in Japan as an oral treatment for IDA in adult patients for the improvement of hyperphosphatemia in such patients with DD-CKD and NDD-CKD under the trade name Riona (ferric citrate hydrate).

Vadadustat, the Company's lead investigational product candidate, is an investigational oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH), inhibitor designed to mimic the physiologic effect of altitude on oxygen availability. On March 29, 2022, the Company received a complete response letter (CRL) from the FDA. The CRL provided that the FDA had completed its review of the Company's new drug application (NDA) for vadadustat for the treatment of anemia due to CKD in adult patients and had determined that it could not approve the NDA in its present form. In October 2022, the Company submitted a Formal Dispute Resolution Request with the FDA and focused on the favorable balance between the benefits and risks of vadadustat for the treatment of anemia due to CKD in adult DD-CKD patients in light of safety concerns expressed by the FDA in the CRL for dialysis patients related to the rate of adjudicated thromboembolic events driven by vascular access thrombosis for vadadustat compared to the active comparator and the risk of drug-induced liver injury. In May 2023, the Office of New Drugs (OND) denied the Company's appeal but provided a path forward for the Company to resubmit the NDA for vadadustat for the treatment of anemia due to CKD for dialysis dependent patients without the need for the Company to generate additional clinical data. In July 2023, the Company held an End of Dispute Type A meeting with the FDA to align on the contents of the NDA resubmission. The Company expects to resubmit the NDA by the end of the third quarter of 2023, with a potential Prescription Drug User Fee Act (PDUFA) date that the Company projects will be in March 2024.

In October 2021, the Company's former collaboration partner, Otsuka Pharmaceutical Co. Ltd. (Otsuka), submitted a Marketing Authorization Application (MAA) for vadadustat for the treatment of anemia due to CKD in adult patients with DD-CKD and NDD-CKD to the European Medicines Agency (EMA). In connection with the Termination and Settlement Agreement with Otsuka dated June 30, 2022 (Termination Agreement), Otsuka transferred the MAA for vadadustat with each of the EMA, the United Kingdom, Switzerland and Australia to the Company. In April 2023, the European Commission (EC) approved the marketing authorization of vadadustat under the trade name Vafseo for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis. In May 2023, the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency approved the marketing authorization of vadadustat under the trade name Vafseo for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis. In June 2023, the Swiss Agency for Therapeutics Products approved the marketing authorization for vadadustat under the trade name Vafseo for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis. Vadadustat is approved in Japan as a treatment for anemia due to CKD in both DD-CKD and NDD-CKD patients under the trade name Vafseo, and marketed and sold in Japan by Mitsubishi Tanabe Pharma Corporation (MTPC). Vadadustat is also approved in Korea as a treatment for anemia due to CKD in DD-CKD patients.

In addition, the Company continues to explore additional development opportunities to expand its pipeline and portfolio of novel therapeutics.

Since inception, the Company has devoted most of its resources to research and development, including its preclinical and clinical development activities, commercializing Auryxia, and providing general and administrative support for these operations. The Company began recording revenue from the U.S. sales of Auryxia and revenue from sublicensing rights to Auryxia in Japan from the Company's Japanese partners, Japan Tobacco, Inc. and its subsidiary Torii Pharmaceutical Co., Ltd. (collectively, JT and Torii), in December 2018. Additionally, following regulatory approval of vadadustat in Japan, the Company began recognizing royalty revenues from MTPC from the sale of Vafseo in August 2020. In February 2021, the Company entered into a royalty interest acquisition agreement with HealthCare Royalty Partners IV, L.P. (HCR) (Royalty Agreement), whereby the Company sold its right to receive royalties and sales milestones under its Collaboration Agreement with MTPC (MTPC Agreement), subject to certain caps and other terms and conditions (see Note 6 for additional information). The Company has not generated a profit to date, and may never generate profits, from product sales. Vadadustat and the Company's other potential product candidates are subject to long development cycles, and the Company may be unsuccessful in its efforts to develop, obtain marketing approval for or market vadadustat and its other potential product candidates. If the Company does not successfully commercialize Auryxia, vadadustat, if approved, or any other potential product candidate, it may be unable to achieve profitability.

The Company's management completed its going concern assessment in accordance with Accounting Standards Codification, or ASC, 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or ASC 205-40. As of June 30, 2023, the Company had cash and cash equivalents of approximately $53.6 million. Based on its current operating plan, the Company believes that its cash resources will be sufficient to allow the Company to fund its current operating plan through at least the next twelve months from the filing of this Quarterly Report on Form 10-Q. If the Company's operating performance deteriorates significantly from the levels expected in the Company's operating plan, it would have an effect on the Company's liquidity and its ability to continue as a going concern in the future. The Company expects to finance future cash needs through product revenue, potential strategic transactions, public or private equity or debt transactions, operating expense management, or a combination of these approaches. Assuming the Company is successful in executing its operating plan, the Company will require additional funding to fund its strategic growth beyond Auryxia or to pursue later stage development and commercial activities for its product candidates and any additional product or product candidates, including those that may be in-licensed or acquired. 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 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, 2022, and notes thereto, which are included in the Company's Annual Report on Form 10-K, as amended by Amendment No. 1 on Form 10-K/A that was filed with the Securities and Exchange Commission (SEC) on August 28, 2023 (2022 Annual Report on Form 10-K/A). 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 six months ended June 30, 2023 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2023 or any other future period.

Basis of Presentation and Principals of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. (GAAP) for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the ASC and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

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.

Segment Information

Operating segments are components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker as of June 30, 2023 was its President and Chief Executive Officer. Based on the criteria established by Accounting Standards Codification 280, *Segment Reporting*, the Company has one operating and reportable segment, which is the business of developing and commercializing novel therapeutics for people with kidney disease.

Revision of Previously Issued Financial Statements

In connection with the preparation of its consolidated financial statements as of and for the three and six months ended June 30, 2023, the Company identified immaterial prior period errors related to the identification, evaluation and accounting for product returns in its previously issued consolidated financial statements.

In accordance with SAB No. 99, "Materiality," and SAB No. 108, "Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements," and as described further in Note 3, Revision of Previously Issued Financial Statements, the Company evaluated the errors and determined the related impacts were not material to its financial statements for the prior year periods when they occurred, but that correcting the errors in the current period would be

significant to the Company's results of operations for the three and six months ended June 30, 2023. Accordingly, the Company has revised previously reported financial information for such immaterial errors. A summary of revisions to certain previously reported financial information presented herein for comparative purposes is included in Note 3, Revision of Previously Issued Financial Statements.

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, and the disclosure of contingent assets and liabilities as of and during the reported period. Management bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. In certain circumstances, management must apply significant judgment in this process. In addition, other factors may affect estimates, including expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Significant estimates and assumptions reflected in these unaudited condensed consolidated financial statements include, but are not limited to: prepaid and accrued research and development expense, right-of-use assets and liabilities, embedded debt derivative, refund liabilities to customers, other long-term liabilities, stock-based compensation expense, and certain judgments regarding product and collaboration revenues including various rebates, returns and reserves related to product sales, non-cash interest expense on the liability related to sale of future royalties, inventories, income taxes, intangible asset and goodwill.

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.

Reconciliation of 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 which as of June 30, 2023 primarily included funds invested in money market funds. The following table reconciles cash, cash equivalents and restricted cash reported within the Company's consolidated balance sheet to the total amounts showing in the consolidated statement of cash flows:

(in thousands)	**June 30, 2023**	**December 31, 2022**
Cash and cash equivalents	$ 53,572	$ 90,466
Restricted cash included in other long-term assets	1,722	2,703
Total cash, cash equivalents and restricted cash	$ 55,294	$ 93,169

3. REVISION OF PREVIOUSLY ISSUED FINANCIAL STATEMENTS

As previously disclosed, including in the Company's Form 12b-25 filed with the SEC on August 10, 2023, in the course of preparing its financial statements for the quarter ended June 30, 2023, the Company identified certain accounting errors relating to the recording and reporting of reserves for returns of the Company’s product, Auryxia® (ferric citrate) at the time the Company acquired Keryx Biopharmaceuticals, Inc. ("Keryx") on December 12, 2018 and when calculating the product return reserves for subsequent annual and quarterly periods through March 31, 2023 (collectively, the "Product Return Reserve Errors"). This resulted in errors in the Company's consolidated financial statements previously filed by the Company with the SEC for each of the fiscal years ended December 31, 2022, 2021 and 2020. Specifically, the Company utilized an incorrect methodology to calculate, record and report the Auryxia product return reserves at the time the Company acquired Keryx on December 12, 2018, which resulted in errors in the calculation of and understatement of goodwill of $2.6 million in each of the subsequent annual periods. The Company continued to utilize the incorrect methodology to calculate, record and report the product return reserves in the consolidated financial statements it issued with respect to its fiscal years ended December 31, 2022, 2021 and 2020, which resulted in the product return reserves and other product revenue allowances being understated by $8.2 million, $7.9 million and $6.0 million as of December 31, 2022, 2021 and 2020, respectively. A breakdown of the understatement of the product return reserves between current and long-term in the consolidated balance sheet are as follows:

(in thousands)	December 31, 2020	2021	2022
Included in accrued expenses and other current liabilities:			
Product return reserves and other product revenue allowances	$ 1,956	$ 4,557	$ 5,051
Included in other long-term liabilities:			
Product return reserves	4,048	3,360	3,132
Total understatement of product return reserves and other product revenue allowances	**$ 6,004**	**$ 7,917**	**$ 8,183**

Further, as a result of the Product Return Reserve Errors, revenue was overstated by $0.1 million, $1.9 million and $0.6 million, and accounts receivable was understated by $1.1 million, $0.7 million and $0.7 million for the years ended December 31, 2022, 2021 and 2020, respectively. The changes did not impact cash or ending cash balances in the Company's consolidated balance sheets in the periods presented in this report or in previously issued annual and quarterly financial statements.

In addition to the Product Return Reserve Errors, the Company has corrected other immaterial misstatements in the revised consolidated financial statements for the years ended December 31, 2022, 2021 and 2020 and related quarterly periods, including a $1.4 million to goodwill in each of the years ended December 31, 2022, 2021 and 2020 related to an excess purchase commitment recorded in connection with the Keryx acquisition. The changes did not impact cash or ending cash balances in the Company's consolidated balance sheets in the periods presented in this report or in previously issued annual and quarterly financial statements.

The Company assessed the materiality of the Product Return Reserve Errors, including the presentation on prior period consolidated financial statements in accordance with the SEC Staff Accounting Bulletin No. 99, *Materiality*, codified in ASC Topic 250, *Accounting Changes and Error Corrections* (ASC 250). Based on this assessment, the Company evaluated the materiality of the impacts caused by the Product Return Reserve Errors and concluded that they do not result in a material misstatement of the Company's previously issued consolidated financial statements but would materially misstate the Company's unaudited condensed consolidated financial statements for the three and six months ended June 30, 2023. As a result, the Company determined that it was necessary to revise the consolidated financial statements it previously issued with respect to the fiscal years ended December 31, 2022, 2021 and 2020 and filed an amendment to its Annual Report on Form 10-K for the fiscal year ended December 31, 2022 with the SEC on August 28, 2023 to reflect the revisions.

The following tables reflect the impact of this revision on the Company's condensed consolidated financial statements as of and for the three and six months ended June 30, 2022 (*dollars in thousands, except per share amounts*):

Condensed Consolidated Balance Sheet	June 30, 2022 As Previously Reported	Adjustment	As Revised
Inventories	$ 36,272	$ 3,954	$ 40,226
Accounts receivable, net	81,869	133	82,002
Total current assets	**304,163**	**4,087**	**308,250**
Goodwill	55,053	3,991	59,044
Total assets	**$ 521,804**	**$ 8,078**	**$ 529,882**
Accrued expenses and other current liabilities	$ 91,284	$ 3,721	$ 95,005
Total current liabilities	**233,680**	**3,721**	**237,401**
Other non-current liabilities	66,889	7,721	74,610
Total liabilities	**459,504**	**11,442**	**470,946**
Accumulated deficit	(1,493,496)	(3,363)	(1,496,859)
Total liabilities and stockholders' equity	**$ 521,804**	**$ 8,078**	**$ 529,882**

Akebia Therapeutics, Inc.
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Condensed Consolidated Statement of Operations and Comprehensive Income	Three Months Ended June 30, 2022		
	As Previously Reported	Adjustment	As Revised
Product revenue, net	$ 43,703	$ (394)	$ 43,309
Selling, general and administrative	32,807	(567)	32,240
Operating income	33,902	173	34,075
Net income	$ 29,276	$ 173	$ 29,449
Comprehensive income	$ 29,276	$ 173	$ 29,449
Earnings per share - basic	$0.16	$ —	$0.16
Earnings per share - diluted	$0.15	$ —	$0.15

Condensed Consolidated Statement of Operations and Comprehensive Income	Six Months Ended June 30, 2022		
	As Previously Reported	Adjustment	As Revised
Product revenue, net	$ 85,151	$ (470)	$ 84,681
Cost of goods sold, product	31,923	771	32,694
Selling, general and administrative	77,134	(328)	76,806
Operating loss	(24,591)	(913)	(25,504)
Net loss and comprehensive loss	(33,145)	(913)	(34,058)
Net loss per share - basic and diluted	$(0.18)	$(0.01)	$(0.19)

Condensed Consolidated Statement of Stockholders' (Deficit) Equity	June 30, 2022		
	As Previously Reported	Adjustment	As Revised
Accumulated deficit	$ (1,493,496)	$ (3,363)	$ (1,496,859)
Net income	$ 29,276	$ 173	$ 29,449

Condensed Consolidated Statement of Cash Flows	Six Months Ended June 30, 2022		
	As Previously Reported	Adjustment	As Revised
Net loss	$ (33,145)	$ (913)	$ (34,058)
Adjustments to reconcile net loss to net cash used in operating activities:			
Change in excess inventory purchase commitments	(773)	5,627	4,854
Changes in operating assets and liabilities:			
Accounts receivable	(30,994)	573	(30,421)
Inventory	1,159	(5,521)	(4,362)
Other long-term assets	9,347	665	10,012
Accrued expenses and other current liabilities	(18,625)	(839)	(19,464)
Other non-current liabilities	(9,030)	408	(8,622)
Net cash used in operating activities	$ (52,280)	$ —	$ (52,280)

The following tables reflect the impact of this revision on the Company's condensed consolidated financial statements as of and for the three months ended March 31, 2023 and 2022 (*dollars in thousands, except per share amounts*):

	March 31, 2023		
Condensed Consolidated Balance Sheet	**As Previously Reported**	**Adjustment**	**As Revised**
Inventories	$ 20,604	$ (194)	$ 20,410
Accounts receivable, net	17,781	950	18,731
Prepaid expenses and other current assets	25,381	(678)	24,703
Total current assets	**120,719**	**79**	**120,798**
Goodwill	55,053	3,991	59,044
Total assets	**$ 276,858**	**$ 4,070**	**$ 280,928**
Accrued expenses and other current liabilities	$ 46,367	$ 4,712	$ 51,079
Total current liabilities	**82,944**	**4,712**	**87,656**
Other non-current liabilities	12,643	4,129	16,772
Total liabilities	**291,210**	**8,841**	**300,051**
Accumulated deficit	(1,579,130)	(4,773)	(1,583,903)
Total liabilities and stockholders' equity	**$ 276,858**	**$ 4,070**	**$ 280,928**

	Three Months Ended March 31, 2023		
Condensed Consolidated Statement of Operations and Comprehensive Income	**As Previously Reported**	**Adjustment**	**As Revised**
Product revenue, net	$ 34,828	$ (122)	$ 34,706
Cost of goods sold, product	10,473	705	11,178
Selling, general and administrative	25,221	(168)	25,053
Operating loss	(24,938)	(661)	(25,599)
Net loss	$ (26,217)	$ (661)	$ (26,878)
Comprehensive loss	$ (26,217)	$ (661)	$ (26,878)
Earnings per share - basic and diluted	$ (0.14)	$ (0.01)	$ (0.15)

	March 31, 2023		
Condensed Consolidated Statement of Stockholders' (Deficit) Equity	**As Previously Reported**	**Adjustment**	**As Revised**
Accumulated deficit	$ (1,579,130)	$ (4,773)	$ (1,583,903)
Net loss	$ (26,217)	$ (661)	$ (26,878)

	Three Months Ended March 31, 2023		
Condensed Consolidated Statement of Cash Flows	**As Previously Reported**	**Adjustment**	**As Revised**
Net loss	$ (26,217)	$ (661)	$ (26,878)
Changes in operating assets and liabilities:			
Accounts receivable	21,399	154	21,553
Accrued expenses and other current liabilities	(25,047)	(68)	(25,115)
Other non-current liabilities	—	573	573
Net cash used in operating activities	$ (17,538)	$ (2)	$ (17,540)

Akebia Therapeutics, Inc.
NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

	March 31, 2022		
Condensed Consolidated Balance Sheet	**As Previously Reported**	**Adjustment**	**As Revised**
Inventories	$ 39,422	$ 1,676	$ 41,098
Accounts receivable, net	64,582	776	65,358
Total current assets	**302,687**	**2,452**	**305,139**
Goodwill	55,053	3,991	59,044
Total assets	**$ 535,356**	**$ 6,443**	**$ 541,799**
Accrued expenses and other current liabilities	$ 109,660	$ 4,583	$ 114,243
Total current liabilities	**253,914**	**4,583**	**258,497**
Other non-current liabilities	77,743	5,398	83,141
Total liabilities	**509,240**	**9,981**	**519,221**
Accumulated deficit	(1,522,772)	(3,536)	(1,526,308)
Total liabilities and stockholders' equity	**$ 535,356**	**$ 6,443**	**$ 541,799**

	Three Months Ended March 31, 2022		
Condensed Consolidated Statement of Operations and Comprehensive Income	**As Previously Reported**	**Adjustment**	**As Revised**
Product revenue, net	$ 41,448	$ (76)	$ 41,372
Cost of goods sold, product	22,333	772	23,105
Selling, general and administrative	44,327	239	44,566
Operating loss	(58,493)	(1,088)	(59,581)
Net loss	$ (62,421)	$ (1,088)	$ (63,509)
Comprehensive loss	$ (62,421)	$ (1,088)	$ (63,509)
Earnings per share - basic and diluted	$(0.35)	$ —	$(0.35)

	March 31, 2022		
Condensed Consolidated Statement of Stockholders' (Deficit) Equity	**As Previously Reported**	**Adjustment**	**As Revised**
Accumulated deficit	$ (1,522,772)	$ (3,536)	$ (1,526,308)
Net loss	$ (62,421)	$ (1,088)	$ (63,509)

	Three Months Ended March 31, 2022		
Condensed Consolidated Statement of Cash Flows	**As Previously Reported**	**Adjustment**	**As Revised**
Net loss	$ (62,421)	$ (1,088)	$ (63,509)
Adjustments to reconcile net loss to net cash used in operating activities:			
Change in excess inventory purchase commitments	(773)	773	—
Changes in operating assets and liabilities:			
Accounts receivable	(13,707)	(71)	(13,778)
Inventory	(5,247)	(3,243)	(8,490)
Other long-term assets	3,297	669	3,966
Accrued expenses and other current liabilities	4,426	2,960	7,386
Net cash used in operating activities	$ (21,620)	$ —	$ (21,620)

Condensed Consolidated Statement of Stockholders' (Deficit) Equity	December 31, 2021		
	As Previously Reported	Adjustment	As Revised
Accumulated deficit	$ (1,460,351)	$ (2,448)	$ (1,462,799)
Net loss	$ (282,840)	$ 816	$ (282,024)

The consolidated balance sheet as of December 31, 2022 has been revised in this Quarterly Report on Form 10-Q.

4. PRODUCT REVENUE AND RESERVES FOR VARIABLE CONSIDERATION

To date, the Company's only source of product revenue has been from the U.S. sales of Auryxia. Total net product revenue was $42.2 million and $43.3 million for the three months ended June 30, 2023 and 2022, respectively, and $77.0 million and $84.7 million for the six months ended June 30, 2023 and 2022, respectively. Product revenue allowance and reserve categories were as follows:

(in thousands)	Chargebacks and Discounts	Rebates, Fees and other Deductions	Product Returns	Total
Balance at December 31, 2022	$ 1,259	$ 30,043	$ 10,923	$ 42,225
Current provisions related to sales in current year	5,216	37,270	2,462	44,948
Adjustments related to prior year sales	(8)	(473)	—	(481)
Credits/payments made	(5,616)	(41,474)	(5,510)	(52,600)
Balance at June 30, 2023	$ 851	$ 25,366	$ 7,875	$ 34,092

(in thousands)	Chargebacks and Discounts	Rebates, Fees and other Deductions	Product Returns	Total
Balance at December 31, 2021	$ 1,047	$ 27,100	$ 10,065	$ 38,212
Current provisions related to sales in current year	4,965	42,562	2,735	50,262
Adjustments related to prior year sales	131	784	—	915
Credits/payments made	(5,236)	(43,803)	(2,968)	(52,007)
Balance at June 30, 2022	$ 907	$ 26,643	$ 9,832	$ 37,382

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 statement 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 unaudited condensed consolidated balance sheets. Estimated product returns for the period related to product sales are recorded as other long-term liabilities in the unaudited condensed consolidated balance sheet.

Accounts receivable, net related to product sales, was approximately $18.2 million and $37.3 million as of June 30, 2023 and December 31, 2022, respectively.

5. LICENSE, COLLABORATION AND OTHER REVENUE

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

	Three Months Ended June 30,		Six Months Ended June 30,	
License, collaboration and other revenue:	**2023**	**2022**	**2023**	**2022**
MTPC Collaboration Agreement	$ 516	$ 434	$ 4,678	$ 8,398
Otsuka U.S. Agreement	2,225	81,135	2,225	86,773
Otsuka International Agreement	—	—	—	5,503
Total collaboration revenue	$ 2,741	$ 81,569	$ 6,903	$ 100,674
JT and Torii Sublicense Agreement	1,391	1,487	2,528	2,633
Medice License Agreement	10,000	—	10,000	—
Total license, collaboration and other revenue	$ 14,132	$ 83,056	$ 19,431	$ 103,307

The following table presents changes in the Company's contract assets and liabilities (in thousands):

	Six Months Ended June 30, 2023			
	Balance at Beginning of Period	**Additions**	**Deductions**	**Balance at End of Period**
Contract assets:				
Accounts receivable[1]	$ 1,901	$ 943	$ (2,319)	$ 525
Prepaid expenses and other current assets	$ 781	$ —	$ (781)	$ —
Contract liability:				
Deferred revenue	$ 47,034	$ —	$ (3,738)	$ 43,296

	Six Months Ended June 30, 2022			
	Balance at Beginning of Period	**Additions**	**Deductions**	**Balance at End of Period**
Contract assets:				
Accounts receivable[1]	$ 19,094	$ 92,146	$ (54,614)	$ 56,626
Prepaid expenses and other current assets	$ 4,309	$ 9,550	$ (4,309)	$ 9,550
Contract liabilities:				
Deferred revenue	$ 42,380	$ 65,042	$ (59,079)	$ 48,343
Accounts payable	$ 3,171	$ —	$ (3,171)	$ —

[1] Excludes accounts receivable related to amounts due to the Company from product sales of Auryxia which are included in the accompanying unaudited condensed consolidated balance sheet as of June 30, 2023 and 2022.

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 June 30,		Six Months Ended June 30,	
Revenue Recognized in the Period:	**2023**	**2022**	**2023**	**2022**
Deferred revenue — beginning of the period	$ —	$ 15,503	$ —	$ 22,105

During the three and six months ended June 30, 2023 and 2022, the Company recognized no revenue from performance obligations satisfied in previous periods.

MTPC Collaboration Agreement

On December 11, 2015, the Company and MTPC entered into the MTPC Agreement, providing MTPC with exclusive development and commercialization rights to vadadustat in Japan and certain other Asian countries (collectively, the MTPC Territory), which was amended effective as of December 2, 2022. In addition, the Company supplies vadadustat to MTPC for both clinical and commercial use in the MTPC Territory. In February 2021, the Company entered into the Royalty Agreement

with HCR, whereby the Company sold its right to receive royalties and sales milestones under the MTPC Agreement, subject to certain caps and other terms and conditions (see Note 6 for additional information). See Note 5 of the Notes to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K/A for a more detailed description of the MTPC Agreement.

The Company identified two performance obligations in connection with its material promises under the MTPC Agreement as follows: (i) *License, Research and Clinical Supply Performance Obligation* and (ii) *Rights to Future Know-How Performance Obligation.* The 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. The deliverables associated with the License, Research and Clinical Supply Performance Obligation were satisfied as of June 30, 2018.

As of June 30, 2023, the transaction price was comprised of: (i) the up-front payment of $20.0 million, (ii) the cost for the Phase 2 studies of $20.5 million, (iii) the cost of all clinical supply provided to MTPC for the Phase 3 studies, (iv) $10.0 million in development milestones received, (v) $25.0 million in regulatory milestones received, comprised of $10.0 million relating to the NDA filing in Japan and $15.0 million relating to regulatory approval of vadadustat in Japan, and (vi) $4.0 million in royalties from net sales of Vafseo. As of June 30, 2023, all development milestones and $25.0 million in regulatory milestones have been achieved. No other regulatory milestones have been assessed as probable of being achieved and as a result have been fully constrained. The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur. Revenue for the License, Research and Clinical Supply Performance Obligation for the MTPC Agreement is being recognized using a proportional performance method, for which all deliverables have been completed. During the three and six months ended June 30, 2023, the Company recognized revenue from MTPC royalties totaling approximately $0.5 million and $0.9 million, respectively, and approximately $0.4 million and $0.7 million during the three and six months ended June 30, 2022, respectively. As noted above, in February 2021, the Company entered into the Royalty Agreement, whereby the Company sold its right to receive these royalties and sales milestones under the MTPC Agreement, subject to certain caps and other terms and conditions (see Note 6 for additional information). The revenue is classified as license, collaboration and other revenue in the accompanying unaudited condensed consolidated statements of operations and comprehensive loss. As of June 30, 2023, there were no accounts receivable, no deferred revenue, and no contract assets. There were no asset or liability balances classified as long-term in the unaudited condensed consolidated balance sheet as of June 30, 2023.

Supply of Drug Product to MTPC

On July 15, 2020, the Company and its collaboration partner MTPC entered into a supply agreement (MTPC Supply Agreement). The MTPC Supply Agreement includes the terms and conditions under which the Company will supply vadadustat drug product to MTPC for commercial use in Japan and certain other Asian countries, as contemplated by the MTPC Agreement. See Note 5 of the Notes to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K/A for a more detailed description of this supply agreement.

On December 16, 2022, the Company, MTPC, and Esteve Química, S.A. (Esteve) executed an Assignment of Supply Agreement (Esteve Assignment Agreement), pursuant to which the Supply Agreement between the Company and Esteve (Esteve Agreement) (see Note 13) was assigned to MTPC. The Esteve Assignment Agreement transferred the rights and obligations of the Company under the Esteve Agreement to MTPC, including the obligations under certain purchase orders issued by the Company and accepted by Esteve. As such, the transferred purchase orders will continue to have a binding effect on MTPC to take delivery of the product from Esteve in accordance with the terms of the Esteve Agreement. The Company will have no further obligation to take delivery of, or pay for, product delivered by Esteve under the transferred purchase orders.

The Company recognized no revenue and $3.7 million in revenue under the MTPC Supply Agreement during the three and six months ended June 30, 2023, respectively, and no revenue and $7.6 million during the three and six months ended June 30, 2022, respectively. As of June 30, 2023, the Company recorded no accounts receivable, deferred revenue or other current liabilities.

Cyclerion License Agreement

On June 4, 2021, the Company entered into a License Agreement (Cyclerion Agreement) with Cyclerion Therapeutics Inc. (Cyclerion), pursuant to which Cyclerion granted the Company an exclusive global license under certain intellectual property rights to research, develop and commercialize praliciguat, an investigational oral soluble guanylate stimulator.

Under the terms of the Cyclerion Agreement, the Company made an upfront payment of $3.0 million in cash to Cyclerion, which was paid and recorded to research and development expense in June 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 upfront payment was charged to expense at acquisition, as it relates to a development stage compound with no alternative future use. In addition, Cyclerion is eligible to receive up to an aggregate of $222.0 million from the Company in specified development and regulatory milestone payments on a product-by-product basis. Cyclerion will also be eligible to receive specified commercial milestones as well as tiered royalties ranging from a low-single-digit- to mid-double-digit percentage of net sales, on a product-by-product basis, and subject to reduction upon expiration of patent rights or the launch of a generic product in the territory. A more detailed description of this agreement can be found in Note 5 of the Notes to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K/A.

CSL Vifor License Agreement

On May 12, 2017, the Company entered into a License Agreement (Vifor Agreement) with Vifor (International) Ltd. (now a part of CSL Limited) (CSL Vifor), pursuant to which the Company granted CSL Vifor an exclusive license to sell vadadustat solely to Fresenius Kidney Care Group LLC, an affiliate of Fresenius Medical Care North America (FMCNA) in the United States. On April 8, 2019, the Company and CSL Vifor entered into an Amended and Restated License Agreement (Vifor First Amended Agreement), which amended and restated in full the Vifor Agreement. On February 18, 2022, the Company and CSL Vifor entered into a Second Amended and Restated License Agreement (Vifor Second Amended Agreement), which amends and restates the Vifor First Amended Agreement.

Pursuant to the Vifor Second Amended Agreement, the Company granted CSL Vifor an exclusive license to sell vadadustat to FMCNA and its affiliates, including Fresenius Kidney Care Group LLC, to certain third party dialysis organizations approved by the Company, to independent dialysis organizations that are members of certain group purchasing organizations, and to certain non-retail specialty pharmacies (collectively, the Supply Group) in the United States (Vifor Territory). Pursuant to the Vifor Second Amended Agreement, CSL Vifor agreed that it would not sell or otherwise supply vadadustat until the FDA has granted regulatory approval for vadadustat for the treatment of anemia due to CKD in adult patients with DD-CKD in the Vifor Territory and until CSL Vifor has entered a supply agreement with the applicable member of the Supply Group.

Similar to the Vifor First Amended Agreement, the Vifor Second Amended Agreement is structured as a profit share arrangement between the Company and CSL Vifor in which the Company will receive approximately 66% of the profit, net of certain pre-specified costs. Under the Vifor Second Amended Agreement, CSL Vifor made an upfront payment to the Company of $25.0 million in lieu of the previously disclosed milestone payment of $25.0 million that CSL Vifor was to pay the Company following approval of vadadustat by the FDA, as established under the Vifor First Amended Agreement.

Unless earlier terminated, the Vifor Second Amended Agreement will expire upon the later of the expiration of all patents that claim or cover vadadustat or expiration of marketing or regulatory exclusivity for vadadustat in the Vifor Territory. CSL Vifor may terminate the Vifor Second Amended Agreement in its entirety upon 30 months' prior written notice after the first anniversary of the receipt of regulatory approval, if approved from the FDA for vadadustat for dialysis-dependent CKD patients. The Company may terminate the Vifor Second Amended Agreement in its entirety for convenience, following the earlier of a certain period of time elapsing or following certain specified regulatory events, and upon six months’ prior written notice. If the Company so terminates for convenience, subject to specified exceptions, the Company will pay a termination fee to CSL Vifor. In addition, either party may, subject to a cure period, terminate the Vifor Second Amended Agreement in the event of the other party’s uncured material breach or bankruptcy.

Investment Agreement

In connection with the Vifor Agreement, in May 2017, the Company and CSL Vifor entered into an investment agreement (First Investment Agreement), pursuant to which the Company sold an aggregate of 3,571,429 shares of the Company’s common stock (2017 Shares) to CSL Vifor at a price per share of $14.00 for a total of $50.0 million. The amount representing the premium over the closing stock price of $12.69 on the date of the transaction, totaling $4.7 million, was determined by the Company to represent consideration related to the Vifor Agreement.

CSL Vifor agreed to a lock-up restriction such that it agreed not to sell the 2017 Shares for a period of time following the effective date of the First Investment Agreement as well as a customary standstill agreement. In addition, the First Investment Agreement contains voting agreements made by CSL Vifor with respect to the 2017 Shares. The 2017 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.

In connection with entering into the Vifor Second Amended Agreement, on February 18, 2022, the Company and CSL Vifor entered into an investment agreement (Second Investment Agreement), pursuant to which the Company sold an aggregate of 4,000,000 shares of its common stock (2022 Shares) to CSL Vifor for a total of $20 million on February 22, 2022. The amount representing the premium over the grant date fair value on the date of the transaction, $13.6 million, was determined by the Company to represent the consideration related to the Vifor Second Amended Agreement. CSL Vifor has agreed to a lock-up restriction to not sell or otherwise dispose of the 2022 Shares for a period of time following the effective date of the Second Investment Agreement as well as a customary standstill agreement. In addition, the Second Investment Agreement contains voting agreements made by CSL Vifor with respect to the 2022 Shares. The 2022 Shares have not been registered pursuant to the Securities Act and were issued and sold in reliance upon the exemption from registration contained in Section 4(a)(2) of the Securities Act and/or 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. See Note 5 of the Notes to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K/A for a more detailed description of the Vifor Second Amended Agreement.

Revenue Recognition

The Company identified one performance obligation in connection with its obligations under the Vifor Second Amended Agreement, the License Deliverable, or License Performance Obligation. The transaction price at inception was comprised of: (i) the up-front payment of $25.0 million, (ii) the premium paid by CSL Vifor on the First Investment Agreement of $4.7 million, and (iii) the premium paid by CSL Vifor on the Second Investment Agreement of $13.6 million. Pursuant to the terms of the Vifor Second Amended Agreement, these payments from CSL Vifor are non-refundable and non-creditable against any other amount due to the Company. Also pursuant to the Vifor Second Amended Agreement, if the Centers for Medicare & Medicaid Services (CMS) determines that vadadustat is excluded from the Transitional Drug Add-on Payment Adjustment (TDAPA), the Company can terminate the Vifor Second Amended Agreement and will be required to repay the up-front payment and the premiums paid by CSL Vifor in the First Investment Agreement and Second Investment Agreement, respectively. CSL Vifor also agreed that it will not sell or otherwise supply vadadustat until the FDA has granted regulatory approval for vadadustat for the treatment of anemia due to CKD in adult patients with DD-CKD. The Company constrains the variable consideration to an amount for which a significant revenue reversal is not probable. Therefore, the Company determined that the entire transaction price at inception was constrained under ASC 606, and the Company has recorded the transaction price of $43.3 million to long-term deferred revenue as of June 30, 2023.

Refund Liability to Customer

Pursuant to the Vifor Second Amended Agreement, CSL Vifor contributed $40.0 million to a working capital fund established to partially fund the Company’s costs of purchasing vadadustat from its contract manufacturers (Working Capital Fund), which amount of funding will fluctuate, and which funding the Company is required to repay to CSL Vifor over time. The $40 million initial contribution to the Working Capital Fund represents 50% of the amount of purchase orders that the Company has placed with its contract manufacturers for the supply of vadadustat for the Vifor Territory already delivered as of the effective date of the Vifor Second Amended Agreement, and to be delivered through the end of 2023. The amount of the Working Capital Fund will be reviewed at specified intervals and is adjusted based on a number of factors including outstanding supply commitments for vadadustat for the Vifor Territory and agreed upon vadadustat inventory levels held by the Company for the Vifor Territory. Upon termination or expiration of the Vifor Second Amended Agreement for any reason other than convenience by CSL Vifor (including following receipt of the CRL for vadadustat), the Company will be required to refund the outstanding balance of the Working Capital Fund on the date of termination or expiration.

The Company has recorded the Working Capital Fund as a refund liability under ASC 606. The Company has determined that the refund liability itself does not represent an obligation to transfer goods or services to CSL Vifor in the future. The Company has therefore determined that this refund liability is not a contract liability under ASC 606. The Company accounted for the refund liability as a debt arrangement with zero coupon interest. The Company imputed interest on the refund liability to the customer 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 of the Working Capital Fund. The Company recorded an initial discount on the refund liability to the customer and a corresponding deferred gain to the refund liability to customer on the condensed consolidated balance sheet as of the date the funds were received from CSL Vifor, which was March 18, 2022. The discount on the note payable is being amortized to interest expense using the effective interest method over the expected term of

the refund liability. The deferred gain is being amortized to interest income on a straight-line basis over the expected term of the refund liability. The amortization of the discount was $0.9 million and $1.7 million for the three and six months ended June 30, 2023, respectively, and $1.1 million for the three and six months ended June 30, 2022. The amortization of the deferred gain was $1.0 million and $2.0 million for the three and six months ended June 30, 2023, respectively, and $0.8 million for the three and six months ended June 30, 2022. As of June 30, 2023, the $40.6 million total refund liability is classified as a long-term refund liability based on management's estimate of potential amounts that could be refundable exceeding a one-year period.

Panion License Agreement

The Company had a license agreement, which was amended from time to time, with Panion & BF Biotech, Inc. (Panion), under which Keryx, the Company's wholly owned subsidiary, was the contracting party (Panion License Agreement), pursuant to which Keryx in-licensed the exclusive worldwide rights, excluding certain Asian-Pacific countries (Licensor Territory) for the development and commercialization of ferric citrate.

On April 17, 2019, the Company and Panion entered into a second amended and restated license agreement (Panion Amended License Agreement), which amends and restates in full the Panion License Agreement, effective as of April 17, 2019. The Panion Amended License Agreement provides Keryx with an exclusive license under Panion-owned know-how and patents with the right to sublicense, develop, make, use, sell, offer for sale, import and export ferric citrate worldwide, excluding the Licensor Territory. The Panion Amended License Agreement also provides Panion with an exclusive license under the Keryx-owned patents, with the right to sublicense (with the Company’s written consent), develop, make, use, sell, offer for sale, import and export ferric citrate in certain countries in the Licensor Territory. Under the Panion Amended License Agreement, Panion is eligible to receive from the Company or any sublicensee royalty payments based on a mid-single digit percentage of sales of ferric citrate in the Company’s licensed territories. The Company is eligible to receive from Panion or any sublicensee royalty payments based on a mid-single digit percentage of net sales of ferric citrate in Panion’s licensed territories. See Note 5 of the Notes to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K/A for a more detailed description of this license agreement.

The Company recognized royalty payments due to Panion of approximately $3.2 million and $6.0 million during the three and six months ended June 30, 2023, respectively, and $3.5 million and $6.6 million during the three and six months ended June 30, 2022, respectively, relating to the Company’s sales of Auryxia in the United States and JT and Torii’s net sales of Riona in Japan, as the Company is required to pay a mid-single digit percentage of net sales of ferric citrate in the Company’s licensed territories to Panion under the terms of the Panion Amended License 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 (JT and Torii Sublicense Agreement), under which Keryx, the Company’s wholly owned subsidiary, remains the contracting party. Under the JT and Torii Sublicense Agreement, 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 5 of the Notes to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K/A for a more detailed description of this sublicense agreement.

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 allocated 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 immaterial. As such, the Company did not develop a best estimate of standalone selling price for the License and Supply Performance Obligation and allocated the entire transaction price to this performance obligation.

The Company recognized license revenue of $1.4 million and $2.5 million during the three and six months ended June 30, 2023, respectively, and $1.5 million and $2.6 million during the three and six months ended June 30, 2022, 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.

Averoa License Agreement

On December 22, 2022, the Company and Averoa SAS (Averoa) entered into a license agreement (Averoa License Agreement), pursuant to which the Company granted to Averoa an exclusive license to develop and commercialize ferric citrate (Averoa Licensed Product), in the European Economic Area, Turkey, Switzerland and the United Kingdom (Averoa Territory).

Under the Averoa License Agreement, the Company is entitled to receive tiered, escalating royalties ranging from a mid-single digit percentage to a low double-digit percentage of Averoa's annual net sales in the Averoa Territory, including certain minimum royalty amounts in certain years, and subject to reduction in certain circumstances. The Company and Averoa will establish a joint steering committee to oversee the development, manufacturing and commercialization of the Averoa Licensed Product in the Averoa Territory. The Averoa License Agreement expires on the date of expiration of all royalty obligations due thereunder with respect to the Averoa Licensed Product on a country-by-country basis in the Averoa Territory, unless earlier terminated in accordance with the agreement.

The Averoa License Agreement provides that the Company and Averoa will enter into a supply agreement pursuant to which the Company will supply the Averoa Licensed Product to Averoa for commercial use in the Averoa Territory. The Company will have the right to terminate the supply agreement upon 24 months' notice, which may be provided on or after January 1, 2024. The Company did not receive any consideration under this agreement as of June 30, 2023. A more detailed description of this license agreement can be found in Note 5 of the Notes to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K/A.

Medice License Agreement

On May 24, 2023 (Medice Effective Date), the Company and MEDICE Arzneimittel Pütter GmbH & Co. KG (Medice) entered into a license agreement (Medice License Agreement), pursuant to which the Company granted to Medice an exclusive license to develop and commercialize vadadustat (Medice Licensed Product) for the treatment of anemia in adult patients with chronic kidney disease in the European Economic Area, the United Kingdom, Switzerland and Australia (Medice Territory).

Under the Medice License Agreement, the Company is entitled to receive the following payments:

(i) an up-front payment of $10.0 million,
(ii) commercial milestone payments up to an aggregate of $100.0 million, and
(iii) tiered royalties ranging from 10% to 30% of Medice's annual net sales of the Medice Licensed Product 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 the Medice Licensed Product in such country in the Medice Territory, (b) the date of expiration of data or regulatory exclusivity for the Medice Licensed Product in such country in the Medice Territory, and (c) the date that is 12 years from first commercial sale of the Medice Licensed Product in such country in the Medice Territory.

Under the Medice License Agreement, the Company retains the right to develop the Medice Licensed Product for non-dialysis patients with anemia due to chronic kidney disease in the Medice Territory. If the Company develops the Medice Licensed Product for non-dialysis patients and such Medice Licensed Product receives marketing approval in the Medice Territory, Medice will commercialize the Medice Licensed Product for both indications in the Medice Territory. In this instance, the Company would receive 70% of the net product margin of any sales of the Medice Licensed Product in the non-dialysis patient population, unless Medice requests to share the cost of the development necessary to gain approval to market the Medice Licensed Product for non-dialysis patients in the Medice Territory and the parties agree on alternative financial terms. If the Company develops the licensed product 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 the Medice Licensed Product for non-dialysis patients the Company will account for the joint activities in accordance with ASC No. 808, *Collaborative Arrangements* (ASC 808). Additionally, the Company has determined that in the context of the development of the Medice Licensed Product for non-dialysis patients, Medice does not represent a customer as contemplated by ASC 606-10-15, *Revenue from Contracts with Customers – Scope and Scope Exceptions*. As a result, the activities conducted pursuant to development activities for the Medice Licensed Product for non-dialysis patients will be accounted for as a component of the related expense in the period incurred.

The Company and Medice will establish a joint steering committee to oversee the development and commercialization of the Medice Licensed Product in the Medice Territory.

The Medice License Agreement expires on the date of expiration of all payment obligations due thereunder with respect to the Medice Licensed Product 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 12 months' prior written notice delivered on or after the date that is 12 months after the Medice Effective Date.

The Medice License Agreement includes customary terms relating to, among others, indemnification, confidentiality, remedies, and representations and warranties. The Medice License Agreement provides that the Company and Medice will enter into a supply agreement pursuant to which the Company will supply the Medice Licensed Product to Medice for commercial use in the Medice Territory.

Revenue Recognition

The Company evaluated the elements of the Medice License Agreement in accordance with the provisions of ASC 606 and concluded the contract counterparty, Medice, is a customer. The Company's arrangement with Medice contains one material promise under the contract at inception, which is the exclusive license under the Company's intellectual property to develop and commercialize the Medice Licensed Product in the Medice Territory during the term of the Medice License Agreement and use the Akebia Trademark solely in connection with the commercialization of the Medice Licensed Product (**License Deliverable**).

The Company identified one performance obligation in connection with its obligations under the Medice License Agreement, which is the License Deliverable (License Performance Obligation). The transaction price at inception was comprised of the up-front payment of $10.0 million, of which the Company received $8.6 million as of June 30, 2023. The remaining $1.4 million was withheld by the German Federal Tax Office and was recorded to other long-term assets on the condensed consolidated balance sheet as of June 30, 2023. The Company allocated the up-front payment of $10.0 million to the License Performance Obligation. Pursuant to the terms of the Medice License Agreement, this payment from Medice is non-refundable and non-creditable against any other amount due to the Company. In accordance with ASC 606, the Company will recognize sales-based royalties and milestone payments based on the level of sales, when the related sales occur as these amounts have been determined to relate to the license granted to Medice and therefore are recognized at the later of when the performance obligation is satisfied, or the related sales occur.

The License Performance Obligation was satisfied as of the Medice Effective Date of the Medice License Agreement. As such, the Company recognized the $10.0 million up-front payment as License, collaboration, and other revenue in the condensed consolidated statement of operations and comprehensive income (loss) during the three and six months ended June 30, 2023.

Past Collaboration and License Agreements

U.S. Collaboration and License Agreement with Otsuka Pharmaceutical Co. Ltd.

On December 18, 2016, the Company entered into a collaboration and license agreement with Otsuka (Otsuka U.S. Agreement). The collaboration was focused on the development and commercialization of vadadustat in the United States. The Company was responsible for leading the development of vadadustat, for which it submitted an NDA to the FDA in March 2021, and for which it received the CRL in March 2022. On May 12, 2022, the Company received notice from Otsuka that Otsuka had elected to terminate the Otsuka U.S. Agreement and the April 25, 2017 collaboration and license agreement with Otsuka (Otsuka International Agreement).

On June 30, 2022, the Company and Otsuka entered into the Termination Agreement, pursuant to which, among other things, the Company and Otsuka agreed to terminate the Otsuka U.S. Agreement and the Otsuka International Agreement as of June 30, 2022.

During the three and six months ended June 30, 2022, the Company recognized collaboration revenue totaling $81.1 million and $86.8 million, respectively, with respect to the Otsuka U.S. Agreement. During the three months ended June 30, 2023, the Company recognized $2.2 million in collaboration revenue in connection with the Packaging Validation Transfer Agreement entered into with Otsuka on April 20, 2023. The Company evaluated the agreement under ASC 606 and concluded it was closely tied to the prior collaboration revenue agreements and under ASC606 recognized collaboration revenue in the current quarter. A more detailed description of the Otsuka U.S. Agreement can be found in Note 5 of the Notes to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K/A.

International Collaboration and License Agreement with Otsuka Pharmaceutical Co. Ltd.

On April 25, 2017, the Company entered into the Otsuka International Agreement. The collaboration was focused on the development and commercialization of vadadustat in Europe, Russia, China, Canada, Australia, the Middle East and certain other territories (collectively, the Otsuka International Territory). As discussed above, the Otsuka International Agreement was terminated on June 30, 2022 pursuant to the Termination Agreement.

During the three and six months ended June 30, 2022, the Company recognized no collaboration revenue and $5.5 million with respect to the Otsuka International Agreement, respectively. A more detailed description of this collaboration agreement and the Company's evaluation of this agreement under ASC 606 can be found in Note 5 of the Notes to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K/A.

6. LIABILITY RELATED TO SALE OF FUTURE ROYALTIES

On February 25, 2021, the Company entered into the Royalty Agreement with HCR, pursuant to which the Company sold to HCR its right to receive royalties and sales milestones for vadadustat in Japan and certain other Asian countries, such countries collectively, the MTPC Territory, and such payments collectively the Royalty Interest Payments, in each case, payable to the Company under the MTPC Agreement, subject to an annual maximum "cap" of $13.0 million (Annual Cap) and an aggregate maximum "cap" of $150.0 million (Aggregate Cap). The Company received $44.8 million from HCR (net of certain transaction expenses) under the Royalty Agreement. The Company retains the right to receive all potential future regulatory milestones for vadadustat under the MTPC Agreement. Although the Company sold its right to receive royalties and sales milestones for vadadustat in the MTPC Territory as described above, as a result of its ongoing involvement in the cash flows related to these royalties, the Company will continue to account for these royalties as revenue. The Company recognized the proceeds received from HCR as a liability that is being amortized using the effective interest method over the life of the arrangement. At the transaction date, the Company recorded the net proceeds of $44.8 million as a liability. In order to determine the amortization of the liability, the Company is required to estimate the total amount of future net royalty payments to be made to HCR over the term of the Royalty Agreement. The total threshold of net royalties to be paid, less the net proceeds received, will be recorded as interest expense over the life of the liability. The Company imputes interest on the unamortized portion of the liability using the effective interest method. The annual effective interest rate as of June 30, 2023 was 0% which is reflected as interest expense in the unaudited condensed consolidated statements of operations and comprehensive loss. On a quarterly basis, the Company reassesses the effective interest rate and adjusts the rate prospectively as needed. A more detailed description of Royalty Agreement can be found in Note 7 of the Notes to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K/A.

The following table shows the activity within the liability account for the six months ended June 30, 2023 (in thousands):

Liability related to sale of future royalties, beginning balance at December 31, 2022	$	57,484
MTPC royalties payable		(936)
Liability related to sale of future royalties, ending balance at June 30, 2023	$	56,548

7. FAIR VALUE OF FINANCIAL INSTRUMENTS

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

	June 30, 2023			
	Level 1	Level 2	Level 3	Total Fair Value
Cash equivalents:				
Money market funds	$ 17,929	$ —	$ —	$ 17,929
Long-term liability:				
Embedded debt derivative	$ —	$ —	$ 760	$ 760

	December 31, 2022			
	Level 1	Level 2	Level 3	Total Fair Value
Cash equivalents:				
Money market funds	$ 52,442	$ —	$ —	$ 52,442
Long-term liability:				
Embedded debt derivative	$ —	$ —	$ 760	$ 760

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.

Embedded debt derivative —As described in Note 11, the Company's Loan Agreement with Pharmakon contains certain provisions that change the underlying cash flows of the debt instrument, including a potential extension to the interest-only period dependent on both (i) no event of default having occurred and continuing and (ii) the Company achieving certain regulatory and revenue conditions. The Company did not meet one of the regulatory conditions and therefore, the Company is no longer eligible for the interest-only extension period and this no longer changes the underlying cash flows of the debt instrument.

The Company concluded the acceleration of the obligations under the Loan Agreement under certain events of default, and under certain circumstances, the application of a default interest rate on all outstanding obligations during the occurrence and continuance of an event of default represent a single compound embedded debt derivative required to be bifurcated from the debt host instrument that is required to be re-measured at fair value on a quarterly basis.

The estimated fair value of the embedded debt derivative on both June 30, 2023 and December 31, 2022 was determined using a scenario-based approach and discounted cash flow model that includes principal and interest payments under various cash flow assumptions. Should the Company's assessment of the probabilities around these scenarios change, including for changes in market conditions, there could be a change to the fair value of the embedded debt derivative. The determination of the fair value of the embedded debt derivative includes inputs not observable in the market and as such, represents Level 3 measurement. The methodology utilized requires inputs based on certain subjective assumptions, specifically, probabilities of acceleration of the obligations under the Loan Agreement by Pharmakon under certain events of default. The probabilities used in the valuation of the embedded debt derivative included a 95% probability that the obligations under the Loan Agreement will not be accelerated due to an event of default under the Loan Agreement.

The fair value of the embedded debt derivative related to the Company's Loan Agreement with Pharmakon was $0.8 million as of June 30, 2023 and December 31, 2022.

8. INVENTORIES

Inventories related to our commercial product, Auryxia, consists of the following (in thousands):

	June 30, 2023	December 31, 2022
Work-in-process	$ 8,571	$ 7,892
Finished goods	12,334	13,676
Inventories, current	$ 20,905	$ 21,568
Raw materials included in other long-term assets	229	610
Total inventories	$ 21,134	$ 22,178

Inventory written down as a result of excess, obsolescence, scrap or other reasons charged to cost of goods in the unaudited condensed consolidated statement of operations and comprehensive income (loss) totaled approximately $0.3 million and $2.1 million during the three months ended June 30, 2023 and 2022, respectively, and $0.6 million and $7.4 million during the six months ended June 30, 2023 and 2022, respectively.

In accordance with GAAP, to date, the Company recorded prepaid amounts related to vadadustat drug substance as prepaid manufacturing costs. As of June 30, 2023 and December 31, 2022, the Company has $15.6 million included in other current assets on the condensed consolidated balance sheet. Released batches are expensed as research and development expense. During the quarter ended June 30, 2023, vadadustat received marketing authorization in the European Commission (EC) under the trade name Vafseo. Future costs associated with converting the drug substance to finished goods will be capitalized as inventory on the condensed consolidated balance sheet of the Company.

9. INTANGIBLE ASSET AND GOODWILL

Intangible Asset

Intangible asset, net of accumulated amortization, prior impairments and adjustments as of June 30, 2023 and December 31, 2022 consisted of the following (in thousands):

	Three Months Ended June 30, 2023			December 31, 2022	
Intangible asset:	**Gross Carrying Value**	**Accumulated Amortization**	**Net Book Value**	**Net Book Value**	**Estimated Useful Life**
Developed product rights for Auryxia	$ 214,705	$ (160,642)	$ 54,063	$ 72,084	6 years

The Company recorded $9.0 million in amortization expense for each of the three month periods ended June 30, 2023 and 2022, and $18.0 million for each of the six month periods ended June 30, 2023 and 2022.

Goodwill

On December 12, 2018, in connection with the consummation of the merger (Merger) of the Company and Keryx Biopharmaceuticals, Inc. (Keryx), Keryx became a wholly owned subsidiary of the Company, and the Company recorded goodwill representing the excess of the purchase price over the fair market value, at the date of the Merger, of the assets that were not individually identified and separately recognized as net assets. As of June 30, 2023 and December 31, 2022, the Company had goodwill of $59.0 million and no accumulated impairment losses related to goodwill. The Company's assessment included events that could indicate impairment and trigger an interim impairment assessment include, but are not limited to, an adverse change in current economic or market conditions, including a significant prolonged decline in market capitalization, a significant adverse change in legal factors, unexpected adverse business conditions, and an adverse action by a regulator.

10. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	June 30, 2023	December 31, 2022
Product revenue allowances	$ 23,303	$ 26,268
Product return reserves, current portion	4,626	7,789
Clinical trial costs	754	5,755
Compensation and related benefits	6,582	11,481
Operating lease liabilities, current portion	4,757	4,744
Royalties	3,198	3,804
Professional fees	2,800	1,886
Accrued manufacturing costs	5,578	4,310
Restructuring costs	334	2,751
Other	4,476	6,989
Total accrued expenses and other current liabilities	$ 56,408	$ 75,777

Accrued manufacturing costs includes the costs associated with the Company's commercial product Auryxia and vadadustat for which the Company is seeking approval from the FDA to market in the U.S. and for which the Company recently signed a license agreement with Medice to market in Europe and other territories (see Note 5 for further details).

11. DEBT

Pharmakon Term Loans

On November 11, 2019, the Company, with Keryx as guarantor, entered into a loan agreement (Loan Agreement), with BioPharma Credit PLC as collateral agent and a lender (Collateral Agent), and BioPharma Credit Investments V (Master) LP as a lender. BioPharma Credit PLC subsequently transferred its interest in the loans, solely in its capacity as a lender, to its

affiliate, BPCR Limited Partnership. The Collateral Agent and the lenders are collectively referred to as Pharmakon. The Loan Agreement, as amended, consists of a secured term loan facility in an aggregate amount of up to $100.0 million (Term Loans), which was made available under two tranches: (i) the first tranche of $80.0 million (Tranche A), and (ii) the second tranche of $20.0 million (Tranche B). On November 25, 2019, the Company drew $77.3 million on Tranche A, net of fees and expenses, incurred by Pharmakon and reimbursed by the Company, or Lender Expenses. On December 10, 2020, the Company drew $20.0 million on Tranche B, net of immaterial Lender Expenses and issuance costs.

Proceeds from the Term Loans may be used for general corporate purposes. The Company and Keryx entered into a Guaranty and Security Agreement with the Collateral Agent (Guaranty and Security Agreement) on the Tranche A Funding Date. Pursuant to the Guaranty and Security Agreement, the Company's obligations under the Term Loans are unconditionally guaranteed by Keryx (Guarantee). Additionally, the obligations of the Company and Keryx under the Term Loans and the Guarantee are secured by a first priority lien on certain assets of the Company and Keryx, including Auryxia and certain related assets, cash and certain equity interests held by the Company and Keryx, collectively the Collateral.

The Term Loans bear interest through maturity at a variable rate, payable quarterly in arrears. Through June 30, 2023, this rate was based upon the three-month LIBOR rate plus 7.50%, subject to a 2.00% LIBOR floor and a 3.35% LIBOR cap. On June 30, 2023, the three-month LIBOR rate was above the 3.35% LIBOR cap, therefore, the Company's interest rate as of June 30, 2023 was 10.85%. On June 29, 2023, the Company and Pharmakon entered into the Third Amendment to the Loan Agreement, which replaced LIBOR with the Secured Overnight Financing Rate (SOFR), effective June 30, 2023. The three-month SOFR rate was also above the 3.35% SOFR cap and therefore, the Company's interest rate as of June 30, 2023 would still have been 10.85% should SOFR been utilized for the quarter ended June 30, 2023. On August 11, 2023, the Company received an extension from Pharmakon of the deadline in the Loan Agreement with respect to the Company's obligation to deliver quarterly financial statements for the period ended June 30, 2023 through August 28, 2023.

The Term Loans will mature on November 25, 2024 (Maturity Date). The Company is required to repay the principal under the Term Loans in equal quarterly payments starting on the 33rd-month anniversary of the applicable Funding Date (Amortization Schedule). During the three and six months ended June 30, 2023, the Company made quarterly principal payments under the Term Loans totaling $8.0 million and $24.0 million, respectively. Under certain circumstances, unless certain liquidity conditions are met, the Maturity Date may decrease by up to one year, and the Amortization Schedule may correspondingly commence up to one year earlier.

If the Company prepays the loan prior to the Maturity Date, it will be required to make a prepayment fee. The prepayment fee would be 1.00% on or after the third anniversary, but prior to the fourth anniversary, of the applicable Funding Date of Tranche A, and 0.50% on or after the fourth anniversary of the applicable Funding Date of Tranche A but prior to the Maturity Date, and a make-whole premium on or prior to the second anniversary of the applicable Funding Date in an amount equal to foregone interest through the second anniversary of the applicable Funding Date. A change of control, which includes a new entity or group owning a majority (greater than 50%) of the Company's voting stock, triggers a mandatory prepayment of the Term Loans.

The Loan Agreement contains customary representations, warranties, events of default and covenants of the Company and its subsidiaries, including maintaining, on an annual basis, a minimum liquidity threshold which started in 2021, and on a quarterly basis, a minimum net sales threshold for Auryxia for the trailing twelve-month period of $85.0 million which started in the fourth quarter of 2020. On February 18, 2022, the Loan Agreement was amended by the First Amendment and Waiver (First Amendment and Waiver), which waived the provision under the Loan Agreement that required the Company to not be subject to any qualification as a going concern within the Company's 2021 Annual Report on Form 10-K. Pursuant to the First Amendment and Waiver, the Company's filings of Form 10-Q for fiscal quarters ending June 30, 2022 and September 30, 2022, and its future Annual Reports on Form 10-K, must not be subject to any qualification as to going concern, which requirement as to the Company's filings on Form 10-Q was waived in the Second Amendment and Waiver. If the Company does not satisfy the covenant as to going concern in any of these filings, the Company will be in default under the Loan Agreement. If an event of default occurs and is continuing under the Loan Agreement, the Collateral Agent is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement. Under certain circumstances, a default interest rate will apply on all outstanding obligations during the occurrence and continuance of an event of default. As of June 30, 2023 and December 31, 2022, the Company determined that no events of default had occurred.

On July 15, 2022 (Effective Date), the Company and Pharmakon entered into the Second Amendment and Waiver (Second Amendment and Waiver), which amended and waived certain provisions of the Loan Agreement, as amended by the First Amendment and Waiver. In addition, in connection with the Second Amendment and Waiver, on the Effective Date, the Company made a $5.0 million prepayment of the principal of the Tranche A loan, or the Second Amendment Effective Date Tranche A Prepayment, and a $20.0 million prepayment of principal of the Tranche B loan, or the Second Amendment Effective Date Tranche B Prepayment, in each case, together with any and all accrued and unpaid interest on such prepayments of principal to the Effective Date. In connection therewith, the Company also paid $0.5 million in prepayment fee under the Loan Agreement. During the three months ended September 30, 2022, the Company recorded a debt extinguishment loss of $0.9 million. See Note 12 of the Notes to the Consolidated Financial Statements in the 2022 Annual Report on Form 10-K/A for further details.

The Company assessed the terms and features of the Loan Agreement in order to identify any potential embedded features that would require bifurcation or any beneficial conversion feature. As part of this analysis, the Company assessed the economic characteristics and risks of the Loan Agreement, including put and call features. The terms and features assessed include a potential extension to the interest-only period dependent on both no event of default having occurred and continuing and the Company achieving certain regulatory and revenue conditions. The Company also assessed the acceleration of the obligations under the Loan Agreement under an event of default. In addition, under certain circumstances, a default interest rate will apply on all outstanding obligations during the occurrence and continuance of an event of default. In accordance with ASC 815, the Company concluded that these features are not clearly and closely related to the host instrument, and represent a single compound embedded derivative that is required to be re-measured at fair value on a quarterly basis.

The fair value of the embedded debt derivative related to the Company's Loan Agreement with Pharmakon was $0.8 million as of June 30, 2023 and December 31, 2022. The Company classified the embedded debt derivative as a long-term liability on the unaudited condensed consolidated balance sheet as of June 30, 2023.

The Company recognized interest expense related to the Loan Agreement of $1.6 million and $2.7 million during the three months ended June 30, 2023 and 2022, respectively, and $3.3 million and $5.4 million during the six months ended June 30, 2023 and 2022, respectively. Unamortized discount and issuance costs were $0.5 million as of June 30, 2023.

12. CAPITAL STOCK, STOCK-BASED COMPENSATION AND BENEFIT PLAN

Authorized and Outstanding Capital Stock

On June 5, 2020, the Company filed a Certificate of Amendment to its Ninth Amended and Restated Certificate of Incorporation, or its Charter, to increase the number of authorized shares of common stock from 175,000,000 to 350,000,000. As of June 30, 2023, the authorized capital stock of the Company included 350,000,000 shares of common stock, $0.00001 par value per share, of which 188,128,869 and 184,135,714 shares were issued and outstanding as of June 30, 2023 and December 31, 2022, 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 June 30, 2023 and December 31, 2022.

At-the-Market Facility

On April 7, 2022, the Company entered into an Open Market Sale Agreement℠ (Sales Agreement), with Jefferies LLC (Jefferies) as agent, for the offer and sale of common stock at current market prices in amounts to be determined from time to time. Also, on April 7, 2022, the Company filed a prospectus supplement relating to the Sales Agreement, pursuant to which it is able to offer and sell under the Sales Agreement up to $26.0 million of its common stock at current market prices from time to time. From the date of filing of the prospectus supplement through the date of the filing of this Quarterly Report on Form 10-Q, the Company has not sold any shares of its common stock under this program.

Terminated At-the-Market Facility

On March 12, 2020, the Company filed a prospectus supplement relating to the Company's sales agreement with Cantor Fitzgerald & Co. (Prior Sales Agreement) pursuant to which it was able to offer and sell up to $65.0 million of its common stock at current market prices from time to time.

On February 25, 2021, the Company filed a prospectus relating to the Prior Sales Agreement with its new shelf registration statement (which replaced the prior shelf registration statement and the sales agreement prospectus supplement), pursuant to which it was able to offer and sell up to $100.0 million of its common stock at current market prices from time to time. On March 1, 2022, the Company filed a prospectus relating to the Prior Sales Agreement, pursuant to which it was authorized to offer and sell up to $25.3 million of its common stock at current market prices from time to time. On March 16, 2022, the

Company terminated the Prior Sales Agreement. During the three months ended March 31, 2022, the Company sold 404,600 shares of common stock under this program with net proceeds (after deducting commissions and other offering expenses) of $0.8 million.

Stock-Based Compensation and Benefit Plans

The Company incurred stock-based compensation expenses of $3.5 million and $6.0 million for the three and six months ended June 30, 2023, respectively and $6.9 million and $11.5 million for the three and six months ended June 30, 2022, respectively.

Equity Incentive Plans

The following table contains information about our equity plans:

			June 30, 2023	
Title of Plan	**Group Eligible**	**Type of Award Granted (or to be Granted)**	**Awards Outstanding**	**Additional Awards Authorized for Grant**
Keryx Equity Plans[1][2]*	Employees, directors and consultants	Stock options and RSUs	287,100	—
Akebia Therapeutics, Inc. Amended and Restated 2008 Equity Incentive Plan (the 2008 Plan)[2]	Employees, directors and consultants	Stock options and RSUs	419	—
Akebia Therapeutics, Inc. 2014 Incentive Plan, as amended[2] (the 2014 Plan) *(replaces 2008 Plan)*	Employees, directors, consultants and advisors	Stock options, RSUs, SARs and performance awards	17,513,530	—
Akebia Therapeutics, Inc. 2023 Stock Incentive Plan (the 2023 Plan) *(replaces 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	549,000	16,256,679

(1) The Keryx Equity Plans consist of the Keryx Biopharmaceuticals, Inc. 1999 Share Option Plan, Keryx Biopharmaceuticals, Inc., as amended, the 2004 Long-Term Incentive Plan, as amended, the Keryx Biopharmaceuticals, Inc. 2007 Incentive Plan, the Keryx Biopharmaceuticals Inc. Amended and Restated 2013 Incentive Plan and the Keryx Biopharmaceuticals, Inc. 2018 Equity Incentive Plan.
(2) Shares are no longer being issued under these plans.

Common Stock Options and SARs

During the six months ended June 30, 2023, the Company issued 2,564,500 options to employees under the 2014 Plan and 315,000 options to directors under the 2023 Plan. During the six months ended June 30, 2023, the Company issued 635,313 SARs to one executive 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. 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 10 years after the date of grant.

The Company also maintains an inducement award program 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 six months ended June 30, 2023, the Company granted 75,000 options to purchase shares of the Company's common stock to new hires as inducements material to such employees' entering into employment with the Company, of which 72,000 options remained outstanding as of June 30, 2023.

The Company grants annual service-based stock options to employees and directors and SARs to certain executives under the 2023 and 2014 Plans. In addition, the Company issues stock options to directors, new hires and occasionally to other employees not in connection with the annual grant process. During the six months ended June 30, 2023, the Company granted options not

in connection with the annual grant process with an aggregate grant date fair values of $0.1 million calculated using the Black-Scholes option-pricing model.

The fair value of stock options that vested during the six months ended June 30, 2023 was $4.1 million.

The combined stock option activity for the six months ended June 30, 2023, is as follows:

	Stock Options	Weighted Average Exercise Price	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	11,775,411	$ 5.82	7.26 years	—
Granted	3,514,813	$ 0.69	—	—
Exercised	—	—	—	—
Canceled and forfeited	(1,130,737)	$ 6.35	—	—
Outstanding at June 30, 2023	14,153,498	$ 4.50	7.33 years	$ 1,435,662
Exercisable at June 30, 2023	7,800,000	$ 6.64	6.01 years	

Performance Awards

The performance-based stock options granted by the Company 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 Company also grants performance-based restricted stock units (PSUs) to employees under the 2023 Plan and 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. The Company did not issue any performance-based stock options under the 2023 Plan or the 2014 Plan during the six months ended June 30, 2023.

Restricted Stock Units

Generally, restricted stock units (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 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.

RSU activity is as follows:

	2014 Plan		2023 Plan	
	Number of Shares	Weighted Average Fair Value	Number of Shares	Weighted Average Fair Value
Outstanding as of December 31, 2022	5,674,406	$ 2.10	—	—
Granted	2,759,675	$ 0.68	210,000	$ 1.20
Forfeited and canceled	(564,606)	$ 1.00	—	—
Outstanding as of June 30, 2023	7,869,475	$ 1.30	210,000	$ 1.20

As of June 30, 2023, there was $4.4 million of unrecognized compensation costs related to time-based RSUs which is expected to be recognized over a weighted-average period of 1.77 years.

Employee Stock Purchase Plan

On June 6, 2019, the Company's stockholders approved the Amended and Restated 2014 Employee Stock Purchase Plan (ESPP). Under the ESPP substantially all employees may voluntarily enroll to purchase shares of the Company's common stock through payroll deductions at a price equal to 85% of the lower of the fair market values of the stock as of the beginning or the end of the six-month offering period. An employee's payroll deductions under the ESPP are limited to 15% of the employee's compensation, and an employee may not purchase more than $25,000 worth of stock during any calendar year. In addition, an employee may not purchase more than 1,500 shares in any offering period. As of June 30, 2023, a total of 4,734,495 shares of the Company's common stock are available for future issuance under the ESPP. The Company issued 103,500 shares under the ESPP during the six months ended June 30, 2023.

Stock-Based Compensation Expense

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

	Three Months Ended June 30,		Six Months Ended June 30,	
Stock Options	**2023**	**2022**	**2023**	**2022**
Risk-free interest rate	3.67 % - 3.99%	2.80 % - 3.01%	3.54 % - 3.99%	1.69 % - 3.01%
Expected volatility	102.31 % - 111.71%	87.99 % - 91.57%	100.97 % - 111.71%	79.77 % - 91.57%
Expected term (years)	5.51 years - 6.25 years	5.51 years - 6.25 years	5.51 years - 6.25 years	5.51 years - 6.25 years
Expected dividend yield	—%	—%	—%	—%
Fair value at grant date	$0.97	$0.31	$0.56	$1.21

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Research and development	$ 605	$ 905	$ 1,341	$ 2,094
Selling, general and administrative	2,685	2,709	4,220	6,056
Restructuring	$ 200	$ 3,303	$ 418	$ 3,303
Total stock-based compensation	$ 3,490	$ 6,917	$ 5,979	$ 11,453

13. COMMITMENTS AND CONTINGENCIES

Cambridge Leases

The Company leases approximately 65,167 square feet of office and lab space in Cambridge, Massachusetts under a lease which was most recently amended in November 2020 (collectively, the Cambridge Lease). Under the Third Amendment to the Cambridge Lease (Third Amendment), executed in July 2016, total monthly lease payments under the initial base rent were approximately $0.2 million and are subject to annual rent escalations. In addition to such annual rent escalations, base rent payments for a portion of said premises commenced on January 1, 2017 in the monthly amount of approximately $22,000. The Fourth Amendment to the Cambridge Lease, executed in May 2017, provided additional storage space to the Company and did not impact rent payments. In April 2018, the Company entered into a Fifth Amendment to the Cambridge Lease (Fifth Amendment) for an additional 19,805 square feet of office space on the 12th floor. Monthly lease payments for the existing 45,362 square feet of office and lab space, under the Third Amendment, remain unchanged. The new space leased by the Company was delivered in September 2018 and additional monthly lease payments of approximately $0.1 million commenced in February 2019 and are subject to annual rent escalations, which commenced in September 2019. In November 2020, the Company entered into a Sixth Amendment to the Cambridge Lease (Sixth Amendment) to extend the term of the Cambridge Lease with respect to the lab space from November 30, 2021 to January 31, 2025. The Sixth Amendment includes two months of free rent starting in December 2020 and additional monthly lease payments of approximately $48,000, which commenced in December 2021, and is subject to annual rent escalations, which commenced in December 2022.

The term of the Cambridge Lease with respect to the office space expires on September 11, 2026, with one five-year extension option available. The renewal option in this real estate lease was not included in the calculation of the right-of-use asset and operating lease liability as the renewal is not reasonably certain. The term of the Cambridge Lease with respect to the lab space expires on January 31, 2025, with an extension option for one additional period through September 11, 2026. The renewal option in this real estate lease was included in the calculation of the right-of-use assets and operating lease liabilities as the renewal is reasonably certain. The lease agreements do not contain residual value guarantees. Operating lease costs were $1.4 million and $1.8 million for the three months ended June 30, 2023 and 2022, respectively, and $3.2 million and $3.6 million for the six months ended June 30, 2023 and 2022, respectively. Cash paid for amounts included in the measurement of operating lease liabilities was $1.4 million and $1.8 million for the three months ended June 30, 2023 and 2022, respectively, and $3.1 million and $3.7 million for the six months ended June 30, 2023 and 2022, respectively. The security deposit in connection with the Cambridge Lease is $1.7 million in the form of a letter of credit, which is included as restricted cash in prepaid expenses and other current assets in the Company’s unaudited condensed consolidated balance sheets as of June 30, 2023.

The Company has not entered into any material short-term leases or financing leases as of June 30, 2023.

Former Boston Lease

Previously, the Company leased 27,924 square feet of office space in Boston, Massachusetts (Boston Lease). In February 2022, the Company entered into the First Amendment to the Boston Lease (First Lease Amendment) to extend the term of the Boston Lease from February 2023 to July 2031. The First Lease Amendment included five months of free rent starting in March 2023 and monthly lease payments of $0.2 million commencing on August 1, 2023, with an annual rent escalation of approximately 2% commencing on August 1, 2024. In May 2023, the Company entered into an Assignment and Assumption of Lease Agreement (Lease Assignment Agreement) with LG Chem Life Sciences Innovation Center, Inc. (LG Chem), pursuant to which the Company assigned all of its rights, title, and interest in, to, and under the Boston Lease to LG Chem, or the Assignment. As part of the Lease Assignment Agreement, the Company made a payment to LG Chem of $1.3 million (Lease Assignment Amount) and LG Chem assumed all of the rights and obligations of the Company under the Boston Lease. Subsequent to the Assignment, the Company has no further obligations for rent or other payments under the Boston Lease. In accordance with ASC 842, *Leases*, the Company wrote off the right-of-use asset and lease liability associated with the Boston Lease, and recognized the difference between the right-of-use asset and the lease liability offset by the Assignment Amount as a loss on lease termination in the condensed consolidated statement of operations and comprehensive income (loss) of $0.5 million during the three and six months ended June 30, 2023. Under the terms of the Lease Assignment Agreement the Company was entitled to, and received back, its security deposit of $1.0 million as of June 30, 2023, which had been recorded as restricted cash in prepaid expenses and other current assets in the Company's condensed consolidated balance sheet as of December 31, 2022.

In September 2019, the Company entered into an agreement to sublease the Boston office space to Foundation Medicine, Inc.(Foundation). The sublease was subject and subordinate to the Boston Lease between the Company and the landlord. The term of the sublease commenced on October 16, 2019, upon receipt of the required consent from the landlord for the sublease

agreement, and expired on February 27, 2023. Foundation was obligated to pay the Company rent that approximated the rent due from the Company to its landlord with respect to the Boston Lease. Sublease rental income is recorded to other income in the condensed consolidated statement of operations and other comprehensive income (loss). The Company was obligated for all payment terms pursuant to the Boston Lease, and the Company guaranteed the obligations under the sublease. The Company did not record any sublease rental income for the three months ended June 30, 2023 and recorded $0.3 million in sublease rental income from Foundation during the six months ended June 30, 2023. The Company recorded sublease rental income of $0.4 million and $0.9 million during the three and six months ended June 30, 2022, respectively.

Future Lease Commitments

Future commitments under non-cancelable lease agreements are as follows:

Years ending December 31,	Operating Lease Commitments
Remainder of 2023	$ 2,835
2024	5,740
2025	5,818
2026	3,613
Total lease commitments	$ 18,006
Less: present value adjustment	(1,769)
Current and long-term operating lease liabilities	$ 16,237

In arriving at the operating lease liabilities, the Company applied incremental borrowing rates ranging from 6.65% to 6.94%, which were based on the remaining lease term at either the date of adoption of ASC 842 or the effective date of any subsequent lease term extensions. As of June 30, 2023, the remaining lease term for the Cambridge Lease was 3.20 years.

Manufacturing and Unconditional Purchase Commitment Agreements

The Company's contractual obligations include a commercial supply agreement with Siegfried Evionnaz SA (Siegfried) to supply commercial drug substance for Auryxia.

Pursuant to the Master Manufacturing Services and Supply Agreement between the Company and Siegfried, as amended (the most recent amendment having been executed on February 28, 2023) (Siegfried Agreement), the Company has agreed to purchase a minimum quantity of drug substance of Auryxia at a predetermined price. The term of the Siegfried Agreement expires on December 31, 2024, unless otherwise agreed by the parties and subject to the Company's option to extend the term through December 31, 2026 by providing 12 months' prior written notice to Siegfried. The Siegfried Agreement provides the Company and Siegfried with certain early termination rights. As of June 30, 2023, the Company is required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $20.8 million through the end of 2024.

On April 9, 2019, the Company and Esteve entered into the Esteve Agreement, which included the terms and conditions under which Esteve would manufacture vadadustat drug substance for commercial use. Pursuant to the Esteve Agreement, the Company provided rolling forecasts to Esteve on a quarterly basis, or the Esteve Forecast. The Esteve Forecast reflected the Company's needs for vadadustat drug substance produced by Esteve over a certain number of months, represented as a quantity of vadadustat drug substance per calendar quarter. The parties agreed to a volume-based pricing structure under the Esteve Agreement. On December 16, 2022, the Company, MTPC, and Esteve executed the Esteve Assignment Agreement, pursuant to which the Supply Agreement between the Company and Esteve was assigned to MTPC. The Esteve Assignment Agreement transferred the rights and obligations of the Supply Agreement to MTPC, specifically including the obligations under certain purchase orders issued by the Company and accepted by Esteve. As such, the Company will have no further obligation to take delivery of or pay for product delivered by Esteve under the transferred Esteve Agreement and the purchase orders.

On March 11, 2020, the Company entered into a Supply Agreement with Patheon Inc. (Patheon) or the Patheon Agreement. The Patheon Agreement includes the terms and conditions under which Patheon will manufacture vadadustat drug product for commercial use. Pursuant to the Patheon Agreement, the Company provides Patheon a long-term forecast on an annual basis, as well as short-term forecasts on a quarterly basis, or the Patheon Forecast. The Patheon Forecast reflects the Company's needs for commercial supply of vadadustat drug product produced by Patheon, represented as a quantity of drug product per calendar quarter. The parties have agreed to a volume-based pricing structure under the Patheon Agreement. The Patheon Agreement has an initial term beginning March 11, 2020 and ending June 30, 2023 and automatically renews for successive one-year terms unless either party gives the other party eighteen months' prior written notice. The current term of the Patheon Agreement ends

June 30, 2025. Pursuant to the Patheon Agreement, the Company has agreed to purchase a certain percentage of the global demand for vadadustat drug product from Patheon. As of June 30, 2023, the Company had a minimum commitment with Patheon for $1.9 million through the third quarter of 2023.

On April 2, 2020, the Company entered into a Supply Agreement with STA Pharmaceutical Hong Kong Limited, a subsidiary of WuXi AppTec (WuXi STA), as amended on April 15, 2021 (WuXi STA DS Agreement). The WuXi STA DS Agreement includes the terms and conditions under which WuXi STA will manufacture vadadustat drug substance for commercial use. Pursuant to the WuXi STA DS Agreement, the Company provides rolling forecasts to WuXi STA on a quarterly basis, or the WuXi STA DS Forecast. The WuXi STA DS Forecast reflects the Company's needs for vadadustat drug substance produced by WuXi STA over a certain number of quarters. The parties have agreed to a volume-based pricing structure under the WuXi STA DS Agreement. The WuXi STA DS Agreement has an initial term of four years, beginning April 2, 2020 and ending April 2, 2024. 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 June 30, 2023, the Company has committed to purchase $15.3 million of vadadustat drug substance from WuXi STA through the end of 2023.

On February 10, 2021, the Company entered into a Supply Agreement with WuXi STA, or the WuXi STA DP Agreement. The WuXi STA DP Agreement includes the terms and conditions under which WuXi STA will manufacture and supply vadadustat drug product for commercial purposes. Pursuant to the WuXi STA DP Agreement, the Company will provide rolling forecasts to WuXi STA on a quarterly basis, or the WuXi STA DP Forecast. Each WuXi STA DP Forecast will reflect the quantities of vadadustat drug product that the Company expects to order from WuXi STA over a certain number of months, represented as a quantity of vadadustat drug product per calendar quarter. 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 parties have agreed to a volume-based pricing structure under the WuXi STA DP Agreement. The vadadustat drug product price will remain fixed for the first 12 months and thereafter shall be annually reviewed by the Company and WuXi STA. The Company will also reimburse WuXi STA for certain reasonable expenses. The WuXi STA DP Agreement has an initial term of four years, beginning February 10, 2021 and ending February 10, 2025. The WuXi STA DP Agreement may be renewed or extended by mutual agreement of the Company and WuXi STA with at least 18 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.

Former Manufacturing and Unconditional Purchase Commitments

Pursuant to the Manufacture and Supply Agreement with BioVectra and the Amended and Restated Product Manufacture and Supply and Facility Construction Agreement with BioVectra, the Company agreed to purchase minimum quantities of Auryxia drug substance annually at predetermined prices as well as reimburse BioVectra for certain costs in connection with construction of a new facility for the manufacture and supply of Auryxia drug substance.

On December 22, 2022, the Company and BioVectra entered into a termination agreement (BioVectra Termination Agreement), pursuant to which the parties agreed, among other things, to terminate, effective immediately, any and all existing agreements entered into between the parties in connection with the manufacture and supply, by BioVectra to the Company, of Auryxia drug substance. Under the terms of the BioVectra Termination Agreement, each of the Company and BioVectra have released one another from all existing and future claims and liabilities and the return of certain materials and documents. Furthermore, as it relates to all open purchase orders, BioVectra is relieved from any obligations to manufacture any product or perform services under any such open purchase orders, and the Company is relieved from any obligations to purchase any product under such open purchase orders. The Company is also relieved from any obligations to pay any outstanding invoices related to performance by BioVectra of services and all other obligations under the agreements. In addition, the Company agreed to pay BioVectra a total of $32.5 million consisting of (i) an upfront payment of $17.5 million and (ii) six quarterly payments of $2.5 million commencing in April 2024, totaling $15.0 million. The upfront payment of $17.5 million was made during the quarter ended December 31, 2022 and was recognized to cost of goods sold. In accordance with ASC 420, *Exit or Disposal Cost Obligations*, the Company recognized a liability and corresponding expense for the remaining termination fees based on estimated fair value as of December 22, 2022 (BioVectra Effective Date). The Company imputed interest on the liability for the remaining termination fees at a rate of 17.0% per annum, which was determined based on certain factors, including the Company's credit rating, comparable securities yield, and expected repayment period of the remaining termination fees. The Company recorded an initial discount on the remaining termination fees on the consolidated balance sheet as of the BioVectra Effective Date. This resulted in the recording of a liability and corresponding charge to cost of goods sold of $11.2 million during the quarter ended December 31, 2022. The discount on the liability balance is being amortized to interest expense using the effective interest rate method over the term of the liability. The amortization of the discount was $0.5 million and $0.9 million for the three and six months ended June 30, 2023, respectively.

Other Third-Party Contracts

The Company contracts with various organizations to conduct research and development activities with remaining contract costs to the Company of approximately $54.9 million at June 30, 2023. The scope of the services under these research and

development contracts can be modified and the contracts cancelled by the Company upon written notice. In some instances, the contracts may be cancelled by the third party upon written notice.

Litigation and Related Matters

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

Guarantees and Indemnifications

As permitted under Delaware law, the Company may indemnify its officers, directors and employees for certain events or occurrences that happen by reason of their relationship with, or position held at, the Company. The Company may also be subject to indemnification obligations by law with respect to the actions of its employees under certain circumstances and in certain jurisdictions. The Company maintains director and officer liability insurance coverage that is intended to cover a portion of amounts that may be due with respect to indemnification after a deductible is met. Further, the Company is a party to a variety of agreements in the ordinary course of business under which it may be obligated to indemnify third parties with respect to certain matters. For the three and six months ended June 30, 2023 and 2022, the Company did not experience any losses related to these indemnification obligations, and no claims were outstanding as of June 30, 2023. The Company does not have any claims related to these indemnification obligations and consequently concluded that the fair value of these obligations is negligible and no related accruals were recorded.

14. NET LOSS PER SHARE

Potentially dilutive securities, common stock options, RSUs and SARs have been excluded from the calculation of diluted net loss per share as their effects would be anti-dilutive. For periods in which the Company reports a net loss, the weighted average number of shares outstanding used to calculate both basic and diluted net loss per share were the same except for the three months ended June 30, 2022, as the Company had net income for that period. The shares in the table below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, due to their anti-dilutive effect:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Outstanding common stock options and SARs	13,753,498	13,502,015	13,753,498	13,508,217
Unvested RSUs	4,596,551	—	4,596,551	6,771,349
Total	18,350,049	13,502,015	18,350,049	20,279,566

15. SUBSEQUENT EVENTS

The Company has completed an evaluation of all subsequent events after the balance sheet date of June 30, 2023, through the filing date of this Quarterly Report on Form 10-Q with the SEC, to ensure that the condensed consolidated financial statements include appropriate disclose of events both recognized in the consolidated financial statements as of June 30, 2023, 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.

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

The following information 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, 2022 as amended by Amendment No. 1 on Form 10-K/A filed with the U.S. Securities and Exchange Commission, or the SEC, on August 28, 2023, or the 2022 Annual Report on Form 10-K/A, including the audited consolidated financial statements and related notes therein. This discussion and analysis contains forward-looking statements 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 committed to addressing patients' unmet needs. Since our initial public offering in 2014, we have built a business focused on developing and commercializing innovative therapeutics that we believe serves as a foundation for future growth. Our purpose is to better the life of each person impacted by kidney disease, and we have established ourselves as a leader in the kidney community. We believe our demonstrated ability to deliver value broadly to the kidney community has enabled us to build a sustainable company. While our current focus centers on people living with kidney disease, we believe our continued commitment to our products and pipeline assets, focusing on all patients who can realize a meaningful benefit from our medicines, will result in delivering value for shareholders.

Our current portfolio includes:

- ***Auryxia® (ferric citrate)***, a medicine approved and marketed in the United States, or U.S., for two indications: (1) the control of serum phosphorus levels in adult patients with dialysis dependent chronic kidney disease, or DD-CKD, or the Hyperphosphatemia Indication, and (2) the treatment of iron deficiency anemia, or IDA, in adult patients with non-dialysis-dependent chronic kidney disease, or NDD-CKD. The product is also available in Japan and Taiwan.
- ***Vafseo (vadadustat)***, an oral hypoxia-inducible factor prolyl hydroxylase, or HIF-PH, inhibitor, is approved in Europe, the United Kingdom, and Switzerland for the treatment of symptomatic anemia due to chronic kidney disease, or CKD, in adult patients on chronic maintenance dialysis. Vadadustat is also approved in Japan for the treatment of anemia due to CKD in adult patients on dialysis and not on dialysis. Additionally, vadadustat is approved in Korea as an anemia treatment for patients with CKD on hemodialysis. Vadadustat is also under regulatory review for the treatment of anemia due to CKD in Australia and Taiwan. We continue to pursue a path to potentially gain approval for vadadustat in the U.S. Further, we have several lifecycle management and indication expansion opportunities currently under evaluation or in development for vadadustat.
- ***HIF-PH inhibitors*** in preclinical development. The discovery of hypoxia-inducible factor, or HIF, laid the foundation to explore the central role of oxygen sensing in many diseases. As we have seen through the development of vadadustat as a treatment for anemia due to CKD, when stabilized, HIF triggers wide-ranging adaptive, protective responses during hypoxic or ischemic conditions. Our clinical team and research scientists are eager to further develop HIF-PH inhibitors for various indications including acute kidney injury, or AKI, and retinopathy of prematurity, or ROP.

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.

Auryxia

Today we market Auryxia in the U.S. with our well-established, nephrology-focused commercial organization. Auryxia is a non-calcium, non-chewable, orally administered tablet that was approved for marketing by the U.S. Food and Drug Administration, or FDA, in September 2014 as a phosphate binder for the Hyperphosphatemia Indication and was commercially launched in the U.S. shortly thereafter. In November 2017, Auryxia received marketing approval from the FDA for a second indication, the treatment of iron deficiency anemia, and was commercially launched for this indication in the U.S. shortly thereafter. Our Japanese sublicensee, Japan Tobacco, Inc., and its subsidiary, Torii Pharmaceutical Co., Ltd., collectively, JT and Torii, commercialize ferric citrate hydrate as Riona® in Japan. Averoa SAS, or Averoa, has an exclusive license to develop and commercialize ferric citrate in the European Economic Area, or EEA, Turkey, Switzerland and the United Kingdom.

Vadadustat

We are seeking regulatory approval in the United States for vadadustat as an oral treatment of anemia in adult DD-CKD patients. We and Mitsubishi Tanabe Pharma Corporation, or MTPC, are also seeking regulatory approval for vadadustat as a treatment for anemia in adult DD-CKD and NDD-CKD patients in Taiwan.

In April 2023, the European Commission, or EC, approved the marketing authorization of vadadustat under the trade name Vafseo for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis, which is applicable to all 27 European Union member states and Iceland, Norway and Liechtenstein. In May 2023, the UK Medicines and Healthcare products Regulatory Agency approved the marketing authorization of vadadustat under the trade name Vafseo for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis. In June 2023, the Swiss Agency for Therapeutic Products approved the marketing authorization of vadadustat under the trade name Vafseo for the treatment of symptomatic anemia associated with CKD in adults on chronic maintenance dialysis. Following the termination of our U.S. and international collaboration agreements with Otsuka Pharmaceutical Co. Ltd., or Otsuka, in June 2022, we regained full rights to vadadustat in Europe, Australia, China, Canada, Latin America, the Middle East and Russia. In May 2023, we entered into a License Agreement, or the Medice License Agreement, with MEDICE Arzneimittel Pütter GmbH & Co. KG, or Medice, pursuant to which we granted Medice an exclusive license to develop and commercialize vadadustat for the treatment of anemia in patients with CKD in the EEA, the UK, Switzerland and Australia, or the Medice Territory.

We submitted a new drug application, or NDA, to the FDA for vadadustat in March of 2021. On March 29, 2022, the FDA issued a complete response letter, or CRL, to our NDA for vadadustat. The FDA concluded that the data in the NDA do not support a favorable benefit-risk assessment of vadadustat for dialysis and non-dialysis patients. The FDA expressed safety concerns noting failure to meet non-inferiority in MACE in the non-dialysis patient population, the increased risk of thromboembolic events, driven by vascular access thrombosis in dialysis patients, and the risk of drug-induced liver injury. We believe there are compelling data supporting a positive benefit-risk profile for the use of vadadustat broadly in patients with CKD, including non-dialysis patients though we have always remained cautious about receiving a broad label for vadadustat that would extend to non-dialysis patients with anemia due to CKD. As such, we began the process to dispute the FDA ruling, and in October 2022, we submitted a Formal Dispute Resolution Request with the FDA regarding the CRL, specifically related to DD-CKD adult patients and focused on the favorable balance of the benefits and risks of vadadustat for the treatment of adult DD-CKD patients in light of safety concerns expressed by the FDA in the CRL related to the rate of adjudicated thromboembolic events driven by vascular access thrombosis for vadadustat compared to the active comparator and the risk of drug-induced liver injury. In May 2023, the Office of New Drugs, or OND, denied our appeal but provided a path forward for us to resubmit the NDA for vadadustat for the treatment of anemia due to CKD for dialysis dependent patients without the need for us to generate additional clinical data. In July 2023, we held an End of Dispute Type A meeting with the FDA to align on the contents of the NDA resubmission. We expect to resubmit the NDA by the end of the third quarter of 2023, with a potential Prescription Drug User Fee Act, or PDUFA, date that we project will be in March 2024.

Following the termination of our collaboration agreement with Otsuka we own full rights to vadadustat in the U.S., subject to our licensing agreement with CSL Vifor. If we obtain FDA approval of vadadustat for DD-CKD adult patients, we plan to commercialize vadadustat in the U.S. with CSL Vifor.

Leveraging our learnings from the research and development of vadadustat, and a breadth of scientific expertise on the HIF pathway, we believe there is potential to leverage HIFs to treat other hypoxic conditions and to explore the use of HIFs in acute settings. We believe this potential applies to vadadustat as well as other preclinical assets we are internally developing.

Regarding broader uses of vadadustat, in July 2020 we partially funded an investigator-sponsored clinical trial conducted by The University of Texas Health Science Center at Houston, or UTHealth, in Houston, Texas, evaluating the use of vadadustat as a potential therapy to prevent and treat acute respiratory distress syndrome, or ARDS, in adult patients who have been hospitalized due to COVID-19 and hypoxemia (O2 saturation ≤94%). The study was a phase 2, randomized, double-blind, placebo-controlled trial that measured the proportion of patients who had scores of 6, 7, or 8 on the National Institute of Allergy and Infectious Disease Ordinal Scale, or NIAID-OS, at Day 7 and Day 14, with Day 14 being the primary endpoint. While the study missed the primary endpoint, the data, detailed in the Clinical Development Program section, were encouraging. For reference, subjects receiving vadadustat demonstrated 94% probability for conferring benefit on the NIAID-OS at Day 14, slightly below the primary superiority threshold of >95% probability. We believe vadadustat has the potential to prevent the worsening of ARDS more broadly since the mechanism underlying the benefits are not specific to COVID-19, and we will further explore vadadustat in an acute care setting.

Operating Segments

We operate our business in a single segment and as one reporting unit, which is how our chief operating decision maker (who is our president and chief executive officer) reviews financial performance and allocates resources.

Operating Overview

We have incurred net losses in each year since inception. Our net loss was $11.2 million for the three months ended June 30, 2023 and our net income was $29.4 million for the three months ended June 30, 2022. Our net losses were $38.1 million and $34.1 million for the six months ended June 30, 2023 and 2022, respectively. Substantially all of our net losses resulted from costs incurred in connection with the continued commercialization of Auryxia and development efforts relating to vadadustat, including conducting clinical trials of, and seeking regulatory approval for, vadadustat, providing general and administrative support for these operations and protecting our intellectual property.

We expect to continue to incur additional operating expenses, including additional research and development expenses to our pipeline, additional costs related to vadadustat, and research and development and selling, general and administrative expenses for ongoing development and commercialization of Auryxia, which could lead to operating losses for the foreseeable future. In addition to any additional costs not currently contemplated due to the events associated with or resulting from the workforce reductions noted above, our ability to achieve profitability and our financial position will depend, in part, on the rate of our future expenditures, on our net product revenue from Auryxia, our collaboration revenue, our ability to successfully implement cost avoidance measures and reduce overhead costs and our ability to obtain additional funding. We expect to continue to incur significant expenses if and as we:

- continue our commercialization activities for Auryxia and vadadustat, if we are able to obtain marketing approval for vadadustat following our anticipated NDA resubmission, and any other product or product candidate, including those that may be in-licensed or acquired;
- address the issues identified in the CRL for vadadustat that we received from the FDA and pursue our anticipated NDA resubmission for vadadustat with the FDA;
- conduct and enroll patients in any clinical trials, including post-marketing studies or any other clinical trials for Auryxia, vadadustat or any other product or product candidate, including those that may be in-licensed or acquired;
- seek marketing approvals for vadadustat and any other product candidate, including those that may be in-licensed or acquired;
- maintain marketing approvals for Auryxia and vadadustat, if we are able to obtain marketing approval for vadadustat following our anticipated NDA resubmission, and any other product, including those that may be in-licensed or acquired;
- manufacture Auryxia, vadadustat and any other product or product candidate, including those that may be in-licensed or acquired, for commercial sale and clinical trials;
- conduct discovery and development activities for additional product candidates or platforms that may lead to the discovery of additional product candidates;
- engage in transactions, including strategic, merger, collaboration, acquisition and licensing transactions, pursuant to which we would market and develop commercial products, or develop and commercialize other product candidates and technologies;
- continue to repay, and pay any associated pre-payment penalties, if applicable, the senior secured term loans in an aggregate principal amount of $43.0 million as of June 30, 2023, that were made available to us pursuant to the loan agreement that we entered into with funds managed by Pharmakon Advisors LP, or Pharmakon, in November 2019, or the Loan Agreement;
- make royalty, milestone or other payments under our license agreements and any future license agreements;
- maintain, protect and expand our intellectual property portfolio;
- make decisions with respect to our personnel, including the retention of key employees;
- make decisions with respect to our infrastructure, including to support our operations as a fully integrated publicly traded biopharmaceutical company; and
- experience any additional delays or encounter issues with any of the above.

We have not generated, and may not generate, enough net product revenue to realize net profits from product sales. We have no manufacturing facilities, and all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize contract research organizations, or CROs, to carry out our clinical development activities. If we obtain marketing approval for vadadustat, and as we continue to commercialize Auryxia, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. We expect to finance future cash needs through product revenue, potential strategic transactions, public or private equity or debt transactions, or a combination of these approaches. If we are unable to raise additional capital in sufficient amounts when needed or on attractive terms, we may not be able to pursue development and commercial activities related to Auryxia and vadadustat, if approved, 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.

From inception through June 30, 2023, we raised approximately $793.5 million of net proceeds from the sale of equity, including $519.8 million from various underwritten public offerings, $223.7 million from at-the-market offerings, or ATM offerings, pursuant to 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. As of June 30, 2023, through our collaboration agreement with MTPC and our prior collaboration agreements with Otsuka we received approximately $837.1 million in cost-share funding, and are not entitled to receive any additional cost-share funding. On June 30, 2022, we entered into the Termination and Settlement Agreement, or the Termination Agreement, with Otsuka, pursuant to which we received a nonrefundable and non-creditable payment of $55.0 million in consideration for the covenants and agreements set forth in the Termination Agreement.

On November 11, 2019, we entered into the Loan Agreement pursuant to which term loans in an aggregate principal amount of $100.0 million were made available to us in two tranches, subject to certain terms and conditions, or the Term Loans. On July 15, 2022, or the Effective Date, we entered into the Second Amendment and Waiver with BioPharma Credit PLC, or the Collateral Agent, BPCR Limited Partnership, as a Lender, and BioPharma Credit Investments V (Master) LP, as a Lender, or the Second Amendment and Waiver, which amends and waives certain provisions of the Loan Agreement as amended by the First Amendment and Waiver between the Collateral Agent, the Lenders and us, dated February 18, 2022. The Collateral Agent and the Lenders are collectively referred to as Pharmakon. Pursuant to the Second Amendment and Waiver, we made prepayments totaling $25.0 million together with a prepayment premium of $0.5 million plus all accrued and unpaid interest on such prepayments of principal to the Effective Date, and Pharmakon agreed to waive or modify certain covenants in the Loan Agreement. In addition, on February 25, 2021, we received an upfront payment of $44.8 million (net of certain transaction expenses) in connection with our sale to HealthCare Royalty Partners IV, L.P., or HCR, of the right to receive all royalties and sales milestones payable to us under our collaboration agreement with MTPC, or the MTPC Agreement, subject to certain caps and other terms and conditions described elsewhere in this Quarterly Report on Form 10-Q. On February 18, 2022, we entered into a Second Amended and Restated License Agreement, or the Vifor Second Amended Agreement, with CSL Vifor. Pursuant to the Vifor Second Amended Agreement, CSL Vifor made an upfront payment to us of $25.0 million in lieu of the previously disclosed milestone payment of $25.0 million that CSL Vifor was to pay to us following approval of vadadustat by the FDA. Also pursuant to the Vifor Second Amended Agreement, Vifor contributed $40.0 million to a working capital fund established to partially fund our costs of purchasing vadadustat from our contract manufacturers, or the Working Capital Fund, which amount of funding may fluctuate, and which funding we are required to repay to CSL Vifor over time. Finally, on May 24, 2023, we entered into the Medice License Agreement pursuant to which Medice made an upfront payment to us of $10.0 million.

Impacts of COVID-19 Pandemic

Certain changes that occurred during the recent COVID-19 pandemic, including remote work arrangements, closures, limited access to healthcare facilities and labor shortages impacted us and the broader healthcare industry. During the pandemic, the CKD patient population that we serve experienced both higher hospitalization and mortality rates due to COVID-19 which may or may not continue post-pandemic. Further, the pandemic had an adverse impact on the phosphate binder market in which Auryxia competes. Please see the section captioned "Part II. Item 1A. Risk Factors" of this Quarterly Report on Form 10-Q for additional information with respect to the risks faced by our business in light of the recent COVID-19 pandemic. While the pandemic has ended, we caution that there continues to be a possibility for potential future challenges associated with infections, staffing shortages or supply chain disruptions due to current or new variants of COVID-19 in certain jurisdictions. The impact of these challenges is currently unknown but could be significant, and we continue to take precautions so as not to disrupt our business.

Financial Highlights

Product and Collaboration Revenue

To date, our revenues have been derived from net product revenue from commercial sales of Auryxia, royalties from the sale of Auryxia in Japan and collaboration revenues. Collaboration revenue includes license and milestone payments, royalty and cost-sharing revenue generated through collaboration and license agreements with partners for the development and commercialization of vadadustat, a nonrefundable, non-creditable termination fee pursuant to the terms of the Termination Agreement with Otsuka, and royalty revenue from sales of Riona in Japan. Our net product revenue requires judgement and estimates of rebates and returns which can fluctuate from quarter-to-quarter and year-over-year. In addition, we evaluate at least annually and more frequently if needed, price increases of our commercial product Auryxia.

We expect our product revenue to continue to be generated primarily from our commercial sales of Auryxia. In addition, we expect to continue to generate revenue through our collaborations with Medice, MTPC and JT and Torii and any other collaborations into which we have entered or may enter. We will not recognize any future revenue pursuant to our former collaborations with Otsuka.

Cost of Goods Sold

Cost of goods sold includes costs closely correlated or directly related to the costs to manufacture commercial drug substance and drug product for Auryxia, as well as indirect costs. Direct and indirect costs, including costs for packaging, shipping, insurance and quality assurance, idle capacity charges, write-offs for inventory that fails to meet specifications or is otherwise no longer suitable for commercial sale, changes in our excess 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 goods sold also includes costs to manufacture drug product provided to MTPC for commercial sale of Vafseo in Japan and personnel-related costs, including salaries and bonuses, employee benefits, and stock-based compensation attributable to employees in a particular function and associated with our products.

On June 28, 2018, we entered into an Agreement and Plan of Merger with Keryx and Alpha Therapeutics Merger Sub, Inc., or Merger Sub, pursuant to which Merger Sub merged with and into Keryx, with Keryx becoming a wholly owned subsidiary of ours, or the Merger. On December 12, 2018, we completed the Merger. As part of the purchase price allocation, we identified developed product rights for Auryxia as the primary intangible asset which is being amortized to cost of goods sold over its estimated useful life, which as of June 30, 2023 is estimated to be six years.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of vadadustat, which include:

- personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred under agreements with CROs and investigative sites that conduct our clinical trials;
- the cost of acquiring, developing and manufacturing clinical trial materials through CMOs;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies;
- costs associated with preclinical, clinical and regulatory activities; and
- costs associated with pre-launch inventory build for vadadustat in the United States and Europe, for which we received the CRL from the FDA in the United States in March 2022.

Research and development costs are expensed as incurred. 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 current or future clinical trials of Auryxia and vadadustat or if, when, or to what extent we will receive marketing approval for vadadustat or generate revenue from the commercialization and sale of vadadustat, if approved. We may never succeed in achieving marketing approval for vadadustat.

The duration, costs and timing of clinical trials and development of Auryxia and vadadustat will depend on a variety of factors including, but not limited to, those described in Part II, Item 1A. Risk Factors. A change in the outcome of any of these variables with respect to the development of Auryxia and vadadustat could mean a significant change in the costs and timing associated with that development. For example, if the FDA, the EMA, or other regulatory authorities were to require us to conduct clinical trials in addition to or different from those that we currently anticipate, or if we experience delays in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

From inception through June 30, 2023, we have incurred $1.6 billion in research and development expenses. We expect to incur significant research and development expenditures for the foreseeable future as we continue the development of Auryxia, vadadustat and any other product or product candidate, including those that may be in-licensed or acquired.

Our direct research and development expenses consist principally of external costs, such as fees paid to clinical trial sites, consultants, central laboratories and CROs in connection with our clinical trials, and drug substance and drug product manufacturing for clinical trials.

In 2020, we completed our global Phase 3 clinical program for vadadustat to which the majority of our research and development costs are attributable. A significant portion of our research and development costs have been external costs, which we track on a program-by-program basis. 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. Our internal research and development costs are primarily personnel-related costs, depreciation and other indirect costs. We do not track our internal research and development expenses on a program-by-program basis as they are deployed across multiple projects under development.

The following table summarizes our external research and development expenses by program, as well as expenses not allocated to programs, for the three and six months ended June 30, 2023 and 2022 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Vadadustat external costs	$ 7,418	$ 11,760	$ 13,858	$ 28,913
Other programs external costs	3,423	5,087	5,897	11,440
Total external research and development expenses	10,841	16,847	19,755	40,353
Internal personnel, consulting, facilities and other costs	9,356	9,180	20,128	29,507
Total research and development expenses	$ 20,197	$ 26,027	$ 39,883	$ 69,860

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our commercial personnel, including our field sales force and other commercial support personnel, as well as personnel in executive and other administrative or non-research and development functions. Other selling, general and administrative expenses include facility-related costs, fees for directors, professional service fees (including legal, patent, accounting, audit, tax and consulting fees), insurance costs, general corporate expenses and allocated facilities-related expenses, including rent and maintenance.

Recent Events

Medice License Agreement

On May 24, 2023, we entered into the Medice License Agreement pursuant to which we granted Medice an exclusive license to develop and commercialize vadadustat for the treatment of anemia in patients with CKD in the Medice Territory. We retain the rights to develop and commercialize in the Medice Territory for all other indications. During the quarter ended June 30, 2023 we received an upfront payment of $10.0 million. In the future we may receive commercial milestone payments up to an aggregate of $100 million, and tiered royalties ranging from 10% to 30% of Medice's annual net sales of vadadustat in the Medice Territory, subject to reduction in certain circumstances. See Note 5 of the Notes to the Condensed Consolidated Financial Statements included in Part I, Item I of this Quarterly Report on Form 10-Q.

Boston Lease Assignment

Previously, we leased 27,924 square feet of office space in Boston, Massachusetts, or the Boston Lease. On May 26, 2023, we entered into an Assignment and Assumption of Lease Agreement, or the Lease Assignment Agreement, with LG Chem Life Sciences Innovation Center, Inc., or LG Chem, pursuant to which we assigned all of our rights, title, and interest in, to, and under the Boston Lease to LG Chem, or the Lease Assignment. As part of the Lease Assignment Agreement, we made a payment to LG Chem of $1.3 million, or the Lease Assignment Amount, and LG Chem assumed all of our rights and obligations under the Boston Lease. Subsequent to the Lease Assignment, we have no further obligations for rent or other payments under the Boston Lease. See Note 13 of the Notes to the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Impact of Inflation

We are experiencing rising costs for certain inflation-sensitive operating expenses such as labor and certain service providers that are heavily dependent on labor. We do not believe these impacts were material to net loss during the six months ended June 30, 2023 or will be going forward. However, significant sustained inflation driven by the macroeconomic environment or other factors could negatively impact our margins, profitability, and results of operations in future periods.

Restructuring/Reduction in Workforce

Our ability to achieve profitability depends in part on our ability to manage our operating expenses. Following receipt of the CRL, in the second quarter of 2022, we implemented a restructuring and reduction of our workforce by approximately 42% across all areas of our company including several members of management. On November 7, 2022, we implemented a further reduction in workforce by approximately 14% consisting solely of individuals within the commercial organization as a result of our decision to shift to a strategic account management focused model for our commercial efforts. These actions reflect our determination to refocus our strategic priorities around our commercial product, Auryxia®, and our development portfolio, and were steps in a broader cost savings plan to significantly reduce our operating expense profile. We continue to decrease our operating expenses by seeking to operate more efficiently and curtail non-headcount related expense growth and expect to keep 2023 headcount relatively flat with current levels.

Results of Operations

The tables and discussion below present the results for the periods indicated and the three months ended June 30, 2022 have been updated to reflect the impact of errors revised in prior periods and as described in more detail in Note 3 in the Notes to the Condensed Consolidated Financial Statements found in Part I, Item 1 of this Quarterly Report on Form 10-Q:

Comparison of the Three Months Ended June 30, 2023 and 2022
(dollars in thousands)

	Three Months Ended		Change	
	June 30, 2023	June 30, 2022	$	%
Revenues				
Product revenue, net	$ 42,244	$ 43,309	$ (1,065)	(2)%
License, collaboration and other revenue	14,132	83,056	(68,924)	(83)%
Total revenues	56,376	126,365	(69,989)	(55)%
Cost of goods sold				
Product	8,273	9,589	(1,316)	(14)%
Amortization of intangible asset	9,011	9,011	—	— %
Total cost of goods sold	17,284	18,600	(1,316)	(7)%
Operating expenses				
Research and development	20,197	26,027	(5,830)	(22)%
Selling, general and administrative	27,036	32,240	(5,204)	(16)%
License expense	949	892	57	6 %
Restructuring	(94)	14,531	(14,625)	*
Total operating expenses	48,088	73,690	(25,602)	(35)%
Operating (loss) income	(8,996)	34,075	(43,071)	(126)%
Other expense, net	(1,652)	(4,626)	2,974	(64)%
Loss on lease termination	(524)	—	(524)	*
Net (loss) income	$ (11,172)	$ 29,449	$ (40,621)	(138)%

*Percentage change not meaningful.

Product Revenue, Net—Net product revenue is derived from sales of our only commercial product in the U.S., Auryxia. We distribute our product principally through a limited number of wholesale distributors as well as certain specialty pharmacy providers. Net product revenue was $42.2 million for the three months ended June 30, 2023, compared to $43.3 million for the three months ended June 30, 2022. The decrease was primarily due to the impact of shifting payor mix and a volume decrease partially caused by contracting dynamics and a decline in the phosphate binder market. The decline was partially offset by higher revenues resulting from a price increase in January 2023

License, Collaboration and Other Revenue—License, collaboration and other revenue was $14.1 million for the three months ended June 30, 2023, compared to $83.1 million for the three months ended June 30, 2022. The decrease was primarily due to a reduction in revenue from the Otsuka collaboration agreement that was terminated on June 30, 2022. The Termination Agreement, among other things, terminated the cost sharing arrangement under the Otsuka collaboration agreement for the U.S. the Otsuka U.S. Agreement, and the Otsuka collaboration agreement for certain territories outside the U.S., or the Otsuka International Agreement. During the three months ended June 30, 2022, we recognized $55.0 million in collaboration revenue related to a payment to be received pursuant to the terms of the Termination Agreement with Otsuka, $15.5 million related to previously deferred revenue as of the date of termination and $9.6 million of non-cash consideration related to Otsuka's obligations to complete certain agreed upon clinical activities related to the Phase 3b clinical trial of vadadustat that Otsuka was conducting, or the MODIFY Study, in accordance with the current study protocol, at its own cost and expense. During the three months ended June 30, 2023, we recognized $2.2 million in collaboration revenue in connection with the Packaging Validation Transfer Agreement we entered into with Otsuka on April 20, 2023. However, we do not expect to recognize any future revenue under the Otsuka U.S. Agreement or the Otsuka International Agreement. This decrease was partially offset by the $10.0 million upfront payment recognized in connection with the Medice License Agreement during the three months ended June 30, 2023.

Cost of Goods Sold - Product—Cost of goods sold was $8.3 million for the three months ended June 30, 2023 compared to $9.6 million for the three months ended June 30, 2022. The decrease of $1.3 million is primarily due to a decrease in inventory

write-downs as a result of excess, obsolescence, scrap or other reasons and charged to cost of goods sold during the three months ended June 30, 2023.

Cost of Goods Sold - Amortization of Intangible Asset—Amortization of intangible asset relates to the acquired developed product rights for Auryxia, which is being amortized using a straight-line method over its estimated useful life of approximately six years. Amortization of intangible asset during each of the three months ended June 30, 2023 and 2022 was $9.0 million.

Research and Development Expenses—Research and development expenses were $20.2 million for the three months ended June 30, 2023, compared to $26.0 million for the three months ended June 30, 2022, a decrease of $5.8 million. The decrease was primarily due to a reduction in spending on vadadustat development, including decreased clinical trial costs as well as decreased outsourced contract services. Although we expect our research and development expenses to continue to decrease in the near term, we will continue to incur significant research and development expenses in future periods in support of ongoing or planned studies with respect to Auryxia and vadadustat and development of other potential product candidates.

Selling, General and Administrative Expenses—Selling, general and administrative expenses were $27.0 million for the three months ended June 30, 2023, compared to $32.2 million for the three months ended June 30, 2022. The decrease of $5.2 million was primarily due to decreased headcount related costs as a result of the April and November 2022 reductions in force, reduced Auryxia marketing and promotional expenses and reduced professional service expenses.

License Expenses—License expense related to royalties due to Panion relating to sales of Riona in Japan were $0.9 million for each of the three months ended June 30, 2023 and 2022.

Restructuring—Restructuring expenses were $14.5 million for the three months ended June 30, 2022 that were incurred in connection with our reductions of our workforce in the second quarter 2022 by approximately 42% across all areas of our company including several members of management.

Other Expense, Net—Other expense, net, was $1.7 million for the three months ended June 30, 2023, compared to $4.6 million for the three months ended June 30, 2022. The decrease of $3.0 million was primarily due to a decrease in interest expense as a result of reducing our outstanding principal balance on the Pharmakon Term Loans by $57.0 million since the period ended June 30, 2022. This decrease was offset by nearly a 135 basis point increase in the interest rate as a result of the current rising interest rate macroeconomic environment. In addition, our non-cash interest expense from our liability for the sale of future royalties decreased due to a drop in the effective interest rate on the liability for the three months ended June 30, 2023 compared to the three months ended June 30, 2022.

Loss on Lease Termination—Loss on lease termination was $0.5 million for the three months ended June 30, 2023. On May 26, 2023, we entered into the Lease Assignment Agreement with LG Chem, pursuant to which we assigned all of our rights, title, and interest in, to, and under the Boston Lease to LG Chem. In accordance with ASC 842, *Leases*, we wrote off the right-of-use asset and lease liability associated with the Boston Lease, and recognized the difference between the right-of-use asset and the lease liability offset by the payment we made to LG Chem of $1.3 million, or the Lease Assignment Amount, as a loss on lease termination in the condensed consolidated statement of operations and comprehensive income (loss) of $0.5 million during the three months ended June 30, 2023.

The tables and discussion below present the results for the periods indicated and the six months ended June 30, 2022 have been updated to reflect the impact of errors revised in prior periods and as described in more detail in Note 3 in the Notes to the Condensed Consolidated Financial Statements found in Part I, Item 1 of this Quarterly Report on Form 10-Q:

Comparison of the Six Months Ended June 30, 2023 and 2022
(dollars in thousands)

	Six Months Ended		Change	
	June 30, 2023	June 30, 2022	$	%
Revenues				
Product revenue, net	$ 76,950	$ 84,681	$ (7,731)	(9)%
License, collaboration and other revenue	19,431	$ 103,307	(83,876)	(81)%
Total revenues	96,381	187,988	(91,607)	(49)%
Cost of goods sold				
Product	19,452	$ 32,694	(13,242)	(41)%
Amortization of intangible asset	18,021	18,021	—	— %
Total cost of goods sold	37,473	50,715	(13,242)	(26)%
Operating expenses				
Research and development	39,883	69,860	(29,977)	(43)%
Selling, general and administrative	52,090	76,806	(24,716)	(32)%
License expense	1,517	1,580	(63)	(4)%
Restructuring	12	14,531	(14,519)	*
Total operating expenses	93,502	162,777	(69,275)	(43)%
Operating loss	(34,594)	(25,504)	(9,090)	36 %
Other expense, net	(2,932)	(8,554)	5,622	(66)%
Loss on lease termination	(524)	—	(524)	*
Net loss	$ (38,050)	$ (34,058)	$ (3,992)	12 %

*Percentage change not meaningful.

Product Revenue, Net—Net product revenue is derived from sales of our only commercial product in the U.S., Auryxia. We distribute our product principally through a limited number of wholesale distributors as well as certain specialty pharmacy providers. Net product revenue was $77.0 million for the six months ended June 30, 2023, compared to net product revenue of $84.7 million for the six months ended June 30, 2022. The decrease was primarily due to a decline in volume and impact of shifting payor mix partially caused by contracting dynamics and a decline in the phosphate binder market. In addition, the decline was partially offset by higher revenues resulting from a price increase in January 2023.

License, Collaboration and Other Revenue—License, collaboration and other revenue was $19.4 million for the six months ended June 30, 2023 compared to $103.3 million for the six months ended June 30, 2022. The decrease was primarily due to a reduction in revenue from the Otsuka collaboration agreement that we terminated on June 30, 2022 pursuant to the Termination Agreement which, among other things, terminated the cost sharing arrangement under the Otsuka collaboration agreement for the Otsuka U.S. Agreement, and the Otsuka International Agreement. During the six months ended June 30, 2022, we recognized $55.0 million in collaboration revenue related to a payment to be received pursuant to the terms of the Termination Agreement with Otsuka, $15.5 million related to previously deferred revenue as of the date of termination and $9.6 million of non-cash consideration related to Otsuka's obligations to complete certain agreed upon clinical activities related to the MODIFY Study in accordance with the current study protocol, at its own cost and expense. We also recognized $19.1 million in collaboration revenue for the six months ended June 30, 2022 from the Otsuka U.S. Agreement and the Otsuka International Agreement prior to the termination, as well as royalty revenue under the MTPC Agreement. We recognized $2.2 million in collaboration revenue in connection with the Packaging Validation Transfer Agreement during the six months ended June 30, 2023. However, we do not expect to recognize any future revenue under the Otsuka U.S. Agreement, the Otsuka International Agreement or the Packaging Validation Transfer Agreement.

Additionally, on December 16, 2022, we, MTPC, and Esteve Química, S.A., or Esteve, executed an Assignment of Supply Agreement, or the Esteve Assignment Agreement, pursuant to which the supply agreement between us and Esteve, or the Esteve Agreement, was assigned to MTPC. The Esteve Assignment Agreement transferred the rights and obligations of the

Esteve Agreement to MTPC, including the obligations under certain purchase orders issued by us and accepted by Esteve. Therefore, we expect significantly less revenue in the future under our supply agreement with MTPC. This decrease was partially offset by the $10.0 million upfront payment received as part of the Medice License Agreement signed during the three months ended June 30, 2023.

Cost of Goods Sold - Product. Cost of goods sold was $19.5 million for the six months ended June 30, 2023, compared to $32.7 million for the six months ended June 30, 2022. The decrease of $13.2 million is primarily due to a decrease in inventory write-downs as a result of excess, obsolescence, scrap or other reasons and charged to cost of goods sold during the six months ended June 30, 2023, as well as a decrease in sales volume.

Cost of Goods Sold - Amortization of Intangible Asset—Amortization of intangible asset relates to the acquired developed product rights for Auryxia, which is being amortized using a straight-line method over its estimated useful life of approximately six years. Amortization of intangible asset during each of the six months ended June 30, 2023 and 2022 was $18.0 million.

Research and Development Expenses—Research and development expenses were $39.9 million for the six months ended June 30, 2023, compared to $69.9 million for the six months ended June 30, 2022, a decrease of $30.0 million. The decrease was primarily due to a reduction of vadadustat development expenses of approximately $20.6 million.

In addition, research and development expense declined by approximately $9.4 million due to the reduced headcount related costs as a result of the 2022 reduction in force, decreased outsourced consulting and contract services, and decreased clinical trial costs and development expenses related to vadadustat. Although we expect our research and development expenses to continue to decrease in the near term, we will continue to incur significant research and development expenses in future periods in support of ongoing or planned studies with respect to Auryxia and vadadustat and development of other potential product candidates.

Selling, General and Administrative Expenses—Selling, general and administrative expenses were $52.1 million for the six months ended June 30, 2023, compared to $76.8 million for the six months ended June 30, 2022.The decrease of $24.7 million was primarily due to decreased headcount related costs as a result of the 2022 reductions in force and lower marketing and promotional expenses.

License Expenses—License expense related to royalties due to Panion relating to sales of Riona in Japan was $1.5 million and $1.6 million for the six months ended June 30, 2023 and 2022, respectively.

Restructuring—Restructuring expenses were $14.5 million for the six months ended June 30, 2022 that were incurred in connection with our reduction of our workforce in the second quarter 2022 by approximately 42% across all areas of our company including several members of management.

Other Expense, Net—Other expense, net, was $2.9 million for the six months ended June 30, 2023 compared to $8.6 million for the six months ended June 30, 2022. The decrease of $5.6 million was primarily due to a decrease in interest expense as a result of reducing our outstanding principal balance on the Pharmakon Term Loans by $57.0 million since the period ended June 30, 2022. This decrease was offset by nearly 135 basis point increase in the interest rate as a result of the current rising interest rate macroeconomic environment. In addition, our non-cash interest expense from our liability for the sale of future royalties decreased due to a drop in the effective interest rate on the liability for the six months ended June 30, 2023 compared to the six months ended June 30, 2022.

Loss on Lease Termination—On May 26, 2023 we incurred a loss on lease termination of $0.5 million in connection with the Lease Assignment Agreement, with LG Chem pursuant to which we assigned all of our rights, title, and interest in, to, and under the Boston Lease to LG Chem. In accordance with ASC 842, *Leases*, we wrote off the right-of-use asset and lease liability associated with the Boston Lease, and recognized the difference between the right-of-use asset and the least liability offset by the Lease Assignment Amount as a loss on lease termination in the condensed consolidated statement of operations and comprehensive income (loss) of $0.5 million during the six months ended June 30, 2023.

Liquidity and Capital Resources

Historical Cash Flows

We have incurred recurring losses from inception and anticipate net losses and negative operating cash flows for the near future. For the six months ended June 30, 2023 and 2022, we incurred net operating losses of $38.1 million and $34.1 million, respectively.

As of June 30, 2023 and December 31, 2022, we had an accumulated deficit of $1,595.1 million and $1,557.0 million, respectively.

Our primary uses of capital are, and we expect will continue to be for the near future, funding operating activities, principal payments on our debt and funding our vadadustat inventory on hand which is included in research and development expense on the condensed consolidated statement of operations and comprehensive income (loss). Our cash flows may fluctuate and are difficult to forecast and will depend on many factors.

Cash and Cash Equivalents

As of June 30, 2023 and December 31, 2022, we had cash and cash equivalents of $53.6 million and $90.5 million, respectively.

Sources of Liquidity

Term Loans

As of June 30, 2023, we had outstanding debt of $42.5 million, net of debt issuance costs. See Note 11, *Debt*, in the accompanying notes to the consolidated financial statements included in Part I, Item 1 of this Form 10-Q for further information. As of June 30, 2023, we were in compliance with these covenants. On August 11, 2023, we received an extension from Pharmakon of the deadline in the Loan Agreement with respect to our obligation to deliver quarterly financial statements for the period ended June 30, 2023 through August 28, 2023.

At-the-Market Offering

On April 7, 2022, we entered into an Open Market Sale Agreement℠, or the Sales Agreement, with Jefferies LLC, or Jefferies, as agent, for the offer and sale of common stock at current market prices in amounts to be determined from time to time. Also, on April 7, 2022, we filed a prospectus supplement relating to the Sales Agreement, pursuant to which we are able to offer and sell under the Sales Agreement up to $26.0 million of our common stock at current market prices from time to time. From the date of filing of the prospectus supplement through the date of the filing of this Quarterly Report on Form 10-Q, we have not sold any shares of our common stock under this program.

Cost-Share Funding

As of June 30, 2023, through our former and current collaboration agreements with Otsuka and MTPC, respectively, we received approximately $837.1 million in cost-share funding, and are not entitled to receive any additional cost-share funding.

Contractual Obligations, Commitments and Contingencies Other than Debt

We are party to contractual obligations involving commitments to make payments to third parties in the future. Certain contractual obligations are reflected on our condensed consolidated balance sheet as of June 30, 2023, while others are considered future obligations. Our material cash requirements as of June 30, 2023, include the following contractual obligations and commitments arising in the normal course of business, including leases, purchases commitments, and purchase obligations described in more detail below.

As of June 30, 2023, other than as disclosed in Note 11, *Debt*, and Note 13, *Commitments and Contingencies*, in the accompanying notes to the consolidated financial statements included in Part I, Item 1 of this From 10-Q, there have been no material changes to our contractual obligations and commitments from those described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our 2022 Annual Report on Form 10-K/A.

Off-Balance Sheet Arrangements

Letter of Credit

As of June 30, 2023, in connection with our leased properties in Cambridge, MA, we had $1.7 million in a letter of credit outstanding.

Director and Officer Indemnification

We have entered into indemnification agreements with our directors and certain officers that will require us, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. No demands have been made upon us to provide indemnification under such agreements and there are no claims that we are aware of that could have a material effect on our consolidated financial statements.

Cash Flows

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

	Six Months Ended	
NET CASH PROVIDED BY/(USED IN) (*in thousands*):	**June 30, 2023**	**June 30, 2022**
Operating activities	$ (13,909)	$ (52,280)
Investing activities	—	(114)
Financing activities	(23,966)	47,536
Decrease in cash, cash equivalents and restricted cash	$ (37,875)	$ (4,858)
Cash, cash equivalents and restricted cash — beginning of period	93,169	151,839
Cash, cash equivalents and restricted cash — end of period	**$ 55,294**	**$ 146,981**

Operating Activities

Net cash used in operating activities was $13.9 million for the six months ended June 30, 2023. Net cash used in operating activities consists of a net loss of $38.1 million, adjusted for non-cash items such as amortization of our intangible asset of $18.0 million, stock-based compensation expense of $6.0 million and the effect of changes in working capital. In addition, we had a one time expense related to the termination of our Boston Lease of $0.8 million.

Net cash used in operating activities was $52.3 million for the six months ended June 30, 2022. Net cash used in operating activities consists of a net loss of $34.1 million, adjusted for non-cash items such as amortization of intangible asset of $18.0 million, stock-based compensation expense of $11.5 million, non-cash collaboration revenue decrease of $9.6 million, non-cash interest and royalty revenue related to the sale of future royalties and the effect of changes in working capital.

Investing Activities

No net cash was used in investing activities for the six months ended June 30, 2023.

Net cash used in investing activities for the three months ended June 30, 2022 was $0.1 million and was primarily comprised of purchases of equipment.

Financing Activities

Net cash used in financing activities for the six months ended June 30, 2023 primarily consisted of principal payments of debt of $24.0 million. On June 29, 2023, we entered into the Third Amendment to the Loan Agreement with Pharmakon, which replaced LIBOR with the Secured Overnight Financing Rate, or SOFR, effective June 30, 2023. As of and for the six months ended June 30, 2023, the effect of switching from LIBOR to SOFR would not have been material to our consolidated financial statements.

Net cash provided by financing activities for the three months ended June 30, 2022 was $47.5 million and consisted of net proceeds from a refund liability to a customer of $40.0 million, net proceeds from the issuance of common stock of $7.1 million, and proceeds from the sale of stock under our employee stock purchase plan.

Operating Capital Requirements

We have funded our operations principally through sales of our common stock, including through our employee stock purchase plan, payments received from our collaboration and licensing partners, product sales, a working capital payment from Vifor, debt and a royalty transaction. We have one product, Auryxia, approved for commercial sale in the United State, and we have not generated, and may not generate, enough product revenue from the sale of Auryxia to realize net profits from product sales. We currently have exclusive rights under a series of patents and patent applications to commercialize Auryxia in the U.S. that currently protect us from generic drug competition until March 2025. Following loss of exclusivity in the U.S., we may not be

able realize enough product revenue from sales of Auryxia to realize net profits from product sales after March 2025. We have incurred losses and cumulative negative cash flows from operations in each year since our inception in February 2007, and as of June 30, 2023, we had an accumulated deficit of $1.6 billion.

Our current operating plan anticipates continued increasing levels of cash flows from operations. We also expect to continue to incur additional research and development expenses related to our pipeline, additional costs related to vadadustat, and research and development and selling, general and administrative expenses for our ongoing development and commercialization of Auryxia. The revenue from sales of our only commercial product Auryxia at the present time is not sufficient to cover our long-term operating costs. Our ability to achieve sufficient revenue to cover our long-term operating costs is highly dependent upon us obtaining market approval for vadadustat in the U.S.

We expect our cash resources to fund our current operating plan for at least twelve months from the date of this filing. We expect to finance future cash needs through product revenue, potential strategic transactions, public or private equity or debt transactions, expense management, or a combination of these approaches. We plan to reduce our need for future financing through product sales, expense management, and cost avoidance measures in line with being a single commercial product company. We believe our expense management, future decisions by the FDA or foreign regulatory agencies related to the potential regulatory approval of vadadustat, and our ability to generate additional value from vadadustat, if approved, could potentially further extend our cash runway for a period greater than twelve months. However, these future decisions and transactions are not contemplated in our operating plan and are outside of our control. Additionally, with loss of exclusivity, or LOE, for Auryxia in March of 2025, we believe the Centers for Medicare & Medicaid Services, or CMS, decision to include phosphate binders in the dialysis bundle could potentially lead to higher sales of Auryxia after the LOE date than in other LOE scenarios, and plan to work with payors and providers to continue the use of Auryxia beyond LOE. Assuming we are successful in those endeavors, we will require additional funding to fund our strategic growth beyond Auryxia or to pursue later stage development and commercial activities for our product candidates and any additional product or product candidates, including those that may be in-licensed or acquired.

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. If our operating performance deteriorates significantly from the levels expected in our operating plan, it would have an effect on our liquidity and our ability to continue as a going concern in the future. 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."

Critical Accounting Estimates and Significant Judgments

Our management’s discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our unaudited condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue, inventory, our excess purchase commitment liability, liabilities related to sale of future royalties, refund liabilities to customers, impairment of intangible asset, stock-based compensation expense and income taxes. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies.

During the six months ended June 30, 2023, there were no material changes to our methodologies used for our critical accounting estimates as reported in our 2022 Annual Report on Form 10-K/A.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, please see Note 2 of the Notes to the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2023 and December 31, 2022, we had cash and cash equivalents of $53.6 million and $90.5 million, respectively, consisting primarily of money market mutual funds.

Interest rate sensitivity is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our investments are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

In addition, we are exposed to market risk related to exchange rates. A portion of our revenues for the six months ended June 30, 2023 was received in royalty payments converted to U.S. dollars based on the net sales of Riona and Vafseo in Japanese yen. 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 against the U.S. dollar.

For the royalty payments we received based on net sales of Riona and Vafseo in Japan for the six months ended June 30, 2023, a 5.0% appreciation or depreciation of the Japanese yen against the U.S. dollar would have increased or decreased, respectively, our revenues in the six months ended June 30, 2023 by approximately $0.2 million.

We have generally accepted the exposure to exchange rate movements without using derivative financial instruments to manage this foreign currency risk.

Item 4. Controls and Procedures.

Management's Evaluation of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits 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 the Company's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure

Based on an evaluation under the supervision and with the participation of the Company's management, the Company's principal executive officer and principal financial officer have concluded that the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, were not effective as of June 30, 2023 due to the material weakness in internal control over financial reporting described below.

As previously disclosed in the Company's 2022 Annual Report on Form 10-K/A, in connection with the preparation of its financial statements for the quarter ended June 30, 2023, the Company's management identified a material weakness in its internal control over financial reporting. Specifically, the Company did not appropriately design the controls for the accrual of product returns to capture the return lag based on the Company's customer returns policy for Auryxia, or Product Return Reserve Material Weakness. While this control deficiency did not result in a material misstatement of the Company's consolidated financial statements, there is a reasonable possibility this control deficiency could have resulted in a material misstatement of the Company's annual or interim consolidated financial statements that would not be prevented or detected on a timely basis. Therefore, management concluded this control deficiency constitutes a material weakness.

Remediation Efforts of Product Return Reserve Material Weakness

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

For example, we are in the process of: (i) implementing and documenting a new methodology and new controls to help to ensure the completeness and accuracy of our product return reserves, (ii) engaging additional third party subject matter experts and accounting personnel with U.S. GAAP experience specific to product returns accounting and (iii) establishing effective monitoring and oversight controls to help to ensure the completeness and accuracy of our accrued product returns included in our financial statements and related disclosures.

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

Changes in Internal Control over Financial Reporting

Except for the material weakness as noted in the preceding paragraphs, there have been no changes in the Company's internal control over financial reporting during the three months ended June 30, 2023, which were identified in connection with management's evaluation required by paragraph (d) of Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act,

that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Legal Proceedings Relating to Vadadustat

Opposition Proceedings Against Akebia

In September 2018, Dr. Reddy's Laboratories Limited filed an opposition to our issued Indian Patent No. 287720 in the Indian Patent Office.

On July 26, 2022, Sandoz AG filed an opposition against our issued European Patent No. 3277270 in the European Patent Office. An oral hearing is scheduled for February 6, 2024.

On February 13, 2023, FibroGen, Inc., or FibroGen, filed an opposition against our issued European Patent No. 3357911 in the European Patent Office.

Proceedings Filed by Akebia Against FibroGen, Inc.

Japan

In 2018, we and our collaboration partner in Japan, Mitsubishi Tanabe Pharma Corporation, or MTPC, jointly filed a Request for Trial before the JPO to challenge the validity of certain of FibroGen's HIF-related patents in Japan: JP4845728, JP5474872 and JP5474741. On September 26, 2019, the JPO conducted an invalidation trial for JP5474872 and JP4845728. On November 11, 2019, the JPO conducted an invalidation trial for JP5474741. On April 1, 2022, the JPO issued a final decision for JP4845728, which invalidated all claims except claims directed to the medical use to treat anemia that does not respond to erythropoiesis. On May 18, 2022, the JPO issued a final decision for JP5474741 and JP5474872, which maintained the claims in amended form. In May 2022, MTPC filed revocation lawsuits for the three patents in the Intellectual Property High Court requesting cancellation of the JPO's decisions. In July 2022, we filed a revocation lawsuit for JP4845728 in the Intellectual Property High Court requesting cancellation of the JPO's decision. In August 2022, we filed revocation lawsuits for JP5474741 and JP5474872 in the Intellectual Property High Court requesting cancellation of the JPO's decisions. In September 2022, FibroGen filed a revocation lawsuit for JP4845728 in the Intellectual Property High Court requesting cancellation of the JPO's decision on the claims that were invalidated. We do not believe the JPO's decisions will prevent our collaboration partner MTPC from continuing to commercialize vadadustat for the treatment of anemia due to CKD in Japan.

United Kingdom

On December 13, 2018, we filed Particulars of Claim in the Patents Court of the United Kingdom to challenge the validity of FibroGen's six HIF-related patents in the UK: the '823 EP Patent (UK), the '333 EP Patent (UK), the '153 EP Patent (UK), the '155 EP Patent (UK), European Patent (UK) No. 2,289,531, or the '531 EP Patent (UK), and European Patent (UK) No. 2,298,301, or the '301 EP Patent (UK). In May 2019, Astellas Pharma Inc., or Astellas, the exclusive licensee of FibroGen's HIF-related patents, sued Akebia for patent infringement in the Patents Court of the UK. In September 2019, we filed an Amended Particulars of Claim to include FibroGen's European Patent No. 1487472, or the '472 EP Patent (UK). On February 28, 2020, the parties agreed to dismiss the '472 EP Patent (UK) from the trial.

A trial was conducted in March 2020. On April 20, 2020, the Patents Court of the UK issued a judgment in favor of Akebia, which invalidated all the claims at issue in each of the '823 EP Patent (UK), the '333 EP Patent (UK), the '153 EP Patent (UK), the '155 EP Patent (UK) and the '301 EP Patent (UK). The '531 EP Patent (UK) was amended to a single claim to recite one specific compound; this claim was held to be valid but not infringed by vadadustat. On June 11, 2020, FibroGen and Astellas appealed the Patents Court's judgment on the invalidity of the '823 EP Patent (UK), the '301 EP Patent (UK), the '333 EP Patent (UK), the '153 EP Patent (UK), and the '155 EP Patent (UK) in the Court of Appeal (Civil Division). On June 8, 2021 - June 10, 2021, the United Kingdom Court of Appeal held a three-day hearing for the appeal. On August 24, 2021, the Court of Appeal issued a judgment, which reversed the Patents Court's judgment on the invalidity of the '823 EP Patent (UK) and maintained certain claims of the '823 EP Patent (UK) and the '301 EP Patent (UK) in amended form, and which affirmed the Patents Court's judgment on the invalidity of the '333 EP Patent (UK), the '155 EP Patent (UK), and the '153 EP Patent (UK). Akebia sought permission to appeal to the UK Supreme Court, which was granted on October 3, 2022. Hearing for the appeal is scheduled for March 5-7, 2024. We do not expect the UK Court of Appeal's judgment to have any effect on our commercialization of vadadustat in the UK because the patents expired in December 2022.

Legal Proceedings Relating to Auryxia

ANDA Litigation

In February 2023, Keryx Biopharmaceuticals, Inc., or Keryx, received a Paragraph IV certification notice letter regarding an Abbreviated New Drug Application, or ANDA, submitted to the U.S. Food and Drug Administration, or FDA, by Zydus Worldwide DMCC requesting approval for a generic version of Auryxia tablets (210 mg ferric iron per tablet). On March 24, 2023, Keryx and Panion & BF Biotech, Inc., or Panion, filed a complaint for patent infringement against Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited, or collectively Zydus, in the Delaware District Court arising from Zydus' ANDA filing with the FDA. On May 30, 2023, Keryx and Panion entered into a settlement and license agreement with Zydus, which resolved the patent litigation brought by Keryx and Panion. Such settlement and license agreement, consistent with Keryx's prior ANDA settlements, granted Zydus a license to market a generic version of Auryxia in the United States beginning on March 20, 2025 (subject to FDA approval), or earlier under certain circumstances customary for settlement agreements of this nature. Additionally, in accordance with the settlement and license agreement, the parties terminated all ongoing litigation among Keryx, Panion, and Zydus regarding Auryxia patents pending in the Delaware District Court. The settlement and license agreement is confidential and subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice. On June 5, 2023, the Delaware District Court entered a stipulation and order of dismissal filed by the parties to terminate the action against Zydus.

Stockholder Litigation Relating to the Merger

On June 28, 2018, we entered into an Agreement and Plan of Merger with Keryx and Alpha Therapeutics Merger Sub, Inc., or the Merger Sub, pursuant to which the Merger Sub merged with and into Keryx, with Keryx becoming a wholly owned subsidiary of ours, or the Merger. On December 12, 2018, we completed the Merger.

On July 15, 2021, a purported former Keryx stockholder filed a putative class action in the Supreme Court of the State of New York against Akebia, a current officer of Akebia (John P. Butler), a former officer of Akebia (Jason A. Amello), former directors of Akebia (Muneer A. Satter, Scott A. Canute, Michael D. Clayman, Maxine Gowen, Duane Nash, Ronald C. Renaud, Jr., and Michael S. Wyzga), a current director of Akebia (Cynthia Smith), a former director and officer of Keryx (Jodie P. Morrison), a former officer of Keryx (Scott A. Holmes) and former directors of Keryx (Michael Rogers, Kevin J. Cameron, Steven C. Gilman, Daniel P. Regan, Mark J. Enyedy, and Michael T. Heffernan, some of whom are current members of our Board of Directors). The action is captioned Loper v. Akebia Therapeutics, Inc., et al., or the *Loper* Action. The complaint in the *Loper* Action alleges that the registration statement filed in connection with the Merger contained allegedly false and misleading statements or failed to disclose certain allegedly material information in violation of Section 11, 12(a)(2), and 15 of the Securities Act of 1933, as amended. It alleges, among other things, that Akebia failed to disclose heightened safety risks that allegedly threatened the prospects of the Phase 3 PRO2TECT clinical trial and the commercial viability of vadadustat. The complaint in the *Loper* Action seeks damages including interest thereon, an award of plaintiffs' and the class's costs and expenses, including counsel fees and expert fees, and rescission, disgorgement, or such other equitable or injunctive relief that the Court deems appropriate.

On August 16, 2021, another purported former Keryx stockholder filed a putative class action making substantially similar allegations and asserting the same claims as the *Loper* Action, also in the Supreme Court of the State of New York against Akebia and many of the same individual defendants named in the *Loper* Action. The action is captioned Panicho v. Akebia Therapeutics, Inc., et al., or the *Panicho* Action.

On September 13, 2021, the parties in the *Loper* Action and *Panicho* Action entered into a joint stipulation and proposed order, which provided for the consolidation of the two actions under the caption In re Akebia Therapeutics, Inc. Securities Litigation, or the Consolidated State Action. On October 27, 2021, plaintiffs filed a consolidated complaint in the Consolidated State Action. On January 10, 2022, defendants moved to dismiss the consolidated complaint in its entirety. Briefing on defendants' motion to dismiss was completed on April 22, 2022. Oral argument was held on October 7, 2022, and the Court dismissed the complaint without prejudice on October 17, 2022, giving plaintiffs thirty days to amend their complaint. On November 16, 2022, plaintiffs filed an amended consolidated complaint, asserting the same claims and seeking the same relief as the consolidated complaint. On January 18, 2023, defendants moved to dismiss the amended consolidated complaint in its entirety. Briefing on defendants' motion to dismiss the amended consolidated complaint was completed on April 5, 2023. Oral argument is currently scheduled to be held on October 18, 2023.

We deny any allegations of wrongdoing and intend to continue vigorously defending against the one active stockholder lawsuit described in this Legal Proceedings section, the Consolidated State Action. There is no assurance, however, that we will be successful in the defense of this action, or any associated appeals, or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of this action. Moreover, we are unable to predict the outcome or reasonably estimate a range of possible losses at this time. A resolution of the Consolidated State Action in a manner adverse to us, however, could have a material effect on our financial position and results of operations in the period in which the action is resolved.

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 significant losses and cannot guarantee when, if ever, we will become profitable or attain positive cash flows.

Investment in pharmaceutical product development and commercialization is highly speculative because it requires upfront capital expenditures and 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 research and development, including our preclinical and clinical development activities, commercializing Auryxia, and providing general and administrative support for these operations. We have financed our operations primarily through sales of equity securities, our strategic collaborations and product revenues, a royalty monetization transaction and debt. Prior to our merger, or the Merger, with Keryx Biopharmaceuticals, Inc., or Keryx, whereby Keryx became our wholly owned subsidiary, we had no products approved for commercial sale and had not generated any revenue from the sale of products. We are not currently profitable, and we have incurred net losses each year since our inception, including a net loss of $11.2 million for the three months ended June 30, 2023. As of June 30, 2023, we had an accumulated deficit of $1.6 billion. We cannot guarantee when, if ever, we will become profitable.

In March 2022, we received a complete response letter, or CRL, from the U.S. Food and Drug Administration, or FDA, regarding our new drug application, or NDA, for vadadustat, our lead investigational product candidate, for the treatment of anemia associated with CKD. The FDA concluded that the data in the NDA do not support a favorable benefit-risk assessment of vadadustat for dialysis and non-dialysis patients. In October 2022, we submitted a Formal Dispute Resolution Request, or FDRR, to the FDA and focused on the favorable balance between the benefits and risks of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis in light of safety concerns expressed by the FDA in the CRL for dialysis patients related to the rate of adjudicated thromboembolic events driven by vascular access thrombosis for vadadustat compared to the active comparator and the risk of drug-induced liver injury. In May 2023, the Office of New Drugs, or OND, denied our appeal but provided a path forward for us to resubmit the NDA for vadadustat for the treatment of anemia due to CKD for dialysis dependent patients without the need for us to generate additional clinical data. In July 2023, we held an End of Dispute Type A meeting with the FDA to align on the contents of the NDA resubmission. We expect to resubmit the NDA by the end of the third quarter of 2023, with a potential Prescription Drug User Fee Act, or PDUFA, date that we project will be in March 2024. There can be no assurances that we will be successful in our anticipated NDA resubmission and obtain approval for vadadustat in a timely manner, on favorable terms, or at all. As a result, the regulatory approval process for vadadustat in the U.S. is highly uncertain. We may not obtain approval at all, and if we are able to obtain approval, the expense and time to do so could adversely impact our ability to successfully commercialize vadadustat or conduct our other business operations, and our financial condition could be materially harmed.

Our ability to generate product revenue and achieve profitability depends on the overall success of Auryxia(R), vadadustat, if approved, and any current or future product candidates, including those that may be in-licensed or acquired, which depends on several factors, including:

- obtaining adequate or favorable pricing and reimbursement from private and governmental payors for Auryxia, vadadustat, if approved, and any other product or product candidate, including those that may be in-licensed or acquired;
- obtaining and maintaining market acceptance of Auryxia, vadadustat, if approved, and any other product candidate, including those that may be in-licensed or acquired;
- the size of any market in which Auryxia, vadadustat and any other product or product candidate, including those that may be in-licensed or acquired, receives approval and obtaining adequate market share in those markets;
- addressing the issues identified in the CRL for vadadustat that we received from the FDA and the outcome of our anticipated NDA resubmission;
- the timing and scope of marketing approvals for vadadustat, if approved, and any other product candidate, if approved, including those that may be in-licensed or acquired;
- maintaining marketing approvals for Auryxia, vadadustat, if approved, and any other product, including those that may be in-licensed or acquired;

- actual or perceived advantages or disadvantages of our products or product candidates as compared to alternative treatments, including their respective safety, tolerability and efficacy profiles, the potential convenience and ease of administration and cost;
- maintaining an acceptable safety and tolerability profile of our approved products, including the frequency and severity of any side effects;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, based, in part, on their perception of our clinical trial data and/or the actual or perceived safety, tolerability and efficacy profile;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate supplies of products that are compliant with good manufacturing practices, or GMPs, to support the clinical development and the market demand for Auryxia, vadadustat, if approved, and any other product and product candidate, including those that may be in-licensed or acquired;
- current and future restrictions or limitations on our approved or future indications and patient populations or other adverse regulatory actions or in the event that the FDA requires Risk Evaluation and Mitigation Strategies, or REMS, or risk management plans that use restrictive risk minimization strategies;
- the effectiveness of our collaborators' and our sales, marketing, manufacturing and distribution strategies and operations;
- competing effectively with any products for the same or similar indications as our products;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents and trade secrets; and
- the impact of the recent COVID-19 pandemic on the above factors, including the disproportionate impact of the recent COVID-19 pandemic on CKD patients, the adverse impact on the phosphate binder market in which we compete, and the limitation of our sales professionals to meet in person with healthcare professionals as the result of limitations on access for non-patients.

Our revenue also depends on our partners' ability to successfully market and sell vadadustat 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 vadadustat for the treatment of anemia in patients with chronic kidney disease in the European Economic Area, the United Kingdom, Switzerland and Australia, or Medice Territory. If Medice's launch of vadadustat in the Medice Territory is delayed or their sales are lower than anticipated, we may not receive the revenue that we expect from Medice on the timing anticipated, or at all.

Our ability to achieve profitability also depends on our ability to manage our expenses. Following receipt of the CRL, in April and May 2022, we implemented a reduction of our workforce, by approximately 42% across all areas of the Company (47% inclusive of the closing of the majority of open positions), including several members of management. In November 2022, we also implemented a reduction of our workforce, by approximately 14% consisting of individuals within our commercial organization as a result of our decision to shift to a strategic account management focused model for our commercial efforts. We recorded a restructuring charge of approximately $15.9 million in the year ended December 31, 2022 primarily related to contractual termination benefits including severance, non-cash stock-based compensation expense, healthcare and related benefits. The reductions in workforce could impact our operations, including our commercialization of Auryxia, which could affect our ability to generate revenue. Additionally, we may incur additional costs not currently contemplated due to events associated with or resulting from the workforce reductions or other operating expenses, including additional costs related to vadadustat and selling, general and administrative expenses.

We expect to continue to incur additional operating expenses, including additional research and development expenses to our pipeline, additional costs related to vadadustat, and research and development and selling, general and administrative expenses for ongoing development and commercialization of Auryxia, which could lead to operating losses for the foreseeable future. In addition to any additional costs not currently contemplated due to events associated with or resulting from the workforce reductions noted above, our ability to achieve profitability and our financial position will depend, in part, on the rate of our future expenditures, on product revenue, collaboration revenue, and our ability to obtain additional funding. In addition, we expect to continue to incur significant expenses if and as we:

- continue our commercialization activities for Auryxia and vadadustat, if we are able to obtain marketing approval for vadadustat following our anticipated NDA resubmission, and any other product or product candidate, including those that may be in-licensed or acquired;
- address the issues identified in the CRL for vadadustat that we received from the FDA and pursue our anticipated NDA resubmission for vadadustat with the FDA;
- conduct and enroll patients in any clinical trials, including post-marketing studies or any other clinical trials for Auryxia, vadadustat or any other product or product candidate, including those that may be in-licensed or acquired;
- seek marketing approvals for vadadustat and any other product candidate, including those that may be in-licensed or acquired;

- maintain marketing approvals for Auryxia and vadadustat, if we are able to obtain marketing approval for vadadustat following our anticipated NDA resubmission, and any other product, including those that may be in-licensed or acquired;
- manufacture Auryxia, vadadustat and any other product or product candidate, including those that may be in-licensed or acquired, for commercial sale and clinical trials;
- conduct discovery and development activities for additional product candidates or platforms that may lead to the discovery of additional product candidates;
- engage in transactions, including strategic, merger, collaboration, acquisition and licensing transactions, pursuant to which we would market and develop commercial products, or develop and commercialize other product candidates and technologies;
- continue to repay, and pay any associated pre-payment penalties, if applicable, the senior secured term loans in an aggregate principal amount of $43.0 million as of June 30, 2023, that were made available to us pursuant to the Loan Agreement;
- make royalty, milestone or other payments under our license agreements and any future license agreements;
- maintain, protect and expand our intellectual property portfolio;
- make decisions with respect to our personnel, including the retention of key employees;
- make decisions with respect to our infrastructure, including to support our operations as a fully integrated, publicly traded biopharmaceutical company; and
- experience any additional delays or encounter issues with any of the above.

We have and will continue to expend significant resources on our legal proceedings, as described below under Part II, Item 1. Legal Proceedings, or any other legal proceedings brought by or against us in the future.

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. The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter, the progress of our clinical development and our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We will continue to incur substantial expenditures relating to continued commercialization and post-marketing requirements for Auryxia and vadadustat, if we are able to obtain marketing approval for vadadustat following our anticipated NDA resubmission, and any other products, including those that may be in-licensed or acquired, as well as costs relating to the research and development of any other product candidate, including those that may be in-licensed or acquired. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our expenses could increase beyond expectations if we are required by the FDA, the European Medicines Agency, or the EMA, or other regulatory authorities, or if we otherwise believe it is necessary, to change our manufacturing processes or assays, to amend or replace our study protocols, to conduct any additional clinical trials, whether in order to obtain approval or as a post-approval study, including any additional clinical trial that we decide to conduct for vadadustat, to perform studies in addition to, different from or larger than those currently planned, if there are any delays in completing our clinical trials or if there are further delays in or issues with obtaining marketing approval for vadadustat in the United States or other jurisdictions. In addition, our ability to generate revenue would be negatively affected if the size of our addressable patient population is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we sought or the patient population for treatment is narrowed by competition, physician choice, coverage or reimbursement, or payor or treatment guidelines. Even though we generate product revenue from Auryxia and royalties from Riona and Vafseo in Japan 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 funding to continue to fund our operating plan beyond Auryxia and certain development activities, and achieve strategic growth.

We will require substantial additional financing to achieve our goals. 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 June 30, 2023, our cash and cash equivalents were $53.6 million. We expect to continue to expend substantial amounts of cash for the foreseeable future as we continue to commercialize Auryxia; pursue our anticipated NDA resubmission for vadadustat in the U.S. with the FDA; support the regulatory process with respect to vadadustat in Australia; and develop and commercialize any other product or product candidate, including those that may be in-licensed or acquired. These expenditures will include costs associated with research and development, 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, including vadadustat depending on what is required to address the issues identified in the CRL for vadadustat, including the outcome of our anticipated NDA resubmission, or to complete post-marketing studies for Auryxia and vadadustat, if approved. Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of conducting clinical trials or any post-marketing requirements or any other clinical trials for Auryxia, vadadustat 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, vadadustat, if approved, and any other product or product candidate, including those that may be in-licensed or acquired;
- the results of our meetings with the FDA, the EMA and other regulatory authorities and any consequential effects, including on timing of and ability to obtain and maintain marketing approval, study design, study size and resulting operating costs;
- any difficulties or delays in conducting our clinical trials, or enrolling patients in our clinical trials, for Auryxia, vadadustat or any other product candidates;
- the outcome of our efforts to obtain marketing approval for vadadustat in the United States and in other jurisdictions and any other product candidates, including those that may be in-licensed or acquired, including any additional clinical trials or post-approval commitments imposed by regulatory authorities;
- the timing of, and the costs involved in obtaining, marketing approvals for vadadustat, including in the United States and certain other markets, and any other 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 or any other product, including those that may be in-licensed or acquired;
- the number of generic versions of Auryxia that enter the market following loss of exclusivity for Auryxia in March 2025, and the timing of, and the magnitude of, the impact on the price of Auryxia;
- the cost of securing and validating commercial manufacturing for any of our product candidates, including those that may be in-licensed or acquired, and maintaining our manufacturing arrangements for Auryxia and vadadustat or any other product, including those that may be in-licensed or acquired, or securing and validating additional arrangements;
- the costs involved in preparing, filing and prosecuting patent applications and maintaining, defending and enforcing our intellectual property rights, including litigation costs, and the outcome of such litigation;
- the costs involved in any legal proceedings to which we are a party;
- our status as a publicly traded company on the Nasdaq Capital Market;
- our decisions with respect to personnel;
- our decisions with respect to infrastructure; and
- the extent to which we engage in transactions, including strategic, merger, collaboration, acquisition and licensing transactions, pursuant to which we could develop and market commercial products, or develop other product candidates and technologies.

We will need to obtain substantial additional funding to fund our operating plan beyond Auryxia and certain development activities, and achieve strategic growth. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. We failed to timely file our Quarterly Report on Form 10-Q for the three months ended June 30, 2023, or the Second Quarter 10-Q. When we file our Annual Report on Form 10-K for the year ending December 31, 2023, or the 2023 Form 10-K, such filing will serve as an update of our current Registration Statement on Form S-3, or the Current Form S-3, for purposes of Section 10(a)(3) of the Securities Act and Rule 401(b) promulgated under the Securities Act. Because of our failure to timely file the Second Quarter 10-Q, we will not be eligible to file or use a Registration Statement on Form S-3, including the Current Form S-3, after we file our 2023 Form 10-K. At such time, if we have not already done so, we will be required to cease the at-the-market offering contemplated by the April 7, 2022 prospectus supplement and accompanying prospectus (to the extent such at-the-market offering has not already been terminated) and in no event later than March 31, 2024. This may make it more difficult for us to conduct a public offering of our securities.

We expect our cash resources to fund our current operating plan through at least the next twelve months from the filing of this Quarterly Report on Form 10-Q. However, if our operating performance deteriorates significantly from the levels expected in our operating plan, it would have an effect on our liquidity and our ability to continue as a going concern in the future. Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves numerous risks and uncertainties, and actual results could vary as a result of a number of factors, many of which are outside our control. We have based this estimate on assumptions that may be substantially different than actual results, and we could utilize our available capital resources sooner than we currently expect. In addition, if we fail to satisfy any of the covenants under our Loan Agreement with Pharmakon, including the covenant that our Annual Report on Form 10-K for the fiscal year ending December 31, 2023 not be qualified as to going concern, and the loan is accelerated, we may not have sufficient resources to fund our operating plan through the next twelve months. 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 anticipated by us, or that additional funding will be available on terms acceptable to us, or at all.

Any additional fundraising efforts may divert our management's attention away from their day-to-day activities, which may adversely affect our ability to develop and commercialize Auryxia and any other products or product candidates, including those that may be in-licensed or acquired, or to continue to seek regulatory approval for vadadustat. Also, additional funds may not be available to us in sufficient amounts or on acceptable terms or at all. 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 and any other products or product candidates, including those that may be in-licensed or acquired, or to take any actions with respect to vadadustat depending on future decisions with respect to vadadustat in the U.S. 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 product and product candidates on unfavorable terms to us.

We expect to finance future cash needs through product revenue, potential strategic transactions, public or private equity or debt transactions, or a combination of these approaches. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, our fixed payment obligations may increase, any such securities may have rights senior to those of our common stock, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect the rights of our common stockholders. Additional debt financing, if available, may involve agreements that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, make capital expenditures, declare dividends, acquire, sell or license intellectual property rights, and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic transactions, we may have to relinquish valuable rights to our portfolio and future revenue streams, and enter into agreements that would restrict our operations and strategic flexibility. If we raise additional funds through strategic transactions with third parties, we may have to do so at an earlier stage than otherwise would be desirable. In connection with any such strategic transactions, we may be required to relinquish valuable rights to our product and product candidates, future revenue streams or research programs or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds when needed, we may not be able to pursue planned development and commercialization activities and we may need to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

If we fail to comply with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

We must satisfy Nasdaq's continued listing requirements, including, among other things, a minimum closing bid price of $1.00 per share and timely filing of all periodic financial reports, or risk delisting, which would have a material adverse effect on our business. In the event we are delisted from Nasdaq, the only established trading market for our common stock would be eliminated, and we would be forced to list our shares on the OTC Markets or another quotation medium, depending on our ability to meet the specific listing requirements of those quotation systems. As a result, an investor would likely find it more difficult to trade or obtain accurate price quotations for our shares. Delisting would likely also reduce the visibility, liquidity, and value of our common stock, reduce institutional investor interest in our company, and may increase the volatility of our common stock. Delisting could also cause a loss of confidence of potential industry partners, lenders, and employees, which could further harm our business and our future prospects.

On May 9, 2023, we received a letter from Nasdaq stating that the Company had not regained compliance with the minimum bid price rule during the compliance period and was subject to delisting. We timely requested an appeal hearing which stayed delisting pending the decision of a Nasdaq Hearings Panel, or the Panel. On May 22, 2023, we received a letter from the Office of General Counsel of Nasdaq informing us that Nasdaq confirmed that we had regained compliance with the $1.00 per share minimum bid price requirement. Following this notice, the scheduled hearing before the Panel on June 22, 2023 was cancelled and our securities continue to be listed and traded on The Nasdaq Capital Market.

On August 11, 2023, we received a notification letter from Nasdaq informing us that since we had not yet filed our Second Quarter 10-Q, we are not in compliance with Nasdaq's listing rule requiring timely filing of all required periodic financial reports with the U.S. Securities and Exchange Commission, or the SEC. The Nasdaq notification letter specifies that we have 60 calendar days, or until October 10, 2023, to submit a plan to regain compliance with this rule. If Nasdaq accepts our plan, Nasdaq can grant an exception of up to 180 calendar days from the Second Quarter 10-Q's due date, or until February 5, 2024, to regain compliance. Our common stock will continue to trade on The Nasdaq Capital Market pending Nasdaq's review of our plan to regain compliance.

Although the minimum bid price deficiency matter is now closed, and we expect to regain compliance with the Nasdaq periodic report filing requirement upon filing of this Quarterly Report on Form 10-Q, there can be no assurance that we will be able to continue to comply with the Nasdaq continued listing requirements.

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

Although we continue to focus a substantial amount of our efforts on the commercialization of Auryxia and to pursue our anticipated NDA resubmission for vadadustat in the U.S. with the FDA and to seek regulatory approval for vadadustat in other territories, a key element of our long-term growth strategy is to develop additional product candidates and acquire, in-license, develop and/or market additional products and product candidates.

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

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

If any of these events occur, we may be forced to abandon our research and development efforts for one or more of our programs, or we may not be able to identify, discover, develop or commercialize additional product candidates, which may have a material adverse effect on our business.

Because we have limited financial and managerial resources, especially as a result of the CRL for vadadustat that we received in March 2022 and the reductions in workforce that we implemented in 2022, we focus on products, research programs and product candidates for specific indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications, or out license rights to product candidates, that later prove to have greater commercial potential. For example, as a result of receipt of the CRL and implementation of the reductions in workforce, we delayed certain research activities. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities on a timely basis, or at all. Our spending on current and future research and development 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. The success of this strategy depends partly upon our ability to identify, select, and acquire promising product candidates and products. The process of identifying, selecting, negotiating and implementing a license or acquisition of a product candidate or an approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of a product candidate or an approved product. We have limited resources to identify and execute the acquisition or in-licensing of third party products, businesses, and technologies and integrate them into our current infrastructure.

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

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

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

As part of our business strategy, we may engage in additional strategic transactions to expand and diversify our portfolio, including through the merger, acquisition or in-license of assets, businesses, or rights to products, product candidates or technologies or through strategic alliances or collaborations, similar to the Merger and our existing and prior collaboration and license arrangements. We may not identify suitable strategic transactions, or complete such transactions in a timely manner, on favorable terms, on a cost-effective basis, or at all. Moreover, we may devote resources to potential opportunities that are never completed or we may incorrectly judge the value or worth of such opportunities. Even if we successfully execute a strategic transaction, we may not be able to realize the anticipated benefits of such transaction and may experience losses related to our investments in such transactions. Integration of an acquired company or assets into our existing business may not be successful and may disrupt ongoing operations, require the hiring of additional personnel and the implementation and integration of additional internal systems and infrastructure, and require management resources that would otherwise focus on developing our existing business. Even if we are able to achieve the long-term benefits of a strategic transaction, our expenses and short-term costs may increase materially and adversely affect our liquidity. Any of the foregoing could have a detrimental effect on our business, results of operations and financial condition. For example, on June 4, 2021, we entered into a license agreement, the Cyclerion Agreement, with Cyclerion Therapeutics Inc., or Cyclerion, pursuant to which Cyclerion granted us an exclusive global license under certain intellectual property rights to research, develop and commercialize praliciguat, an investigational oral soluble guanylate cyclase, or sGC, stimulator. Although we have progressed preclinical studies for praliciguat, we need to do additional work to manufacture product for clinical trials before we can initiate the trials, and when started, we may be unsuccessful in developing praliciguat. If any of the assumptions that we made in valuing the transaction, including the costs or timing of development of, or the potential benefits of, praliciguat, were incorrect, we may not recognize the anticipated benefits of the transaction and our business could be harmed.

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

- incurring substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- exposure to known and unknown liabilities, including contingent liabilities, possible intellectual property infringement claims, violations of laws, tax liabilities and commercial disputes;
- higher than expected acquisition and integration costs;
- difficulty in integrating operations, processes, systems and personnel of any acquired business;
- increased amortization expenses or, in the case of a write-down of the value of acquired assets, impairment losses, such as the Auryxia intangible asset impairment in the second quarter of 2020 and corresponding adjustments to the estimated useful life of the developed product rights for Auryxia;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain personnel, customers, distributors, vendors and other business partners integral to an in-licensed or acquired product, product candidate or technology;
- potential failure of the due diligence processes to identify significant problems, liabilities or other shortcomings or challenges;
- entry into indications or markets in which we have no or limited development or commercial experience and where competitors in such markets have stronger market positions; and
- other challenges associated with managing an increasingly diversified business.

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

Our business has been and may continue to be, directly or indirectly, adversely affected by the recent COVID-19 pandemic.

The recent COVID-19 pandemic has presented a substantial public health and economic challenge around the world and has affected, and may continue to affect, our business, patients, healthcare providers with whom we interact, customers, our contract manufacturing organizations, or CMOs, and other vendors. The full extent to which the recent COVID-19 pandemic and the lasting effects of the pandemic will directly or indirectly impact our business, results of operations and financial condition continues to depend on future developments that are highly uncertain and cannot be accurately predicted, including any resurgences or variants of COVID-19, the actions taken to contain it or treat its impact and the economic and other impacts on local, regional, national and international markets where the healthcare providers with whom we interact, our CMOs, and our other vendors operate. The public health emergency declarations related to COVID-19 ended on May 11, 2023. The FDA ended twenty-two COVID-19-related policies on May 11, 2023 and allowed twenty-two to continue for 180 days. The FDA plans to retain twenty-four COVID-19-related policies with appropriate changes and four whose duration is not tied to the end of the public health emergency. At this point, it is unclear how, if at all, these developments will impact our efforts to develop and commercialize our product candidates.

We believe our revenue growth was negatively impacted by the recent COVID-19 pandemic in 2021, 2022 and the first half of 2023 primarily as the CKD patient populations that we serve experienced both high hospitalization and mortality rates due to COVID-19, and the pandemic had an adverse impact on the phosphate binder market in which Auryxia competes. Labor shortages and costs have adversely impacted dialysis providers. These impacts have refocused clinical efforts in addressing bone and mineral disorders like hyperphosphatemia to more acute operational issues to ensure patients receive dialysis treatments and still some patients have been rescheduled or missed treatments due to labor shortages. We believe, this and potentially other factors, led to the reduction in the phosphate binder market, which has not experienced growth since early 2020. While we are unable to quantify the impact of the recent COVID-19 pandemic on future revenues and revenue growth, the recent COVID-19 pandemic and the ongoing impacts from the recent COVID-19 pandemic continue to adversely and disproportionately impact CKD patients and the phosphate binder market; therefore, we expect the impacts from the pandemic to continue to have a negative impact on our revenue growth for the foreseeable future.

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

In addition, the direct and indirect impacts of the pandemic or the response efforts to the pandemic, including, among others, competition for labor and resources and increases in labor, sourcing, manufacturing and shipping costs, may cause disruptions to, closures of or other impacts on our CMOs and other vendors in our supply chain on which we rely for the supply of our products and product candidates. For example, areas of China have recently continued to implement lockdowns for COVID-19, which could impact the global supply chain. At this time, our CMOs continue to operate at or near normal levels. However, it is possible that the recent COVID-19 pandemic and response efforts may have an impact in the future on our contract manufacturers' ability to manufacture and deliver Auryxia and vadadustat (if approved in the United States and which is currently marketed under the trade name Vafseo by MTPC in Japan and approved in Europe), which may result in increased costs and delays, or disruptions to the manufacturing and supply of our products. These impacts could have a negative effect on our inventory reserves, which could result in an increase in inventory write-offs due to expiry.

If we or any of the third parties with whom we engage, including our collaboration partners, vendors, or any of our customers were to experience further shutdowns, delays or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned, and our revenue expectations, could be materially and negatively impacted, which could have a material adverse effect on our business and our financial results.

While we are working to mitigate the impacts on our business, we are mindful that many of these risks and the impact to the larger healthcare market are outside of our control. The recent COVID-19 pandemic has, and may continue to, significantly impact the phosphate binder market in which we compete and economies and financial markets worldwide, which could result in adverse effects on our business and operations, impact our ability to raise additional funds and impact the volatility of our stock price and trading in our stock. Even now that the COVID-19 pandemic has been largely contained, we may continue to experience adverse impacts to our business as a result of the adverse impact on the patient population for Auryxia, the decline in the phosphate binder market and any economic recession or depression that has occurred or may occur in the future.

Risks Related to our Financial Arrangements

Our obligations in connection with the loan agreement with Pharmakon and requirements and restrictions in the loan agreement could adversely affect our financial condition and restrict our operations.

We entered into the Loan Agreement with Pharmakon, pursuant to which the Term Loans were made available to us in two tranches. The first tranche of $80.0 million closed on November 25, 2019, and the second tranche of $20.0 million closed on December 10, 2020. See Note 11, *Debt*, to our condensed consolidated financial statements in Part I, Item 1. Financial Statements of this Quarterly Report on Form 10-Q for additional information regarding our obligations under the Loan Agreement.

The Loan Agreement contains affirmative and negative covenants applicable to us and our subsidiaries, including maintaining, on an annual basis, a minimum liquidity threshold and, on a quarterly basis, a minimum net sales threshold for Auryxia. In addition, the Loan Agreement contains covenants that our Annual Reports on Form 10-K, must not be subject to any qualification as to going concern. Failure to maintain compliance with these or other covenants would result in an event of default under the Loan Agreement, which could result in enforcement action, including acceleration of amounts due under the Loan Agreement. Additionally, the liabilities under the Loan Agreement will be accelerated, subject to certain exceptions, if we are required to repay to CSL Vifor all or more than a specified amount of the working capital facility established in connection with the Second Amended and Restated License Agreement that we entered into with CSL Vifor, in February 2022, or the Vifor Second Amended Agreement, as a result of certain terminations of the Vifor Second Amended Agreement or due to a reduction in the balance of the working capital facility by more than a prespecified amount.

In the event there is an acceleration of our and certain of our subsidiaries' liabilities under the Loan 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 Pharmakon could seek to enforce security interests in the collateral securing the Loan Agreement and our guarantee of the Term Loans, which would have a material adverse effect on our business, financial condition and results of operations.

The Loan Agreement permits voluntary prepayment at any time in whole or in part, subject to prepayment premiums and make-whole premiums prior to certain dates. We made a voluntary prepayment of $25.0 million, including $0.5 million of prepayment penalties on July 15, 2022, pursuant to the Second Amendment and Waiver. This represented the repayment of $5.0 million of the first tranche and the full $20.0 million of the second tranche. Upon a change of control, mandatory prepayment provisions require us to prepay the principal amount outstanding, the applicable prepayment premium and make-whole premium and accrued and unpaid interest. In addition, our obligations in connection with the Loan 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, including the Vifor Second Amended Agreement, incurring certain additional indebtedness, creating certain liens, paying 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, research and development 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.

On February 25, 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 vadadustat, collectively the Royalty Interest Payments, in each case, payable to us under our Collaboration Agreement dated December 11, 2015, or the MTPC Agreement, with Mitsubishi Tanabe Pharma Corporation, or MTPC, subject to an annual maximum "cap" of $13.0 million, or the Annual Cap, and an aggregate maximum "cap" of $150.0 million, or the Aggregate Cap. Under the Royalty Agreement, we are required to comply with various covenants, including obligations to take certain actions, such as actions with respect to the Royalty Interest Payments, the MTPC Agreement, our agreement with MTPC for the commercial supply of vadadustat 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. In the event we violate certain covenants and other provisions, we may not receive sales milestones from HCR even if the applicable sales thresholds are met. 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. If we are unable to continue to successfully commercialize Auryxia, our results or 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. Our ability to generate revenue depends on our ability to execute on our commercialization plans, and

the size of the market for, and the level of market acceptance of, Auryxia and any other product or product candidate, including those that may be in-licensed or acquired. 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 phosphate binder market has declined since 2020, which we believe was partially a result of the recent COVID-19 pandemic. In addition, dialysis organizations continue to experience business continuity challenges that arise due to labor constraints and staffing shortages, facility closures and a decline in new patients, all of which could impact the phosphate binder market. If the phosphate binder market does not recover or continues to decline, our revenue from Auryxia could be materially adversely affected.

Market acceptance is also critical to our ability to generate significant product revenue. Any product may achieve only limited market acceptance or none at all. If Auryxia, or any of our future products, is not accepted by the market to the extent that we expect or market acceptance decreases, we may not be able to generate significant product revenue and our business would be materially harmed. Market acceptance of Auryxia 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 from third party payors, pharmacy benefit managers, or PBMs, and governmental authorities;
- the safety and efficacy of the product, as demonstrated in clinical trials and in the post-marketing setting;
- the prevalence and complications of the disease treated by the product;
- the clinical indications for which the product is approved and the product label approved by regulatory authorities, including any warnings or limitations that may be required on the label as a consequence of potential safety risks associated with the product;
- the countries in which marketing approvals are obtained;
- the claims we and our partners are able to make regarding the safety and efficacy of the product;
- the success of our physician and patient communications and education programs;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety and efficacy of the product in relation to alternative treatments;
- the timing of receipt of marketing approvals and product launch relative to competing products and potential generic entrants;
- 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 expenses, our net product revenue may decrease and/or we may incur additional expenses. In addition, our net product revenue requires judgement and includes estimates for rebates and product returns, which can fluctuate from quarter-to-quarter and year-over-year. If our net product revenue is lower than anticipated, our business could be harmed.

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

In order to market Auryxia and any other approved product, we intend to continue to invest in sales and marketing, which will require substantial effort and significant management and financial resources. We have built a commercial infrastructure and sales force in the United States for Auryxia, our only commercial product. However, following receipt of the CRL, in April and May 2022, we implemented a reduction of our workforce by approximately 42% across all areas of the Company (47% inclusive of the closing of the majority of open positions), including several members of our sales and marketing team and management. In November 2022, we also implemented a reduction of our workforce, by approximately 14% consisting of individuals within our commercial organization as a result of our decision to shift to a strategic account management focused model for our commercial efforts. If the remaining sales and marketing team cannot successfully commercialize Auryxia, or if additional sales and marketing employees decide to leave as a result of the reduction in workforce or otherwise, it could have a material adverse effect on Auryxia revenue and our financial condition.

If we obtain regulatory approval to market vadadustat in the U.S., we believe that we can leverage the current commercial foundation for vadadustat in the U.S., but if we are unable to do so successfully this would materially harm our business. Additionally, training a sales force to successfully sell and market a new commercial product is expensive and time-consuming and could delay any commercial launch of such product candidate or distract the sales force from promoting Auryxia. We may underestimate the size of the sales force required for a successful product launch and we may need to expand our sales force earlier and at a higher cost than we anticipated. In 2021 and early 2022, we incurred commercialization expenses for vadadustat that were premature or unnecessary as a result of the receipt of the CRL for vadadustat, and may in the future incur additional commercialization expenses prematurely or unnecessarily if we do not receive marketing approval in the timeframe we expect, or at all.

We devote significant effort, in particular, to recruiting individuals with experience in the sales and marketing of pharmaceutical products. Competition for personnel with these skills is significant and retaining qualified personnel with experience in our industry is difficult. Further, our reductions in workforce may further exacerbate these conditions and interfere with our ability to find and retain qualified personnel. As a result, we may not be able to retain our existing employees or hire new employees quickly enough to meet our needs. At the same time, we may face high turnover, requiring us to expend time and resources to source, train and integrate new employees.

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

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

If we are unable to maintain our own sales and marketing capabilities, we will not be successful in commercializing Auryxia, vadadustat, if approved, and any other product candidate that may be approved.

Furthermore, if we are unable to maintain our arrangements with third parties with respect to sales and marketing, if we are unsuccessful in entering into additional arrangements with third parties to sell and market our products or we are unable to do so on terms that are favorable to us, or if such third parties are unable to carry out their obligations under such arrangements, it will be difficult to successfully commercialize our product and product candidates, including vadadustat, if approved. For example, if in connection with the Vifor Second Amended Agreement, we experience difficulties with CSL Vifor, or if CSL Vifor experiences difficulties with other parties to whom it expects to sell vadadustat, if approved, our ability to commercialize vadadustat, if approved, will be severely hindered and our business operations will be materially harmed.

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

Market acceptance and sales of any approved products, including Auryxia and, if approved, vadadustat, depends significantly on the availability of adequate coverage and reimbursement from third party payors and may be affected by existing and future healthcare reform measures. Governmental authorities, 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, vadadustat, if approved, 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 commercialize certain of our products. Coverage and reimbursement by a governmental authority, third-party payor or PBM 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, 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 United States, there are multiple governmental authorities, PBMs and third-party payors with varying coverage and reimbursement levels for pharmaceutical products, and the timing of commencement of

reimbursement by a governmental payor can be dependent on the assignment of codes via the Healthcare Common Procedural Coding System, which codes are assigned on a quarterly basis. Within Medicare, for oral drugs dispensed by pharmacies and also administered in facilities, coverage and reimbursement may vary depending on the setting. CMS, local Medicare administrative contractors, Medicare Part D plans and/or PBMs operating on behalf of Medicare Part D plans, may have some responsibility for determining the medical necessity of such drugs, and therefore coverage, for different patients. Different reimbursement methodologies may apply, and CMS may have some discretion in interpreting their application in certain settings.

As an oral drug, Auryxia is covered by Medicare under Part D. However, in September 2018, CMS decided that Auryxia would no longer be covered by Medicare for the treatment of iron deficiency anemia, or IDA, in adult patients with NDD-CKD, or the CMS Decision. While this decision does not impact CMS coverage for the control of serum phosphorus levels in adult patients with DD-CKD, or the Hyperphosphatemia Indication, it requires Part D plan sponsors to impose prior authorization or other steps to ensure that Auryxia is reimbursed only for the Hyperphosphatemia Indication. While we believe that the vast majority of the Medicare prescriptions written for Auryxia today are for the Hyperphosphatemia Indication and therefore will continue to be covered by Medicare with prior authorization, the CMS Decision has had and will continue to have an adverse impact on the sales and future growth of Auryxia for the Hyperphosphatemia Indication and the IDA Indication.

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 may be required to enter into contracts with 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 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, third party payors, PBMs and other entities that purchase our products may impose restrictions on our ability to raise prices for our products over time without incurring additional costs. Four distributors, Fresenius Medical Care Rx, McKesson Corporation, Cardinal Health, Inc. and Amerisource Bergen Drug Corporation, in the aggregate, accounted for a significant percentage of our gross revenue during the three months ended June 30, 2023. If we are not able to maintain our arrangements with these key distributors on favorable terms, on a timely basis or at all, or if there is any adverse change in one or more of these distributors' business practices or financial condition, it would adversely impact the market opportunity for Auryxia, our product revenues and operating results.

Furthermore, vadadustat was approved in Japan for the treatment of adult patients with anemia due to CKD and is being marketed by MTPC in Japan under the trade name Vafseo. Pricing and reimbursement strategy is a key component of MTPC's commercialization plans for Vafseo in Japan. If coverage and reimbursement terms change, MTPC may not be able to, or may decide not to, continue commercialization of Vafseo in Japan.

We currently believe it is likely that vadadustat, if approved, will be reimbursed using the Transitional Drug Add-on Payment Adjustment, or TDAPA, followed by inclusion in the bundled reimbursement model for Medicare beneficiaries. For those that obtain dialysis through commercial insurance during the 30-month coordination period or through Medicaid prior to Medicare becoming primary payer after 90 days, patients may access vadadustat through contracts we negotiate with third party payors for reimbursement of vadadustat, which would be subject to the risks and uncertainties described above. Additionally, applying for and obtaining reimbursement under the TDAPA is expected to take at least six months following approval, which will affect adoption, uptake and product revenue for vadadustat during that time, and if there are updates to the TDAPA rule that decrease the basis for reimbursement or eligibility criteria during the transition period or if the TDAPA is eliminated, then our profitability may be adversely affected. For example, the Medicare Payment Advisory Commission, or MedPAC, an independent legislative branch advisory body to Congress on issues related to the Medicare program, has recommended that TDAPA not be provided to newly approved drug products considered to fall within "functional categories" for which costs are already accounted for in the bundled reimbursement model, such as for anemia management drugs.

Further, if vadadustat is approved in the United States and included in the fixed reimbursement model for a bundle of dialysis services, or the bundle, we would be required to enter into contracts to supply vadadustat to specific dialysis providers, instead of through distributors, which we believe could be challenging. The dialysis market is unique and is dominated by two providers: DaVita and Fresenius Medical Care, which account for a vast majority of the dialysis population in the United States. Under the Vifor Second Amended Agreement, we granted CSL Vifor an exclusive license to sell vadadustat to Fresenius Medical Care North America and its affiliates, including Fresenius Kidney Care Group LLC, to certain third-party dialysis organizations approved by us, to independent dialysis organizations that are members of group purchase organizations, and to certain non-retail specialty pharmacies in the United States. We refer to Fresenius Medical Care North America and its affiliates, these organizations and specialty pharmacies collectively as the "Supply Group". See Note 5 to our consolidated

financial statements in Part I, Item 1. Financial Statements of this Quarterly Report on Form 10-Q for additional information regarding the Vifor Second Amended Agreement. If vadadustat is approved and we are not able to maintain the Vifor Second Amended Agreement or enter into a supply agreement with DaVita or other dialysis clinics, our business may be materially harmed.

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

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

Further, in many countries outside the United States, 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 United States does not ensure approval by any other reimbursement authorities. However, the failure to obtain reimbursement in one jurisdiction may negatively impact our ability to obtain reimbursement in another jurisdiction. We or 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 control. In addition, we plan to rely on a partner to obtain approval by reimbursement authorities outside the United States. In May 2023, we entered into the license agreement with Medice, pursuant to which we granted Medice an exclusive license to develop and commercialize vadadustat for the treatment of anemia in patients with chronic kidney disease in the Medice Territory. If Medice is not able to obtain favorable pricing in the Medice Territory, or if such approvals are delayed, it will effect Medice's sales of vadadustat in the Medice Territory, which could have an adverse effect on our results of operations.

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

The development and commercialization of new drugs is highly competitive and subject to rapid and significant technological change. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the development and commercialization of Auryxia, vadadustat, if approved, and any other product or product candidate, including those that may be in-licensed or acquired. Our objective is to continue to commercialize Auryxia 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.

Auryxia is competing in the hyperphosphatemia market in the United States with other FDA-approved phosphate binders such as Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate), both marketed by Sanofi, PhosLo® and Phoslyra® (calcium acetate), marketed by Fresenius Medical Care North America, Fosrenol® (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, and Velphoro® (sucroferric oxyhydroxide), marketed by Fresenius Medical Care North America, as well as over-the-counter calcium carbonate products such as TUMS® and metal-based options such as aluminum, lanthanum and magnesium. Most of the phosphate binders listed above are now also available in generic forms. In addition, other agents are in development, including OPKO Health Inc.'s Alpharen™ Tablets (fermagate tablets) and Unicycive's Renazorb™ (lanthanum dioxycarbonate) or could otherwise enter the market, including Ardelyx, Inc.'s tenapanor (which is approved in the United States for the treatment of adults with irritable bowel syndrome with constipation, and for which Ardelyx resubmitted a new drug application to the FDA in April 2023 with respect to the control of serum phosphorus in adult patients with CKD on dialysis), that may impact the market for Auryxia.

Auryxia is competing in the IDA market in the United States with over-the-counter oral iron, ferrous sulfate, other prescription oral iron formulations, including ferrous gluconate, ferrous fumerate, and polysaccharide iron complex, and intravenous iron formulations, including Feraheme® (ferumoxytol injection), Venofer® (iron sucrose injection), Ferrlicit® (sodium ferric gluconate complex in sucrose injection), Injectafer® (ferric carboxymaltose injection), and Triferic® (ferric pyrophosphate citrate). In addition, other new therapies for the treatment of IDA may impact the market for Auryxia, such as Shield

Therapeutics plc's Feraccru® (ferric maltol), which is available in Europe for the treatment of IDA and Accrufer® (ferric maltol), which was launched in the United States for the treatment of IDA in July 2021.

Furthermore, Auryxia's commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective, safer or offer greater patient convenience than Auryxia. Other companies have product candidates in various stages of preclinical or clinical development to treat diseases and complications of the diseases for which we are marketing Auryxia. In addition, we and Keryx's licensors, Panion & BF Biotech, Inc., or Panion, and, as applicable, Dr. Hsu, entered into settlement agreements with all but one of the third parties who submitted Paragraph IV certification notice letters regarding Abbreviated New Drug Applications, or ANDAs, submitted to the FDA, pursuant to which we granted licenses to market a generic version of Auryxia in the United States beginning in March 2025 (subject to FDA approval), or earlier under certain circumstances customary for settlement agreements of this nature, which may impact our business and results of operation.

Drugs that may compete with vadadustat include Epogen® (epoetin alfa) and Aranesp® (darbepoetin alfa), both commercialized by Amgen, Procrit® (epoetin alfa) and Eprex® (epoetin alfa), commercialized by Johnson & Johnson in the United States and Europe, respectively, and Mircera® (methoxy PEG-epoetin beta), commercialized by CSL Vifor in the United States and Roche Holding Ltd. outside of the United States. Further, in February 2023 the FDA approved daprodustat, an oral hypoxia-inducible factor prolyl hydroxylase, or HIF-PH, inhibitor to be marketed as Jesduvroq by GlaxoSmithKline plc, or GSK, in the United States, as a once-a-day treatment of anemia due to CKD in adult patients who have been receiving dialysis for at least four months.

We and our partners may also face competition from potential new anemia therapies. There are several other HIF-PH inhibitor product candidates in various stages of development for anemia indications that may be in direct competition with vadadustat if and when they are approved and launched commercially. These candidates are being developed by companies such as FibroGen Inc., or FibroGen, together with its collaboration partners, Astellas Pharma Inc. and AstraZeneca PLC, Japan Tobacco International, or JT, and Bayer HealthCare AG, or Bayer. For example, FibroGen filed an NDA for its product candidate, roxadustat, with the FDA, but the FDA issued a complete response letter indicating the FDA will not approve the NDA in its present form and requested that an additional clinical trial for roxadustat be conducted prior to resubmission of the NDA or additional response to the FDA's complete response letter. In Europe however, roxadustat is approved for the treatment of anemia in patients with CKD. If we obtain approval for vadadustat in the U.S., and roxadustat is also approved by the FDA, then roxadustat will compete with vadadustat.

Furthermore, certain companies are developing potential new therapies for renal-related diseases that could potentially reduce injectable erythropoiesis stimulating agent, or ESA, utilization and thus limit the market potential for vadadustat if they are approved and launched commercially. Other new therapies are in development for the treatment of conditions inclusive of renal anemia that may impact the market for anemia-targeted treatment.

In Japan, Vafseo, which is approved for both the DD and NDD indications, competes with roxadustat, daprodustat and enarodustat. Roxadustat is approved for the treatment of anemia due to CKD in patients on dialysis, or DD-CKD, and patients not on dialysis, or NDD-CKD. In addition, daprodustat, GSK's product, and enarodustat, JT's product, are approved in Japan for the treatment of anemia due to CKD. In addition. Bayer HealthCare AG has submitted an NDA for its product candidate for the treatment of renal anemia in Japan. In China, roxadustat is commercialized for the treatment of anemia of DD-CKD and for the treatment of anemia due to CKD in NDD-CKD patients.

A biosimilar is a biologic product that is approved based on demonstrating that it is highly similar to an existing, FDA-approved branded biologic product. The patents for the existing, branded biologic product must expire in a given market before biosimilars may enter that market without risk of being sued for patent infringement. In addition, an application for a biosimilar product cannot be approved by the FDA until 12 years after the existing, branded product was approved under a Biologics License Application, or BLA. The patents for epoetin alfa, an injectable ESA, expired in 2004 in the EU, and the remaining patents expired between 2012 and 2016 in the United States. Because injectable ESAs are biologic products, the introduction of biosimilars into the injectable ESA market in the United States will constitute additional competition for vadadustat if we are able to obtain approval for and commercially launch vadadustat. In the United States, Pfizer's biosimilar version of injectable ESAs, Retacrit® (epoetin alfa-epbx), was approved by the FDA in May 2018 and launched in November 2018 and several biosimilar versions of injectable ESAs are available for sale in the EU.

Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining marketing approvals, recruiting patients and manufacturing pharmaceutical products. Large and established companies such as Amgen, Roche and GSK, among others, compete in the market for drug products to treat kidney disease. In particular, these companies have greater experience and expertise in conducting preclinical testing and clinical trials, obtaining marketing approvals, manufacturing such products on a broad scale and marketing approved products. These companies also

have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we are developing obsolete. Smaller and other early-stage companies may also prove to be significant competitors. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or marketing approval, or discovering, developing and commercializing competitive products, before, or more effectively than, we do. If we are not able to compete effectively against potential competitors, our business will not grow and our financial condition and operations will suffer.

The commercialization of Riona and Vafseo in Japan, Vafseo in Europe and our current and potential future efforts with respect to the development and commercialization of our products and product candidates outside of the United States 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 Pharmaceutical Co., Ltd., or Torii, commercialize Riona, the trade name for ferric citrate hydrate in Japan, as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including DD-CKD and NDD-CKD, and for the treatment of adult patients with IDA in Japan. In Japan and certain other countries in Asia, we granted MTPC exclusive rights to commercialize vadadustat, which has been approved and is being marketed by MTPC in Japan under the trade name Vafseo. We also granted Averoa SAS, or Averoa, an exclusive license to develop and commercialize ferric citrate in the EEA, Turkey, Switzerland and the United Kingdom.

In 2023, the marketing authorization for vadadustat was approved by the EMA, the Medicines and Healthcare Products Regulatory Agency, or the MHRA, and the Swiss Agency for Therapeutic Products, or Swissmedic. In May 2023, we entered into the license agreement with Medice, pursuant to which we granted Medice an exclusive license to develop and commercialize vadadustat for the treatment of anemia in patients with chronic kidney disease in the Medice Territory, and we will transfer the marketing authorizations for the Medice Territory to Medice. In addition, we have conducted and in the future plan to conduct clinical trials outside of the United States for Auryxia, vadadustat and any other 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 vadadustat outside the United States, 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 United States;
- 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, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, global pandemics, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

Risks Related to Product Development

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

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

We may be unable to successfully complete clinical trials of Auryxia, vadadustat and other product candidates or to successfully obtain approval of vadadustat or other 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 profile due to efficacy or safety. Further, the results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, interim results of a clinical trial do not necessarily predict final results, and results of Phase 3 clinical trials for one indication may not be predictive of results of Phase 3 clinical trials for another indication. For example, we announced positive top-line results from INNO$_2$VATE and vadadustat achieved the primary and key secondary efficacy endpoint in each of the two PRO$_2$TECT studies, but 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. In addition, in March 2022, we received the CRL for vadadustat indicating that the FDA had determined that it could not approve the NDA in its present form, thus delaying any potential approval of vadadustat. In October 2022, we submitted the FDRR to the FDA. In May 2023, the OND denied our appeal but provided a path forward for us to resubmit the NDA for vadadustat for the treatment of anemia due to CKD for dialysis dependent patients without the need for us to generate additional clinical data. In July 2023, we held an End of Dispute Type A meeting with the FDA to align on the contents of the NDA resubmission. We expect to resubmit the NDA by the end of the third quarter of 2023, with a potential PDUFA date that we project will be in March 2024. However, it is impossible to predict when or if vadadustat or any of our other product candidates will prove effective or safe in humans or will receive marketing approval or on what terms. If we are unsuccessful in obtaining approval for vadadustat in the U.S. or other territories, it would have an adverse effect on our results of operations.

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

- the costs may be greater than we anticipate;
- the number of patients required for clinical trials may be larger than we anticipate;
- enrollment in our clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third party contractors, such as our CROs, may fail to comply with regulatory requirements, perform effectively, or meet their contractual obligations to us in a timely manner, or at all, or we may fail to communicate effectively or provide the appropriate level of oversight of such third party contractors;
- the supply or quality of our starting materials, drug substance and drug product necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators, independent data monitoring committees, or IDMCs, institutional review boards, or IRBs, 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 of or failure to complete a clinical trial as a result of an Investigational New Drug application, or IND, being placed on clinical hold by the FDA, the EMA, the PMDA, or other regulatory authorities, or

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

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

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

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

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

Identifying and qualifying patients to participate in clinical trials is critical to our success. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our clinical trials. Patients may be unwilling to participate in our clinical trials because of concerns about investigational research studies, the time and commitment needed to participate in a study, adverse events observed with the product candidate under study, the current standard of care, competitor products and/or other investigational agents, in each case for the same indications and/or similar patient populations. In addition, in the case of clinical trials of any product candidate, patients currently receiving treatment with the current standard of care or a competitor product may be reluctant to participate in a clinical trial with an investigational drug. Additionally, it is often more difficult to enroll special or particular subpopulations of patients, such as pediatric or elderly patients, due to a number of factors including parental or other caregiver considerations, concerns and burdens. For example, we enrolled sites in

a post-approval pediatric study for the Hypophosphatemia Indication of Auryxia in the second quarter of 2022, which began patient recruitment in the third quarter of 2022, but enrollment of eligible pediatric patients in study sites continues to be very slow despite efforts to do so. Furthermore, the recent COVID-19 pandemic resulted in temporary closures of, and may continue to impact, clinical trial sites on which we rely for the conduct of clinical trials and recent COVID-19 pandemic precautions and staffing shortages have caused moderate delays in enrolling new clinical trials and may cause delays in enrolling other new clinical trials.

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

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

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

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

Further, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of Food and Drug Omnibus Reform Act, Congress required sponsors to develop and submit a diversity action plan for each phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products.

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

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

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

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

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

Auryxia, vadadustat 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, vadadustat 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 vadadustat in which the FDA concluded that the data in the NDA do not support a favorable benefit-risk assessment of vadadustat for dialysis and non-dialysis patients. The FDA expressed safety concerns noting failure to meet non-inferiority in MACE in the non-dialysis patient population, the increased risk of thromboembolic events, driven by vascular access thrombosis in dialysis patients, and the risk of drug-induced liver injury. In October 2022, we submitted the FDRR to the FDA and focused on the favorable balance between the benefits and risks of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis in light of safety concerns expressed by the FDA in the CRL for dialysis patients related to the rate of adjudicated thromboembolic events driven by vascular access thrombosis for vadadustat compared to the active comparator and the risk of drug-induced liver injury. In May 2023, the OND denied our appeal but provided a path forward for us to resubmit the NDA for vadadustat for the treatment of anemia due to CKD for dialysis dependent patients without the need for us to generate additional clinical data. In July 2023, we held an End of Dispute Type A meeting with the FDA to align on the contents of the NDA resubmission. We expect to resubmit the NDA by the end of the third quarter of 2023, with a potential PDUFA date that we project will be in March 2024. There can be no assurances that we will be successful in our anticipated NDA resubmission. If we are unable to overcome these concerns, vadadustat may not be approved by the FDA on favorable terms, or at all, and our financial condition could be materially harmed.

If we or others identify undesirable effects caused by, or other undesirable properties of, Auryxia, vadadustat, 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;
- REMS or FDA-imposed risk management plans that use restrictive risk minimization strategies may be required;
- we may decide to, or be required to, send drug warnings or safety alerts to physicians, pharmacists and hospitals (or the FDA or other regulatory authorities may choose to issue such alerts), or we may decide to conduct a product recall or be requested to do so by the FDA or other regulatory authority;
- reformulation of the product, additional non-clinical or clinical trials, restrictive changes in labeling or changes to or re-approvals of manufacturing facilities may be required;
- we may be precluded from pursuing additional development opportunities to enhance the clinical profile of a product within its indicated populations, or studying the product or product candidate in additional indications and populations or in new formulations; and

- we could be investigated by the government or sued and held liable for harm caused to patients, including in class action lawsuits; and
- our reputation may suffer.

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

The patient populations treated with Auryxia and potential patient populations for vadadustat, if approved, 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 during the *Correction and Conversion* study in vadadustat treated patients was 83.8% and 85.5% in darbepoetin alfa treated patients. During the study, the most common treatment emergent adverse events reported in vadadustat/darbepoetin alfa treated patients were hypertension (16.2%/ 12.9%) and diarrhea (10.1%/ 9.7%). Serious treatment emergent adverse events were lower in vadadustat treated patients at 49.7% compared to 56.5% for darbepoetin alfa treated patients. The incidence of treatment emergent adverse events during the prevalent dialysis patient study (*Conversion*) in the vadadustat treated patients was 88.3%, and 89.3% in darbepoetin alfa treated patients. During the study, the most common treatment emergent adverse events reported in vadadustat/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 treatment emergent adverse events were slightly lower for vadadustat treated patients at 55.0% and 58.3% for darbepoetin alfa-treated patients. Patients with DD-CKD experienced an increased risk of thromboembolic events compared to darbepoetin alfa with a time to first event HR of 1.20 (95% CI 0.96 - 1.50) driven by thrombosis of vascular access.

With respect to the global PRO$_2$TECT Phase 3 program, the incidence of treatment emergent adverse events during the erythropoiesis stimulating agent, or ESA, untreated patients study (*Correction*) in the vadadustat-treated patients was 90.9%, and 91.6% in darbepoetin alfa-treated patients. During the study, the most common treatment emergent adverse events reported in vadadustat/darbepoetin alfa-treated patients were end-stage renal disease (34.7%/ 35.2%), hypertension (17.7%/ 22.1.%), hyperkalemia (12.3.%/ 15.6%), urinary tract infection (12.9%/ 12.0%), diarrhea (13.9%/ 10.0%), peripheral oedema (12.5%/ 10.5%), fall (9.6%/ 10%) and nausea (10%/ 8.2%). Serious treatment emergent adverse events were 65.3% for vadadustat-treated patients and 64.5% for darbepoetin alfa-treated patients. The incidence of treatment emergent adverse events during the ESA-treated patients study (*Conversion*) in vadadustat treated patients was 89.1% and 87.7% in darbepoetin alfa-treated patients. During the study, the most common treatment emergent adverse events reported in vadadustat/darbepoetin alfa-treated patients were end-stage renal disease (27.5%/ 28.4%), hypertension (14.4%/ 14.8%), urinary tract infection (12.2%/ 14.5%), diarrhea (13.8.%/ 8.8.%), peripheral oedema (9.9%/ 10.1%) and pneumonia (10.0%/ 9.7%). Serious treatment emergent adverse events were 58.5% for vadadustat-treated patients and 56.6% for darbepoetin alfa-treated patients.

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

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

Any of the above safety data or other occurrences could delay or prevent us from achieving or maintaining marketing approval, harm or prevent sales of Auryxia or, if approved, vadadustat 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, vadadustat or any other products or product candidates.

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

Clinical trials, manufacturing and marketing of any product or product candidate are subject to extensive and rigorous review and regulation by numerous governmental authorities in the United States and other jurisdictions. Before obtaining marketing approval for the commercial sale of any product candidate, we must demonstrate through extensive preclinical testing 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 United States and in other jurisdictions, only a small percentage successfully complete the FDA's and other jurisdictions' marketing approval processes and are commercialized. Accordingly, even if we are able to obtain the requisite capital to continue to fund our development and commercialization efforts, we may be unable to successfully obtain regulatory approval for or commercialize vadadustat or any other product or product candidate, including those that may be in-licensed or acquired.

We are not permitted to market vadadustat in the United States until we receive approval from the FDA or in any other jurisdiction until the requisite approval from regulatory authorities in such jurisdiction is received. As a condition to receiving marketing approval for vadadustat, we may be required by the FDA or other regulatory authorities to conduct additional preclinical studies or clinical trials.

In March 2022, we received the CRL from the FDA regarding our NDA for vadadustat for the treatment of anemia due to CKD. The FDA concluded that the data in the NDA do not support a favorable benefit-risk assessment of vadadustat for dialysis and non-dialysis patients. In October 2022, we submitted the FDRR to the FDA and focused on the favorable balance between the benefits and risks of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis in light of safety concerns expressed by the FDA in the CRL for dialysis patients related to the rate of adjudicated thromboembolic events driven by vascular access thrombosis for vadadustat compared to the active comparator and the risk of drug-induced liver injury. In May 2023, the OND denied our appeal but provided a path forward for us to resubmit the NDA for vadadustat for the treatment of anemia due to CKD for dialysis dependent patients without the need for us to generate additional clinical data. In July 2023, we held an End of Dispute Type A meeting with the FDA to align on the contents of the NDA resubmission. We expect to resubmit the NDA by the end of the third quarter of 2023, with a potential PDUFA date that we project will be in March 2024. There can be no assurances that we will be successful in our anticipated NDA resubmission and obtain approval for vadadustat in a timely manner, on favorable terms, or at all. As a result, the regulatory approval process for vadadustat in the U.S. is highly uncertain. We may not obtain approval at all, and if we are able to obtain approval, it will only be for patients with DD-CKD and, in any event, the expense and time to do so could adversely impact our ability to successfully commercialize vadadustat, and our financial condition could be materially harmed.

Further, vadadustat and any other product candidate may not receive marketing approval in the United States even if it is approved in other countries. For example, although vadadustat is approved in Japan for the treatment of anemia due to CKD in DD-CKD and NDD-CKD adult patients and in Europe for the treatment of anemia due to CKD in DD-CKD patients, such approval does not guarantee approval in the United States by the FDA for these indications or at all. In addition, while each regulatory authority makes their own assessment as to the safety and efficacy of a drug, FDA's concern about the safety or efficacy of vadadustat or any other product candidate could impact the regulatory authority's decision in another country.

Obtaining marketing approval in the United States 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, following completion of the review process, may not grant marketing approval or such marketing approval may be limited. Furthermore, approval of a drug does not ensure successful commercialization. For example, on September 23, 2015, the European Commission, or EC, approved Fexeric for the control of hyperphosphatemia in adult patients with CKD. Pursuant to the sunset clause under EU law, the EC's approval of Fexeric in the

EU was contingent on, among other things, our commencing marketing of Fexeric within three years; although we successfully negotiated an extension to December 23, 2019, we did not commence marketing Fexeric by such date and therefore the Fexeric approval in the EU has ceased to be valid.

We could face heightened risks with respect to seeking marketing approval in the United Kingdom, or UK, as a result of the recent withdrawal of the UK from the EU, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK withdrew from the EU, effective December 31, 2020. On December 24, 2020, the UK and the EU entered into a Trade and Cooperation Agreement. The agreement sets out certain procedures for approval and recognition of medical products in each jurisdiction. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of the Trade and Cooperation Agreement would prevent us from commercializing vadadustat or any other product candidate, including those that may be in-licensed or acquired, in the UK and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK for vadadustat or any other product candidate, which could significantly and materially harm our business. As of January 1, 2021, the MHRA became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to European Union rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended) as the basis for regulating medicines.

In addition, the safety concerns associated with the current standard of care for the indications for which we are seeking marketing approval for vadadustat may affect the FDA's or other regulatory authorities' review of the safety results of vadadustat. Additionally, these regulatory authorities may not agree with our assessment of adverse events. Further, the policies or regulations, or the type and amount of clinical data necessary to gain approval, may change during the course of a product candidate's clinical development and may vary among jurisdictions. It is possible that vadadustat will never obtain marketing approval in the United States 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 vadadustat for many reasons including, among others:

- we may not be able to demonstrate that vadadustat is safe and effective in treating adult patients with anemia due to CKD to the satisfaction of the relevant regulatory authority;
- the results of our clinical trials may only be modestly positive, or there may be concerns with the profile due to efficacy or safety;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the relevant regulatory authority for review and/or marketing approval;
- the relevant regulatory authority may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the relevant regulatory authority may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the relevant regulatory authority may not approve the formulation, labeling or specifications we request for vadadustat;
- the relevant regulatory authority may approve vadadustat or any other product candidate for use only in a small patient population or for fewer or more limited indications than we request;
- the relevant regulatory authority may require that we conduct additional clinical trials or repeat one or more clinical trials;
- the FDA or other relevant regulatory authority may require development of a REMS as a condition of approval or post-approval;
- the relevant regulatory authority may grant approval contingent on the performance of costly post-marketing clinical trials;
- the relevant regulatory authority's onsite inspections may be delayed due to the recent COVID-19 pandemic or otherwise;
- we, or our CROs or other vendors, may fail to comply with GXP or fail to pass any regulatory inspections or audits;
- we or our third party manufacturers may fail to perform in accordance with the FDA's or other relevant regulatory authority's cGMP requirements and guidance;
- the FDA may disagree with inclusion of data obtained from certain regions outside the United States to support the NDA for potential reasons such as differences in clinical practice from United States standards;
- the relevant regulatory authority could deem that our financial relationships with certain principal investigators constitute a conflict of interest, such that the data from those principal investigators may not be used to support our applications;
- as part of any future regulatory process, the FDA may ask an Advisory Committee to review portions of the NDA, the FDA may have difficulty scheduling an Advisory Committee meeting in a timely manner or, if convened, an FDA

Advisory Committee could recommend non-approval, conditions of approval or restrictions on approval, and the FDA may ultimately agree with the recommendations;
- the relevant regulatory authority's review process and decision-making regarding vadadustat and any other 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 vadadustat 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.

If we experience further delays in obtaining approval, or if we fail to obtain approval of vadadustat for some or all of the indications for which we have sought approval, the commercial prospects for vadadustat may be harmed and our ability to generate revenues will be materially impaired, which could have a material adverse effect on our business. For example, the FDRR we submitted to the FDA in October 2022 focused on the favorable balance between the benefits and risks of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis.

Finally, our ability to develop and market new drug products may be threatened by ongoing litigation challenging the FDA's approval of mifepristone. Specifically, on April 7, 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a REMS. In reaching that decision, the district court made a number of findings that numerous representatives of the pharmaceutical and biotechnology industry believe will chill the development, approval and distribution of new drug products in the United States. Among other determinations, the district court substituted its scientific judgement for that of the FDA and it held that FDA must provide a special justification for any differences between an approved drug's labeling and the conditions that existed in the drug's clinical trials. Further, the district court read the jurisdictional requirements governing litigation in federal court so as to potentially allow virtually any party to bring a lawsuit against the FDA in connection with its decision to approve an NDA or establish requirements under a REMS. On April 13, 2023, the district court decision was stayed, in part, by the U.S. Court of Appeals for the Fifth Circuit. Thereafter, on April 21, 2023, the U.S. Supreme Court entered a stay pending disposition of the appeal of the district court decision in the Court of Appeals for the Fifth Circuit or the Supreme Court. That court held oral arguments in the case on May 17, 2023 and a decision is expected soon. Depending on the outcome of this litigation and the regulatory uncertainty it has engendered, our ability to develop new drug product candidates and to maintain approval of existing drug products and measures adopted under a REMS is at risk and could be delayed, undermined or subject to protracted litigation.

Products approved for marketing are subject to extensive post-marketing regulatory requirements 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 any of them is approved.

Marketing approvals may be subject to limitations on the approved indicated uses for which the product may be marketed or other conditions of approval, or contain requirements or commitments for potentially costly post-marketing studies and surveillance to monitor the safety and efficacy of the product, including REMS, or registries or observational studies. For example, in connection with the FDA approvals of Auryxia, we initially committed to the FDA to conduct certain post-approval pediatric studies of Auryxia under the Pediatric Research Equity Act of 2003, or PREA. With regard to the Hyperphosphatemia Indication for Auryxia, we initially committed to completing the original post-approval pediatric study and submitting a final report to the FDA by December 31, 2019. However, we did not complete the study according to the original schedule and therefore did not submit the required final report by December 31, 2019. Consequently, we received a notification of noncompliance with PREA. However, we have since been released from the original post marketing requirement, or PMR, and a new PMR was issued that provided that the final report is due in April 2024. Therefore, this PMR trial is no longer considered delayed and is open and actively enrolling patients. In June 2023 we requested an extension of time for the submission of the final report and such request was denied by the FDA in August 2023. Therefore, the final report for this PMR trial is still due in April 2024, and we are unlikely to complete the trial by that time. With regard to our IDA Indication, we initially committed to completing the post-approval pediatric study and submitting a final report to the FDA by January 2023. We did not meet a milestone relating to this post-approval pediatric study of Auryxia in a timely manner and received a notification from the FDA. Subsequently, the FDA agreed to extend the pediatric clinical trial timelines for the IDA Indication. We subsequently communicated to the FDA that we would be delaying the start of the clinical trial in the IDA Indication while we work to produce smaller size tablets. In response, the FDA issued a partial clinical hold until we manufacture the smaller tablets and provide the FDA with relevant information regarding the smaller sized tablets for review. The FDA lifted the partial clinical hold in June 2022, however, we have not commenced start up of this study pending resolution of the manufacturing of the smaller size tablets. If we are unable to complete these studies successfully by the applicable deadline, or have further delays in completing these studies, we will need to inform the FDA, have further discussions and, if the FDA finds that we failed to comply with pediatric study requirements, in violation of applicable law, it could institute enforcement proceedings to seize or

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

Moreover, the FDA and other regulatory authorities closely regulate the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other regulatory authorities impose stringent restrictions on companies' communications regarding use of their products, and if we promote any approved product beyond its approved indications or inconsistent with the approved label, we may be subject to enforcement actions or prosecution arising from such activities. Violations of the U.S. Federal Food, Drug, and Cosmetic Act, or the FDCA, relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws, insurance fraud laws, third party payor actions, stockholder actions and other lawsuits.

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

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

For example, we previously had three limited, voluntary recalls of Auryxia. These and any other recalls or any supply, quality or manufacturing issues in the future 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 Japan, Vafseo in Japan and Europe or vadadustat, if approved 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 United States or in other jurisdictions. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would materially adversely affect our business.

Risks Related to Governmental Regulation and Compliance

We are subject to a complex regulatory scheme that requires 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 United States 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 United States;
- data privacy laws existing in the United States, 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, and 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, or the EU GDPR;
- 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 vadadustat, if approved, 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 FDCA which among other things, strictly regulates drug product marketing and promotion and prohibits manufacturers from marketing such products for off-label use;
- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs, and laws requiring notification of price increases;
- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties, and violations of the FDCA, the federal government pricing laws, and the federal Anti-Kickback Statute trigger liability under the federal False Claims Act;
- HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the HITECH, and their respective implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act (renamed the Open Payments 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 and foreign laws and regulations, such as state anti-kickback and false claims laws and gift ban and transparency statutes, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by state Medicaid or other programs, or non-governmental third party payors, including private insurers, and which are not preempted by federal laws and often differ from state to state, thus complicating compliance efforts; and

- U.S. state laws restricting interactions with healthcare providers and other members of the healthcare community or requiring pharmaceutical manufacturers to implement certain compliance standards, which vary from state to state.

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

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

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

Physicians are permitted to prescribe drug products for uses that differ from those approved by the FDA or other applicable regulatory agencies. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies do restrict manufacturer communications regarding unapproved uses of an approved drug. Companies are not permitted to promote drugs for unapproved uses or in a manner that is inconsistent with the FDA-approved labeling. There are also restrictions about making comparative or superiority claims based on safety or efficacy that are not supported by substantial evidence. Accordingly, we may not promote Auryxia in the United States for use in any indications other than the Hyperphosphatemia Indication and the IDA Indication, and all promotional claims must be consistent with the FDA-approved labeling for Auryxia.

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

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. In addition, under some relatively recent guidance from the FDA, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We intend to engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. Although we believe we have put in place a robust compliance program and processes designed to ensure that all such activities are performed in a legal and compliant manner, such program and processes may not be sufficient to deter or detect all violations.

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

Disruptions in the FDA, regulatory authorities outside the U.S. and other government agencies caused by global health concerns or funding shortages could prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.

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

Disruptions may still result also from the recent COVID-19 pandemic or any similar event that may occur in the future. During the recent COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. The FDA has now indicated that it can and will conduct timely reviews of applications for medical in line with its user fee performance goals, including conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, in the event of a resurgence of the recent COVID-19 pandemic or a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to the recent COVID-19 pandemic or a similar public health emergency and may also experience delays in their regulatory activities.

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

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

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which took effect across all member states of the EEA, in May 2018. Following the withdrawal of the U.K. from the EU, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the U.K. 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 global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric or health data and permits EU member states to adopt further penalties for violations that are not subject to the administrative fines outlined in the GDPR.

The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the United States and, as a result, increases the scrutiny that we should apply to transfers of personal data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. There is ongoing uncertainty about the transfer mechanisms that companies rely upon to enable the legal transfer of personal data from the EU to other countries. For example, in July 2020, the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S. As court decisions and regulatory guidance evolves, challenges remain with respect to GDPR compliance. Companies must continue to monitor the regulatory landscape and implement necessary changes, all of which may be costly and may put the company out of compliance while any changes are being implemented.

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

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

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

New laws also are being considered at both the state and federal levels. For example, the CCPA, which went into effect on January 1, 2020, and the CPRA, which amends CCPA by expanding the scope and applicability, while also introducing new

privacy protections, is creating similar risks and obligations as those created by GDPR. In November 2020, California voters passed a ballot initiative for the CPRA, which went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also creates a new agency that is specifically responsible for enforcing the new law. Because of this, we may need to engage in additional activities (e.g., data mapping) to identify the personal information we are collecting and the purposes for which such information is collected. In addition, we will need to ensure that our policies recognize the rights granted to consumers (as that phrase is broadly defined in the CCPA and can include business contact information).

In addition to California, at least eleven other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond, including New York and New Jersey. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. 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.

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

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of vadadustat, or any other product candidate, restrict or regulate post-approval activities and affect our ability to profitably sell Auryxia and vadadustat, if approved. 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 vadadustat, if approved, or any reimbursement that physicians receive for administering any approved product.

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

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the ACA. In addition, other legislative and regulatory changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which will remain in effect through 2031. However, pursuant to the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, and subsequent legislation, these Medicare sequester reductions were suspended and reduced through the end of June 2022, but the full 2% cut resumed as of July 1, 2022.

The American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, other legislative and regulatory changes have been proposed, but not yet adopted. For example, in July

2019, the U.S. Department of Health and Human Services, or HHS, proposed regulatory changes in kidney health policy and reimbursement. Any new legislative or regulatory changes may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for Auryxia or vadadustat, if approved, or the frequency with which Auryxia and vadadustat, if approved, is prescribed or used.

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

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

At the same time, the administration may seek to limit Medicare Part D and public option drug prices through a tax penalty on manufacturers for increases in the cost of drugs and biologics above the general inflation rate. The American Rescue Plan Act of 2021, comprehensive COVID-19 pandemic relief legislation recently enacted under the current administration, includes a number of healthcare-related provisions, such as support to rural health care providers, increased tax subsidies for health insurance purchased through insurance exchange marketplaces, financial incentives to states to expand Medicaid programs and elimination of the Medicaid drug rebate cap effective in 2024.

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

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

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year.

On June 6, 2023, Merck & Co. Inc., or Merck, filed a lawsuit against HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the United States Constitution. Subsequently, other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, and the Pharmaceutical Research and Manufacturers of America also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. On July 11, 2023, Merck moved for summary judgment in its action and, the next day, the U.S. Chamber of Commerce moved for preliminary injunctive relief seeking to stop implementation of the drug pricing provisions of the IRA. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.

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 United States 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 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 and any products 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 or any other approved product;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

In addition, in some countries, including member states of the EU 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 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.

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

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

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

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

Risks Related to our Reliance on Third Parties

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

We sublicensed the rights to commercialize Riona to JT and Torii in Japan. We also entered into a collaboration agreement with MTPC to develop and commercialize vadadustat in Japan and certain other Asian countries. In addition, we entered into the Vifor Second Amended Agreement pursuant to which we granted CSL Vifor an exclusive license to sell vadadustat to the Supply Group in the United States. We also granted to Averoa an exclusive license to develop and commercialize ferric citrate in the EEA, Turkey, Switzerland and the United Kingdom. Furthermore, in May 2023, we entered into the license agreement with Medice, pursuant to which we granted Medice an exclusive license to develop and commercialize vadadustat for the treatment of anemia in patients with chronic kidney disease in the Medice Territory. We may form or seek other strategic alliances, joint ventures, or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our and our partners' commercialization efforts with respect to Auryxia, Riona, Vafseo and our and our partners' development and, if approved, commercialization efforts with respect to vadadustat and any other product candidates. We may not be able to maintain our collaborations for development and commercialization. For example, on May 13, 2022, Otsuka Pharmaceutical Co. Ltd., or Otsuka, elected to terminate our collaboration agreements with them, and we subsequently negotiated a Termination and Settlement Agreement with Otsuka. This termination by Otsuka may delay the launch of vadadustat in Europe or other territories previously licensed to Otsuka or adversely affect how we are perceived in scientific and financial communities. For example, in August 2023, Medice informed us that their launch of Vafseo in certain countries in the Medice Territory was going to be later than previously anticipated due to the activities required to enable the launch. In addition, our current and any future collaborations may not be successful due to a number of important factors, including the following:

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

delayed timelines, re-prioritization of our programs, decreasing resources or funding allocated to support our programs, or termination of the collaborations; and
- collaborators may not comply with all applicable regulatory and legal requirements.

If any of these events occurs, the market potential of Auryxia, Riona, Vafseo or vadadustat, if and 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 will require substantial additional cash to fund the continued commercialization of Auryxia and the development and potential commercialization of any of our product candidates, including vadadustat, if approved. We may decide to enter into additional collaborations for the development and commercialization of Auryxia or our product candidates, including vadadustat, both within and outside of the United States. For example, in May 2023, we entered into the license agreement with Medice, pursuant to which we granted Medice an exclusive license to develop and commercialize vadadustat for the treatment of anemia in patients with chronic kidney disease in the Medice Territory. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, divert management's attention, or disrupt our business.

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

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

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

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 vadadustat under our MTPC Agreement will likely fluctuate and will impact our rights to receive future payments under our Royalty Agreement with HCR.

Pursuant to the Royalty Agreement with HCR, we sold to HCR our right to receive the Royalty Interest Payments payable to us under the MTPC Agreement, subject to the Annual Cap and the Aggregate Cap. After HCR receives Royalty Interest Payments equal to the Annual Cap in a given calendar year, we will receive 85% of the Royalty Interest Payments for the remainder of that year. After HCR receives Royalty Interest Payments equal to the Aggregate Cap, or we pay the Aggregate Cap to HCR (net of the Royalty Interest Payments already received by HCR), the Royalty Interest Payments will revert back to us, and HCR would have no further right to any Royalty Interest Payments. We received $44.8 million from HCR (net of certain transaction expenses) under the Royalty Agreement, and we are eligible to receive up to an additional $15.0 million under the Royalty

Agreement if specified sales milestones are achieved for vadadustat in the territory covered by the MTPC Agreement, subject to the satisfaction of certain customary conditions.

The royalty revenues under the MTPC Agreement may fluctuate considerably because they depend upon, among other things, the rate of growth of sales of vadadustat in the territory covered by the MTPC Agreement. Negative fluctuations in these royalty revenues could delay, diminish or eliminate our right to receive up to the additional $15.0 million under the Royalty Agreement upon achievement of the specified sales milestones, 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 in many instances only have a single supplier, and the loss of these manufacturers, their failure to supply us on a timely basis, or at all, or their failure to successfully carry out their contractual duties or comply with regulatory requirements, cGMP requirements, or guidance could cause delays in or disruptions to our supply chain and substantially harm our business.

We do not have any manufacturing facilities and do not expect to independently manufacture any product 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. 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 sufficient quantities of Auryxia and vadadustat or the ability to obtain such quantities at an acceptable cost or quality, which could delay, prevent or impair our and our partners' development or commercialization efforts.

We currently rely on a single source supplier for each of Auryxia drug substance and drug product and vadadustat drug substance and drug product, and alternate sources of supply may not be readily available. If any of the following occurs, we may not have sufficient quantities of Auryxia and/or vadadustat to support our clinical trials, development, commercialization, or obtaining and maintaining marketing approvals, which could materially and adversely impact our business and results of operations:

- we are unsuccessful in maintaining our current supply arrangements for commercial quantities of Auryxia and vadadustat;
- we are unsuccessful in validating new sites;
- our commercial supply arrangements for Auryxia or vadadustat are terminated;
- any of our third party manufacturers are unable to fulfill the terms of their agreements with us due to technical issues, natural disasters or other reasons, including with respect to quality and quantity, or are unable or unwilling to continue to manufacture on the manufacturing lines included in our regulatory filings; or
- 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.

If any of our third party manufacturers cannot or do not perform as agreed or expected, including as a result of catastrophic events, including pandemics, including the recent COVID-19 pandemic, terrorist attacks, wars or other armed conflicts, geopolitical tensions or natural disasters, if they misappropriate our proprietary information, if they terminate their engagements with us, if we terminate our engagements with them, or if there is a significant disagreement, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into agreements with other third party manufacturers, which we may not be able to do in a timely manner or on favorable or reasonable terms, if at all. If any of these events occur, especially with respect to one of our sole source suppliers, we may not have sufficient quantities of product for the commercialization of Auryxia and/or vadadustat, if approved, or may experience delays in the development of our products or product candidates, which could materially and adversely impact our business and results of operation. For example, one of our manufacturers has notified us that it will be discontinuing operations at one site at a future date. In some cases, there may be a limited number of qualified replacement manufacturers, or the technical skills or equipment required to manufacture a product or product candidate may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third party, or a feasible alternative may not exist. These factors would increase our reliance on our current manufacturers or require us to obtain necessary regulatory approvals and licenses in order to have another third party manufacture Auryxia or vadadustat. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays and costs associated with the qualification of a new manufacturer and validation of manufacturing processes would negatively affect our ability to supply clinical trials, obtain and maintain marketing approval, or commercialize or satisfy patient demand for Auryxia and vadadustat, where approved, in a timely manner, within budget, or at all.

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

Moreover, issues that may arise in any scale-up and technology transfer and continued commercial scale manufacture of our products may lead to significant delays in our development, marketing approval and commercial timelines and negatively impact our financial performance. For example, a production-related issue resulted in an interruption in the supply of Auryxia in the third and fourth quarters of 2016. This supply interruption negatively impacted Keryx's revenues in 2016. This supply interruption was resolved, and we have taken and continue to take actions designed to prevent future interruptions in the supply of Auryxia. However, we recently experienced issues in manufacturing Auryxia, and if we continue to experience manufacturing issues or our actions to prevent future interruptions are not successful, we may experience additional supply issues. In addition, before we can manufacture product at a new site, we must validate the process at that site. If the process validation is unsuccessful, or takes longer than we anticipate, we may have to expend additional resources and could experience a supply interruption. Any future supply interruptions, whether quality or quantity based, for Auryxia or vadadustat, if and where approved, would negatively and materially impact our reputation and financial condition.

There are a limited number of manufacturers that are capable of manufacturing Auryxia and vadadustat for us and complying with cGMP regulations and guidance and other stringent regulatory requirements and guidance enforced by the FDA, EMA, PMDA and other regulatory authorities. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation, which occur in addition to our own quality assurance releases. The facilities and processes used by our third party manufacturers to manufacture Auryxia may be inspected by the FDA and other regulatory authorities at any time, and the facilities and processes used by our third party manufacturers to manufacture vadadustat will be inspected by the FDA, the EMA and other regulatory authorities prior to or after we submit our marketing applications. Although we have general visibility into the manufacturing processes of our third party manufacturers, we do not ultimately control such manufacturing processes of, and have little control over, our third party manufacturers, including, without limitation, their compliance with cGMP requirements and guidance for the manufacture of certain starting materials, drug substance and finished drug product. Similarly, although we review final production, we have little control over the ability of our third party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Our third party manufacturers may experience problems with their manufacturing and distribution operations and processes, including, for example, quality issues, such as product specification and stability failures, procedural deviations, improper equipment installation or operation, utility failures, contamination, natural disasters and public health epidemics. We may also encounter difficulties relating to our own quality processes and procedures, including regulatory compliance, lot release, quality control and quality assurance, as well as shortages of qualified personnel. If our third party manufacturers cannot successfully manufacture material that conforms to our specifications and regulatory requirements and guidance, or if we or our third party manufacturers experience manufacturing, operations and/or quality issues, including an inability or unwillingness to continue manufacturing our products at all, in accordance with agreed-upon processes or on currently validated manufacturing lines, we may not be able to supply patient demand or maintain marketing approval for Auryxia, secure and maintain marketing approval for vadadustat, and we might be required to expend additional resources to obtain material from other manufacturers. If any of these events occur, our reputation and financial condition would be negatively and materially impacted. In addition, during the year ended December 31, 2022, we had higher write-downs to inventory reserves related to Auryxia drug substance that will not be forward processed into drug product. If we have additional write-downs to inventory reserves in the future, it could negatively impact our ability to supply Auryxia, and our financial condition could be harmed.

If the FDA, the EMA or other regulatory authorities do not approve the facilities being used to manufacture vadadustat, or if they withdraw any approval of the facilities being used to manufacture Auryxia or vadadustat, we may need to find alternative manufacturing facilities, which would significantly impact our ability to continue commercializing Auryxia or Vafseo in Japan, or develop, obtain marketing approval for or market vadadustat or our other product candidates, if approved.

Moreover, our failure or the failure of our third party manufacturers 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, including, where applicable, clinical holds, fines, injunctions, civil penalties, delays in, suspension of or withdrawal of approvals, license revocation, seizures or recalls of Auryxia or Vafseo in Japan, operating restrictions, receipt of a Form 483 or warning letter, or criminal prosecutions, any of which could significantly and adversely affect the supply of Auryxia or vadadustat. For example, we previously conducted three limited, voluntary recalls of Auryxia. These and any other recalls or any supply, quality or manufacturing issues in the future and any related write-downs of inventory or other consequences could result in significant negative consequences, including reputational harm, loss of customer confidence, and a negative impact on our financials, any of which could have a material adverse effect on our business and results of operations, and may impact our ability to supply Auryxia, Vafseo in Japan or Europe or vadadustat, if approved in other countries, 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' control, it may adversely impact our ability to supply Auryxia or vadadustat, and we may incur significant financial harm.

In addition, Auryxia and vadadustat may compete with other products and product candidates for access to third party manufacturing facilities. A third party manufacturer 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 or vadadustat due to exclusivity provisions in agreements with our competitors. Any of the foregoing could negatively impact our third party manufacturers' ability to meet our demand, which could adversely impact our ability to supply Auryxia or vadadustat, and we may incur significant financial harm.

Our current and anticipated future dependence on third parties for the manufacture of Auryxia and vadadustat may adversely affect our and our partners' ability to commercialize Auryxia and vadadustat, 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, vadadustat or any of our product candidates, and our business could be substantially harmed.

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

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

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

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

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

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

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

We do not own all of the rights to our product, Auryxia. We have licensed and sublicensed certain rights, patent and otherwise, to Auryxia from a third party, Panion & BF Biotech, Inc., or Panion, who in turn licenses certain rights to Auryxia from one of the inventors of Auryxia. The license agreement with Panion, or the Panion License Agreement, requires us to meet development milestones and imposes development and commercialization due diligence requirements on us. In addition, under the Panion License Agreement, we must pay royalties based on a mid-single digit percentage of net sales of product resulting from the licensed technologies, including Auryxia, and pay the patent filing, prosecution and maintenance costs related to the license. If we do not meet our obligations in a timely manner, or if we otherwise breach the terms of the Panion License Agreement, Panion could terminate the agreement, and we would lose the rights to Auryxia. For example, following announcement of the Merger, Panion notified Keryx in writing that Panion would terminate the Panion License Agreement on November 21, 2018 if Keryx did not cure the breach alleged by Panion, specifically, that Keryx failed to use commercially reasonable best efforts to commercialize Auryxia outside the United States. Keryx disagreed with Panion's claims, and the parties entered discussions to resolve this dispute. On October 24, 2018, prior to the consummation of the Merger, we, Keryx and Panion entered into a letter agreement, or the Panion Letter Agreement, pursuant to which Panion agreed to rescind any and all prior termination threats or notices relating to the Panion License Agreement and waived its rights to terminate the license agreement based on any breach by us of our obligation to use commercially reasonable efforts to commercialize Auryxia outside the United States until the parties executed an amendment to the Panion License Agreement in accordance with the terms of the Panion Letter Agreement, following consummation of the Merger. On April 17, 2019, we and Panion entered into an amendment and restatement of the Panion License Agreement, or the Panion Amended License Agreement, which reflects certain revisions consistent with the terms of the Panion Letter Agreement. See Note 5 to our consolidated financial statements in Part I, Item 1. Financial Statements of this Quarterly Report on Form 10-Q for additional information regarding the Panion Amended License Agreement. Even though we entered into the Panion Amended License Agreement, there are no assurances that Panion will not allege other breaches of the Panion Amended License Agreement or otherwise attempt to terminate the Panion Amended License Agreement in the future. In addition, if Panion breaches its agreement with the inventor from whom it licenses rights to Auryxia, Panion could lose its license, which could impair or delay our ability to develop and commercialize Auryxia.

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

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 United States and certain foreign jurisdictions. The process for obtaining patent protection is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in a cost effective or timely manner. In addition, we may fail to identify patentable subject matter early enough to obtain patent protection. Further, license agreements with third parties may not allow us to control the preparation, filing and prosecution of patent applications, or the maintenance or enforcement of patents. Such third parties may decide not to enforce such patents or enforce such patents without our involvement. Thus, these patent applications and patents may not, under these circumstances, be prosecuted or enforced in a manner consistent with the best interests of the company.

Our pending patent applications may not issue as patents and may not issue in all countries in which we develop, manufacture or potentially sell our product 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 product.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in pharmaceutical and biotechnology patents has emerged to date. Changes in the patent laws or the interpretation of the patent laws in the United States 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 product and technologies which may have an adverse effect on our business. If our competitors prepare and file patent applications in the United States 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 United States, 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 United States 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 United States, 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 United States. 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 United States 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 United States and abroad. As a result of such challenges, we may lose exclusivity or freedom-to-operate or patent claims may be narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to prevent third parties from using or commercializing similar or identical products, or limit the duration of the patent protection for our products.

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

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

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

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

Filing, prosecuting and defending patents on our products and product candidates in all countries throughout the world would be prohibitively expensive. Consequently, the breadth of our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some countries do not protect intellectual property rights to the same extent as laws in the United States. As a result, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States 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 United States. 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 United States could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage for our products and product candidates from the intellectual property that we develop or license.

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

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

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

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

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

In addition to patent rights in the United States, we may seek non-patent exclusivity for vadadustat and other product candidates under other provisions of the FDCA such as new chemical entity, or NCE, exclusivity, or exclusivity for a new use or new formulation, but there is no guarantee that vadadustat or any other product candidates will receive such exclusivity. The FDCA provides a five-year period of non-patent exclusivity within the United States to the first sponsor to gain approval of an NDA for an NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which consists of the molecule(s) or ion(s) responsible for the action of the drug substance (but not including those portions of the molecule that cause it to be a salt or ester or which are not bound to the molecule by covalent or similar bonds). During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the sponsor does not own or have a legal right of reference to all the data required for approval.

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

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

In addition to NCE, in the United States, 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.

We cannot assure you that Auryxia, vadadustat, if approved, or any of our potential future products will obtain such pediatric exclusivity, NCE exclusivity or any other market exclusivity in the United States, EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any non-patent exclusivity protection. We also cannot assure you that Auryxia, vadadustat, if approved, or any of our potential future products will obtain patent term extension.

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

Although the composition and use of Auryxia is currently claimed by 14 issued patents that are listed in the FDA's Orange Book, we cannot assure you that we will be successful in defending against third parties attempting to invalidate or design around our patents or asserting that our patents are invalid or otherwise unenforceable or not infringed, or in competing against third parties introducing generic equivalents of Auryxia or any of our potential future products. If our Orange Book-listed patents are successfully challenged by a third party and a generic version of Auryxia is approved and launched sooner than we anticipate, revenue from Auryxia could decline significantly, which would have a material adverse effect on our sales, results of operations and financial condition.

We previously received Paragraph IV certification notice letters regarding ANDAs submitted to the FDA requesting approval for generic versions of Auryxia tablets (210 mg ferric iron per tablet). We filed complaints for patent infringement relating to such ANDAs, and subsequently entered into settlement and license agreements with all such ANDA filers that allow such ANDA filers to market a generic version of Auryxia in the United States beginning on March 20, 2025. It is possible that we may receive Paragraph IV certification notice letters from additional ANDA filers and may not ultimately be successful in an ANDA litigation. Generic competition for Auryxia or any of our potential future products could have a material adverse effect on our sales, results of operations and financial condition.

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

We may be forced to initiate litigation to enforce our contractual and intellectual property rights, or we may be sued by third parties asserting claims based on contract, tort or intellectual property infringement. Competitors may infringe our patents or misappropriate our trade secrets or confidential information. We may not be able to prevent infringement of our patents or misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. In addition, third parties may have or may obtain patents in the future and claim that our products or other technologies infringe their patents. If we are required to defend against suits brought by third parties, or if we sue third parties to protect our rights, we may be required to pay substantial litigation costs, and our management's attention

may be diverted from operating our business. In addition, any legal action against our licensor, licensees or us that seeks damages or an injunction of commercial activities relating to Auryxia, vadadustat or any other product candidates or other technologies, including those that may be in-licensed or acquired, could subject us to monetary liability, a temporary or permanent injunction preventing the development, marketing and sale of such products or such technologies, and/or require our licensor, licensees or us to obtain a license to continue to develop, market or sell such products or other technologies. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. We cannot predict whether our licensor, licensees or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. However, there may be patents of third parties of which we are currently unaware with claims to compounds, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Also, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. The pharmaceutical and biotechnology industries are characterized by extensive litigation over patent and other intellectual property rights. We have in the past and may in the future become a party to, or be threatened with, future adversarial litigation or other proceedings regarding intellectual property rights with respect to our product and product candidates. As the pharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that our drug 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 United States 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 United States or import into the United States 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 one commercial product, Auryxia. We received the CRL from the FDA regarding our NDA for vadadustat in March 2022, and, if in the future vadadustat is approved, vadadustat could be commercialized. We attempt to ensure that our products and product candidates and the methods we employ to manufacture them, as well as the methods for their use which we intend to promote, do not infringe other parties' patents and other proprietary rights. There can be no assurance they do not, however, and competitors or other parties may assert that we infringe their proprietary rights in any event.

FibroGen has filed patent applications in the United States 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. We have, and may in the future, initiate opposition or other legal proceedings with respect to such patents. If we are not successful in such proceedings, FibroGen could try to claim that our products infringe their patent rights. For example, we filed oppositions in the EPO, against certain of FibroGen's patents. A number of those patents were revoked during oppositions or have since expired, but one of the patents, European Patent No 1633333, or the '333 EP Patent was maintained in restricted form. The remaining claims are directed to: treatment of anemia of chronic disease in subjects having a percent transferrin saturation of less than 20% (claim 1), treatment of anemia that is refractory to treatment with exogenously administered erythropoietin (claim 6), and treatment of iron deficiency (claim 15). We discussed the status of the opposition and/or invalidation proceedings against certain FibroGen patents in Part I, Item 3. Legal Proceedings of our Annual Report on Form 10-K for the year ended December 31, 2022 filed on March 10, 2023.

Third parties, including FibroGen, may in the future claim that our product and product candidates and other technologies infringe upon their patents and may challenge our ability to commercialize Auryxia and vadadustat, if approved. 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 further develop and commercialize vadadustat or any other 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 and invalidation proceedings in the European Patent Office, Intellectual Property High Court of Japan, and the Patents Court of the UK. These proceedings may be ongoing for a number of years and may involve substantial expense and diversion of employee resources from our business. In addition, we may become involved in additional opposition proceedings or other legal or administrative proceedings in the future. For more information, see the other risk factors under "Risks Related to our Intellectual Property".

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

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

We have received confidential and proprietary information from potential collaborators, prospective licensees and other third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to our Business and Managing Growth

If we fail to attract, retain and motivate senior management and qualified personnel, we may be unable to successfully develop, obtain and/or maintain marketing approval of and commercialize vadadustat or commercialize Auryxia.

Recruiting and retaining qualified personnel is critical to our success. We are also highly dependent on our executives, certain members of our senior management and certain members of our commercial organization. The loss of the services of our

executives, senior managers or other employees could impede the achievement of our research, development, regulatory and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Specifically, following receipt of the CRL, in April and May 2022, we implemented a reduction of our workforce by approximately 42% across all areas of our company (47% inclusive of the closing of the majority of open positions), including several members of management. In November 2022, we also implemented a reduction of our workforce, by approximately 14% consisting of individuals within our commercial organization as a result of our decision to shift to a strategic account management focused model for our commercial efforts. In addition, uncertainty related to the timing and outcome of regulatory decisions, could increase attrition. Losing members of management and other key personnel subjects us to a number of risks, including the failure to coordinate responsibilities and tasks, the necessity to create new management systems and processes, the impact on corporate culture, and the retention of historical knowledge.

Furthermore, replacing executives, senior managers and other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, obtain and/or maintain marketing approval of and commercialize Auryxia, vadadustat and other product candidates. Our future financial performance and our ability to develop, obtain and/or maintain marketing approval of and commercialize Auryxia and vadadustat and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to hire, train, integrate, and retain additional qualified personnel with sufficient experience. We may be unable to hire, train, retain or motivate these personnel on acceptable terms given the intense competition among numerous biopharmaceutical companies for similar personnel, particularly in our geographic region.

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

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

Following receipt of the CRL, in April and May 2022, we implemented a reduction in workforce by approximately 42% across all areas of our Company (47% inclusive of the closing of the majority of open positions), including several members of management. In November 2022, we also implemented a reduction of our workforce, by approximately 14% consisting of individuals within our commercial organization. The reductions in workforce reflect our strategic pillars to drive Auryxia revenue while also continuing to decrease operating costs. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. We recorded a restructuring charge of approximately $15.9 million in the year ended December 31, 2022 primarily related to contractual termination benefits including severance, non-cash stock-based compensation expense, healthcare and related benefits. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. We also cannot guarantee that we will not have to undertake additional workforce reductions or restructuring activities in the future, including as a result of the FDA's decision related to our anticipated NDA resubmission for vadadustat. Furthermore, our cost savings plan may be disruptive to our operations, including our commercialization of Auryxia, which could affect our ability to generate product revenue. In addition, our workforce reductions could yield unanticipated consequences, such as attrition beyond planned staff reductions, or disruptions in our day-to-day operations. Our workforce reductions could also harm our ability to attract and retain qualified management, scientific, clinical, manufacturing and sales and marketing personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully commercializing Auryxia and from successfully developing and commercializing our product candidates in the future, including vadadustat, if approved. If we are ultimately successful in obtaining approval of vadadustat in the United States, we will need to hire additional employees to support the commercialization of vadadustat in the United States, and if we are unsuccessful or delayed in doing so, the potential launch of vadadustat could be delayed.

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

In our day-to-day operations, we may encounter difficulties in managing the size of our operations as well as challenges associated with managing our business. We have strategic collaborations for the commercialization of Riona and the development and commercialization of vadadustat, which is now being or will be marketed under the trade name Vafseo by our collaboration partner, MTPC, in Japan and our collaboration partner, Medice, in the Medice Territory. Additionally, in the United States, we have a strategic relationship with CSL Vifor related to the commercialization of vadadustat, if approved. As our operations continue, we expect that we will need to manage our current relationships and enter into new relationships with

various strategic collaborators, consultants, vendors, suppliers and other third parties. These relationships are complex and create numerous risks as we deal with issues that arise.

For example, we supply or have agreed to supply, as applicable, Auryxia in Europe, Vafseo in Japan and Europe and vadadustat in the United States, if approved, for commercial and clinical use to MTPC, Medice, Averoa and CLS Vifor, 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 vadadustat, if and where approved, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. This future growth will impose significant added responsibilities on the business and members of management. To manage any future growth, we must continue to implement and improve our managerial, operational and financial systems, procedures and processes. We may not be able to implement these improvements in an efficient or timely manner and may discover deficiencies in existing systems, procedures and processes. Moreover, the systems, procedures and processes currently in place or to be implemented may not be adequate for any such growth. Any expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully managing and, as applicable, growing our company.

In addition, we may need to further adjust the size of our workforce as a result of changes to our expectations for our business, which can result in management being required to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth-related activities and related expenses. Further, we rely on independent third parties to provide certain services to us. We structure our relationships with these outside service providers in a manner that we believe results in an independent contractor relationship, not an employee relationship. If any of our service providers are later legally deemed to be employees, we could be subject to employment and tax withholding liabilities and other additional costs as well as other multiple damages and attorneys' fees.

We have identified a material weakness in our internal control over financial reporting as of December 31, 2022 relating to our product return reserves that resulted in a revision of our financial statements for the years ended December 31, 2022, 2021 and 2020. If we are not able to remediate this material weakness, or if we experience additional material weaknesses or other deficiencies in our internal control over financial reporting in the future or otherwise fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to maintain or implement required new or improved controls, or difficulties encountered in implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404 of the Sarbanes-Oxley Act, or Section 404, or any testing by our independent registered public accounting firm may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement.

During the quarter ended June 30, 2023 we identified a material weakness in our internal control over financial reporting that existed as of December 31, 2022 and continues to be unremediated through the date of this filing. Specifically, we did not appropriately design the controls for accrual of product returns to capture the return lag based on our customer returns policy for Auryxia, or the Product Return Reserve Material Weakness. This resulted in, among other things, errors to the following as of and for the years ended December 31, 2022, 2021 and 2020:

- an understatement of accrued expenses and other current liabilities by$5.1 million, $4.6 million and $2.0 million, respectively;
- an understatement of other non-current liabilities by $3.1 million, $3.4 million and $4.0 million, respectively;
- an overstatement of revenue by $0.1 million, $1.9 million and $0.6 million, respectively;
- an understatement of accounts receivable by $1.1 million, $0.7 million and $0.7 million, respectively; and
- an understatement of goodwill by $2.6 million.

For further discussion of the material weakness, see Part I, Item 4, "Controls and Procedures."

We have taken certain steps and plan to take additional steps to remediate this material weakness, including (i) implementing and documenting a new methodology and new controls to help to ensure the completeness and accuracy of our product return reserves, (ii) engaging additional third party subject matter experts and accounting personnel with U.S. GAAP experience

specific to product returns accounting and (iii) establishing effective monitoring and oversight controls to help to ensure the completeness and accuracy of our accrued product returns included in our financial statements and related disclosures. However, we cannot provide assurance that we will be able to correct this material weakness in a timely manner or that our remediation efforts will be adequate to allow us to conclude that our internal control over financial reporting will be effective in the future. Even if this material weakness is remediated in the future, we could identify additional material weaknesses or deficiencies in our internal control over financial reporting that could require correction or remediation. In addition, our conclusion that we have a material weakness could give rise to increased scrutiny, review, audit and investigation over our accounting controls and procedures, which could then lead to additional areas of deficiency or errors in our financial statements.

We will need to continue to dedicate internal resources, engage outside consultants and maintain a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to remediate the material weakness relating to our reserve for Auryxia product returns described above and any future control deficiencies or material weaknesses, and improve control processes as appropriate, validate through testing that controls are functioning as documented and maintain a continuous reporting and improvement process for internal control over financial reporting. If we are not able to correct material weaknesses or deficiencies in internal controls in a timely manner or otherwise comply with the requirements of Section 404 in a timely manner, our ability to record, process, summarize and report financial information accurately and within applicable time periods may be adversely affected, and we could be subject to sanctions or investigations by the SEC, the Nasdaq Stock Market or other regulatory authorities as well as stockholder litigation which, even if resolved in our favor, would require additional financial and management resources and could adversely affect the market price of our common stock. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock and could also effect our ability to raise capital to fund future business initiatives.

Security breaches and unauthorized use of our information technology systems and information, or the information technology systems or information in the possession of our collaborators and other third parties, could damage the integrity of our clinical trials, impact our regulatory filings, compromise our ability to protect our intellectual property, and subject us to regulatory actions that could result in significant fines or other penalties.

We, our collaborators, contractors and other third parties rely significantly upon information technology, and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively. In addition, we and our collaborators, contractors and other third parties rely on information technology networks and systems, including the Internet, to process, transmit and store clinical trial data, patient information, and other electronic information, and manage or support a variety of business processes, including operational and financial transactions and records, personal identifying information, payroll data and workforce scheduling information. We purchase most of our information technology from vendors, on whom our systems depend. We rely on commercially available systems, software, tools and monitoring to provide security for the processing, transmission and storage of company and customer information.

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

Companies and other entities and individuals have been increasingly subject to a wide variety of security incidents, cyber-attacks and other attempts to gain unauthorized access to systems and information. These threats can come from a variety of sources, ranging in sophistication from individual hackers to state-sponsored attacks. Cyber threats may be broadly targeted, or they may be custom-crafted against our information systems or those of our vendors or third party service providers. A security breach, cyberattack or unauthorized access of our clinical data or other data could damage the integrity of our clinical trials, impact our regulatory filings, cause significant risk to our business, compromise our ability to protect our intellectual property, and subject us to regulatory actions, including under the GDPR and CCPA discussed elsewhere in these risk factors and the privacy or security rules under federal, state, or other local laws outside of the United States 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 or other unauthorized access or other significant compromise of our computer, communications and related systems. Although we take steps to manage and avoid these risks and to be prepared to respond to attacks, our preventive and any remedial actions may not be successful and no such measures can eliminate the possibility of the systems' improper functioning or the improper access or disclosure of confidential or personally identifiable information such as in the event of cyberattacks. Security breaches, whether through physical or electronic break-ins, computer viruses, ransomware, impersonation of authorized users, attacks by hackers or other means, can create system disruptions or shutdowns or the unauthorized disclosure of confidential information.

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

Such attacks, whether successful or unsuccessful, or other compromises with respect to our information security and the measures we implement to prevent, detect and respond to them, could:

- result in our incurring significant costs related to, for example, rebuilding internal systems, defending against litigation, responding to regulatory inquiries or actions, paying damages or fines, or taking other remedial steps with respect to third parties;
- lead to public exposure of personal information of participants in our clinical trials, Auryxia patients and others;
- damage the integrity of our studies or delay their completion, disrupt our development programs, our business operations and commercialization efforts;
- compromise our ability to protect our trade secrets and proprietary information;
- damage our reputation and deter business partners from working with us; or
- divert the attention of our management and key information technology resources.

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

Our employees, independent contractors, principal investigators, CROs, CMOs, consultants and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading. In addition, laws and regulations governing any international operations we have or may have in the future may require us to develop and implement costly compliance programs.

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

- FDA and other healthcare authorities' regulations, including those laws that require the reporting of true, complete and accurate information to regulatory authorities, and those prohibiting the promotion of unapproved drugs or approved drugs for an unapproved use;
- quality standards, including GXP;
- federal and state healthcare fraud and abuse laws and regulations and their non-U.S. equivalents;
- anti-bribery and anti-corruption laws, such as the FCPA and the UK Bribery Act or country-specific anti-bribery or anti-corruption laws, as well as various import and export laws and regulations;
- laws that require the reporting of true and accurate financial information and data; and
- U.S. state and federal securities laws and regulations and their non-U.S. equivalents, including those related to insider trading.

We hold a marketing authorization for vadadustat from the EMA, the MHRA and Swissmedic, we are seeking regulatory approval for vadadustat with countries in the ACCESS Consortium, and we conducted our global clinical trials for vadadustat, and may in the future conduct additional trials, in countries where corruption is prevalent, and violations of any of these laws by

our personnel or by any of our vendors or agents, such as our CROs or CMOs, could have a material adverse impact on our clinical trials and our business and could result in criminal or civil fines and sanctions. We are subject to complex laws that govern our international business practices. These laws include the FCPA, which prohibits U.S. companies and their intermediaries, such as CROs or CMOs, from making improper payments to foreign government officials for the purpose of obtaining or keeping business or obtaining any kind of advantage for the company. The FCPA also requires companies to keep accurate books and records and maintain adequate accounting controls. A number of past and recent FCPA investigations by the Department of Justice and the SEC have focused on the life sciences sector.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. Some of the countries in which we have conducted clinical trials and in which we have CMOs have a history of corruption, which increases our risks of FCPA violations. In addition, the FCPA presents unique challenges in the pharmaceutical industry because in many countries' hospitals are operated by the government, and doctors and other hospital employees are considered foreign government officials. Certain payments made by pharmaceutical companies, or on their behalf by CROs, to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Additionally, the UK Bribery Act applies to our global activities and prohibits bribery of private individuals as well as public officials. The UK Bribery Act prohibits both the offering and accepting of a bribe and imposes strict liability on companies for failing to prevent bribery, unless the company can show that it had "adequate procedures" in place to prevent bribery. There are also local anti-bribery and anti-corruption laws in countries where we have conducted clinical trials, and many of these also carry the risk of significant financial or criminal penalties.

We are also subject to trade control regulations and trade sanction laws that restrict the movement of certain goods, currency, products, materials, services and technology to, and certain operations in, various countries or with certain persons. Our ability to transfer commercial and clinical product and other clinical trial supplies, and for our employees, independent contractors, principal investigators, CROs, CMOs, consultants and vendors ability to travel, between certain countries is subject to maintaining required licenses and complying with these laws and regulations.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of HIPAA, other U.S. federal and state laws, and requirements of non-U.S. jurisdictions, including the GDPR. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us.

The internal controls, policies and procedures, and training and compliance programs we have implemented to deter prohibited practices may not be effective in preventing our employees, contractors, consultants, agents or other representatives from violating or circumventing such internal policies or violating applicable laws and regulations. The failure to comply with laws governing international business practices may impact any future clinical trials, result in substantial civil or criminal penalties for us and any such individuals, including imprisonment, suspension or debarment from government contracting, withdrawal of our products, if approved, from the market, or being delisted from The Nasdaq Capital Market. In addition, we may incur significant costs in implementing sufficient systems, controls and processes to ensure compliance with the aforementioned laws. The laws and regulations referenced above may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements that could adversely affect our business.

Additionally, it is not always possible to identify and deter misconduct by employees and third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling known or unknown risks or preventing losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, or if any such action is instituted against our employees, consultants, independent contractors, CROs, CMOs, vendors or principal investigators, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, curtailment of our operations, disclosure of our confidential information and imprisonment, any of which could adversely affect our ability to operate our business and our results of operations.

Our financial statements include goodwill and an intangible asset as a result of the Merger. The intangible asset has become impaired and could become further impaired in the future under certain conditions. In addition, goodwill could become impaired in the future under certain conditions. Any potential future impairment of goodwill or intangible asset may significantly impact our results of operations and financial condition.

As of June 30, 2023, we had approximately $113.1 million in the aggregate of goodwill and a definite lived intangible asset from the Merger. In accordance with generally accepted accounting principles, or GAAP, we are required annually, or more frequently upon certain indicators of impairment, to review our estimates and assumptions underlying the fair value of our goodwill and our definite lived intangible asset when indicators of impairment are present. Events giving rise to impairment of goodwill or intangible asset are an inherent risk in the pharmaceutical industry and often cannot be predicted.

Conditions that could indicate impairment and necessitate such a review include, but are not limited to, Auryxia's commercial performance, our inability to execute on our strategic initiatives, the deterioration of our market capitalization such that it is significantly below our net book value, a significant adverse change in legal factors, unexpected adverse business conditions, and an adverse action or assessment by a regulator. To the extent we conclude that goodwill and/or definite lived intangible asset 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. For example, in the second quarter of 2020, in connection with a routine business review, we reduced our short-term and long-term Auryxia revenue forecast. This reduction was primarily driven by the impact of the September 2018 CMS decision that Auryxia would no longer be covered by Medicare for the treatment of the IDA Indication. While this decision does not impact CMS coverage for the use of Auryxia for the control of serum phosphorus levels in adult patients with CKD on dialysis, or the Hyperphosphatemia Indication, it requires all Auryxia prescriptions for Medicare patients to undergo a prior authorization to ensure their use of Auryxia for the Hyperphosphatemia Indication. As a result, we recorded an impairment charge of $114.4 million during the three months ended June 30, 2020, which was entirely allocated to our only intangible asset, the developed product rights for Auryxia, and made a corresponding adjustment to the estimated useful life of the developed product rights for Auryxia, which we again adjusted during the three months ended December 31, 2020. The estimates, judgments and assumptions used in our impairment testing, and the results of our testing, are discussed in Note 9, *Intangible Assets and Goodwill*, to our consolidated financial statements in Part I, Item 1. Financial Statements of this Quarterly Report on Form 10-Q. If these estimates, judgments and assumptions change in the future, including if the Auryxia asset group does not meet its current forecasted projections, additional impairment charges related to goodwill or our intangible asset could be recorded in the future and additional corresponding adjustments may need to be made to the estimated useful life of the developed product rights for Auryxia, which could materially impact our financial position, certain of our material agreements, and our future operating results.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of Auryxia or vadadustat, if approved.

We face an inherent risk of product liability as a result of the clinical and commercial use of Auryxia and vadadustat. For example, we may be sued if Auryxia or vadadustat allegedly causes injury or is found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product or product candidate, negligence, strict liability and breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of Auryxia or vadadustat, if approved. 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 vadadustat, if approved;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- delay or termination of clinical trials;
- our inability to continue to develop Auryxia or vadadustat;
- significant costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to study subjects or patients;
- product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- decreased demand for Auryxia or vadadustat, if approved;
- loss of revenue;
- the inability to commercialize Auryxia or vadadustat, if approved; and
- a decline in our stock price.

Failure to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We currently carry product liability insurance that we believe is appropriate for our company. Although we maintain product liability insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and

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

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

As a public company, we operate in a demanding regulatory environment, and we have and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and certain corporate governance practices. In particular, our compliance with Section 404 of the Sarbanes-Oxley Act has required and will continue to require that we incur substantial accounting-related expenses and expend significant management efforts. Our testing, or the testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls that we would be required to remediate in a timely manner. If we are not able to comply with the requirements of the Sarbanes-Oxley Act, we could be subject to sanctions or investigations by the SEC, the Nasdaq Capital Market or other regulatory authorities, which would require additional financial and management resources and could adversely affect the market price of our securities. Furthermore, if we cannot provide reliable financial reports or prevent fraud, including as a result of remote working by our employees, our business and results of operations would likely be materially and adversely affected.

We cannot predict or estimate the amount of additional costs we may incur to continue to operate as a public company, nor can we predict the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our Ninth Amended and Restated Certificate of Incorporation, as amended, or Charter, and our Second Amended and Restated Bylaws, or Bylaws, as amended to date, contain provisions that eliminate, to the maximum extent permitted by the General Corporation Law of the State of Delaware, or DGCL, the personal liability of our directors and executive officers for monetary damages for breach of their fiduciary duties as a director or officer. Our Charter and our Bylaws also provide that we will indemnify our directors and executive officers and may indemnify our employees and other agents to the fullest extent permitted by the DGCL.

In addition, as permitted by Section 145 of the DGCL our Bylaws and our indemnification agreements that we have entered into with our directors and executive officers provide that:

- We will indemnify our directors and officers, as defined in our Bylaws, for serving us in those capacities or for serving other related business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of Akebia and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful.
- We may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law.
- We are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification.
- The rights conferred in our Bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons.

Any claims for indemnification made by our directors or officers could impact our cash resources and our ability to fund the business.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

Under Section 382 of the Internal Revenue Code, or Section 382, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. On December 12, 2018, we completed the Merger, which we believe has resulted in an ownership change under Section 382. In addition, the Tax Cuts and Jobs Act, including amendments made by the CARES Act, includes changes to U.S. federal tax rates and the rules governing net operating loss carryforwards that may significantly impact our ability to utilize our net operating losses to fully offset taxable income in the future. Future changes in our stock ownership, many of which are outside of our control, could result in an additional ownership change under Section 382. As a result, if we generate taxable income, our ability to use our pre-change NOL carryforwards to offset federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. At the state level, state net operating losses generated in one state cannot be used to offset income generated in another state and there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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

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

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

We are currently subject to legal proceedings that could result in substantial costs and divert management's attention, and we could be subject to additional legal proceedings.

We are currently subject to legal proceedings, including those described in Part II, Item 1. Legal Proceedings in this Quarterly Report on Form 10-Q, and additional claims may arise in the future. In addition, securities class action and derivative lawsuits and other legal proceedings are often brought against companies for any of the risks described in this Quarterly Report on Form 10-Q following a decline in the market price of their securities. For example, we were party to a putative class action lawsuit in state court filed by purported Keryx stockholders challenging the disclosures made in connection with the Merger, including those that relate to vadadustat's safety, approvability and commercial viability. Oral argument was held on October 7, 2022, and the Court dismissed the complaint without prejudice on October 17, 2022, giving plaintiffs thirty days to amend their complaint. On November 16, 2022, plaintiffs filed an amended consolidated complaint, asserting the same claims and seeking the same relief as the consolidated complaint. On January 18, 2023, defendants moved to dismiss the amended consolidated complaint in its entirety. Briefing on defendants' motion to dismiss the amended consolidated complaint was completed on April 5, 2023 and oral argument is currently scheduled to be held on October 18, 2023. In connection with any litigation or other legal proceedings, we could incur substantial costs, 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.

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.

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. Since our initial public offering in March 2014, the price of our common stock as reported on The Nasdaq Stock Market has ranged from a low of $0.24 on October 24, 2022 to a high of $31.00 on June 20, 2014. The daily closing market price for our common stock varied between a high price of $1.43 on May 24, 2023 and a low price of $0.51 on April 5, 2023 in the three-month period ended June 30, 2023. During that time, the price of our common stock ranged from an intra-day low of $0.49 per share to an intra-day high of $1.63 per share. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section, including, among others, developments related to and results of our research or clinical trials, developments related to our regulatory submissions and meetings with regulatory authorities, in particular as it relates to vadadustat, commercialization of Auryxia, vadadustat in Europe and, if and as approved in the U.S. and other foreign markets, and any other product candidates, announcements by us or our competitors of significant transactions or strategic collaborations, negative publicity around Auryxia or vadadustat, regulatory or legal developments in the United States and other countries, developments or disputes concerning our intellectual property, the recruitment or departure of key personnel including as a result of our reductions in workforce, actual or anticipated changes in estimates as to financial results, changes in the structure of healthcare payment systems, market conditions in the biopharmaceutical sector, potential delisting from The Nasdaq Stock Market and other factors beyond our control. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price at which they purchased it.

In addition, companies that have experienced volatility in the market price of their stock have frequently been the subject of securities class action and shareholder derivative litigation. See Part II, Item 1. Legal Proceedings of this Quarterly Report on Form 10-Q for information concerning securities class action initiated against Keryx and certain current and former directors and officers of ours and Keryx's. In addition, we could be the target of other such litigation in the future. Class action and shareholder derivative lawsuits, whether successful or not, could result in substantial costs, damage or settlement awards and a diversion of our management's resources and attention from running our business, which could materially harm our reputation, financial condition and results of operations.

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 June 30, 2023 and based on the amounts reported in the most recent filings made under Section 13(d) and 13(g) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, Muneer A. Satter, or Satter, beneficially owned approximately 8% of our outstanding shares of common stock, the Vanguard Group, or Vanguard, beneficially owned approximately 6% of our outstanding shares of common stock, and CSL Vifor beneficially owned approximately 4% of our outstanding shares of common stock. By selling a large number of shares of common stock, Satter or Vanguard could cause the price of our common stock to decline. The shares beneficially owned by CSL Vifor have not been registered pursuant to the Securities Act and were issued and sold in reliance upon the exemption from registration contained in Section 4(a)(2) of the Securities Act and Rule 506 promulgated thereunder, but if they are registered in the future, those shares would become freely tradable and, if a large portion of such shares are sold, could cause the price of our common stock to decline.

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

In addition, we currently have on file with the SEC a shelf registration statement, which allows us to offer and sell up to $300 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 $26 million of our common stock that may be issued and sold from time to time under a sales agreement with Jefferies LLC.

Sales of substantial amounts of shares of our common stock or other securities by our employees or our other stockholders or by us under our shelf registration statement, pursuant to at-the-market offerings or otherwise, could dilute our stockholders, lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities.

Our executive officers, directors and principal stockholders maintain the ability to significantly influence all matters submitted to stockholders for approval.

As of June 30, 2023, our executive officers, directors and principal stockholders, in the aggregate, beneficially owned shares representing a significant percentage of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons could significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Provisions in our organizational documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our Charter and our Bylaws contain provisions that may have the effect of discouraging, delaying or preventing a change in control of us or changes in our management. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing certain members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions:

- authorize “blank check” preferred stock, which could be issued by our Board of Directors without stockholder approval and may contain voting, liquidation, dividend and other rights superior to our common stock;
- create a classified Board of Directors whose members serve staggered three-year terms;
- specify that special meetings of our stockholders can be called only by our Board of Directors pursuant to a resolution adopted by a majority of the total number of directors;
- prohibit stockholder action by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our Board of Directors;
- provide that our directors may be removed only for cause;
- provide that vacancies on our Board of Directors may be filled only by a majority of directors then in office, even though less than a quorum;
- require a supermajority vote of 75% of the holders of our capital stock entitled to vote or the majority vote of our Board of Directors to amend our Bylaws; and
- require a supermajority vote of 85% of the holders of our capital stock entitled to vote to amend the classification of our Board of Directors and to amend certain other provisions of our Charter.

These provisions, alone or together, could delay or prevent hostile takeovers, changes in control or changes in our management.
In addition, Section 203 of the DGCL prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Because we do not anticipate paying any cash dividends on our capital in the foreseeable future, capital appreciation, if any, will be our stockholders’ sole source of gain.

We have never declared or paid cash dividends on our capital stock and we currently intend to retain all of our future earnings, if any, to finance the development and growth of our business. Any payment of cash dividends in the future would be at the discretion of our Board of Directors and would depend on, among other things, our earnings, financial condition, capital requirements, level of indebtedness, statutory and contractual restrictions applying to the payment of dividends and other considerations that the Board of Directors deems relevant. In addition, the terms of the Loan Agreement preclude us from

paying cash dividends 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 June 30, 2023, 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 (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 defined in Item 408(c) of Regulation S-K) during the quarterly period covered by this report.

Immaterial Correction of Prior Period Financial Statements

As discussed in Note 3 to the Condensed Consolidated Financial Statements included in Part I, Item 1 of this Form 10-Q, the Company identified certain accounting errors relating to the recording and reporting of reserves for returns of the Company's commercial product, Auryxia® (ferric citrate) at the time the Company acquired Keryx Biopharmaceuticals, Inc. on December 12, 2018 and when calculating the product return reserves for subsequent annual and quarterly periods through March 31, 2023. The Company determined that the errors were not material to any prior annual or interim period; however, the Company determined that the effect of correcting the errors in the quarter ended June 30, 2023, would materially misstate the Company's unaudited condensed consolidated financial statements for the three and six months ended June 30, 2023. As a results, the Company has revised the historical consolidated financial statements it previously issued with respect to the fiscal years ended December 31, 2022, 2021 and 2020 and interim periods.

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, 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, filed on June 9, 2020).
3.3	Second Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on April 28, 2023).
10.1*#	License Agreement, dated May 24, 2023, by and between the Company and MEDICE Arzneimittel Pütter GmbH & Co. KG
10.2*#	Third Amendment to Loan Agreement, dated as of June 30, 2023, by and among the Company, Biopharma Credit plc, BPCR Limited Partnership and Biopharma Credit Investments V (Master) LP
10.3*#	Packaging Validation Transfer Agreement, dated April 20, 2023, by and between the Company and Otsuka Pharmaceutical Co. Ltd.
10.4*†#	Form of May 2023 Amendment to Retention and Separation Agreement for Michel Dahan and Nicole R. Hadas
10.5*†#	July 2023 Amendment to Retention and Separation Agreement for Michel Dahan
10.6*†#	July 2023 Amendment to Retention and Separation Agreement for Nicole R. Hadas
10.7*†	Separation Agreement with David Spellman, dated June 9, 2023 and Amendment to Separation Agreement dated July 6, 2023.
10.8*†	Second Amended and Restated Non-Employee Director Compensation Program, effective June 6, 2023.
10.9*†	Akebia Therapeutics, Inc. 2023 Stock Incentive Plan (incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-272453) filed on June 6, 2023)
10.10*†	Form of Non-Employee Director Stock Option Agreement under 2023 Stock Incentive Plan.
10.11*†	Form of Officer Stock Option Agreement under 2023 Stock Incentive Plan.
10.12*†	Form of Non-Employee Director Restricted Stock Unit Agreement under 2023 Stock Incentive Plan.
10.13*†	Form of Officer Restricted Stock Unit Agreement under 2023 Stock Incentive Plan.
10.14*†	Form of Officer Inducement Award Stock Option Agreement under 2023 Stock Incentive Plan.
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
† Indicates management contract or compensatory plan.

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: August 28, 2023

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

Date: August 28, 2023

By: /s/ Ellen E. Snow
Ellen E. Snow
Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial Officer and Principal Accounting Officer)

CONFIDENTIAL **Exhibit 10.1**

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

License Agreement

By and Between

Akebia Therapeutics, inc.,

and

MEDICE Arzneimittel Pütter GmbH & Co. KG

Dated May 24, 2023

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License Agreement

This **License Agreement** (this "**Agreement**") is made and entered into as of May 24, 2023 (the "**Effective Date**") between Akebia Therapeutics, Inc., a company organized and existing under the laws of the State of Delaware, United States of America with its principal offices at 245 First Street, Cambridge, MA 02142 ("**Akebia**"), and MEDICE Arzneimittel Pütter GmbH & Co. KG, ("**Licensee**"), a limited partnership organized under the laws of Germany, with corporate domicile at Kuhloweg 37, 58638 Iserlohn, Germany, registered at local court Iserlohn, HRA 1037, represented by its general partner Medice Verwaltungs-GmbH, a private liability company with identical corporate domicile, registered at local court Iserlohn, HRB 200, represented by Dr. Richard Ammer.

Akebia and Licensee may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Akebia is the owner of, or otherwise controls, the Akebia Technology and the Licensed Product in the Territory;

WHEREAS, Licensee (itself and through its Affiliates) has expertise in the commercialization of biopharmaceutical products and has regulatory and commercial capabilities in the Territory, and is interested in obtaining an exclusive license to Commercialize the Licensed Product in the Territory;

WHEREAS, Akebia received Regulatory Approval from the EMA for the Licensed Product in the Territory on April 24, 2023; and

WHEREAS, Akebia wishes to grant Licensee an exclusive license to Commercialize the Licensed Product in the Territory as set forth in this Agreement.

NOW THEREFORE, the Parties agree as follows:

Article I
DEFINITIONS

1.1 "**AAA**" has the meaning set forth in Section 16.2.3 (Arbitration Procedure).

1.2 "**Accounting Standards**" means either (a) German GAAP (HGB), or (b) U.S. GAAP.

1.3 "**Affiliate**" means, with respect to a Party, any corporation, or other business entity controlled by, controlling, or under common control with such Party, with "control" meaning (a) direct or indirect beneficial ownership of at least 50% of the voting stock or other ownership interest of, or at least a 50% interest in the income of, the applicable entity, or (b) the possession, directly or indirectly, of the power to direct the management or policies of the applicable entity, whether through the ownership of voting securities or other equity rights, by contract relating to voting rights or corporate governance, or otherwise. Notwithstanding the foregoing, "Affiliates" will not include, with respect to an entity, *bona fide* venture capital investors in such entity or *bona fide* institutional investors in such entity, which institutional investors routinely make venture capital investments for the potential financial return on such investments and not with any view to acquisition or for other strategic purpose, or Affiliates of such venture capital or institutional investors.

1.4 "**Akebia Housemarks**" means (a) the corporate logo of Akebia, (b) the trademarks "AKEBIA," (c) any other trademark, trade name, or service mark (whether registered or unregistered) containing the word "Akebia," (d) any trademark, trade name, or service mark (whether registered or unregistered) used as the name of any clinical trial for the Licensed Product, (e) any other corporate logo or trademark of Akebia used by Akebia to identify Akebia or its Affiliates, (f) all registrations, applications for registrations, and other intellectual property

rights associated with any of the foregoing, and (g) all goodwill associated with any and all of the foregoing in clauses (a) through (f).

1.5 "**Akebia Improvement**" means any Improvement that is made during the Term in the course of performance of activities undertaken by Akebia pursuant to this Agreement or pursuant to the license grants in Section 2.3 (Grant of Licenses to Akebia), solely by one or more Representatives of Akebia.

1.6 "**Akebia Indemnitees**" has the meaning set forth in Section 14.2 (Indemnification by Licensee).

1.7 "**Akebia Know-How**" means all Know-How (excluding Joint Know-How but including any Akebia Improvements) that (a) is Controlled as of the Effective Date or during the Term by Akebia or any of its Affiliates; and (b) is necessary for the Development (solely as set forth in this Agreement), Packaging, or Commercialization of the Licensed Product in the Field in the Territory.

1.8 "**Akebia Patent Rights**" means all Patent Rights (excluding Joint Patent Rights, but including patent rights that cover Akebia Improvements) that (a) are Controlled as of the Effective Date or during the Term by Akebia or any of its Affiliates in the Territory, and (b) are necessary (or, with respect to patent applications, would be necessary if such patent applications were to issue) for the Territory-Specific Development, Packaging, or Commercialization of the Licensed Product in the Field in the Territory. All Akebia Patent Rights as of the Effective Date are set forth on Schedule 1.8.

1.9 "**Akebia Technology**" means Akebia Know-How, Akebia Patent Rights, and Akebia's interest in Joint Technology.

1.10 "**Alliance Manager**" has the meaning set forth in Section 3.3 (Alliance Managers).

1.11 "**API**" means active pharmaceutical ingredient, which is also commonly referred to as drug substance. For the avoidance of doubt, API will include any prodrug form.

1.12 "**Applicable Law**" means any applicable federal, state, local, municipal, foreign or other law, statute, legislation, constitution, principle of common law, resolution, ordinance, code, edict, decree, proclamation, treaty, convention, rule or regulation issued, enacted, adopted, passed, approved, promulgated, made, implemented or otherwise put into effect by or under the authority of any Governmental Authority, including (a) the applicable regulations and guidance of the EMA (and national implementations thereof) that constitute, GMP, GCP, and any regulations or guidances of any applicable Regulatory Authority (and national implementations thereof) concerning healthcare, promotional, or regulatory matters, and, if and as appropriate under the circumstances, International Conference on Harmonization (ICH) guidance or other comparable regulation and guidance of any applicable Governmental Authority; (b) data privacy and protection laws and regulations; and (c) all applicable anti-slavery and human trafficking laws, statutes, regulations, and codes in force from time-to-time including the Modern Slavery Act 2015.

1.13 "**Approved Labeling**" means, with respect to the Licensed Product: (a) the Regulatory Authority-approved full prescribing information for the Licensed Product; and (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for the Licensed Product.

1.14 "**Arbitration Request**" has the meaning set forth in Section 16.2.1 (Arbitration Request).

1.15 "**Breaching Party**" has the meaning set forth in Section 15.2 (Termination for Breach).

1.16 "**Business Day**" means any day (*other than* a Saturday or Sunday) on which the banks in Cambridge, Massachusetts and Iserlohn, Germany are open for business.

1.17 "**Commercialization**" means, with respect to a product, any and all activities directed to the marketing, promotion, distribution, pricing, reimbursement, offering for sale, and sale of such product, and interacting with Regulatory Authorities following Regulatory Approval in the applicable country or region for such product, regarding the foregoing, including seeking any required Reimbursement Approval, but excluding activities directed to the Manufacture, (other than Packaging), Medical Affairs, and Development of such product. "**Commercialize**," "**Commercializing**," and "**Commercialized**" will be construed accordingly.

1.18 "**Commercialization Plan**" means a rolling [**] plan for the Commercialization of the Licensed Product in the Territory that is prepared, updated, and amended by Licensee in accordance with Section 7.2.2 (Commercialization Plan).

1.19 "**Commercially Reasonable Efforts**" means, with respect to the Development, Manufacture, and Commercialization of the Licensed Product by a Party, those efforts and resources, including reasonably necessary personnel, equivalent to the efforts that a biopharmaceutical company that is comparable to such Party would typically devote to a product of similar market potential, profit potential, and strategic value to the Licensed Product.

1.20 "**[**]**" has the meaning set forth in Section [**].

1.21 "**Competing Product**" means any HIF Product other than the Licensed Product that is approved by an applicable Regulatory Authority.

1.22 "**Confidential Disclosure Agreement**" has the meaning set forth in Section 17.5 (Entire Agreement; Amendment).

1.23 "**Confidential Information**" means (a) the terms of this Agreement and (b) all Know-How and any technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property, and other information that may be disclosed by one Party to the other Party pursuant to this Agreement (including information disclosed prior to the Effective Date pursuant to the Confidential Disclosure Agreement), regardless of whether such information is specifically designated as confidential and regardless of whether such information is in written, oral, electronic, or other form.

1.24 "**Controlled**" means, with respect to a Party or its Affiliate, any Know-How, Patent Right, or other intellectual property right that such Party or Affiliate, as the case may be, owns or has a license to and has the ability to grant to the other Party a license or sublicense to, or a right of access with respect to, such Know-How, Patent Right, or other intellectual property right, without violating the terms of any agreement or other arrangements with any Third Party or incurring any additional payment obligations to a Third Party other than payment obligations incurred under licenses taken pursuant to Section 10.8.3 (Responsibility for Third Party Licenses). Notwithstanding the foregoing, no Patent Right, Know-How, or other intellectual property right will be "Controlled" by either Party hereunder if such Patent Right, Know-How, or other intellectual property right is owned or in-licensed by a Third Party that becomes an Affiliate of such Party after the Effective Date as a result of such Party being acquired by such Third Party, whether by merger, stock purchase, or purchase of assets; *provided that* prior to the date of such transaction, neither such Party nor any of its Affiliates had any rights to any such Patent Right, Know-How, or other intellectual property right. Notwithstanding the foregoing, any such Patent Right, Know-How, or other intellectual property right that is owned or in-licensed by such an acquiring Third Party and that is necessary for or used following the date of such transaction by such Third Party or acquired Party in connection with the Development, Manufacture, or Commercialization of the Licensed Product will be "Controlled" by such Third Party (as an Affiliate) or acquired Party for purposes of this Agreement.

1.25 "**Cost of Goods Sold**" or "**COGS**" (a) with respect to the Licensed Product in API form or Tablet Formulation (in bulk form) that is Manufactured and supplied by any Third Party, the total actual prices paid by Akebia to all such Third Party(ies) for released batches of such Licensed Product., together with all reasonably allocated indirect costs and overhead applicable to managing its

supply of Licensed Product and such Third Party suppliers (including internal FTE costs associated therewith); and (b) to the extent any Licensed Product in API form or Tablet Formulation (in bulk form) is Manufactured and supplied by Akebia or its Affiliates, the fully-burdened cost of all direct materials and labor and fully-allocated Manufacturing overhead directly attributable to the Manufacture, storage, packaging, and shipping of such Licensed Product, calculated in accordance with the Accounting Standards applicable to Akebia or its Affiliates, including all Licensed Product testing and yield loss costs, quality control, quality assurance, or other testing of such Licensed Product, together with all reasonably allocated indirect costs and overhead applicable to the Manufacturing of such Licensed Product (including internal FTE costs associated with supply thereof), or technical operations functions, less costs of goods returned in accordance with Akebia's or its Affiliates' or suppliers' return policy. The Parties acknowledge that Akebia has provided the current calculation of COGS for the Licensed Product as of the Effective Date on a cost-per-pill basis to Licensee under separate cover.

1.26 "**Cover**" means, with respect to a particular subject matter at issue and a relevant Patent Right, that the manufacture, use, sale, offer for sale, or importation of the subject matter falls, or with respect to pending applications, would fall, within the scope of a claim in such Patent Right.

1.27 "**Debarred/Excluded**" has the meaning set forth in Section 12.1.6 (Mutual Representations and Warranties).

1.28 "**Development**" means all internal and external research, development, and regulatory activities for a product (*other than* Reimbursement Approval). This includes (a) research, non-clinical testing, toxicology, route of synthesis, non-clinical activities, formulation, and clinical studies of the product, and (b) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct clinical trials and to obtain or maintain Regulatory Approval of the product, but excluding activities directed to the Manufacture, Medical Affairs, and Commercialization of such product. Development will include development and regulatory activities for additional forms, formulations, or indications for the product after Regulatory Approval of the product, including clinical trials initiated following receipt of Regulatory Approval or any clinical trial to be conducted after a Regulatory Approval that was mandated by the applicable Regulatory Authority as a condition of such Regulatory Approval with respect to an approved indication (such as post-marketing studies and observational studies, if required by any Regulatory Authority in any country in the Territory to maintain Regulatory Approval for the product in such country). "**Develop**," "**Developing**," and "**Developed**" will be construed accordingly.

1.29 "**Disclosing Party**" has the meaning set forth in Section 13.1.1 (Duty of Confidence).

1.30 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.31 "**E.U.**" means the economic, scientific, and political organization of member states of the European Union as it may be constituted from time to time; provided that, for the purposes of this Agreement, the term "European Union" will be deemed to include the United Kingdom regardless of whether it is a member of the European Union at the applicable time.

1.32 **"Euro" or "€"** means the official currency of the European Union used by the Euro area countries, or Eurozone.

1.33 "**European Economic Area**" means the E.U., Iceland, Lichtenstein, and Norway.

1.34 "**Executive Officer**" means the chief executive officer of a Party or any of its Affiliates or his or her designee.

1.35 "**Exploit**" means to Develop, Commercialize, perform Medical Affairs, Manufacture, and otherwise exploit. When used as a verb, "**Exploit**" and "**Exploiting**" means to engage in Exploitation and "**Exploited**" has a corresponding meaning.

1.36 "**FD&C Act**" means the United States Federal Food, Drug and Cosmetic Act, as amended from time-to-time, together with any rules, regulations, and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.37 "**Field**" means the treatment of anemia in patients with chronic kidney disease.

1.38 "**Finished Form**" means the Licensed Product in the Tablet Formulation in finished form and with all applicable Packaging and Labeling.

1.39 "**First Commercial Sale**" means, for the Licensed Product in a country in the Territory, the date on which Licensee or its Affiliate or Sublicensee first sells the Licensed Product to a Third Party (other than to any Sublicensee or to an affiliate of any Sublicensee) for monetary consideration.

1.40 "**Force Majeure**" has the meaning set forth in Section 17.3 (Force Majeure).

1.41 "**Generic Product**" means, on a country-by-country basis in a particular country in the Territory, any pharmaceutical product sold by a Third Party (*other than* a sublicensee of Licensee or its Affiliates, sublicensees, distributors, or a person who has purchased such product in a chain of distribution including Licensee or any of its Affiliates, sublicensees, or distributors) in such country that: (a) contains the same API as the Licensed Product in the same dosage form and formulation (*e.g.*, oral, injectable, or intranasal) as the Licensed Product, and (b) if applicable, is categorized by the applicable Regulatory Authority in such country to be therapeutically equivalent to, or interchangeable with, the Licensed Product, such that the pharmaceutical product may be substituted for the Licensed Product at the point of dispensing without any intervention by the prescribing physician in such country.

1.42 "**Global Mark**" means any Marks selected by Akebia for marketing the Licensed Product outside of the Territory in the Field, and all trademark registrations and applications therefor, and all goodwill associated therewith. Global Marks exclude all Local Marks.

1.43 "**Global Trade Control Laws**" means the U.S. Export Administration Regulations, the U.S. International Traffic in Arms Regulations, the economic sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, E.U. Council Regulations on export controls, including Nos. 428/2009, 267/2012, other E.U. Council sanctions regulations, as implemented in the E.U. member states, United Nations sanctions policies, and all relevant regulations made under any of the foregoing.

1.44 "**Good Clinical Practices**" or "**GCP**" means the then-current good clinical practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time.

1.45 "**Good Manufacturing Practices**" or "**GMP**" means the then-current good manufacturing practice standards, practices, and procedures promulgated or endorsed by the applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time-to-time.

1.46 "**Government Official**" means any official, officer, employee, or representative of: (a) any federal, state, provincial, administrative division, county, or municipal government or any department or agency thereof; (b) any public international organization or any department or agency thereof; or (c) any company or other entity owned or controlled by any government or Governmental Authority.

1.47 "**Governmental Authority**" means any arbitrator, court, judicial, legislative, administrative or Regulatory Authority, commission, department, board, bureau or body, or other government authority or instrumentality or any person or entity exercising executive, legislative, judicial, regulatory or administrative functions of or pertaining to government, whether foreign or

domestic, whether federal, state, provincial, municipal, or other. For clarity, Governmental Authorities include all Regulatory Authorities.

1.48 "**HIF Product**" means any product or product candidate that is a hypoxia-inducible factor prolyl-hydroxylase inhibitor for the treatment of anemia related to chronic kidney disease. For the avoidance of doubt, "HIF Product" includes roxadustat, molidustat, daprodustat, and the Licensed Product.

1.49 "**Housemarks**" means the Akebia Housemarks and the Licensee Housemarks.

1.50 "**Improvement**" means any Invention developed or invented by one or more employees of a Party or any Affiliate of a Party, or persons contractually required to assign or license such Invention (or Patent Rights Covering such Invention) to such Party or any Affiliate of such Party, including all subcontractors and sublicensees hereunder (such Party's "**Representatives**"), whether alone or jointly with Representatives of the other Party, in the performance of activities under this Agreement.

1.51 "**IND**" means an Investigational New Drug application required pursuant to 21 C.F.R. Part 312 or any comparable filings outside of the U.S. (such as an application for a Clinical Trial Authorization in the E.U.).

1.52 "**Indemnified Party**" has the meaning set forth in Section 14.3 (Indemnification Procedure).

1.53 "**Indemnifying Party**" has the meaning set forth in Section 14.3 (Indemnification Procedure).

1.54 "**Infringement Claim**" has the meaning set forth in Section 10.8.1 (Infringement Claim).

1.55 "**Invention**" means any process, method, composition of matter, article of manufacture, discovery, or finding that is conceived or reduced to practice (whether or not patentable).

1.56 "**Joint Know-How**" means any Improvement that is made during the Term in the performance of any activities under this Agreement (including under the licenses granted hereunder) jointly by at least one Representative of Akebia and at least one Representative of Licensee.

1.57 "**Joint Patent Rights**" means all Patent Rights that Cover the Joint Know-How.

1.58 "**Joint Technology**" means Joint Know-How and Joint Patent Rights.

1.59 "**JSC**" has the meaning set forth in Section 3.1.1 (Formation and Purpose of the JSC).

1.60 "**Know-How**" means Inventions, discoveries, trade secrets, information, experience, data, formulas, procedures, technology, and results (whether or not patentable), including practices, knowledge, know-how, experience and test data (including physical, chemical, biological, toxicological, pharmacological, clinical and veterinary data), dosage regimens, control assays, product specifications, analytical and quality control data and marketing, pricing and distribution cost, and sales data or descriptions.

1.61 "**Knowledge**" means the actual knowledge, without any inquiry, investigation, or obligation to conduct any freedom to operate analysis, of senior management as of the Effective Date, without any inquiry or investigation. For this purpose, "senior management" means any person holding a C-level position (e.g., chief executive officer or chief financial officer) and employed by a Party.

1.62 "**Launch Countries**" has the meaning set forth in Section 7.2 (Launch Sequence and Commercialization Plan).

1.63 "**Launch Sequence**" has the meaning set forth in Section 7.2 (Launch Sequence and Commercialization Plan).

1.64 "**Licensed Product**" means that certain product referred to as VAFSEO™ or vadadustat in its current tablet formulation in 150 mg, 300 mg and 450 mg dosage strengths, and any future formulation of vadadustat for pediatric use.

1.65 "**Licensee Housemarks**" means (a) the corporate logo of Licensee or any of its Affiliates, (b) the trademark "Medice" and/or "Medice – the Health Family," (c) any other trademark, trade name, or service mark (whether registered or unregistered) containing the word "Medice," and (d) any other corporate logo or trademark used by Licensee to identify Licensee or its Affiliates, (e) all registrations, applications for registrations, and other intellectual property rights associated with any of the foregoing, and (f) all goodwill associated with any and all of the foregoing in clauses (a) through (e).

1.66 "**Licensee Improvement**" means any Improvement that is made during the Term in the course of performance of activities under this Agreement, solely by one or more Representatives of Licensee.

1.67 "**Licensee Improvement Patent Right**" means any Patent Right Controlled by Licensee or any of its Affiliates during the Term that Covers a Licensee Improvement.

1.68 "**Licensee Indemnitees**" has the meaning set forth in Section 14.1 (Indemnification by Akebia).

1.69 "**Licensee Know-How**" means all Know-How (excluding Joint Know-How) that is (a) Controlled as of the Effective Date or during the Term by Licensee or any of its Affiliates, and (b) (i) disclosed to Akebia or any of its Affiliates pursuant to this Agreement, or (ii) necessary for the Exploitation of the Licensed Product, including all Licensee Improvements.

1.70 "**Licensee Patent Rights**" means all Patent Rights (excluding Joint Patent Rights) that (a) are Controlled as of the Effective Date or during the Term by Licensee or any of its Affiliates in the Territory, and (b) (i) include one or more claims that Cover any Licensee Know-How or the Licensed Product or the Exploitation thereof, or (ii) are necessary (or, with respect to patent applications, would be necessary if such patent applications were to issue as patents) for the Exploitation of the Licensed Product. Licensee Patent Rights include any and all Licensee Improvement Patent Rights.

1.71 "**Licensee Technology**" means Licensee Know-How, Licensee Patent Rights, and Licensee's interest in Joint Technology.

1.72 "**Limited Recall**" means a recall or retrieval of the Licensed Product on grounds of product quality or manufacturing defect or public health or safety that is limited as to lots or batches of the Licensed Product.

1.73 "**Local Marks**" has the meaning set forth in Section 7.8.1 (Brand Name in the Territory).

1.74 "**Local Medical Affairs Plan**" has the meaning set forth in Section 6.2 (Medical Affairs Activities).

1.75 "**Losses**" has the meaning set forth in Section 14.1 (Indemnification by Akebia).

1.76 "**MAA**" means (a) a marketing authorization application filed with (i) the EMA under the centralized EMA filing procedure to gain approval to market a pharmaceutical or diagnostic product in the E.U., or (ii) a Regulatory Authority in any E.U. country if the centralized EMA filing procedure is not used to gain approval to market a pharmaceutical or diagnostic product in the E.U., or (b) any other equivalent or related Regulatory Submissions filed in support of approval to market a pharmaceutical or diagnostic product in any country outside the E.U., and, in each case ((a) and (b)), including any amendments thereto, and supplemental applications, but excluding Reimbursement Approval applications.

1.77 "**Manufacture**" or "**Manufacturing**" means with respect to a product, to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store such product or any component thereof, but excluding activities directed to the Development, Medical Affairs, and Commercialization of such product. When used as a noun, "**Manufacture**" or "**Manufacturing**" means any and all activities involved in Manufacturing such product or any component thereof.

1.78 "**Mark**" means any trademark, trade name, service mark, service name, product name, brand, domain name, trade dress, logo, slogan, or other indicia of origin or ownership, and (a) all registrations, applications for registrations, and other intellectual property rights associated with any of the foregoing, and (b) the goodwill associated with each of the foregoing.

1.79 "**Medical Affairs**" means activities conducted by Licensee's medical affairs department, including communications with key opinion leaders, medical education, symposia, advisory boards (to the extent related to medical affairs or clinical guidance), activities performed in connection with patient registries, and other medical programs and communications, including educational grants, research grants (including conducting investigator-initiated studies), and charitable donations, to the extent related to medical affairs. For clarity, this definition of "Medical Affairs" does not include other activities that involve the promotion, marketing, sale, or other Commercialization of a product and are not conducted by Licensee's medical affairs department, and in all cases is exclusive of activities directed to the Development, Manufacture, and Commercialization of such product.

1.80 "**Milestone Payment**" has the meaning set forth in Section 9.2 (Milestone Payments).

1.81 "**National Reimbursement Authorities**" means the National Institute of Clinical Excellence and the Scottish Medicines Consortium in the United Kingdom, the Institute for Quality and Efficiency in Healthcare in Germany, the Technical Scientific Commission in Italy, the Directorate of Pharmacy and Healthcare Products in Spain, the National Union of Health Insurance Funds and the National Authority of Health in France, and any other Governmental Authority in the Territory with the authority to control, approve, recommend, or otherwise determine pricing and reimbursement of pharmaceutical products in such country.

1.82 **"Net Product Margin"** means the Net Sales of the Licensed Product less the Supply Price paid by Licensee for the same Licensed Product within a particular period of time.

1.83 "**Net Sales**" with respect to any Licensed Product means the gross sales (*i.e.*, gross invoice prices) billed by Licensee or its Affiliates, as applicable, or their respective sublicensees to Third Party customers (including Distributors) on all sales of the Licensed Product in the Territory and exclusive of intercompany transfer or sales, less the following deductions from such gross sales:

1.83.1 Actual credited allowances to such Third Party customers for spoiled, damaged, outdated, recalled, or returned Licensed Product and for retroactive price reductions or billing corrections;

1.83.2 The amounts of trade, cash discounts and mandatory and voluntary rebates including, but not limited to, insurance, hospitals, pharmacies, dialysis centers, and procurement centers, to the extent such discounts and rebates were not deducted by Licensee or Akebia, as applicable, or their respective Sublicensees at the time of invoice in order to arrive at the gross invoice prices;

1.83.3 all transportation, handling charges and freight insurance, sales taxes, excise taxes, use taxes, import/export duties paid or distribution fees paid to Third Parties; ;

1.83.4 invoiced amounts from a prior period that have not been collected and have been written off by Akebia or Licensee or its Sublicensee (as applicable), including bad debts, to the extent such amounts have not been previously deducted and do not exceed, in the aggregate, [**]% of Net Sales in the applicable period; provided that any such amounts

that are written off will be added back in a subsequent period to the extent later collected; and

1.83.5 all other reasonable and customary allowances and adjustments whether during the specific royalty period or not.

Subject to the above, Net Sales will be determined in accordance with the applicable Accounting Standards, consistently applied.

If Licensee or a Sublicensee receives [**] for the Licensed Product sold to a Third Party, then the Net Sales amount for such Licensed Product will be [**].

With respect to [**] of the Licensed Product, "Net Sales" will [**]; provided that, upon [**] will be [**].

1.84 "**Non-Breaching Party**" has the meaning set forth in Section 15.2 (Termination for Breach).

1.85 "**OFAC**" means the Office of Foreign Assets Control of the United States Department of the Treasury or any successor agency thereto.

1.86 "**Other Covered Party**" means any political party or party official, or any candidate for political office.

1.87 "**Packaging**" or "**Package**" has the meaning set forth in Section 8.1 (Supply and Purchase Obligations).

1.88 "**Packaging and Labeling**" means primary, secondary, or tertiary packaging and labeling of the Licensed Product (in its commercial packaging presentation) for sale or use in the Territory, including the Approved Labeling and insertion of materials such as patient inserts, patient medication guides, and professional inserts and any other written, printed, or graphic materials accompanying the Licensed Product and any brand security or anti-counterfeiting measures included in the packaging elements for the Licensed Product considered to be part of the finished packaged Licensed Product, and all testing and release thereof.

1.89 "**Patent Challenge**" has the meaning set forth in Section 15.4 (Termination by Akebia Upon Patent Right Challenge).

1.90 "**Patent Rights**" means (a) all patents and patent applications in any country or jurisdiction, (b) all patent applications filed either from such patents or patent applications or from an application claiming priority from any of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications, and (d) any and all substitutions, renewals, registrations, confirmations, extensions, or restorations, including revalidations, reissues, and re-examinations (including any supplementary protection certificates and the like) of the foregoing patents or patent applications.

1.91 "**Pharmacovigilance Agreement**" means an agreement regarding receipt, investigation, and reporting of product complaints, adverse events, product recalls, and any other information related to the safety of the Licensed Product in the Territory.

1.92 "**Privacy Laws**" means all Applicable Laws with respect to the collection, use, transfer, storage, deletion, processing (both by computer and manually), combination, or other use of personal data.

1.93 "**Product Marks**" means any Mark (whether registered or unregistered) selected in accordance with Section 7.8.1 (Brand Name in the Territory) for use on, with, or to refer to the Licensed Product (*other than* Akebia Housemarks and Licensee Housemarks), including the brand name "VAFSEO™", or used with patient support or other information or services or Product Materials

associated with the Licensed Product in the Territory during the Term (including all Global Marks and Local Marks), and (a) all registrations, applications for registrations, and other intellectual property rights associated with any of the foregoing, and (b) the goodwill associated with each of the foregoing.

1.94 "**Product Materials**" means any and all promotional materials, training materials, medical education materials, Packaging and Labeling, and all other literature or other information related to the Licensed Product.

1.95 "**Product Withdrawal**" means removal of the Licensed Product from the market in any country in the Territory on the grounds of public health or safety that results in discontinuation of all or substantially all distribution of the Licensed Product in such country in the Territory. Product Withdrawal does not include a Limited Recall.

1.96 "**Professional Requirements**" means (a) the codes and standards of the European Accreditation Council for Continuing Medical Education (EACCME) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), (b) the codes of the Prescription Medicines Code of Practice Authority (PMCPA) and the Association of the British Pharmaceutical Industry (ABPI), and (c) all other accepted national and international pharmaceutical industry codes of practice in and for the relevant countries in the Territory, as any of the foregoing may be amended from time-to-time.

1.97 "**Quality Agreement**" has the meaning set forth in Section 8.3 (Quality Agreement).

1.98 "**Quarterly Report**" has the meaning set forth in Section 9.3.4(b) (Quarterly Report).

1.99 "**Recall Decision-Makers**" has the meaning set forth in Section 11.4.3 (Voluntary Withdrawal or Recall in the Territory).

1.100 "**Receiving Party**" has the meaning set forth in Section 13.1.1 (Duty of Confidence).

1.101 "**Regulatory Approval**" means, with respect to a particular country or other regulatory jurisdiction, any MAA approval or other approval, product or establishment license, registration, or authorization of any Regulatory Authority necessary for the commercial sale of the Licensed Product in such country or other regulatory jurisdiction, excluding, in each case, Reimbursement Approval.

1.102 "**Regulatory Authority**" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including (a) in the E.U., the EMA and any other applicable Governmental Authority in the countries in the E.U. having jurisdiction over the Licensed Product, and (b) in other countries, other analogous Governmental Authorities having jurisdiction over the Licensed Product.

1.103 "**Regulatory Submissions**" means all applications, filings, dossiers, and other documents submitted to a Regulatory Authority in support of Development of the Licensed Product in the Territory, including for the purpose of obtaining Regulatory Approval from that Regulatory Authority. Regulatory Submissions include all INDs, MAAs, and other Regulatory Approval applications and their equivalents in the Territory.

1.104 "**Reimbursement Approval**" means an approval, agreement, determination, or other decision by the applicable Governmental Authority that establishes prices charged to end-users for biopharmaceutical products that the Licensed Product will be reimbursed by the Governmental Authorities or Regulatory Authorities in the Territory.

1.105 "**Representatives**" has the meaning set forth in Section 1.50 (Improvement).

1.106 "**Restricted Party**" means any individual or entity on one or more of the Restricted Party Lists.

1.107 "**Restricted Party List**" means the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals and Blocked Persons List, the Foreign Sanctions Evaders List and the Sectoral Sanctions Identifications List, all administered by OFAC; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; and the entities subject to restrictive measures and the consolidated list of Persons, Groups, and Entities Subject to E.U. Financial Sanctions, as implemented by the E.U. Common Foreign & Security Policy.

1.108 "**Royalty Payment**" has the meaning set forth in Section 9.3.1 (Royalty Amounts).

1.109 "**Royalty Term**" means, on a country-by-country basis, for the Licensed Product in a country in the Territory, the period during the Term continuing until the latest to occur of (a) the date of expiration of the last-to-expire Valid Claim of any Akebia Patent Right, Licensee Improvement Patent Right, or Joint Patent Right that Covers the Licensed Product in such country in the Territory, (b) the date of expiration of data or regulatory exclusivity for the Licensed Product in such country in the Territory, and (c) the date that is 12 years from First Commercial Sale of the Licensed Product in such country in the Territory.

1.110 "**Safety Data**" has the meaning set forth in Section 11.2 (Pharmacovigilance Agreement).

1.111 "**Study Data**" means all research data and reports, clinical and non-clinical data, and chemistry, manufacturing, and controls data.

1.112 "**Supply Agreement**" has the meaning set forth in Section 8.2 (Supply Agreement). "**Supply Price**" has the meaning set forth in Section 8.2 (Supply Agreement).

1.113 "**Tablet Formulation**" means the Licensed Product in the solid, oral tablet form. For clarity, the Tablet Formulation excludes alternative tablet forms such as orally-disintegrating, sustained-release, or sublingual.

1.114 "**Term**" has the meaning set forth in Section 15.1 (Term).

1.115 "**Territory**" means the European Economic Area, the United Kingdom, Switzerland and Australia.

1.116 "**Territory-Specific Development**" means Development activities for the Licensed Product that are necessary in order to obtain, maintain, expand, or support Regulatory Approval for the Licensed Product from the EMA or any other Regulatory Authority in the Territory, as approved by the JSC.

1.117 "**Third Party**" means any person or entity other than a Party or its Affiliates.

1.118 "**Transferred Regulatory Filings**" has the meaning set forth in Section 5.1 (Transfer of Regulatory Filings)

1.119 "**U.S.**" means the United States of America (including all possessions and territories thereof, including Puerto Rico).

1.120 "**U.S. Dollars**" or "**$**" means the legal tender of the U.S.

1.121 "**Valid Claim**" means (a) a claim in any issued and unexpired Patent Right, which claim has not lapsed, been cancelled or revoked, become abandoned, or been held invalid or unenforceable by a non-appealed or un-appealable decision of a court or government agency or other appropriate body of competent jurisdiction and has not been disclaimed or admitted to be invalid or unenforceable through reissue, reexamination, disclaimer, or otherwise, or has not been made

unenforceable due to failure to pay maintenance fees, or (b) a pending claim of a pending patent application that has not been (i) abandoned or finally rejected without the possibility of appeal or refiling or (ii) pending for more than [**] from the date of the first substantive office action on such pending patent application. A pending claim that ceases to be a Valid Claim due to the foregoing time limit will, if it later issues, qualify again as a Valid Claim, provided that it meets the requirements of clause (a) of this definition.

Article II
LICENSES

2.1 Grant of Licenses to Licensee. Subject to the terms and conditions of this Agreement (including Section 2.7 (No Other Rights and Retained Rights)), Akebia hereby grants to Licensee and its Affiliates an exclusive, royalty-bearing license, with the right to grant sublicenses only as provided in Section 2.2 (Rights of Licensee to Grant Sublicenses), under the Akebia Technology to Develop (solely in accordance with Article IV (Development)), Manufacture (solely in accordance with Article VIII (Manufacturing and Supply)), and Commercialize (including to import, export, distribute, offer for sale, and sell), the Licensed Product in the Field in the Territory during the Term. The license granted to Licensee by Akebia in this Section 2.1 (Grant of Licenses to Licensee) for the Commercialization of the Licensed Product shall be exclusive even as to Akebia. The license granted by Akebia in this Section 2.1 (Grant of Licenses to Licensee) for the Development and Manufacture of the Licensed Product shall be co-exclusive with Akebia.

2.2 Rights of Licensee to Grant Sublicenses. Subject to the terms and conditions of this Agreement, upon Akebia's written consent, not to be unreasonably withheld, Licensee will have the right grant one or more sublicenses of the rights granted to Licensee under this Agreement to Third Parties to Develop (solely in accordance with Article IV (Development)), Commercialize, or Manufacture the Licensed Product in the Field in the Territory during the Term. For the avoidance of doubt, Akebia's consent may be conditioned on the review and approval of the principal terms of the sublicense. Promptly after Licensee enters into negotiations for the grant of a sublicense of any of the rights granted to Licensee under this Agreement, Licensee will provide written notification to Akebia identifying Licensee's intention to negotiate such sublicense, the proposed scope of the sublicense, the purpose of such sublicense, and the identity of the Third Party to whom Licensee intends to grant such sublicense. Any and all sublicenses will be in writing and will be subject to the following requirements, and any sublicense granted hereunder that is inconsistent with this Section 2.2 (Rights of Licensee to Grant Sublicenses) will be null and void. Each sublicensee will hold its rights contingent on the rights licensed to Licensee under the terms of this Agreement and each sublicense will (a) require each sublicensee and Affiliate to comply with the terms and conditions of this Agreement (including the royalty reporting obligations set forth under Section 4.2 (Territory-Specific Development Reports), Section 9.3.4 (Royalty Payments and Reports), and the record keeping and audit requirements set forth under Section 9.4 (Accounting; Audit)), (b) include Akebia as an intended third party beneficiary under the sublicense with the right to enforce the applicable terms of such sublicense, (c) preclude the granting of further sublicenses, and (d) include an assignment back to Licensee of all intellectual property rights made or generated by the sublicensee in the performance of activities under the applicable sublicense agreement. Any loss by Licensee of its rights under this Agreement due to an early termination of this Agreement pursuant to Article XV (Term and Termination) will cause the permitted sublicensees to automatically lose the same rights under any sublicense. In no event will any sublicense relieve Licensee of any of its obligations under this Agreement, and Licensee will remain responsible and liable for the performance of all sublicensees under their sublicensed rights to the same extent as if such activities were conducted by Licensee and any breach of this Agreement by a sublicensee will be deemed a breach by Licensee hereunder. Licensee will furnish to Akebia a true and complete copy of each agreement with a sublicensee and each amendment thereto no later than [**] after the execution of such sublicense or amendment.

2.3 Grant of Licenses to Akebia. Subject to the terms and conditions of this Agreement, Licensee hereby grants to Akebia an exclusive (even as to Licensee, except to exercise its rights or perform its obligations under this Agreement) royalty-free, fully paid-up, perpetual, irrevocable license

(with the right to grant sublicenses through multiple tiers, subject to Section 2.4 (Rights of Akebia to Grant Sublicenses)) under the Licensee Technology to Exploit the Licensed Product and any other product controlled by Akebia containing the same API as the Licensed Product.

2.4 Rights of Akebia to Grant Sublicenses. Akebia will have the right to grant one or more sublicenses under the licenses granted to Akebia under Section 2.3 (Grant of Licenses to Akebia) through multiple tiers without Licensee's consent. All sublicensees will hold their rights contingent on Akebia's rights under this Agreement.

2.5 Responsibility for Sublicensees. Each Party agrees that it will be fully responsible and liable for any breach of the terms of this Agreement by any of its sublicensees to the same extent as if such Party itself has committed any such breach.

2.6 Subcontracting. Subject to the restrictions on granting sublicenses set forth in Section 2.2 (Right of Licensee to Grant Sublicensee), which would apply to the engagement of any subcontractor that requires a sublicense, each Party may engage a Third Party subcontractor to perform services in connection with the performance of its obligations and exercise of its rights under this Agreement; *provided* that (a) no such permitted subcontractor will be Debarred/Excluded, (b) no such permitted subcontracting will relieve the subcontracting Party of its obligations under this Agreement or any liability hereunder, and (c) the agreement pursuant to which Licensee engages any Third Party subcontractor must (i) be consistent in all material respects with this Agreement, (ii) contain obligations of confidentiality and non-use no less stringent than the confidentiality terms of this Agreement, and (iii) contain terms that are consistent with the intellectual property provisions set forth in this Agreement.

2.7 No Other Rights and Retained Rights. Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party, including Akebia Technology or Licensee Technology, in each case, that are not expressly granted herein, whether by implication, estoppel, or otherwise. Licensee will not practice the Akebia Technology other than as expressly licensed and permitted under this Agreement. Any rights not expressly granted to Licensee by Akebia under this Agreement are hereby retained by Akebia. For clarity, Akebia retains (on behalf of itself and its licensees) the right to Develop, Manufacture, and have Manufactured the Licensed Product inside the Territory (a) to perform its obligations and exercise its rights under this Agreement, and (b) for the purpose of obtaining and maintaining Regulatory Approval and Commercializing the Licensed Product (i) outside of the Territory and (ii) outside of the Field, inside the Territory.

Article III
GOVERNANCE

3.1 Joint Steering Committee.

3.1.1 **Formation and Purpose of the JSC**. The Joint Steering Committee ("**JSC**") will coordinate, oversee and monitor the Parties' activities hereunder in accordance with this Section 3.1 (Joint Steering Committee). The JSC will have the responsibilities set forth herein. The JSC may establish a charter that will include details regarding the operation of the JSC consistent with this Article III (Governance). The JSC will dissolve upon the expiration of the Term.

3.1.2 **Membership**. Each Party will designate up to [**] representatives with appropriate knowledge and expertise to serve as members of the JSC. Each Party may replace its JSC representatives at any time upon written notice to the other Party. Licensee will designate one of its JSC members to serve as chairperson. The chairperson or his or her designee, in collaboration with the Alliance Managers, will be responsible for calling meetings, preparing, and circulating an agenda in advance of each meeting, and preparing and issuing minutes of each meeting within [**] thereafter. Such minutes will not be finalized until all JSC members have had an adequate opportunity to review and confirm the accuracy of such minutes.

3.1.3 Meetings. The JSC will hold meetings at such times as it elects to do so, but in no event will such meetings be held less frequently than [**], unless otherwise agreed by the Parties. Meetings of the JSC may be held in person, by audio or by video teleconference with the consent of each Party. The Alliance Manager of each Party will attend each meeting of the JSC as a non-voting participant. Each Party will be responsible for all of its own expenses of participating in any JSC meeting.

3.1.4 **Specific Responsibilities of the JSC**. The responsibilities of the JSC will be to:

(a) manage the overall strategic alignment between the Parties under this Agreement and maintain the relationship between the Parties;

(b) [**] whether to approve any Territory-Specific Development;

(c) [**] any Development to be performed by Akebia in the Territory;

(d) [**] the plans of the Parties regarding planned publication in the Territory of Study Data or other clinical or non-clinical results relating to the Licensed Product;

(e) [**] the Local Medical Affairs Plan and updates thereto, and provide updates on Licensee's Medical Affairs activities, as described in Article VI (Medical Affairs);

(f) [**] the Commercialization activities for the Licensed Product, as described in Article XII (Commercialization);

(g) attempt to resolve any other disputes or disagreements; and

(h) perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties.

3.2 Decision-Making and Committee Dispute Resolution.

3.2.1 **Voting; Consensus**. With respect to decisions of the JSC, the representatives of each Party will have collectively one vote on behalf of such Party. For each meeting of the JSC, at least [**] representatives of each Party will constitute a quorum. Action on any matter may be taken at a meeting by teleconference, videoconference, or by written agreement. The JSC will attempt to resolve any and all disputes before it for decision by consensus.

3.2.2 **Escalation to Executive Officers**. If the JSC is unable to reach consensus with respect to a dispute for a period in excess of [**], then the dispute will be submitted to the Executive Officers of the Parties, or their designees (any such designee to be a senior member of the designating Executive Officer's management team), for resolution in accordance with Section 16.1 (Executive Officers; Disputes).

3.2.3 **Final Decision-Making Authority**. If the Executive Officers of the Parties are not able to agree on the resolution of any issue referred to them pursuant to Section 3.2.2 (Escalation to Executive Officers) within [**] after such issue has been referred to them, then the matter will be decided as follows: (a) any dispute relating to (i) [**], (ii) [**], and (iii) [**], in each case ((i) - (iii)), will be determined by the Executive Officer of [**]; (b) any dispute relating to (i) [**], (ii) [**], (iii) [**], or (iv) [**], in each case ((i) - (iv)), will be determined by the Executive Officer of [**]; and (c) neither Party will have final decision-making authority with respect to any other dispute and the *status quo* will persist (or, if applicable, no decision will be implemented) with respect to such matter unless and until the Parties reach agreement thereon.

3.3 Alliance Managers. Each of the Parties will appoint a single individual to manage Development and Commercialization obligations between the Parties (each, an "**Alliance Manager**"). The role of the Alliance Manager is to act as a single point of contact between the Parties to ensure a successful relationship under this Agreement. The Alliance Managers will attend all JSC meetings and will support the co-chairpersons of the JSC in the discharge of his or her responsibilities. Alliance Managers will be non-voting participants in all JSC meetings. Each Party will designate its initial Alliance Manager promptly after the Effective Date and each Party may change its designated Alliance Manager at any time upon written notice to the other Party.

Article IV
DEVELOPMENT

4.1 Territory-Specific Development. Subject to this Section 4.1 (Territory-Specific Development), Licensee will be responsible for all Territory-Specific Development at its cost and expense. Except as may otherwise be permitted under this Agreement, Licensee will solely conduct Territory-Specific Development of the Licensed Product that has been reviewed, discussed, and approved by the JSC, in each case and will not conduct any other Development activities with the Licensed Product.

4.1.1 **Post-Marketing Studies**. Notwithstanding the foregoing, Licensee may request that Akebia perform certain post-marketing clinical studies recommended by EMA, excluding any pediatric studies, and Akebia may agree to do so at its sole discretion. In the event Akebia agrees to perform such post-marketing studies, Licensee shall reimburse Akebia for any and all costs incurred by Akebia in conducting such Development.

4.1.2 **Pediatric Studies**.

(a) During the [**] of the Term of this Agreement, Akebia shall have the right, but not the obligation, to elect to conduct a global pediatric clinical program for the Licensed Product to support Regulatory Approval in the United States as well as in the Territory, which would be in lieu of pediatric clinical studies solely to support Regulatory Approval in the Territory. If Akebia elects to exercise this option, then Licensee shall reimburse Akebia [**]% of any and all costs incurred by Akebia in conducting such Development, up to a limit of no more than $[**].

(b) In the event Akebia does not elect to exercise the option set forth in Section 4.1.2(a) above, then Licensee shall be responsible for conducting any pediatric clinical studies of the Licensed Product required by EMA as of the Effective Date in a manner consistent with the Pediatric Investigation Plan approved by EMA as of the Effective Date. In this instance, Licensee shall be responsible for [**]% of any and all costs incurred in conducting such Development.

4.2 Territory-Specific Development Reports. At each meeting of the JSC, Licensee will provide Akebia with a written update of the Territory-Specific Development activities executed in each country in the Territory during the period since the last JSC meeting, if any, including the status of each pending and proposed Regulatory Submission for the Licensed Product in such countries and all data and information generated in the performance of Territory-Specific Development. In addition, Licensee will provide prompt written notice to Akebia, through the JSC or Alliance Managers, of any significant Territory-Specific Development events in the Territory (*e.g.*, clinical trial initiation or completion, clinical holds, Regulatory Submissions for the Licensed Product, Regulatory Approvals, or Study Data that Licensee reasonably believes is of interest to Akebia). Licensee will make available to Akebia copies of material documentation related to the Licensed Product, including Study Data, that is necessary or reasonably useful to conduct clinical studies or obtain or maintain Regulatory Approvals of the Licensed Product (a) outside of the Territory and (b) outside of the Field, inside the Territory. Notwithstanding the foregoing, the Parties acknowledge and agree that any information and updates provided pursuant to this Section 4.2 (Territory-Specific Development Reports) will be subject to the rules and regulations set forth by the relevant Regulatory Authorities.

4.3 Non-Dialysis Population Indication Expansion by Akebia. Akebia shall have the right, but not the obligation, to Develop the Licensed Product for the treatment of anemia in adult patients with chronic kidney disease who are not on dialysis in the Territory (the "**NDD Indication Expansion**"). Development of the Licensed Product for the NDD Indication Expansion shall be reviewed and discussed by the JSC. Upon Regulatory Approval of the NDD Indication Expansion, Licensee shall Commercialize the Licensed Product for use in the non-dialysis population and track (to the extent possible), or estimate using commercially reasonable data sources, Net Sales in the non-dialysis population relative to Net Sales in the dialysis population. Licensee shall pay to Akebia 70% of the Net Product Margin generated by Net Sales of Licensed Product in the non-dialysis patient population (hereinafter, the "**NDD Net Product Margin Share**"), while the Milestone Payments agreed to in Section 9.2 (Milestone Payments) and the Royalty Payments agreed to in Section 9.3 (Royalties) would only apply to Net Sales generated by Licensee in the dialysis population.

4.3.1 As an alternative to the NDD Net Product Margin Share, Licensee may request a cost-sharing model for the NDD Indication Extension (the "**NDD Cost-Sharing Option**") which the Parties shall discuss in good faith.

(a) If Licensee exercises the NDD Cost-Sharing Option *prior* to the completion of the Phase 3 clinical study pursuing the NDD Indication Extension (hereinafter, the "**NDD Phase 3 Study**"), then:

(i) If the NDD Phase 3 Study is a global study and meant to support approval of the Licensed Product for the NDD Indication Extension both inside and outside of the Territory (including the United States) then Licensee shall be responsible for (i) [**]% of the total costs of the NDD Phase 3 Study, and (ii) a milestone payment to be paid by Licensee to Akebia upon Regulatory Approval of the Licensed Product for the NDD Indication Extension, in an amount to be negotiated by the Parties in good faith; or

(ii) If the NDD Phase 3 Study is to be conducted solely to enable Regulatory Approval of the Licensed Product for the NDD Indication inside the Territory, then Licensee shall be responsible for (i) [**]% of the total costs of the NDD Phase 3 Study and (ii) a milestone payment to be paid by Licensee to Akebia upon Regulatory Approval of the Licensed Product for the NDD Indication Extension, in an amount to be negotiated by the Parties in good faith.

(b) If Licensee exercises the NDD Cost-Sharing Option *after* the completion of the NDD Phase 3 Study, then Licensee shall be responsible for (i) a milestone payment to be paid by Licensee to Akebia upon Regulatory Approval of the Licensed Product for the NDD Indication Extension and (ii) potential additional commercial milestones, all to be negotiated by the Parties in good faith.

4.3.2 For clarity, if Licensee requests the NDD Cost Sharing Option, all Net Sales of the Licensed Product will then be used to calculate the commercial milestones and royalties to be paid by Licensee to Akebia pursuant to Article IX (Payments) and the payments set forth above in Section 4.3.1 would replace the NDD Net Product Margin Share due to Akebia by Licensee.

4.4 Right of First Offer for New Indications. Subject to the terms and conditions of this Agreement, in the event Akebia engages in the Development of vadadustat outside of the Field inside the Territory, and Akebia seeks to collaborate with a Third Party on the Development and/or Commercialization of vadadustat for such new indication, Akebia shall first offer to Licensee the opportunity to collaborate with Akebia on such new indication. In such a scenario, the formulation of vadadustat shall be different from the formulation of the Licensed Product unless otherwise agreed by the Parties.

4.5 Standards of Conduct. Licensee will perform, and will ensure that its Affiliates and licensees and permitted sublicensees (as applicable) and subcontractors perform, all Development activities under this Agreement in a good scientific manner, in accordance with GMP and GCP, as applicable, and in compliance with Applicable Law.

4.6 Development Records. Licensee and its Affiliates will maintain written or electronic records, in sufficient detail, in a good scientific manner (in accordance with GCP and GMP, as applicable), and appropriate for regulatory and patent purposes, and that are complete and accurate in all material respects and reflect all Territory-Specific Development work performed and results achieved, in each case, by or on behalf of Licensee and its Affiliates, licensees, or permitted sublicensees (as applicable) under this Agreement.

Article V
REGULATORY AFFAIRS

5.1 Transfer of Regulatory Filings. Following the Effective Date, Akebia will provide to Licensee copies (in electronic format/eCTD) of any Regulatory Submissions with respect to the Licensed Product in the Territory that are Controlled by Akebia or its Affiliates as of the Effective Date. Following the Effective Date, Akebia or its Affiliate will promptly submit applications to the EMA (or an equivalent Regulatory Authority) to transfer the marketing authorization for the Licensed Product in the E.U. to Licensee. For any other Regulatory Submissions for the Licensed Product still under review by Regulatory Authorities in the Territory and not yet granted Regulatory Approval as of the Effective Date, Akebia will submit (via its Affiliate, agent, or designee, as applicable) applications to such Regulatory Authority(ies) to transfer the Regulatory Submissions for the Licensed Product to Licensee promptly upon the Regulatory Approval of the Licensed Product by such Regulatory Authority (all Regulatory Submissions transferred from Akebia to Licensee hereunder hereinafter referred to as the "**Transferred Regulatory Filings**"). Licensee will be responsible for the applicable fees associated with the application for such transfers. Upon Licensee's written request, Akebia will execute and deliver, or will cause to be executed and delivered, to Licensee such endorsements, assignments, and other documents as may be reasonably necessary to assign, convey, transfer, and deliver to Licensee all of Akebia's rights, title, and interests in and to the Transferred Regulatory Filings, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with a copy to Licensee) notifying such Regulatory Authority of, or requesting approval from such Regulatory Authority for, the transfer of each MAA and Regulatory Approval included in the Transferred Regulatory Filings and transferred to Licensee pursuant to this Section 5.1 (Transfer of Regulatory Filings). Akebia and its Affiliates and licensees will continue to have a right of reference to the Transferred Regulatory Filings under Section 5.4.2 (Rights Granted to Akebia), and the Know-How included in the Transferred Regulatory Filings will remain Akebia Know-How. For clarity, Akebia's actions outlined above with respect to the Transferred Regulatory Submissions may be carried out by an Affiliate, agent or designee, as may be applicable.

5.2 Collaboration With Respect to Regulatory Interactions. Upon Licensee's request, the Parties' regulatory teams will collaborate with respect to substantive correspondence in support of Regulatory Submissions for the Licensed Product in the Field in the Territory. In addition, Licensee will provide Akebia with (a) copies (in English) of any material written correspondence submitted to or received from the EMA and other Regulatory Authorities in the Territory, and (b) summaries of any material oral communications with the EMA and other Regulatory Authorities in the in the Territory, in each case ((a) and (b)), relating to Regulatory Submissions, Development or Commercialization of the Licensed Product in such country, reasonably promptly after receipt or delivery by Licensee of such correspondence or communication, as the case may be (but in any event, with respect to correspondence or communications with the EMA, no later than [**] after receipt or delivery). In the event that Akebia requests to add comments, changes or edits to any such proposed communications by Licensee with Regulatory Authorities, Licensee will [**].

5.3 Regulatory Meetings. Licensee will provide Akebia with notice of any meeting or discussion with any Regulatory Authority in the Territory related to the Licensed Product no later than [**]

after receiving notice thereof or in any event with as much advanced notice as is possible prior to such meeting or discussion if Licensee receives notice thereof less than [**] in advance of the applicable meeting or discussion. Licensee will invite representatives of Akebia (at Akebia's expense) to attend as a participant all meetings relating to Regulatory Submissions and Development of the Licensed Product in the Territory with (a) the EMA and (b) upon Akebia's request, other Regulatory Authorities in the Territory, in each case ((a) and (b)), to the extent not prohibited by Applicable Law or the applicable Regulatory Authority. Akebia will also have the right to attend any meetings of Licensee to prepare for such meeting or discussion with Regulatory Authorities in the Territory (and Licensee will notify Akebia of all such preparatory meetings sufficiently in advance thereof). If Akebia is unable to or otherwise elects not to attend any meeting or discussion under this Section 5.3 (Regulatory Meetings), then Licensee will provide to Akebia a written summary thereof in English promptly following such meeting or discussion. If either Party requires an interpreter or other translation services in connection with its participation in any such meeting with Regulatory Authorities, then the costs of such translation services will be borne solely by Licensee.

5.4 Rights of Reference; Further Assurances.

5.4.1 **Rights Granted to Licensee**. Akebia will provide access to a complete electronic copy of all relevant Regulatory Submissions Controlled by Akebia that, in Akebia's reasonable judgment, are necessary to Licensee in support of Licensee's preparation and filing of any Regulatory Submissions with respect to the Licensed Product in the Field in the Territory in accordance with this Agreement. Licensee and its Affiliates and permitted sublicensees will be entitled at no cost to access, use, and reference the Regulatory Submissions and Study Data Controlled by Akebia for the Development and Commercialization of the Licensed Product in the Field in the Territory. In furtherance of the foregoing, and subject to the rules of the relevant Regulatory Authority and the terms and conditions of this Agreement, Akebia hereby grants to Licensee a right of reference to any Regulatory Approval Controlled by Akebia during the Term relating to the Licensed Product (including the right to rely upon, access, inspect, copy, and otherwise use all information and data included in or used to support any such Regulatory Approval), solely for Licensee's or its Affiliates' or its permitted sublicensees' use in the Territory-Specific Development and Commercialization of the Licensed Product in the Field in the Territory during the Term in accordance with this Agreement. All Regulatory Submissions and Study Data will be considered Confidential Information of Akebia pursuant to Article XIII (Confidentiality).

5.4.2 **Rights Granted to Akebia**. In support of Akebia's Exploitation of the Licensed Product, Licensee will provide access to a complete electronic copy of all relevant Regulatory Submissions that are necessary or reasonably useful to Akebia in preparing its own IND, MAA, or other Regulatory Submissions for the Licensed Product for use (a) outside of the Territory, (b) outside of the Field inside the Territory, or (c) for the NDD Indication. Akebia and its Affiliates, licensees, and sublicensees will be entitled at no cost to access, use, and reference the Regulatory Submissions and Study Data Controlled by Licensee for the Exploitation of the Licensed Product (i) outside of the Territory and (ii) outside of the Field, inside the Territory. In furtherance of the foregoing and subject to the rules of the relevant Regulatory Authority and the terms and conditions of this Agreement, Licensee hereby grants to Akebia a right of reference to any Regulatory Approval Controlled by Licensee relating to the Licensed Product (including the right to rely upon, access, inspect, copy, and otherwise use all information and data included in or used to support any such Regulatory Approval), solely for Akebia's or its Affiliates', licensees', or sublicensees' use in the Exploitation of the Licensed Product (A) outside the Territory,(B) outside of the Field, inside the Territory or (C) for the NDD Indication. Licensee shall provide regulatory support for Akebia's Exploitation of the Licensed Product, which shall be at Licensee's expense for Exploitation of the Licensed Product in the NDD Indication and at Akebia's expense for Exploitation of the Licensed Product outside of the Territory or outside of the Field.

5.4.3 **Further Assurances**. The Party granting rights to the other Party under Section 5.4.1 (Rights Granted to Licensee) and Section 5.4.2 (Rights Granted to Akebia) will take such actions as may be reasonably requested by the other Party to give effect to the intent of such Sections and to give the other Party the benefit of the granting Party's Regulatory Approvals in the other Party's territory as provided in this Section 5.4 (Rights of Reference; Further Assurances). Such actions may include providing a signed statement that the other Party may rely on, and that the Regulatory Authority may access, in support of the other Party's application for Regulatory Approval in its territory.

Article VI
MEDICAL AFFAIRS

6.1 Medical Affairs Plans. Licensee will prepare a reasonably detailed, [**] plan of the Medical Affairs activities to be undertaken for the Licensed Product in the Field in the Territory (the "**Local Medical Affairs Plan**"), in each case, starting no later than [**] following the Effective Date. The Local Medical Affairs Plan, and any amendments or updates thereto, will be reviewed and discussed by the JSC as provided in Section 3.1.4(e) (Specific Responsibilities of the JSC). Any subsequent review and discussion, to the extent required, will occur [**] thereafter at an appropriate time as agreed by the JSC, or more frequently as may be required during the Term.

6.2 Medical Affairs Activities. Licensee will be responsible for Medical Affairs activities for the Licensed Product in the Field in the Territory, and will conduct such activities in accordance with the Local Medical Affairs Plan. In addition, Licensee will conduct all Medical Affairs in the Territory in a professional and ethical business manner and in compliance with Applicable Law and applicable Professional Requirements. Upon Licensee's request, Akebia will provide Licensee with reasonable cooperation, support, and assistance with respect to preparing Licensee's Medical Affairs Plan. In addition, Licensee will provide to the JSC a written update of the Medical Affairs undertaken for the Licensed Product in the Field in the Territory and progress under the Local Medical Affairs Plan during the period since the last JSC meeting.

Article VII
COMMERCIALIZATION

7.1 General. Subject to the Launch Sequence and the Commercialization Plan as reviewed and discussed by the JSC, Licensee and its Affiliates and permitted sublicensees will be solely responsible for the Commercialization of the Licensed Product in the Field in the Territory, at its own cost and expense. Subject to oversight by the JSC as set forth in this Agreement, Licensee and its Affiliates and permitted sublicensees will have sole responsibility and authority for seeking Reimbursement Approvals, establishing pricing for the Licensed Product, detailing, marketing and promotion activities, booking sales, distributing the Licensed Product, processing, invoicing, and collecting inventory and receivables, and providing customer support.

7.2 Launch Sequence and Commercialization Plan.

7.2.1 **Launch Sequence**. A list of those countries in the Territory in which Licensee intends to commence Commercialization of the Licensed Product within the first [**] after the Effective Date and timelines reflecting potential date ranges for First Commercial Sale following receipt of Regulatory Approval and Reimbursement Approval (if applicable) in such countries, (the "**Launch Sequence**" and the countries included in the Launch Sequence, the "**Launch Countries**") is made part of this Agreement in Schedule 7.2.1. Licensee will amend or update the Launch Sequence [**] thereafter (without formally amending this Agreement), including updating such sequence with additional countries in the Territory in which Licensee plans to commence Commercialization of the Licensed Product. The Launch Sequence and all amendments and updates thereto will be reviewed and discussed by the JSC.

7.2.2 **Commercialization Plan**. No later than [**] following the Effective Date, Licensee will prepare and submit to the JSC to review and discuss a Commercialization Plan which will be a [**] high-level strategic and tactical plan for Commercialization in the Launch Countries included in the then-current Launch Sequence, and shall include planned key marketing and promotional activities for the Licensed Product, positioning of the Licensed Product by Licensee's sales representatives, key messaging, and forecasts of anticipated Net Sales on a rolling [**] basis for the Licensed Product. On a [**] basis thereafter, Licensee will prepare and submit to the JSC to review and discuss an update to the Commercialization Plan, which update will include the then-current Launch Sequence and an updated forecast of anticipated Net Sales for the Licensed Product.

7.3 Commercialization Reports. At each meeting of the JSC, Licensee will provide to the JSC a written update of the Commercialization activities performed in each Launch Country for the Licensed Product during the period since the last JSC meeting and, following First Commercial Sale of the Licensed Product in a country in the Territory, sales performance reports for each such country.

7.4 Reimbursement and Information Sharing. Licensee will be responsible for, and will have sole authority and the final decision-making right with respect to, any payor and pricing studies related to obtaining and maintaining Reimbursement Approval in the Territory (where required), and all submissions, communications, meetings and other dealings with National Reimbursement Authorities, payors, and other Third Parties relating to pricing and reimbursement of Licensed Product in the Territory; *provided* that (a) upon Licensee's reasonable request, Akebia will attend such meetings and Licensee will reimburse Akebia's out-of-pocket costs incurred in connection with such attendance, and (b) prior to receipt of Reimbursement Approval for the Licensed Product from the applicable National Reimbursement Authority in each country in the Territory, upon Akebia's reasonable request, Licensee will use reasonable efforts to allow an Akebia representative to attend, at Akebia's expense, scientific advisory meetings with such National Reimbursement Authority in such country, and if Akebia is not allowed to attend any such scientific advisory meeting, then Licensee will provide Akebia with an update summarizing such meeting reasonably promptly after such meeting. Upon either Party's reasonable request, but subject to local anti-competition laws and any obligations of confidentiality between a Party and any Third Party, the Parties will share key market research and relevant sections of Licensed Product national reimbursement dossiers (or their equivalent), as well as other relevant Commercialization information as may be agreed by the Parties.

7.5 General Commercialization Efforts. Licensee, directly or through its Affiliates or permitted sublicensees, will use Commercially Reasonable Efforts to Commercialize the Licensed Product in the Territory and will achieve First Commercial Sale no later than [**] after receipt of Regulatory Approval and Reimbursement Approval (if applicable) in each country in the Territory, and, after achieving First Commercial Sale in such country, Commercialize the Licensed Product in such country in the Territory in accordance with the Commercialization Plan. Licensee will use Commercially Reasonable Efforts to obtain and maintain Regulatory Approval and Reimbursement Approval (where required) for the Licensed Product in the Field in the Territory.

7.6 Standards of Conduct; Compliance. Licensee will perform, or will ensure that each of its Affiliates, permitted sublicensees (as applicable), and subcontractors perform, all Commercialization activities for the Licensed Product in the Territory in a professional and ethical business manner and in compliance with Applicable Law, applicable Professional Requirements, the Approved Labeling, and the Commercialization Plan.

7.7 Information Sharing. Within [**] of the Effective Date of this Agreement, Akebia shall share any relevant materials, documentation and knowledge that exist as of the date of execution that Akebia believes is reasonably necessary to enable Licensee's successful Commercialization of the Licensed Product in the Field in the Territory pursuant to this Agreement. Upon Licensee's reasonable request, Akebia will provide to Licensee any drafts or samples of Akebia's core promotional materials for the Licensed Product, if any, without translation.

7.8 Trademarks and International Nonproprietary Name.

7.8.1 **Brand Name in the Territory**. Licensee will Commercialize the Licensed Product under the Global Marks using the global brand name for the Licensed Product selected by Akebia, which, as of the Effective Date, is "VAFSEO™", unless Licensee reasonably believes that the use or registration of any Global Mark in a particular country in the Territory (a) would be inappropriate due to such country's linguistic or cultural particularities or would violate the Applicable Laws of such country, (b) is reasonably likely to be rejected by local Regulatory Authorities, or (c) is in conflict with any Third Party's intellectual property rights in such country. If Licensee is unable to use any Global Mark for any of the foregoing reasons, then Licensee will use one of [**] alternative Marks (which Marks will include trademarks and trade dress) selected by Akebia, or if such alternative Marks are unacceptable for the reasons set forth in the preceding sentence, then Licensee will use other Marks (including trademarks and trade dress) to be agreed upon by Licensee and Akebia (the "**Local Marks**"). Akebia will own all such Local Marks, including all trademark registrations and applications therefore and all goodwill associated therewith. Once the brand name for the Licensed Product has been selected for a country in the Territory pursuant to this Section 7.8.1 (Brand Name in the Territory), Licensee will be responsible for obtaining Regulatory Approval of such brand name for use in the Commercialization of the Licensed Product in such country.

7.8.2 **Required Use and Compliance**.

(a) **Housemarks**. Licensee will Commercialize the Licensed Product only under the applicable Product Marks and each Party's Housemarks as set forth herein, and no other Marks.

(b) **Ownership; Use**. Each Party acknowledges that Akebia has sole and exclusive ownership of all rights, title, and interests in and to the Product Marks and Akebia Housemarks. Licensee agrees that it and its Affiliates will: (i) ensure that each use of the Product Marks and the Akebia Housemarks by Licensee is accompanied by an acknowledgement that such Product Marks and Akebia Housemarks are owned by Akebia; (ii) not use such Product Marks or Akebia Housemarks in a way that might materially prejudice their distinctiveness or validity or the goodwill of Akebia therein and includes the trademark registration symbol ® or ™ as appropriate; (iii) not use any trademarks or trade names so resembling any of such Product Marks or the Akebia Housemarks as to be likely to cause confusion or deception; and (iv) place and display the Product Marks and Akebia Housemarks on and in connection with the Licensed Product only in such form and manner as specified in the guidelines adopted from time-to-time by Akebia and provided to Licensee; *provided*, *however*, that Licensee will not be required to place or display any Akebia Housemark on promotional materials or other Product Materials used to Commercialize the Licensed Product in the Territory, except as provided in Section 8.4 (Approved Labeling).

7.8.3 **Trademarks**. Akebia will have sole control over and decision-making authority with respect to (a) registering, prosecuting, protecting, and enforcing the Product Marks in the Territory, (b) preparing any guidelines applicable to the use of Product Marks, (c) registering, in Akebia's name, at least [**] Product Mark and at least [**] alternative Product Marks, (d) if necessary pursuant to Section 7.8.1 (Brand Name in the Territory), registering, prosecuting, and enforcing any Local Marks in the Territory, (e) preparing any guidelines applicable to the use of any Local Mark, and (f) investigating and defending any infringement or threatened infringement relating to any of the foregoing. Licensee will cooperate and assist Akebia with any of the foregoing activities with respect to all Product Marks, including, if requested by Akebia, providing any specifications, affidavits, declarations, or other documents necessary for Akebia to submit to appropriate Regulatory Authorities in order to register and prosecute Product Marks. Licensee will reimburse Akebia for the costs of the activities set forth in clauses

(a), (c), (d), (e), and (f) to the extent related to a Product Mark in the Territory. Licensee will be responsible for securing and protecting any domain names associated with the Product Marks in Akebia's name, at Licensee's cost and expense. Licensee will not obtain or hold any such domain name in its own name. Neither Party will register in its own name any trademark, corporate name, domain name, social media account, or other source identifier containing any trademark owned by the other Party or any word or mark that is confusingly similar to any such trademark. Licensee will promptly notify Akebia of any infringement or threatened infringement of any of the Product Marks in the Territory of which it becomes aware.

7.8.4 **Respect of Marks**. Licensee will not, and will cause its Affiliates and sublicensees to not (a) attack, challenge, oppose, petition to cancel, or initiate legal action or proceedings in connection with any Product Mark or any Akebia Housemark during the Term, or thereafter challenge the registration of any Product Mark or any Akebia Housemark in any country; (b) file, register, or maintain any registrations for any trademarks or trade names that are confusingly similar to any Product Mark (*other than* for the Licensed Product) in any country without the express prior written consent of Akebia; or (c) authorize or assist any Third Party to do any of the foregoing. Licensee will not have, assert, or acquire any rights, title, or interests in or to any Product Marks or Akebia Housemarks or the goodwill pertaining thereto, except, in each case, for the limited licenses explicitly provided in this Agreement. Licensee will maintain the quality standards of Akebia with respect to use of Product Marks and Akebia Housemarks pursuant to the licenses granted under Section 2.1 (Grant of Licenses to Licensee) and Section 7.8.5 (Trademark License), as applicable, and with respect to the goods it sells and the services it provides in connection with the Product Marks and the Akebia Housemarks hereunder. Licensee recognizes and agrees that no ownership rights are vested or created by the limited licenses granted pursuant to Section 2.1 (Grant of Licenses to Licensee), or Section 7.8.5 (Trademark License), and that all goodwill developed by virtue of the use by Licensee of the Product Marks and the Akebia Housemarks inures to the benefit of Akebia.

7.8.5 **Trademark License**. Subject to the terms and conditions of this Agreement, Akebia hereby grants and agrees to grant to Licensee an exclusive, royalty-free license, with the right to sublicense to sublicensees solely in accordance with Section 2.2 (Rights of Licensee to Grant Sublicenses), to use the Product Marks and the Akebia Housemarks solely in connection with the Commercialization of the Licensed Product in the Territory pursuant to this Agreement, including to effect the co-labeling provided for under Section 8.4 (Approved Labeling) and as part of any domain names associated with the Product Marks.

7.8.6 **International Non-Proprietary Name**. Akebia will be responsible for the selection and filing of the international nonproprietary name for the Licensed Product with the World Health Organization and any Regulatory Authorities in the Territory, to which names Licensee will have the right to reference. As of the Effective Date, the international nonproprietary name for the Licensed Product is "vadadustat".

Article VIII
MANUFACTURING AND SUPPLY

8.1 Supply and Purchase Obligations. Subject to the terms and conditions of this Agreement, Akebia will use Commercially Reasonable Efforts to Manufacture or have Manufactured and supply to Licensee the Licensed Product in Tablet Formulation (in bulk form) for commercial supply and Territory-Specific Development in the Territory. Subject to the terms and conditions of this Agreement, Licensee will purchase from Akebia all of Licensee's requirements of the Licensed Product for Territory Specific Development and commercial use in the Territory. Licensee will be responsible, at its sole cost and expense, for all packaging and labeling, and other related activities required to convert the Licensed Product supplied by Akebia into Finished Form (such activities, collectively, "**Packaging**"), including all packaging and labeling of the

Licensed Product for use in the Field in the Territory and for all costs associated therewith. As of the Effective Date of this Agreement, Licensee shall assume responsibility for all costs associated with Packaging activities. Upon Licensee's request, Akebia will, at Akebia's reasonable discretion, provide reasonable cooperation and technical assistance in order to support the tech transfer to Licensee's representatives of Akebia Know-How necessary to support Licensee's analytical methods and stability testing of the Licensed Product in furtherance of Licensee's Packaging activities; *provided that* Licensee will provide to Akebia any information, data, and reports relating to Licensee's analytical methods and stability testing of the Licensed Product. In the event such technology transfer requires more resources of Akebia than that which would be considered reasonable and standard in the industry, upon Akebia's request, prior to Akebia providing further assistance, the Parties shall agree to the terms upon which Licensee will reimburse Akebia for all out-of-pocket costs incurred by or on behalf of Akebia in connection with such technology transfer going forward.

8.2 Supply Agreement. Within [**] after the Effective Date, the Parties will agree upon a supply agreement on reasonable and customary terms for the supply of the Licensed Product by Akebia to Licensee in the Territory at the Supply Price in Tablet Formulation (in bulk form) (the "**Supply Agreement**"). The Supply Agreement will include provisions regarding long-range forecasting of Licensee's requirements for the Licensed Product, specifications, changes to manufacturing process or specifications, ordering, shipment and delivery, failure to supply (including appropriate remedies in the event of a failure to supply), audit and inspection, shortage allocation, acceptance and rejection, and warranties. The supply price for the Licensed Product in Tablet Formulation (in bulk form) supplied by Akebia to Licensee or its manufacturer during the Term for any Territory-Specific Development will be equal to [**]; for commercial use in the Territory, the supply price will be equal to [**] (the "**Supply Price**").

8.3 Quality Agreement. Prior to delivery of any Licensed Product hereunder or under the Supply Agreement, the Parties will also enter into one or more quality technical agreements (each a "**Quality Agreement**") containing reasonable and customary terms and conditions regarding quality assurance and quality control and compliance with GMP and GCP (as applicable). Each Party agrees to provide information to the other Party regarding quality defects and quality complaints associated with the use of the Licensed Product in accordance with the timeframes and procedures for reporting and other terms and conditions set forth in the Quality Agreements. Licensee will be responsible for the management of all product quality complaints with respect to the Licensed Product in the Territory, and the Quality Agreement will define each Party's roles and responsibilities with respect to the same.

8.4 Approved Labeling. The Parties agree that, to the extent permitted under Applicable Law within the Territory, the Approved Labeling will include the Akebia Housemarks and the Licensee Housemarks with equal prominence, subject to the approval of competent authorities.

8.5 Assignment of CMO Agreements. Akebia and Licensee shall discuss in good faith the potential assignment from Akebia to Licensee of certain supply agreements between Akebia and contract manufacturers relating to the Licensed Product, and the transition of responsibilities under those agreements.

Article IX
PAYMENTS

9.1 Upfront Payment. As partial consideration for the rights and licenses granted by Akebia to Licensee under this Agreement, and as partial reimbursement for those expenses incurred by Akebia in the Development of the Licensed Product prior to the Effective Date, no later than [**] after the Effective Date, Licensee will pay to Akebia a nonrefundable and noncreditable payment of $10,000,000.

9.2 Milestone Payments. As additional consideration for the rights and licenses granted to Licensee under this Agreement, Licensee will pay to Akebia, the following nonrefundable and noncreditable milestone payments set forth in Table 9.2 upon the first occurrence of each event

set forth in Table 9.2 below in the Territory during the Term (each a "**Milestone Payment**"). If in any consecutive 12-month period during the Term more than one of the following thresholds for the sales milestones is exceeded with respect to aggregate Net Sales of the Licensed Product during the Term, then Licensee will pay to Akebia a separate milestone payment with respect to each such threshold that is exceeded for the first time for any consecutive 12-month period.

Table 9.2 –Milestones	
Event	***Payment Amount (in U.S. Dollars)***
Achievement of €[**] of aggregate Net Sales of the Licensed Product in the Territory during any consecutive 12-month period	$[**]
Achievement of €[**] of aggregate Net Sales of the Licensed Product in the Territory during any consecutive 12-month period	$[**]
Achievement of €[**] of aggregate Net Sales of the Licensed Product in the Territory during any consecutive 12-month period	$[**]
Achievement of €[**] of aggregate Net Sales of the Licensed Product in the Territory during any consecutive 12-month period	$[**]

9.3 Royalties.

9.3.1 **Royalty Amounts**. Licensee will pay Akebia nonrefundable and noncreditable royalties based on Net Sales of the Licensed Product in the Territory during the Royalty Term at the applicable incremental royalty rates set forth in Table 9.3.1 for Net Sales of the Licensed Product ("**Royalty Payments**"). Net Sales for all countries will be aggregated for purposes of calculating the applicable royalty tier for Net Sales.

Table 9.3.1 – Royalty Rates	
Portion of Annual Net Sales (in U.S. Dollars) of the Licensed Product in the Territory	***Royalty Rate***
0 to ≤ €[**]	10%
>€[**] to ≤ €[**]	[**]%
>€[**] to ≤ €[**]	[**]%
>€[**]	30%

9.3.2 **Royalty Term**. Running royalties paid by Licensee under Section 9.3.1 (Royalty Amounts) will be paid on a country-by-country basis during the Royalty Term in such country. Upon expiration of the Royalty Term in a country in the Territory, the Net Sales in such country will no longer be included in the aggregate Net Sales for purposes of calculating the applicable royalty tier for Net Sales.

9.3.3 **Royalty Reductions.**

(a) **Generic Competition Reduction**. Subject to Section 9.3.3(b) (Cumulative Reductions Floor), on a country-by-country and calendar quarter-by-calendar quarter basis in the Territory, during the Royalty Term in such country following the first commercial sale of a Generic Product for the Licensed Product in such country, [**], then the Net Sales of the Licensed Product in such country that will be included in the aggregate annual Net Sales in such calendar quarter for

purposes of calculating the applicable royalty tier for Net Sales pursuant to Section 9.3.1 (Royalty Amounts) and for purposes of the royalty payments required under Section 9.3.4 (Royalty Payments and Reports) will be reduced by [**]% for the Licensed Product in such country.

(b) **Cumulative Reductions Floor**. In no event will the aggregate amount of Royalty Payments due to Akebia for the Licensed Product in a country or region in the Territory in any given calendar quarter during the Royalty Term for the Licensed Product in such country or region be reduced to less than [**]% of the amount that otherwise would have been due and payable to Akebia in such calendar quarter for the Licensed Product in such country or region but for the reductions set forth in Section 9.3.3(a) (Generic Competition Reduction). Licensee may not carry forward to subsequent calendar quarters any amounts it could not deduct as a result of such floor in any given calendar quarter.

(c) In the event where the commercialization of such Generic Product has created a business condition which renders the terms of this Agreement to no longer be commercially reasonable, the Parties shall discuss in good faith, through the JSC, potential solutions and/or amendments to this Agreement intended to ameliorate such conditions.

9.3.4 **Royalty Payments and Reports**.

(a) **Flash Reports**. Within [**] after the end of each calendar quarter during the Term, on a country-by-country basis, Licensee will provide to Akebia "flash" reports that will set forth (i) for the first and second month of such calendar quarter: (A) the actual gross sales of the Licensed Product sold by Licensee or its Affiliates in the Territory in such months; and (B) the actual total aggregate Net Sales of the Licensed Product sold by Licensee or its Affiliates in the Territory in such months, and (ii) for the third month of such calendar quarter, Licensee's good faith estimate of the amounts set forth in the foregoing clauses (i)(A) and (i)(B) of this Section 9.3.4(a) (Flash Reports).

(b) **Quarterly Report**. In addition to the "flash" reports to be provided in accordance with Section 9.3.4(a) (Flash Reports), within [**] after the end of each calendar quarter during the Term, Licensee will provide to Akebia a written report (each, a "**Quarterly Report**") setting forth in reasonable detail on a country-by-country basis (i) the gross sales of the Licensed Product sold by Licensee or its Affiliate in such country in such calendar quarter; (ii) the aggregate Net Sales of the Licensed Product sold by Licensee or its Affiliates in such country in such calendar quarter; (iii) all deductions taken from gross sales to calculate Net Sales under each of Sections 1.82.1 to 1.82.5 (Net Sales); (iv) the exchange rates used to calculate the royalties payable in U.S. Dollars; (v) any withholding taxes required to be made from such royalties; (vi) any reductions taken pursuant to Section 9.3.3 (Royalty Reductions); and (vii) the quantity and description of the Licensed Product sold by such Party or its Affiliate in such country during such calendar quarter comprising such Net Sales, including detailed sales reports for the Licensed Product for each month of the calendar quarter in such country. The amounts, calculations, and information set forth in the foregoing clauses (i) through (vii) will be broken down on a monthly basis for each country in the Territory. The Parties will seek to resolve any questions or issues related to a Quarterly Report within [**] following receipt by Akebia of the Quarterly Report.

(c) **Royalty Payments**. Within [**] after the end of each calendar quarter, Licensee will make the royalty payment due hereunder for the calendar quarter covered by the applicable Quarterly Report.

9.4 Accounting; Audit. Licensee agrees to keep, and will ensure its Affiliates and sublicensees keep, full, clear, and accurate records in accordance with the Accounting Standards applicable to such party, consistently applied, for a period of at least [**] after the relevant payment is owed pursuant to this Agreement, including Net Sales of the Licensed Product, in sufficient detail to enable amounts owed or payable to Akebia hereunder, to be determined. Licensee further agrees, and will require its Affiliates and sublicensees to agree, to permit its books and records to be examined by an independent accounting firm selected by Akebia to verify the Milestone Payments and Royalty Payments. Such auditor will be bound by a legal agreement obligating it to maintain the confidentiality of such information. Such audit will not be performed more frequently than [**] without cause, or conducted for any calendar year more than [**] after the end of such year. Such examination is to be made at Akebia's expense, except in the event that the results of the audit reveal an underpayment to Akebia of [**]% or more during the period being audited, in which case reasonable audit fees for such examination will be paid by Licensee.

9.5 Currency Conversion. Any Net Sales that are invoiced or incurred in a currency other than U.S. Dollars, and all other payments by Licensee to Akebia, will be converted into U.S. Dollars in compliance with the Accounting Standards, as consistently applied by Licensee.

9.6 Method of Payment. All payments due to a Party under this Agreement will be made in U.S. Dollars by wire transfer to a U.S. bank account of such Party designated from time-to-time in writing by the relevant Party.

9.7 Taxes. Any and all payments due to Akebia from Licensee pursuant to this Agreement will be paid without deduction or withholding for any taxes, except as required by Applicable Law. If under any law or regulation of any country of the Territory withholding of taxes of any type, levies or other charges is required with respect to any amounts payable hereunder to Akebia, Licensee will apply the withholding or deduction as so required, will promptly pay such tax, levy, or charge to the proper Governmental Authority, and will promptly furnish Akebia with proof of such payment. Licensee shall then remit such payment to Akebia, less the amount withheld for such applicable taxes. Licensee shall then provide reasonable assistance to Akebia in recovering any such withheld tax from the applicable governmental agency in the Territory to which such tax was paid. Each Quarterly Report will show the amounts of taxes due and paid by Licensee with respect to payments made by Licensee to Akebia during the applicable calendar quarter. For clarity, the Parties recognize that, as of the Effective Date, Akebia has filed their request for a Certificate of United States Residency for Tax Treaty Purposes with the United States Treasury. Upon receipt of such certificate, Akebia shall promptly provide a copy to Licensee. Upon any new issuance of such certificate, Akebia shall promptly provide a copy of the same to Licensee.

9.8 Late Payments; Disputed Payments. Any amount owed by a Party to the other Party under this Agreement that is not paid within the applicable time period set forth herein will accrue interest at the lesser of (a) the prime rate as quoted by Citibank NA *plus* [**]%, or (b) the highest rate permitted under Applicable Law. If a Party disputes an invoice or other payment obligation under this Agreement, then such Party will timely pay the undisputed amount of the invoice or other payment obligation, and the Parties will resolve such dispute in accordance with Article XVI (Dispute Resolution; Governing Law).

Article X
OWNERSHIP OF INTELLECTUAL PROPERTY

10.1 Akebia Intellectual Property. Ownership of the Akebia Know-How, and Akebia Patent Rights will be and remain vested at all times in Akebia.

10.2 Licensee Intellectual Property. Ownership of the Licensee Know-How and Licensee Patent Rights will be and remain vested at all times in Licensee.

10.3 Joint Technology.

10.3.1 **Invention Disclosure**. The Parties will promptly disclose to each other any Joint Know-How conceived or reduced to practice, but no later than [**] after the applicable Party's intellectual property department receives notice of such conception or reduction to practice.

10.3.2 **Ownership**. All Joint Technology will be jointly owned by the Parties, with each Party entitled to the free use and enjoyment of such Joint Technology, but subject to the terms and conditions of this Agreement, including the license grants under Article II (Licenses). Subject to such terms and conditions of this Agreement, neither Party will have a duty to account to the other or seek any consent with respect to the licensing or exploitation of Joint Technology. To the extent any further consent is required to enable a Party to so license or exploit its interest in the Joint Technology, the other Party will grant such consent promptly upon request.

10.4 Prosecution of Akebia Patent Rights and Joint Patent Rights.

10.4.1 **Akebia's First Right to Prosecute**. Akebia will have the first right, but not the obligation, to file, prosecute, and maintain (excluding oppositions filed by a Third Party, as provided for in Section 10.7 (Defense to Third Party Challenges Against Akebia Patent Rights and Joint Patent Rights)) the Akebia Patent Rights and Joint Patent Rights. On the reasonable request of Akebia, Licensee will cooperate in connection with the filing, prosecution, and maintenance of all Akebia Patent Rights and Joint Patent Rights.

10.4.2 **Status Updates**. On [**] basis, Akebia will provide to Licensee a written summary of the status of all Akebia Patent Rights and Joint Patent Rights, including patent applications, being prosecuted and maintained by Akebia in the Territory. Furthermore, upon Licensee's request, but no more than [**], Akebia will reasonably discuss and consult with Licensee and will provide updates to Licensee by audio or video teleconference regarding Akebia Patent Rights and Joint Patent Rights being prosecuted and maintained by Akebia in the Territory.

10.4.3 **Assistance**. Licensee undertakes without cost to Akebia to obtain all necessary assignment documents for Akebia with respect to prosecution and maintenance of Akebia Patent Rights and Joint Patent Rights, to render all signatures that will be necessary for Akebia Patent Right and Joint Patent Right filings, and to assist Akebia in all other reasonable ways that are necessary for the issuance of the Akebia Patent Rights and Joint Patent Rights as well as for the prosecution and maintenance of such patents.

10.4.4 **Costs**. [**] will be responsible for the costs and expenses incurred with respect to the filing, prosecution, and maintenance of the Akebia Patent Rights and Joint Patent Rights inside and outside the Territory.

10.5 Prosecution of Licensee Patent Rights.

10.5.1 **Licensee's First Right to Prosecute**. Licensee will have the first right, but not the obligation, to file, prosecute, and maintain the Licensee Patent Rights. If Licensee declines to file such applications, then Akebia may do so.

10.5.2 **Territory-Related Status Updates**. On [**] basis, Licensee will provide to Akebia a written summary of the status of all Licensee Patent Rights being prosecuted and maintained by Licensee in the Territory. Furthermore, upon Akebia's request, but no more than [**], Licensee will reasonably discuss and consult with Akebia and will provide updates to Akebia by audio or video teleconference regarding Licensee Patent Rights being prosecuted and maintained by Licensee in the Territory.

10.5.3 **Costs**. [**] will be responsible for the costs and expenses incurred with respect to the filing, prosecution, and maintenance of the Licensee Patent Rights.

10.5.4 **Abandonment**. If Licensee decides that it is no longer interested in maintaining or prosecuting a particular Licensee Patent Right during the Term, then, unless Licensee or its Affiliate has a strategic rationale for ceasing such patent prosecution or such patent prosecution is otherwise inconsistent with any agreement with any Third Party, Licensee will provide written notice to Akebia of such decision at least [**] prior to the date that such the applicable Licensee Patent Right will become abandoned. To the extent consistent with the rights granted to Licensee or its Affiliate under any agreement with any Third Party, Akebia may, upon written notice to Licensee, assume such prosecution and maintenance at its sole expense.

10.6 Enforcement of Akebia Patent Rights, Joint Patent Rights, or Licensee Patent Rights in the Territory.

10.6.1 **Notice of Infringement**. If either Party becomes aware of any Third Party activity in the Territory, including any Development activity in the Territory (whether or not an exemption from infringement liability for such Development activity is available under Applicable Law), that infringes (or that is directed to the Development of a product that would infringe) an Akebia Patent Right, a Joint Patent Right, or a Licensee Patent Right, then the Party becoming aware of such activity will give prompt written notice to the other Party regarding such alleged infringement.

10.6.2 **Rights to Enforce Akebia Patent Rights and Joint Patent Rights in the Territory**. As between the Parties, Akebia will have the first right, but not the obligation, to attempt to resolve such Third Party activity in the Territory that infringes (or that is directed to the Development of a product that would infringe) an Akebia Patent Right or a Joint Patent Right by commercially appropriate steps at Licensee's expense, including the filing of an infringement suit to enforce the Akebia Patent Rights or Joint Patent Rights using counsel of its own choice. If Akebia fails to initiate a suit or take other action to terminate such alleged infringement within [**] after the notice provided under Section 10.6.1 (Notice of Infringement) and does not provide Licensee commercially reasonable reasons why such suit has not been initiated or other action has not been taken within such [**] period, then Licensee will have the second right, but not the obligation, to attempt to resolve such Third Party activity in the Territory by commercially appropriate steps, including the filing of an infringement suit to enforce the Akebia Patent Rights or Joint Patent Rights in the Territory using counsel of its own choice.

10.6.3 **Rights to Enforce Licensee Patent Rights in the Territory**. As between the Parties, Licensee will have the first right, but not the obligation, to attempt to resolve such Third Party activity in the Territory that infringes (or that is directed to the Development of a product that would infringe) a Licensee Patent Right by commercially appropriate steps at its own expense, including the filing of an infringement suit to enforce the Licensee Patent Right using counsel of its own choice; *provided* that Akebia will be entitled to attend any substantive meetings, hearings, or other proceedings related to such infringement suit (to the extent relevant, together with its own counsel, at its own expense). If Licensee fails to initiate a suit or take other action to terminate any such alleged infringement by a product that competes with the Licensed Product in the Territory within [**] after the notice provided under Section 10.6.1 (Notice of Infringement), then Akebia will have the second right, but not the obligation, to attempt to resolve such Third Party activity in the Territory at its own expense, including the filing of an infringement suit to enforce the Licensee Patent Rights using counsel of its own choice.

10.6.4 **Allocation of Recoveries in the Territory**. Any amounts recovered by a Party as a result of an action pursuant to this Section 10.6 (Enforcement of Akebia Patent Rights, Joint Patent Rights, or Licensee Patent Rights in the Territory), whether by settlement or

judgment, will be allocated as follows: (a) first each Party will be reimbursed its out-of-pocket and internal expenses, including expenses associated with FTEs, incurred in conducting, or cooperating with, such action; *provided that* if amounts recovered are insufficient to reimburse all such out-of-pocket expenses incurred by both Parties, then [**], and (b) second, the balance of such recovered amounts shall be divided equally among the Parties.

10.6.5 **Cooperation; Procedures**. In any event, at the request and expense of the Party bringing an infringement action under this Section 10.6 (Enforcement of Akebia Patent Rights, Joint Patent Rights, or Licensee Patent Rights in the Territory), the other Party will provide reasonable assistance and cooperation in any such action (including entering into a common interest agreement if reasonably deemed necessary by any Party) and agrees to be joined as a party to the suit if necessary for the initiating Party to bring or continue an infringement action hereunder. In addition, the Party bringing an infringement action under this Section 10.6 (Enforcement of Akebia Patent Rights, Joint Patent Rights, or Licensee Patent Rights in the Territory) will provide the other Party with copies of all pleadings and other documents filed with the court and will consider reasonable input from the other Party during the course of the action. Neither Party may settle any action or proceeding brought under this Section 10.6 (Enforcement of Akebia Patent Rights, Joint Patent Rights, or Licensee Patent Rights in the Territory) or knowingly take any other action in the course thereof, in a manner that materially adversely affects the other Party's interest in the Akebia Patent Rights, Joint Patent Rights, or Licensee Patent Rights in the Territory, in each case, without the written consent of such other Party. Each Party will have the right to be represented by counsel of its own selection and its own expense in any suit or other action instituted by the other Party pursuant to this Section 10.6 (Enforcement of Akebia Patent Rights, Joint Patent Rights, or Licensee Patent Rights in the Territory). In addition, the Parties will reasonably assist each other and cooperate in any such investigation, pre-litigation preparation, or litigation to ensure that there is an aligned global litigation and enforcement strategy.

10.7 Defense to Third Party Challenges Against Akebia Patent Rights and Joint Patent Rights

10.7.1 **Right to Defend.** As between the Parties, Akebia will have the exclusive right, but not the obligation, to defend against any Third Party challenges to the validity and/or enforceability of an Akebia Patent Right or a Joint Patent Right (including an opposition filed at a patent office or an invalidation proceeding filed in a national court) in the Territory.

10.7.2 **Costs**. As of the Effective Date of this Agreement, Akebia will be responsible for [**]%, and Licensee will be responsible for [**]%, in each case, of any costs associated with defending against any Third Party challenges to the validity and/or enforceability of an Akebia Patent Right or a Joint Patent Right (including filing an opposition at a patent office or an invalidation proceeding at a national court) in the Territory, including any Third Party challenges existing as of the Effective Date.

10.8 Defense of Third Party Infringement Claims; Third Party IP

10.8.1 **Infringement Claim**. If a Third Party asserts that a Patent Right or other right controlled by it is or will be infringed by a Party's activities in the Territory under this Agreement ("**Infringement Claim**") or a Party becomes aware of a Patent Right or other right that might form the basis for an Infringement Claim, then the Party first obtaining knowledge of such Infringement Claim or such potential Infringement Claim will immediately provide the other Party with written notice thereof and the related facts in reasonable detail. The Parties will discuss whether to use commercially appropriate steps to avoid infringement of such Third Party Patent Right or other right controlled by such Third Party in the Territory. Akebia will make the final decision in its sole discretion as to how to address such Infringement Claim or potential Infringement Claim, including whether it will seek a license from such Third Party pursuant to Section 10.8.3 (Responsibility for

Third Party Licenses) or take an action to challenge such Third Party Patent Right or other right controlled by such Third Party in the Territory.

10.8.2 **Responsibility to Defend**. If, during the Term of this Agreement, a Third Party asserts that a Patent Right or other right controlled by such Third Party is infringed or will be infringed in the Territory by the exercise of the licenses granted under Article II (Licenses), then Akebia will be responsible for defending against any such claim at its own expense using Commercially Reasonable Efforts and the counsel of its own choosing. Akebia will be solely responsible for all amounts payable to such Third Party as a result of such claim, whether by settlement or judgment, *except that* Akebia will be responsible for [**]% and Licensee will be responsible for [**]%, in each case, of any payments owed to such Third Party that are attributable to the Licensed Product and allocable to the Territory. Akebia will not settle such claim in a manner that materially adversely affects Licensee's interests and in a manner that is disproportionate to Akebia's interests, without the written consent of Licensee. In addition, the Parties will reasonably assist each other and cooperate and share information with respect to such claim.

10.8.3 **Responsibility for Third Party Licenses**. At any time during the Term, if either Party believes that it is necessary or advisable to seek to acquire or obtain a license under any Patent Rights owned or controlled by a Third Party in order to avoid infringement thereof by the exercise of the licenses granted under Article II (Licenses), whether or not there has been the institution of any infringement claim, then the Parties will discuss whether to acquire or obtain a license under such Patent Rights. Akebia will have the sole right, but not the obligation, to negotiate and acquire or obtain a license under such Patent Rights from such Third Party; *provided*, *however*, that Akebia will consult with and reasonably consider Licensee's views regarding any such decision to acquire or obtain a license under such Patent Rights in the Territory and regarding the terms of such license pertaining to the Territory. Akebia will provide updates to Licensee on a regular basis and reasonably discuss and consult with Licensee, upon Licensee's request, regarding the progress of negotiations for any such acquisition or license. If such acquisition or license agreement relates solely to the Exploitation of the Licensed Product in the Territory, then Akebia will be responsible for [**]% and Licensee will be responsible for [**]%, in each case, of all amounts payable to such Third Party assignor, licensor, or grantor of rights pursuant to such agreement. If such acquisition or license agreement relates to the Exploitation of the Licensed Product in countries both inside and outside of the Territory, then (a) Akebia will be responsible for [**]% and Licensee will be responsible for [**]%, in each case, of any such payments thereunder that arise out of the Exploitation of the Licensed Product in the Territory (*e.g.*, any milestone payments for achievement of milestone events in the Territory or royalties on net sales of the Licensed Product in the Territory) or any upfront payments, and (b) Akebia will be responsible for [**]% of any such payments thereunder that arise out of the Exploitation of the Licensed Product in countries outside of the Territory (*e.g.*, any milestone payments for achievement of any milestone events in a country outside of the Territory or royalties on net sales of the Licensed Product outside of the Territory). This Section 10.8.3 (Responsibility for Third Party Licenses) will not be interpreted as placing on either Party a duty of inquiry regarding Third Party intellectual property rights. Each Party will keep the other Party informed of the status of any Third Party claim of infringement.

10.9 Challenges to Certain Third Party Patents

10.9.1 **Right to Pursue.** As between the Parties, Akebia shall have the exclusive right, but not the obligation, to pursue invalidity actions existing as of the Effective Date, or actions initiated after the Effective Date, against Third Party Patents in the applicable patent office or court in the Territory.

10.9.2 **Costs**. As of the Effective Date of this Agreement, Akebia shall be responsible for [**]%, and Licensee shall be responsible for [**]%, in each case, of any costs associated with invalidity actions against any Third Party Patents (including oppositions at a patent office

or invalidation proceedings at a national court) in the Territory, including any invalidity actions against Third Party Patents existing as of the Effective Date.

10.10 **Patent Right Term Extensions**. Akebia will be solely responsible for making all decisions regarding patent term extensions, including supplementary protection certificates and any other extensions that are now or become available in the future, that are applicable to Akebia Patent Rights or Joint Patent Rights licensed hereunder and that become available directly as a result of the Regulatory Approval of the Licensed Product. The costs of obtaining and maintaining any such patent term extensions will be shared equally by the Parties.

10.11 **Housemarks**. Licensee will be responsible for the registration and maintenance of the Licensee Housemarks throughout the Territory, as well as all expenses associated therewith. Akebia will be responsible for the registration and maintenance of the Akebia Housemarks throughout the Territory, as well as all expenses associated therewith.

Article XI
INFORMATION; PHARMACOVIGILANCE; PRODUCT WITHDRAWAL AND LIMITED RECALL

11.1 **Data Security**. During the Term of this Agreement, each Party will maintain (and, as applicable, cause its Affiliates and sublicensees to maintain) environmental, safety, and facility procedures, data security procedures, and other safeguards against the disclosure, destruction, loss, or alteration of the other Party's information in the possession of such Party or its Affiliates, including procedures to ensure compliance with Privacy Laws, that are no less rigorous than those maintained by such Party (or any of its Affiliates or sublicensees) for its own information of a similar nature. In addition, each Party has implemented and will continue to implement during the Term appropriate controls to comply with Privacy Laws and maintain data privacy of its own information, including for detecting, responding to, and reporting potential breaches in accordance with Applicable Law.

11.2 **Pharmacovigilance Agreement**. Within [**] after the Effective Date, the Parties (under the guidance of their respective pharmacovigilance departments, or equivalent thereof) will define and finalize the Parties' responsibilities with respect to pharmacovigilance activities in a written Pharmacovigilance Agreement. Such Pharmacovigilance Agreement will provide for the receipt, investigation, recording, communication, and exchange by the Parties of information that a Party becomes aware of in the Territory and globally concerning adverse events in or involving a research patient or subject or, in the case of non-clinical studies, an animal in a toxicology study, and the seriousness thereof, whether or not determined to be attributable to the Licensed Product, including any such information received by either Party from a Third Party (subject to receipt of any required consents from such Third Party) (such information, the "**Safety Data**"). Such guidelines and procedures will be in accordance with, and will enable each Party and its Affiliates to fulfill, local and international regulatory reporting obligations to Regulatory Authorities. Subject to compliance with Applicable Law, each Party hereby agrees to comply with its respective obligations under the Pharmacovigilance Agreement (as the Parties may agree to modify it from time-to-time) and to cause its Affiliates and licensees and permitted sublicensees (as applicable) to comply with such obligations. It is understood that each Party and its Affiliates or licensee or permitted sublicensees (as applicable) will have the right to disclose Safety Data if such disclosure is reasonably necessary to comply with Applicable Laws and regulations and requirements of Regulatory Authorities within the Territory (or outside of the Territory with respect to Akebia) with respect to its filings and activities related to the Licensed Product.

11.3 **Safety Reporting and Global Safety Database**. In each case in accordance with, and subject to (once executed), the Pharmacovigilance Agreement to be entered into pursuant to Section 11.2 (Pharmacovigilance Agreement), (a) Akebia will own all of the Safety Data, and the Pharmacovigilance Agreement will include provisions requiring the establishment of a global safety database for the Licensed Product that will be owned and maintained by Akebia, (b) Akebia will have sole control and discretion with respect to the collection, assessment, and safety reporting to Regulatory Authorities with respect to the Licensed Product outside of the Territory,

and (c) Licensee will have sole control and discretion with respect to the collection, assessment, and safety reporting to Regulatory Authorities with respect to the Licensed Product in the Territory. In addition, prior to the execution of the Pharmacovigilance Agreement (and thereafter, to the extent consistent with such Pharmacovigilance Agreement), Akebia will, in accordance with the timeframes set forth in the Pharmacovigilance Agreement, forward to Licensee for handling and reporting to applicable Regulatory Authorities in the Territory all reports received by Akebia of adverse drug events, pregnancy reports, and any other information concerning the safety and benefit-risk profile that are or may be associated with the Licensed Product. To the extent that there are any inconsistencies between this Section 11.3 (Safety Reporting and Global Safety Database), and the Pharmacovigilance Agreement, then the Pharmacovigilance Agreement will control.

11.4 Product Withdrawals and Limited Recalls.

11.4.1 **Notice**. Each Party will notify the other Party promptly following the first Party's determination that any event, incident, or circumstance has occurred that may result in the need for a Product Withdrawal anywhere in the world (including in the Territory) or a Limited Recall in the Territory. Such Party will include in such notice the reasoning behind such determination, and any supporting facts.

11.4.2 **Mandated Withdrawal or Recall**. If a Regulatory Authority in the Territory mandates that any Product Withdrawal be implemented or that any Limited Recall be undertaken, then Licensee, in consultation and coordination with Akebia, will initiate and manage the Product Withdrawal or Limited Recall as and to the extent mandated by the Regulatory Authority in the Territory and in compliance with Applicable Law.

11.4.3 **Voluntary Withdrawal or Recall in the Territory**. With respect to any Product Withdrawal or Limited Recall within the Territory that is not mandated by a Regulatory Authority, immediately after receipt of notification thereof, (a) each Party's quality, safety, compliance, or regulatory affairs personnel with authority to make product recall decisions on behalf of such Party (the "**Recall Decision-Makers**") will discuss and attempt to agree on whether or not to voluntarily implement the Product Withdrawal or undertake the Limited Recall, and (b) if the Parties' Recall Decision-Makers fail to agree within a reasonably appropriate time period (depending upon the circumstances), whether or not to voluntarily implement or undertake a Product Withdrawal or a Limited Recall within the Territory, then Licensee will have the right to determine whether or not to voluntarily undertake a Product Withdrawal or Limited Recall within the Territory. Licensee will carry out all such Product Withdrawal or Limited Recall activities (as applicable) in coordination and collaboration with Akebia, in a manner that enables both Parties to comply with regulatory requirements as expeditiously as possible, and in compliance with all Applicable Laws. If Licensee does not choose to undertake a voluntary Product Withdrawal or Limited Recall in the Territory despite Akebia's notice to Licensee that such Product Withdrawal or Limited Recall should be undertaken (which notice may be given to any of Licensee's Recall Decision-Makers), then, notwithstanding anything to the contrary herein, Licensee will indemnify and hold harmless Akebia in accordance with Section 14.2(c) (Indemnification by Licensee).

11.4.4 **Withdrawals and Recalls; Costs and Cooperation**. Each Party will provide all cooperation reasonably requested by the other Party in connection with any Product Withdrawal or Limited Recall in the Territory. If a Product Withdrawal or Limited Recall in the Territory is required, then Licensee will bear all of the costs incurred in connection with such Product Withdrawal or Limited Recall in the Territory, except if a Product Withdrawal or Limited Recall in the Territory is required as the sole and direct result of Akebia's or its licensees' (other than Licensee) or subcontractors' failure to Manufacture and supply the Licensed Product in accordance with this Agreement, the Supply Agreements, or any Quality Agreement, including as a result of any failure for the Licensed Product to be Manufactured in accordance with GMP or to the applicable specifications, in which case Akebia will bear (and will reimburse Licensee for) all of the

costs incurred in connection with such Product Withdrawal or Limited Recall in the Territory.

Article XII
REPRESENTATIONS, WARRANTIES, AND COVENANTS

12.1 Mutual Representations and Warranties. Each of Licensee and Akebia hereby represents and warrants to the other Party as of the Effective Date:

12.1.1 (a) It is a corporation or entity duly organized and validly existing under the laws of the state, municipality, provinces, administrative division, or other jurisdiction of its incorporation or formation; and (b) it has full power and authority and the legal right to own and operate property and assets and to carry on its business as it is now being conducted and as it is contemplated to be conducted by this Agreement.

12.1.2 The execution, delivery, and performance of this Agreement by it has been duly authorized by all requisite corporate action.

12.1.3 This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid, and binding obligation of such Party and is enforceable against it in accordance with its terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity.

12.1.4 It has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and such performance does not conflict with or constitute a breach of any of its agreements with Third Parties.

12.1.5 The execution and delivery of this Agreement and the performance of its obligations hereunder (a) do not conflict with or violate any requirement of Applicable Law or any provision of its articles of incorporation, bylaws, limited partnership agreement, or any similar instrument, as applicable, in any material way, and (b) do not conflict with, violate, or breach or constitute a default or require any consent under, any Applicable Law or any contractual obligation or court or administrative order by which it is bound.

12.1.6 It has not been debarred or suspended under 21 U.S.C. §335(a) or (b), is not the subject of a conviction described in Section 306 of the FD&C Act, has not been and is not excluded from a federal or governmental health care program, debarred from federal contracting, convicted of or pled nolo contendere to any felony, or to any federal or state legal violation (including misdemeanors) relating to prescription drug products or fraud, is not subject to OFAC sanctions or on the OFAC list of specially designated nationals, and is not subject to any similar sanction of any Governmental Authority in the Territory ("**Debarred/Excluded**"), and no proceeding that could result in it being Debarred/Excluded is pending, and neither it nor any of its Affiliates has used, in any capacity in the performance of obligations relating to the Licensed Product, any employee, subcontractor, consultant, agent, representative, or other person who has been Debarred/Excluded.

12.2 Additional Akebia Warranties. Except as set forth on Schedule 12.2, Akebia hereby represents and warrants as of the Effective Date to Licensee that:

12.2.1 Other than routine patent prosecution, there is no pending, or to Akebia's Knowledge, threatened, litigation relating to it or any Affiliate that seeks to invalidate or challenge the enforceability of any of the Akebia Patent Rights set forth on Schedule 1.8 in the Territory, and no Third Party has challenged in writing, or, to the Knowledge of Akebia, has threatened to challenge, Akebia's right to use and license the Akebia Know-How in the Territory.

12.2.2 To Akebia's Knowledge, there is no use, infringement, or misappropriation of the Akebia Technology in the Territory in derogation of the rights granted to Licensee in this Agreement.

12.2.3 Other than routine patent prosecution, there are no claims asserted in writing, judgments, or settlements in effect against Akebia relating to the Akebia Patent Rights or the Akebia Know-How in the Territory.

12.2.4 Akebia and, to Akebia's Knowledge, its contractors and consultants, have complied in all material respects with all Applicable Law, including GLP and GCP, in the Development and Manufacture of the Licensed Product prior to the Effective Date.

12.2.5 Akebia owns or Controls the rights, title, and interests in and to the Akebia Patent Rights set forth on Schedule 1.8 and licensed to Licensee pursuant to Section 2.1 (Grant of Licenses to Licensee).

12.3 Additional Licensee Warranties. Licensee hereby represents and warrants as of the Effective Date that:

12.3.1 Licensee has immediately available funds sufficient to cover Licensee's financial obligations under this Agreement.

12.3.2 Licensee and its Affiliates have not, directly or indirectly, offered, promised, paid, authorized, or given to any Government Official or Other Covered Party for the purpose, pertaining to this Agreement, of: (a) influencing any act or decision of the Government Official or Other Covered Party; (b) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (c) securing any improper advantage; or (d) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order to obtain or retain business, or direct business to, any person or entity, in each case in any way related to this Agreement.

12.3.3 Licensee is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly, or indirectly, from this Agreement.

12.3.4 Licensee and its Affiliates are in compliance with all applicable global trade laws (including the Global Trade Control Laws), including those related to import controls, export controls, or economic sanctions. Licensee is not, nor is any of its Affiliates or its or their respective directors, officers, employees, agents, or representatives, or in the last five years was, a Restricted Party.

12.4 Additional Covenants. Licensee hereby covenants to Akebia:

12.4.1 It will, and will ensure that its Affiliates, comply with all Applicable Laws and, to the extent applicable, Professional Requirements, with respect to the performance of its obligations under this Agreement, including, as applicable, the Approved Labeling, the European Data Protection Directive 95/46/EC, the European General Data Protection Regulation (Regulation (EU) 2016/679), and any other applicable national data protection legislation.

12.4.2 It will not in the future offer, promise, pay, authorize, or give, money or anything of value, directly or indirectly, to any Government Official or Other Covered Party for the purpose, pertaining to this Agreement, of: (a) influencing any act or decision of the Government Official or Other Covered Party; (b) inducing the Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (c) securing any improper advantage; or (d) inducing the Government Official or Other Covered Party to influence the act or decision of a government or government instrumentality, in order

to obtain or retain business, or direct business to, any person or entity, in each case in any way related to this Agreement.

12.4.3 Neither it nor its Affiliates will export, transfer, or sell the Licensed Product (a) to any country or territory that is subject to comprehensive economic sanctions administered by OFAC, unless the sale of the Licensed Product would be permissible if Licensee or its Affiliates or sublicensees were subject to OFAC's jurisdiction, (b) to any other country or territory in which such activity would violate Applicable Law in the U.S., (c) to any Restricted Party unless the sale of the Licensed Product would be permissible if Licensee or its Affiliates or sublicensees was subject to OFAC's jurisdiction, or (d) in such a manner that would violate the Global Trade Control Laws.

12.4.4 In performing under this Agreement, it and its Affiliates agree to comply with all applicable anti-corruption laws, including the Foreign Corrupt Practices Act of 1977 and the Bribery Act 2010, as amended from time-to-time; the anti-corruption laws of the Territory; and all laws enacted to implement the Organization for Economic Co-operation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions.

12.4.5 In performing under this Agreement, neither it nor its Affiliates shall engage in any activity, practice, or conduct that would constitute an offense under the Modern Slavery Act 2015 if such activity, practice, or conduct were carried out in the United Kingdom. It will not engage, in any capacity in connection with this Agreement or any ancillary agreements, any officer, employee, contractor, consultant, agent, representative, or other person who has been Debarred/Excluded. Licensee will inform Akebia in writing promptly if it or any person engaged by it or any of its Affiliates who is performing any obligations under this Agreement or any ancillary agreements is Debarred/Excluded, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or, to Licensee's Knowledge, is threatened, pursuant to which Licensee, any of its Affiliates or any such person performing obligations hereunder or thereunder may become Debarred/Excluded.

12.5 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH HEREIN, THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY AKEBIA ARE PROVIDED "AS IS" AND WITHOUT WARRANTY. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH OF THE PARTIES EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OR CONDITIONS OF ANY KIND, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR ENFORCEABILITY OF THEIR RESPECTIVE INTELLECTUAL PROPERTY RIGHTS, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES, ARISING FROM A COURSE OF DEALING, USAGE, OR TRADE PRACTICES, IN ALL CASES WITH RESPECT THERETO.

12.6 Limitation of Liability. NEITHER PARTY WILL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES, LOSS OF PROFIT (EVEN IF DEEMED DIRECT DAMAGES) ARISING FROM OR RELATING TO THIS AGREEMENT, IN EACH CASE, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 12.6 (LIMITATION OF LIABILITY) IS INTENDED TO OR WILL LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 14.1 (INDEMNIFICATION BY AKEBIA) OR SECTION 14.2 (INDEMNIFICATION BY LICENSEE), DAMAGES AVAILABLE TO EITHER PARTY FOR THE OTHER PARTY'S BREACH OF ARTICLE XIII (CONFIDENTIALITY), OR DAMAGES AVAILABLE TO EITHER PARTY FOR THE OTHER PARTY'S FRAUD, GROSS NEGLIGENCE, WILLFUL MISCONDUCT, OR BREACH OF ITS OBLIGATIONS HEREUNDER RELATING TO SECTION 17.2 (EXCLUSIVITY) OR AMOUNTS OWED BY EITHER PARTY HEREUNDER (INCLUDING

UNDER ARTICLE IX) (PAYMENTS), OR MISAPPROPRIATION OR INFRINGEMENT OF INTELLECTUAL PROPERTY OWNED OR CONTROLLED BY EITHER PARTY.

Article XIII
CONFIDENTIALITY

13.1 Duty of Confidence. Subject to the other provisions of this Article XIII (Confidentiality):

13.1.1 except to the extent expressly authorized by this Agreement, all Confidential Information of a Party (the "**Disclosing Party**") will be maintained in confidence and otherwise safeguarded, and not published or otherwise disclosed, by the other Party (the "**Receiving Party**") and its Affiliates for the Term and for [**] thereafter;

13.1.2 the Receiving Party will treat all Confidential Information provided by the Disclosing Party at a minimum, with the same degree of care as the Receiving Party uses for its own similar information, but in no event less than a reasonable degree of care;

13.1.3 the Receiving Party may only use any Confidential Information of the Disclosing Party for the purposes of performing its obligations or exercising its rights under this Agreement;

13.1.4 a Receiving Party may disclose Confidential Information of the Disclosing Party to: (a) such Receiving Party's Affiliates, licensees and sublicensees; and (b) employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors of the Receiving Party and its Affiliates, licensees, and sublicensees, in each case ((a) and (b)), to the extent reasonably necessary for the purposes of, and for those matters undertaken pursuant to, this Agreement; provided that such persons or entities are bound by legally enforceable obligations of confidentiality and non-use with respect to the Disclosing Party's Confidential Information no less stringent than the confidentiality and non-use obligations set forth in this Agreement. Each Party will remain responsible for any failure by its Affiliates, licensees, and sublicensees, and its and its Affiliates', licensees', and sublicensees' respective employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors, in each case, to treat such Confidential Information as required under this Section 13.1 (Duty of Confidence) (as if such Affiliates, licensees, sublicensees, employees, directors, officers, agents, contractors, consultants, attorneys, accountants, banks, investors, and advisors were Parties directly bound to the requirements of this Section 13.1 (Duty of Confidence)); and

13.1.5 each Party will promptly notify the other Party of any misuse or unauthorized disclosure of the other Party's Confidential Information.

13.2 Confidential Information. The Akebia Know-How will be the Confidential Information of Akebia notwithstanding the fact that such information may be developed or invented and disclosed to Akebia by Licensee. The Licensee Know-How will be the Confidential Information of Licensee. The Joint Know-How will be the Confidential Information of both Parties. Except as provided in Section 13.4 (Authorized Disclosures), neither Party nor its Affiliates may disclose the existence or the terms of this Agreement.

13.3 Exemptions. Information of a Disclosing Party will not be Confidential Information of such Disclosing Party to the extent that the Receiving Party can demonstrate through competent evidence that such information:

13.3.1 is known by the Receiving Party or any of its Affiliates without an obligation of confidentiality at the time of its receipt from the Disclosing Party, and not through a prior disclosure by or on behalf of the Disclosing Party, as documented by the Receiving Party's business records;

13.3.2 is generally available to the public before its receipt from the Disclosing Party;

13.3.3 became generally available to the public or otherwise part of the public domain after its disclosure by the Disclosing Party and other than through any act or omission of the Receiving Party or any of its Affiliates or disclosees in breach of this Agreement;

13.3.4 is subsequently disclosed to the Receiving Party or any of its Affiliates without obligation of confidentiality by a Third Party who may rightfully do so and is not under a conflicting obligation of confidentiality to the Disclosing Party; or

13.3.5 is developed by the Receiving Party or any of its Affiliates independently and without use of or reference to any Confidential Information received from the Disclosing Party, as documented by the Receiving Party's business records.

No combination of features or disclosures will be deemed to fall within the foregoing exclusions merely because individual features are published or available to the general public or in the rightful possession of the Receiving Party unless the combination itself and principle of operation are published or available to the general public or in the rightful possession of the Receiving Party.

13.4 Authorized Disclosures.

13.4.1 **Permitted Circumstances**. Notwithstanding the obligations set forth in Section 13.1 (Duty of Confidence), a Party may disclose the other Party's Confidential Information (including this Agreement and only the specifically relevant terms herein) to the extent such disclosure is reasonably necessary in the following situations:

(a) disclosure to comply with the terms of any agreement with any Third Party under which Akebia or its Affiliates in-licensed any Akebia Technology;

(b) (i) the patent prosecution or enforcement of Akebia Patent Rights, Joint Patent Rights, or Licensee Patent Rights, in each case, as contemplated by this Agreement; or (ii) in connection with regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), as necessary for the Exploitation of the Licensed Product;

(c) disclosure of this Agreement, its terms, and the status and results of Exploitation of the Licensed Product to actual or bona fide potential investors, acquirers, (sub)licensees, lenders, and other financial or commercial partners (including in connection with any royalty monetization transaction), and their respective attorneys, accountants, banks, investors, and advisors, solely for the purpose of evaluating or carrying out an actual or potential investment, acquisition, (sub)license, debt transaction, or collaboration; provided that, in each such case, on the condition that such persons or entities are bound by obligations of confidentiality and non-use at least as stringent as those set forth in this Article XIII (Confidentiality) or otherwise customary for such type and scope of disclosure any such disclosure is limited to the maximum extent practicable for the particular context in which it is being disclosed;

(d) such disclosure is required to comply with Applicable Law (whether generally or in pursuit of an application for listing of securities) including the United States Securities and Exchange Commission, or equivalent foreign agency or regulatory body, or otherwise required by judicial or administrative process, provided that in each such event, as promptly as reasonably practicable and to the extent not prohibited by Applicable Law or judicial or administrative process, such Party will notify the other Party, unless a shorter time period is required by Applicable Law, no later than [**] in advance of such required disclosure and provide a draft of the disclosure to the other Party reasonably in advance of such filing or

disclosure for the other Party's review and comment. The non-disclosing Party will provide any comments as soon as practicable, and the disclosing Party will consider any reasonable, timely comments provided by the non-disclosing Party; provided that the disclosing Party may or may not accept such comments in its sole discretion. Confidential Information that is disclosed in order to comply with Applicable Law or by judicial or administrative process pursuant to this Section 13.4.1(d) (Permitted Circumstances), in each case, will remain otherwise subject to the confidentiality and non-use provisions of this Article XIII (Confidentiality) with respect to the Party disclosing such Confidential Information, and such Party will take all steps reasonably necessary, including seeking of confidential treatment or a protective order for a period of at least 10 years (to the extent permitted by Applicable Law or Governmental Authority), to ensure the continued confidential treatment of such Confidential Information, and each Party will be responsible for its own legal and other external costs in connection with any such filing or disclosure pursuant to this Section 13.4.1(d) (Permitted Circumstances); or

(e) disclosure pursuant to Section 13.7 (Publications), and Section 13.8 (Publication and Listing of Clinical Trials).

13.5 Confidential Treatment. Notwithstanding any provision to the contrary set forth in this Agreement, in each case of a disclosure to be made pursuant to Section 13.4.1(d) (Permitted Circumstances), where some or all of the terms of this Agreement are to be disclosed, Akebia will, to the extent reasonably possible, provide to Licensee a redacted version of this Agreement to be made in connection with any such disclosure, and Licensee will not disclose or provide any other redacted version hereof, unless such version has been approved in writing by Akebia, not to be unreasonably withheld, conditioned, or delayed. Subject to the foregoing, but notwithstanding any other provision to the contrary set forth in this Agreement, if a Party is required or permitted to make a disclosure of the other Party's Confidential Information pursuant to Section 13.4.1 (Permitted Circumstances), then it will, to the extent not prohibited by Applicable Law or judicial or administrative process, except where impracticable, give reasonable advance notice to the other Party of such proposed disclosure and use reasonable efforts to secure confidential treatment of such information and will only disclose that portion of Confidential Information that is legally required to be disclosed as advised by its legal counsel. In any event, each Party agrees to take all reasonable action to avoid disclosure of Confidential Information of the other Party hereunder.

13.6 Publicity; Use of Names.

13.6.1 **Press Release**. The Parties may each issue a press release announcing this Agreement, to be issued by the Parties on such date and time as may be agreed by the Parties. Other than such press releases and the public disclosures permitted by this Section 13.6 (Publicity; Use of Names), and Section 13.4 (Authorized Disclosures), the Parties agree that except as permitted under Section 13.6.2 (Disclosures by the Parties), the portions of any other news release or other public announcement relating to this Agreement or the performance hereunder that would disclose information other than that already in the public domain will first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld, conditioned, or delayed).

13.6.2 **Disclosures by the Parties**.

(a) Notwithstanding any provision to the contrary set forth in this Agreement, Akebia or its designees may publicly disclose (in written, oral, or other form): (i) the achievement of events requiring Milestone Payments under this Agreement (including the amount, payment, and timing of any such Milestone Payment); (ii) the commencement, completion, material data, or key results of any clinical trials for the Licensed Product conducted under this Agreement; and (iii) the receipt of Regulatory Approval or Reimbursement Approval for the Licensed Product.

(b) Notwithstanding any provision to the contrary set forth in this Agreement, Licensee its designees may publicly disclose (in written, oral, or other form), with prior notice to Akebia: (i) the achievement of events requiring Milestone Payments under this Agreement (including the amount, payment, and timing of any such Milestone Payment); (ii) with Akebia's prior written approval, the commencement, completion, material data, or key results of any Territory-Specific Development for the Licensed Product conducted under this Agreement; and (iii) the receipt of Regulatory Approval or Reimbursement Approval within the Territory for the Licensed Product.

13.6.3 **Use of Names**. Other than the press releases described in Section 13.6.1 (Press Release) and the use of names in public disclosures permitted by Section 13.4 (Authorized Disclosures), the Parties agree that except as permitted under Section 13.6.2 (Disclosures by the Parties), each Party's use of other Party's name and logo in presentations, its website, collateral materials, and corporate overviews to describe the collaboration relationship, as well as in taglines of press releases issued pursuant to this Section 13.6 (Publicity; Use of Names) will first be reviewed and approved by both Parties (with such approval not to be unreasonably withheld, conditioned, or delayed). Except as permitted under this Section 13.6 (Publicity; Use of Names) or with the prior express written permission of the other Party, neither Party will use the name, trademark, trade name, or logo of the other Party or its Affiliates or their respective employees in any publicity, promotion, news release, or disclosure relating to this Agreement or its subject matter except as may be required by Applicable Law. Each Party will use the other Party's corporate name in all publicity relating to this Agreement, including the initial press release and all subsequent press releases. Licensee will include explanatory text such as "*Licensed from Akebia*" in all publicity, promotion, news releases, or disclosures relating to the Licensed Product or such other similar text provided by Akebia and reasonably acceptable to Licensee.

13.6.4 **Repeated Disclosures.** The Parties agree that after (a) the issuance of a disclosure or press release made in accordance with Section 13.6.1 (Press Release) or Section 13.4 (Authorized Disclosures), (b) the use of the other Party's name or logo by a Party in presentations, its website, collateral materials, or corporate overviews to describe the collaboration relationship in accordance with Section 13.6.3 (Use of Names), or (c) use of the other Party's name or logo by a Party in any taglines of press releases issued pursuant to Section 13.6.1 (Press Release) or Section 13.4 (Authorized Disclosures), in each case ((a) – (c)), the disclosing Party may make subsequent public disclosures reiterating such information without having to obtain the other Party's prior consent and approval so long as the information in such press release, other public announcement, or other materials remains true, correct, and the most current information with respect to the subject matters set forth therein. Similarly, after a publication has been made available to the public, each Party may post such publication or a link to it on its corporate website without the prior written consent of the other Party, so long as the information in such publication remains true, correct, and the most current information with respect to the subject matters set forth therein. Notwithstanding any provision to the contrary set forth in this Agreement, neither Party will use the other Party's corporate name in such manner that the distinctiveness, reputation, and validity of any trademarks and corporate or trade names of such other Party will not be impaired, and consistent with best practices used by such other Party for its other collaborators.

13.7 Publications. The JSC will review and discuss the plans of the Parties regarding planned publication in the Territory of Study Data or other clinical or non-clinical results relating to the Licensed Product. With respect to publication in any academic journal, authorship of any publication will be determined based on the accepted standards used in peer-reviewed, academic journals at the time of the proposed publication.

13.7.1 **Publication of Licensee Controlled Study Data**. Notwithstanding the forgoing, except for disclosures permitted pursuant to Section 13.4 (Authorized Disclosures), if Licensee

or its employees or consultants wishes to publish or present to any Third Party results of the Development work in the Territory, any research results or any Study Data, or other clinical information, in each case, related to the Licensed Product and Controlled by Licensee, then it will deliver to Akebia a copy of the proposed written publication or an outline of an oral disclosure as soon as practicable prior to submission for publication or presentation. Akebia will notify Licensee promptly after receipt of such proposed publication whether such draft publication contains (a) Confidential Information of Akebia, or (b) information that if published would have an adverse effect on a Patent Right. Akebia will have the right to (i) propose modifications to the publication or presentation for Patent Right reasons, trade secret reasons, confidentiality reasons, or business reasons, including reasons relating to the pricing or reimbursement of the Licensed Product outside the Territory or outside the Field, or (ii) request a reasonable delay in publication or presentation in order to protect patentable information. If Akebia requests a delay to protect patentable information, then Licensee will delay submission or presentation for a period not to exceed [**] to enable Patent Right applications protecting Akebia's rights in such information to be filed in accordance with the terms of this Agreement. Upon expiration of such [**], Licensee will be free to proceed with the publication or presentation. If Akebia requests modifications to the publication or presentation to prevent disclosure of trade secret or proprietary business information, then Licensee will edit such publication to prevent the disclosure of such information prior to submission of the publication or presentation.

13.7.2 **Licensee Publication of Akebia Study Data.** With respect to any Study Data Controlled by Akebia that Licensee may receive pursuant to Section 5.4.1 (Rights Granted to Licensee) herein, neither Licensee, nor its employees or consultants, shall publish or present such Study Data to any Third Party without first giving Akebia the opportunity to review such publications in accordance with Section 3.1.4(d).

13.8 Publication and Listing of Clinical Trials. With respect to the listing of clinical trials or the publication of clinical trial results for the Licensed Product and to the extent applicable to a Party's activities conducted under this Agreement, each Party will comply with (a) the Pharmaceutical Research and Manufacturers of America (PhRMA) Guidelines on the listing of Clinical Trials and the Publication of Clinical Trial results, (b) the ICH Guidelines for Good Clinical Practice and the Principles for Responsible Clinical Trial Data Sharing adopted by the European Federation of Pharmaceutical Industries and Associations, and (c) any Applicable Law or applicable court order, stipulations, consent agreements, and settlements entered into by such Party, each as applicable. The Parties agree that any such listings or publications made pursuant to this Section 13.8 (Publication and Listing of Clinical Trials) will be considered a Publication for purposes of this Agreement and will be subject to Section 13.7 (Publications).

Article XIV
INDEMNIFICATION

14.1 Indemnification by Akebia. Akebia will indemnify, hold harmless, and defend Licensee and its Affiliates and their respective, directors, officers, employees, and agents (the "**Licensee Indemnitees**") from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses, or losses (including reasonable attorneys' fees, court costs, witness fees, damages, judgments, fines, and amounts paid in settlement) ("**Losses**") to the extent that such Losses arise out of (a) the breach by Akebia or its Affiliates, contractors, or licensees (other than Licensee) of any obligation, representation, warranty, obligation, or covenant set forth in this Agreement, (b) the failure to comply with Applicable Law by or on behalf of Akebia, or its Affiliates, contractors, or licensees (other than Licensee) and (c) the negligence or willful misconduct of any Akebia Indemnitee. Notwithstanding the foregoing, Akebia will not have any obligation to indemnify the Licensee Indemnitees to the extent that any Losses arise out of the negligence or willful misconduct of any Licensee Indemnitee or any breach of this Agreement by Licensee.

14.2 **Indemnification by Licensee**. Licensee will indemnify, hold harmless, and defend Akebia and its Affiliates, and their respective directors, officers, employees, and agents (the "**Akebia Indemnitees**") from and against any and all Losses, to the extent that such Losses arise out of (a) the breach by Licensee or its Affiliates, contractors, or sublicensees of any obligation, representation, warranty, obligation, or covenant set forth in this Agreement, (b) the Exploitation of the Licensed Product by or on behalf of Licensee or its Affiliates or sublicensees, (c) Licensee's failure to undertake any Product Withdrawal or Limited Recall in the Territory in accordance with Section 11.4.3 (Voluntary Withdrawal or Recall in the Territory), and (d) the negligence or willful misconduct of any Licensee Indemnitee. Notwithstanding the foregoing, Licensee will not have any obligation to indemnify the Akebia Indemnitees to the extent that any Losses arise out of the negligence or willful misconduct of any Akebia Indemnitee or any breach of this Agreement by Akebia.

14.3 **Indemnification Procedure**. Each Party, if seeking indemnification under this Article XIV (Indemnification) (the "**Indemnified Party**"), will give written notice of the claim to the other Party (the "**Indemnifying Party**") no later than [**] after becoming aware of the claim; *provided*, *however*, that any failure or delay in providing such notice will not relieve the Indemnifying Party of its indemnification obligation, except to the extent it is actually prejudiced by such failure or delay. Each Party will promptly furnish to the other Party, copies of all papers and official documents received in respect of any Losses. The Indemnifying Party will have the right to assume and control the defense of the indemnification claim at its own expense with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; *provided*, *however*, that an Indemnified Party will have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnifying Party, if representation of such Indemnified Party by the counsel retained by the Indemnifying Party would be inappropriate due to actual or potential differing interests between the Indemnified Party and any other party represented by such counsel in such proceedings. If the Indemnifying Party does not assume the defense of the indemnification claim as described in this Section 14.3 (Indemnification Procedure), then the Indemnified Party may defend the indemnification claim but will have no obligation to do so. The Indemnified Party will not settle or compromise the indemnification claim without the prior written consent of the Indemnifying Party, and the Indemnifying Party will not settle or compromise the indemnification claim in any manner which would have an adverse effect on the Indemnified Party's interests (including any rights under this Agreement or the scope, validity, or enforceability of any Patent Rights, Confidential Information, or other rights licensed to Licensee by Akebia hereunder), without the prior written consent of the Indemnified Party, which consent, in each case (by the Indemnifying Party or Indemnified Party, as the case may be), will not be unreasonably withheld. The Indemnified Party will reasonably cooperate with the Indemnifying Party at the Indemnifying Party's expense and will make available to the Indemnifying Party all pertinent information under the control of the Indemnified Party, which information will be subject to Article XIII (Confidentiality). The Indemnifying Party will not be liable for any settlement or other disposition of Losses by the Indemnified Party if such settlement is reached without the written consent of the Indemnifying Party pursuant to this Section 14.3 (Indemnification Procedure).

14.4 **Insurance**. Licensee will, at its own expense, obtain and maintain insurance with respect to the Development and Commercialization of the Licensed Product under this Agreement in such amount and subject to such deductibles and other limitations as biopharmaceutical companies customarily maintain with respect to the Development, and Commercialization of similar products in their respective territories. Licensee will provide a copy of such insurance policy to Akebia upon request.

Article XV
TERM AND TERMINATION

15.1 **Term**. The term of this Agreement will begin on the Effective Date and, unless earlier terminated in accordance with the terms of this Article XV (Term and Termination), will expire upon the expiration of all payment obligations hereunder in the last country in the Territory (the "**Term**").

15.2 Termination for Breach. Subject to the terms and conditions of this Section 15.2 (Termination for Breach), a Party (the "**Non-Breaching Party**") will have the right, in addition to any other rights and remedies, to terminate this Agreement, in its entirety in the event the other Party (the "**Breaching Party**") is in material breach of any of its obligations under this Agreement. The Non-Breaching Party will first provide written notice to the Breaching Party, which notice will identify with particularity the alleged breach and state the Non-Breaching Party's intent to terminate this Agreement if such breach is not cured. With respect to material breaches of any payment provision hereunder, the Breaching Party will have a period of [**] after such written notice is provided to cure such breach. With respect to all other breaches, the Breaching Party will have a period of [**] after such written notice is provided to cure such breach. The waiver by either Party of any breach of any term or condition of this Agreement will not be deemed a waiver as to any subsequent or similar breach. The Parties stipulate and agree that a breach of Licensee's diligence obligations set forth under Section 7.5 (General Commercialization Efforts) will be considered a material breach of a material obligation under this Agreement for purposes of this Section 15.2 (Termination for Breach).

15.3 Termination by Licensee for Convenience. Commencing on the date that is 12 months following the Effective Date, Licensee may terminate this Agreement in its entirety by providing written notice to Akebia thereof, which termination will be effective 12 months following the date of such notice; *provided*, *however*, that such 12-month notice period may be shortened by Akebia in its sole discretion.

15.4 Termination by Akebia Upon Patent Challenge. Except to the extent unenforceable under Applicable Law, Akebia may terminate this Agreement by providing written notice of termination to Licensee if Licensee, its Affiliates or its sublicensees (individually or in association with any other person or entity) contests or assists a Third Party in contesting the scope, validity, or enforceability of any Akebia Patent Right or Joint Patent Right, or any foreign counterpart thereof anywhere in the world in any court, tribunal, arbitration proceeding, or other proceeding, including the U.S. Patent and Trademark Office and the U.S. International Trade Commission (a "**Patent Challenge**"). In the event of such a Patent Challenge, Akebia will provide prompt written notice of such Patent Challenge to Licensee, and Akebia may terminate this Agreement by providing written notice of such termination to Licensee. If Akebia reasonably believes that termination of this Agreement pursuant to this Section 15.4 (Termination by Akebia Upon Patent Right Challenge by Licensee) is not an available remedy under Applicable Law, then in lieu of such termination, Akebia may instead [**] by providing written notice of such election to Licensee. If Akebia elects the foregoing [**] would be Akebia's sole and exclusive remedy for such Patent Challenge. The Parties hereby stipulate and agree that the damages that Akebia would suffer as a result of such a Patent Challenge would be uncertain in amount and difficult to prove, and therefore the foregoing [**] is a reasonable liquidated damages remedy and not a penalty. As used herein, a Patent Challenge includes: (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patent Right; (b) filing, or joining in, a petition under 35 U.S.C. § 311 to institute inter partes review of any such Patent Right; (c) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patent Right or any portion thereof; (d) filing or commencing any opposition, nullity, or similar proceedings challenging the validity of any such Patent Right in any country or region; or (e) any foreign equivalent of clauses (a), (b), (c), or (d).

15.5 Termination by Written Agreement. This Agreement may be terminated in its entirety upon the written agreement of Akebia and Licensee.

15.6 Effects of Expiration.

15.6.1 **Non-Exclusive License to Licensee; Rights of Reference**. Following expiration (but not termination) of the Term, on a country-by-country basis, all licenses granted to Licensee and Akebia under this Agreement will become non-exclusive, perpetual, irrevocable, fully paid-up, royalty-free (subject to Section 15.7.2 (Trademark License and Royalty)), and freely sublicensable, and the rights of reference granted to each Party under Section 5.4 (Rights of Reference; Further Assurance) will survive.

15.6.2 **Trademark License and Royalty**. If Licensee uses any Product Mark or Akebia Housemark in connection with the Commercialization of the Licensed Product in any country in the Territory following the expiration of the Term, then the licenses granted to Licensee under Section 7.8.5 (Trademark License) to use the Product Marks and Akebia Housemarks will remain non-exclusive as provided in Section 15.6.1 (Non-Exclusive License to Licensee; Rights of Reference) but will bear a royalty of [**]% of Net Sales in each country in the Territory in which Licensee uses the Product Marks or Akebia Housemarks in connection with such Commercialization of the Licensed Product.

15.7 Effects of Termination. In the event of any termination of this Agreement (but not expiration), the following will apply:

15.7.1 **Termination of Licenses**. As of the effective date of termination of this Agreement, all licenses and all other rights granted by Akebia to Licensee under the Akebia Technology and Joint Technology will terminate and all sublicenses granted and subcontractors engaged by Licensee will also terminate, and except as expressly set forth in this Section 15.8 (Effects of Termination), Licensee will not, and will cause its Representatives to not, Exploit the Licensed Product following the effective date of termination of this Agreement.

15.7.2 **Rights of Reference**. On a terminated country-by-terminated country basis, the right of reference granted to Licensee pursuant to Section 5.4 (Rights of Reference; Further Assurances) will terminate in such country. The right of reference granted to Akebia pursuant to Section 5.4 (Rights of Reference; Further Assurances) will survive.

15.7.3 **Return of Confidential Information**. Upon termination of this Agreement in all countries in the Territory, Licensee will cease using the Akebia Technology and will return to Akebia or destroy all copies of any documents containing any Akebia Know-How. Each Party will return or destroy all Confidential Information of the other Party in its possession upon expiration or termination of this Agreement at the disclosing Party's election and written request. The Receiving Party will provide a written confirmation of such destruction within [**] of such request; *provided*, *however*, that the foregoing will not apply to any (a) Confidential Information that is necessary to allow such Party to perform its obligations or exercise any of its rights that expressly survive the termination or expiration of this Agreement, or (b) copies of any Confidential Information on a Receiving Party's standard back-up servers (which shall not be accessed or restored by the Receiving Party).

15.7.4 **License Grants to Akebia**. On a terminated country-by-terminated country basis, Licensee hereby grants and agrees to grant to Akebia with effect from the effective date of termination, an exclusive, fully paid-up, worldwide, perpetual, irrevocable right and license, with the right to grant sublicenses through multiple tiers, under any Licensee Technology, in each case, to Exploit the Licensed Product. If Licensee is unable to sublicense any Patent Rights or Know-How owned by Third Parties to Akebia pursuant to this Section 15.7.4 (License Grants to Akebia) without the consent of the Third Party, then Licensee undertakes, on request from Akebia, to use reasonable efforts to procure such licenses on behalf of Akebia in as far as it is able to do so, and Akebia will pay such fees and agree to be bound by the terms agreed between Akebia and the Third Party licensor.

15.7.5 **Appointment as Exclusive Distributor**. On a terminated country-by-terminated country basis, if the Licensed Product is being Commercialized by Licensee in any country in the Territory as of the effective date of termination in such country, then, at Akebia's election (in its sole discretion), until such time as all Regulatory Approvals with respect to the Licensed Product in such country have been assigned and transferred to Akebia, either (a) Licensee will appoint Akebia or its designee as its exclusive distributor of the Licensed Product in such country and grant Akebia or its designee the right to appoint sub-distributors, to the extent not prohibited by any written agreement between Licensee or

any of its Affiliates and a Third Party, or (b) Licensee will have the continued right to sell the Licensed Product in such country from its inventory; *provided*, *however*, that Licensee's obligations under this Agreement with respect to all Licensed Product that Licensee sells, including the obligation to remit royalties to Akebia hereunder, will continue in full force and effect during such period.

15.7.6 **Protection of Akebia Know-How.** To protect the substantial and proprietary Know-How transferred by Akebia to Licensee under this Agreement, on a terminated country-by-terminated country basis Licensee will not commercialize a Competing Product within such terminated country for a period of [**] from the effective date of termination within such terminated country. Licensee will ensure that its activities that are ongoing under this Agreement are kept separate from activities related to Competing Products in each terminated country, including through the use of internal firewalls. ('Commercialize' in this context includes any and all activities directed to the marketing, promotion, distribution, pricing, reimbursement, offering for sale, and sale of a Competing Product, and interacting with Regulatory Authorities following Regulatory Approval in the applicable country or region for such Competing Product regarding the foregoing, including seeking any required Reimbursement Approval.)

15.7.7 **Assignment and Disclosure**. On a terminated country-by-terminated country basis, Licensee will promptly and will cause its Representatives to (and in any event within [**] after the effective date of termination) and hereby does: (a) assign and transfer to Akebia or its designee all of Licensee's and its Representatives' rights, title, and interests in and to (i) all Regulatory Submissions, Regulatory Approvals, clinical trial agreements, and distribution agreements (to the extent assignable and not cancelled), confidentiality and other agreements, and Study Data (to the extent in Licensee's and its Representatives' Control), in each case, relating to the Licensed Product and that are necessary or reasonably useful for the Development or Commercialization of the Licensed Product, and (ii) to the extent assignment pursuant to clause (i) is delayed or is not permitted by the applicable Regulatory Authority, permit Akebia to cross-reference and rely upon any Regulatory Submissions and Regulatory Approvals filed by Licensee and its Representatives with respect to the Licensed Product, (b) disclose to Akebia all documents that are controlled by Licensee and its Representatives or that Licensee and its Representatives are able to obtain using reasonable efforts, and that embody the foregoing, (c) subject to Licensee's and its Representatives' confidentiality obligations to Third Parties, provide to Akebia for its review unredacted copies of all clinical trial agreements, manufacturing and supply agreements, distribution agreements (to the extent assignable and not cancelled), and confidentiality and other agreements, in each case, relating to the Licensed Product and that are necessary or reasonably useful for the Exploitation of the Licensed Product, and, following such review, upon Akebia's request and solely to the extent permitted under the terms of such agreements, assign and transfer to Akebia or its designee all of Licensee's and its Representatives' rights, title, and interests in and to any such agreements. If such agreement is not assignable, then Licensee will and will cause its Representatives to cooperate with Akebia in all reasonable respects to secure the consent of the applicable Third Party to such assignment or to cause such Third Party to enter into a separate agreement with Akebia on terms substantially similar to those granted to Licensee or such Representative, as applicable, (d) disclose to Akebia or its designee all data, information, documents, records, and materials related to the Licensed Product that are controlled by Licensee or that Licensee is able to obtain using reasonable efforts, and that embody the foregoing, and (e) assign and transfer to Akebia or its designee all of Akebia's rights, title, and interests in and to any promotional materials, training materials, medical education materials, packaging and labeling, and all other literature or other information related to the Licensed Product and copyrights and any registrations for the foregoing. Licensee will and will cause its Representatives to take all steps necessary to transfer ownership of all such assigned agreements and other assets to Akebia, including submitting to each applicable Regulatory Authority a letter or other necessary documentation (with a copy to Akebia) notifying such Regulatory Authority of the transfer of such ownership of each Regulatory

Submission and Regulatory Approval. To the extent that any agreement or other asset described in this Section 15.7.7 (Assignment and Disclosure) is not assignable by Licensee or its Representatives, then such agreement or other asset will not be assigned, and upon the request of Akebia, Licensee will and will cause its Representatives to take such steps as may be necessary to allow Akebia to obtain and to enjoy the benefits of such agreement or other asset, without additional payment therefor, in the form of a license or other right to the extent Licensee or such Representative has the right and ability to do so. In addition, upon Akebia's written request, Licensee will and will cause its Representatives, at Licensee's cost and expense, provide to Akebia copies of all substantive related documentation, including non-clinical, preclinical, and clinical data that are held by or reasonably available to Licensee and its Representatives. The Parties will discuss and establish appropriate arrangements with respect to safety data exchange, *provided* that Akebia will assume all safety and safety database activities with respect to the Licensed Product no later than [**] after the effective date of termination of this Agreement. In addition, on a terminated country-by-terminated country basis, Licensee will and will cause its Representatives to promptly assign and transfer to Akebia or its designee, as of the effective date of termination in such country, all of Licensee's and its Representatives' rights, title, and interests in and to all domain names associated with the Product Marks used in such terminated country (to the extent that they are owned by Licensee or its Affiliates and not used in any non-terminated country in the Territory), and will promptly (in any event, within [**] after the effective date of termination) provide to Akebia all login and password information necessary to maintain such domain names. In furtherance of the assignment of Regulatory Submissions and Regulatory Approvals and other data pursuant to this Section 15.7.7 (Assignment and Disclosure), Licensee will and will cause its Representatives to appoint Akebia as Licensee's and its Representatives' agent for all Licensed Product-related matters involving Regulatory Authorities until all Regulatory Approvals, Regulatory Submissions, and other governmental or regulatory filings that are not then in Akebia's or its Affiliate's name have been assigned to Akebia or its designee. In the event of failure to obtain such assignment, Licensee hereby consents and grants, and will cause its Representatives to consent and grant, to Akebia the right to access and reference (without any further action required on the part of Licensee and its Representatives, whose authorization to file this consent with any Regulatory Authority is hereby granted) any such item with respect to the Licensed Product. The costs associated with the assignments set forth in this Section 15.7.7 (Assignment and Disclosure) will be borne by Licensee.

15.7.8 **Wind Down and Transition**. Licensee will be responsible, at its own cost and expense, for the wind-down of Licensee's and its Affiliates' and its sublicensees' Exploitation of the Licensed Product. Licensee will, and will cause its Affiliates and sublicensees to, reasonably cooperate with Akebia to facilitate orderly transition of the Exploitation of the Licensed Product to Akebia or its designee, including (a) assigning or amending as appropriate, upon request of Akebia, any agreements or arrangements with Third Party vendors (including distributors) to Exploit the Licensed Product or, to the extent any such Third Party agreement or arrangement is not assignable to Akebia, reasonably cooperating with Akebia to arrange to continue to provide such services for a reasonable time after termination of this Agreement with respect to the Licensed Product; and (b) to the extent that Licensee or its Affiliate is performing any activities described in the foregoing clause (a), reasonably cooperating with Akebia to transfer such activities to Akebia or its designee and continuing to perform such activities on Akebia's behalf for a reasonable time after termination of this Agreement with respect to the Licensed Product until such transfer is completed. 15.3.13. Further Assistance. Licensee will provide any other assistance or take any other actions, in each case, reasonably requested by Akebia as necessary to transfer to Akebia the Exploitation of the Licensed Product, and will execute all documents as may be reasonably requested by Akebia in order to give effect to this Section 15.8 (Effects of Termination).

15.8 Survival; Accrued Rights. The following Articles and Sections of this Agreement will survive expiration or early termination for any reason: Article I (Definitions); Section 2.3 (Grant of

Licenses to Akebia); Section 2.4 (Rights of Akebia to Grant Sublicenses); Section 9.3.4 (Royalty Payments and Reports) (but only with respect to Net Sales made during the Term); Section 9.4 (Accounting; Audit) (but only with respect to payment obligations accruing during the Term and only for a period of [**] after expiration or termination); Section 9.8 (Late Payment; Disputed Payment) (but only with respect to payment obligations accruing during the Term); Section 10.1 (Akebia Intellectual Property); Section 10.2 (Licensee Intellectual Property); Section 10.3 (Joint Technology); Section 12.6 (Limitation of Liability); Article XIII (Confidentiality); Article XIV (Indemnification) (excluding Section 14.4 (Insurance)); Section 15.7 (Effects of Expiration); Section 15.7 (Effects of Termination); Section 15.8 (Survival; Accrued Rights); Article XVI (Dispute Resolution; Governing Law); Section 17.1 (Assignment); Section 17.5 (Entire Agreement; Amendment); Section 17.6 (Severability); Section 17.7 (Notices); Section 17.10 (Agency); Section 17.11 (No Waiver); Section 17.12 (No Strict Construction); Section 17.14 (Cumulative Remedies); and Section 17.16 (Counterparts). In addition, Section 5.4.2 (Rights Granted to Akebia) and Section 5.4.3 (Further Assurances) will survive the expiration (but not termination) of this Agreement. In any event, expiration or termination of this Agreement will not relieve the Parties of any liability that accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

15.9 Cumulative Remedies; Termination Not Sole Remedy. Except for Akebia's exercise of its rights under Section 15.4 (Termination by Akebia Upon Patent Challenge) to obtain the sole and exclusive remedy of increasing the Milestone Payments and Royalty Payments as liquidated damages if Akebia determines that termination is not an available remedy in the event of Licensee's Patent Challenge, no other remedies referred to in this Agreement are intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law. Without limiting the generality of the foregoing, termination is not the sole remedy under this Agreement and, whether or not termination is effected and notwithstanding any provision to the contrary set forth in this Agreement, all other remedies will remain available except as expressly set forth herein.

Article XVI
DISPUTE RESOLUTION; GOVERNING LAW

16.1 Executive Officers; Disputes. Each Party will ensure that an Executive Officer is designated for such Party at all times during the Term for dispute resolution purposes, and will promptly notify the other Party of any change in its designated Executive Officer. Except as expressly set forth in this Agreement, including matters subject to resolution under Section 3.2 (Decision-Making and Committee Dispute Resolution), in the event of a dispute arising under this Agreement between the Parties, the Parties will refer such dispute to their respective Executive Officer, and such Executive Officers or designees will attempt in good faith to resolve such dispute.

16.2 Arbitration. If the Parties are unable to resolve a given dispute within [**] after referring such dispute to the designated Executive Officers pursuant to Section 16.1 (Executive Officers; Disputes), then, other than a dispute with respect to the validity, scope, enforceability, or ownership of any Patent Right or other intellectual property rights under this Agreement (unless otherwise agreed by the Parties), either Party may have such dispute settled by binding arbitration in the manner described below:

16.2.1 **Arbitration Request**. If a Party intends to begin an arbitration proceeding to resolve a dispute arising under this Agreement, then such Party will provide written notice (the "**Arbitration Request**") to the other Party of such intention and the issues for resolution. From the date of the Arbitration Request and until such time as the dispute has become finally settled, the running of the time periods within which a Party must cure a breach of this Agreement will be suspended with respect to the subject matter of the dispute.

16.2.2 **Additional Issues**. Within [**] after the receipt of the Arbitration Request, the other Party may, by written notice, add additional issues for resolution.

16.2.3 **Arbitration Procedure**. Except as expressly provided in this Agreement, any dispute, controversy, or claim arising out of or in connection with this Agreement, including any question regarding its existence, validity, or termination, will be referred to and finally resolved by binding arbitration administered by the American Arbitration Association ("**AAA**") in accordance with its International Arbitration Rules as then in effect, which rules are deemed to be incorporated by reference into this Section 16.2.3 (Arbitration Procedure). There will be one arbitrator, and such arbitrator will be chosen pursuant to the AAA Rules. The seat, or legal place, of arbitration will be New York, New York, or such other venue as the Parties agree. The language to be used in the arbitral proceedings will be English. THE PARTIES UNDERSTAND AND ACKNOWLEDGE THAT UNDER THIS SECTION 16.2.3 (ARBITRATION PROCEDURE) EACH PARTY WAIVES THE RIGHT TO A TRIAL BY JURY IN CONNECTION WITH ANY ARBITRABLE CONTROVERSY OR CLAIM. The Parties hereby agree that the arbitrator has authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator deems reasonable and necessary with or without petition therefor by the Parties as well as the final ruling and judgment. All rulings by the arbitrator will be final. Judgment on the award granted in any arbitration hereunder may be entered in any court having jurisdiction over the award or any of the Parties or any of their respective assets. Nothing in this Agreement will prevent either Party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, proprietary information, trade secrets, Know-How, or any other proprietary right or otherwise to avoid irreparable harm. If the issues in dispute involve scientific or technical matters, then any arbitrator chosen hereunder will have educational training or experience sufficient to demonstrate a reasonable level of knowledge in the field of biotechnology and pharmaceuticals. The Parties agree that arbitration of any dispute will be confidential, and all claims, proceedings, and evidence provided in the arbitration and all decisions of the arbitrators will be considered the Confidential Information of both Parties under this Agreement.

16.3 Intellectual Property Disputes. Notwithstanding Section 16.2 (Arbitration), if a dispute arises with respect to the validity, scope, enforceability, or ownership of any Patent Right or other intellectual property rights, and such dispute is not resolved in accordance with Section 16.1 (Executive Officers; Disputes), then such dispute will not be submitted to an arbitration proceeding in accordance with Section 16.2 (Arbitration), unless otherwise agreed by the Parties in writing, and instead, either Party may initiate litigation in a court of competent jurisdiction in any country in which such rights apply.

16.4 Choice of Law; English Language. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the Parties hereunder, will be construed under and governed by the laws of England and Wales, exclusive of its conflicts of laws principles. This Agreement has been prepared in the English language and the English language will control its interpretation. All consents, notices, reports, and other written documents to be delivered or provided by a Party under this Agreement will be in the English language, and in the event of any conflict between the provisions of any document and the English language translation thereof, the terms of the English language translation will control.

Article XVII
MISCELLANEOUS

17.1 Assignment. Neither Party may assign this Agreement and the licenses herein granted without the other Party's prior written consent *unless* such assignment is to (a) a Third Party successor or purchaser of all or substantially all of the assets or businesses to which this Agreement relates whether pursuant to a sale of assets, merger, or other transaction, in which case the assigning Party will provide written notice to the other Party and need not obtain the other Party's consent, or (b) an Affiliate of such Party, in which case the assigning Party need not obtain the other Party's consent; *provided that* the assigning Party remains fully liable for the performance of its obligations hereunder by such assignee. In addition, and notwithstanding the foregoing, Akebia

may assign its right to receive payments under this Agreement as part of a royalty factoring transaction undertaken for *bona fide* financing purposes. Any other assignment of this Agreement by a Party requires the prior written consent of the other Party. Any assignment in violation of this Section 17.1 (Assignment) will be null, void, and of no legal effect. This Agreement will be binding on and will inure to the benefit of the permitted successors and assigns of the Parties.

17.2 **Exclusivity**. Neither Licensee nor its Affiliates will, directly or indirectly, Commercialize (or authorize any Third Party to Commercialize) any Competing Product in such country in the Territory during the Term and for [**] following expiration or termination of this Agreement.

17.3 **Force Majeure**. Both Parties will be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by Force Majeure and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse will continue only so long as the condition constituting Force Majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. When the Force Majeure no longer exists, the affected Party must promptly resume performance. For purposes of this Agreement, "**Force Majeure**" will include conditions beyond the reasonable control of the non-performing Party, including an act of God, war, civil commotion, terrorist act, labor strike or lock-out, epidemic, pandemic, failure or default of public utilities or common carriers, destruction of production facilities or materials by fire, earthquake, storm or like catastrophe, failure of plant or machinery and act (or failure to act) of a government of any country or of any Governmental Authority (other than as a result of the non-performing Party's failure to comply with Applicable Law). The Parties agree the effects of the COVID-19 pandemic that is ongoing as of the Effective Date may be invoked as a Force Majeure for the purposes of this Agreement even though the pandemic is ongoing to the extent those effects are not reasonably foreseeable by the Parties as of the Effective Date. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder because of a Force Majeure affecting such Party. The affected Party will notify the other Party in writing of any Force Majeure circumstances that may affect its performance under this Agreement as soon as reasonably practical, will provide a good faith estimate of the period for which its failure or delay in performance under the Agreement is expected to continue based on currently available information, and will undertake reasonable efforts necessary to mitigate and overcome such Force Majeure circumstances and resume normal performance of its obligations hereunder as soon as reasonably practicable under the circumstances. Throughout the duration of the Force Majeure event, the affected Party will update such notice to the other Party on a [**] basis, or more frequently if requested by the other Party, to provide updated summaries of its mitigation efforts and its estimates of when normal performance under the Agreement will be able to resume. In any event, if a Party's failure to perform its obligations under this Agreement as a result of a Force Majeure event continues for longer than [**], then the other Party may terminate this Agreement by providing written notice to the Party affected by the Force Majeure event.

17.4 **Injunctive Relief**. Each Party acknowledges and agrees that there may be no adequate remedy at law for any breach of its obligations under this Agreement, that any such breach may result in irreparable harm to such other Party, and, therefore, that upon any such breach or any threat thereof, such other Party may seek appropriate equitable relief in addition to whatever remedies it might have at law, without the necessity of showing actual damages.

17.5 **Entire Agreement; Amendment**. This Agreement, together with all exhibits and schedules attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter hereof (including that certain Confidential Disclosure Agreement between the Parties dated [**] ("**Confidential Disclosure Agreement**")); *provided that* all information shared by the Parties pursuant to the Confidential Disclosure Agreement will be Confidential Information under this Agreement, and the use and disclosure thereof will be governed by Article XIII (Confidentiality). This Agreement will not be modified, or amended, except by another agreement in writing executed by the Parties.

17.6 **Severability**. If any provision of this Agreement is declared invalid by a court of last resort or by any court or other governmental body from the decision of which an appeal is not taken within

the time provided by law, then and in such event, this Agreement will be deemed to have been terminated only as to the portion thereof that relates to the provision invalidated by that decision and only in the relevant jurisdiction, but this Agreement will remain in force, in all other respects and all other jurisdictions; *provided, however*, that if the provision so invalidated is essential to the Agreement as a whole, then the Parties will negotiate in good faith to amend the terms hereof as nearly as practical to carry out the original intent of the Parties, and, failing such amendment, either Party may submit the matter for resolution pursuant to Article XVI (Dispute Resolution; Governing Law).

17.7 Notices. Except as expressly provided otherwise in this Agreement, any notice or report required or permitted to be given under this Agreement will be in writing and sufficient if delivered by internationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, and in each case, addressed as follows (with a courtesy copy sent by email, which will not constitute notice):

If to Akebia:

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142
Attention: Chief Executive Officer
Email: [**]

With a copy to (which will not constitute notice for purposes of this Agreement):

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142
Attention: General Counsel
Email: [**]

If to Licensee:

Dr. Dr. Richard Ammer
CEO, Managing Owner
[**]

With a copy to (which will not constitute notice for purposes of this Agreement):

Andreas Kellermann LL.M (Wellington)
Global Head of Legal & IP
[**]

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such notice will be deemed to have been given: (a) on the Business Day after dispatch if sent by internationally-recognized overnight courier; or (b) on the fifth Business Day after dispatch if sent by registered or certified mail, postage prepaid, return receipt requested.

17.8 Further Assurances. The Parties agree to reasonably cooperate with each other in connection with any actions required to be taken as part of their respective obligations under this Agreement, and will (a) furnish to each other such further information; (b) execute and deliver to each other such other documents; and (c) do such other acts and things (including working collaboratively to correct any clerical, typographical, or other similar errors in this Agreement), all as the other Party may reasonably request for the purpose of carrying out the intent of this Agreement.

17.9 Performance by Affiliates. Notwithstanding anything to the contrary set forth herein, either Party will have the right to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any Affiliate. Each Party hereby guarantees the performance by its Affiliates of such Party's obligations under this Agreement, and will cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.

17.10 Agency. Neither Party is, nor will be deemed to be an employee, agent, or representative of the other Party for any purpose. Each Party is an independent contractor, not an employee or partner of the other Party. Neither Party will have the authority to speak for, represent, or obligate the other Party in any way without prior written authority from the other Party.

17.11 No Waiver. Any omission or delay by either Party at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants, or provisions hereof, by the other Party, will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement. Any waiver by a Party of a particular breach or default by the other Party will not operate or be construed as a waiver of any subsequent breach or default by the other Party.

17.12 No Strict Construction. This Agreement has been prepared jointly by the Parties and will not be strictly construed against either Party.

17.13 Headings. The captions to the several Article**s**, Sections and subsections hereof are not a part of this Agreement, but are merely for convenience to assist in locating and reading the several Articles and Sections of this Agreement.

17.14 Cumulative Remedies. No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

17.15 Interpretation. (a) Whenever any provision of this Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation" and "including but not limited to" (or "includes without limitations" and "includes but is not limited to") regardless of whether the words "without limitation" or "but not limited to" actually follow the term "including" (or "includes"); (b) "herein," "hereby," "hereunder," "hereof," and other equivalent words will refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used; (c) all definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural; (d) wherever used herein, any pronoun or pronouns will be deemed to include both the singular and plural and to cover all genders; (e) the recitals set forth at the start of this Agreement, along with the schedules and exhibits to this Agreement, and the terms and conditions incorporated in such recitals and schedules and exhibits will be deemed integral parts of this Agreement and all references in this Agreement to this Agreement will encompass such recitals and schedules and exhibits and the terms and conditions incorporated in such recitals and schedules and exhibits; *provided that* in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions set forth in the recitals, schedules, or exhibits, the terms of this Agreement will control; (f) in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement, or otherwise, the terms and conditions of this Agreement will govern; (g) this Agreement will be construed as if both Parties drafted it jointly, and will not be construed against either Party as principal drafter; (h) unless otherwise provided, all references to Sections, Articles, and Schedules in this Agreement are to Sections, Articles, and Schedules of and to this Agreement; (i) any reference to any federal, national, state, local, or foreign statute or law will be deemed to also refer to all rules and regulations promulgated thereunder, unless the context requires otherwise; (j) wherever used, the word "shall" and the word "will" are each understood to be imperative or mandatory in nature and are interchangeable with one another; (k) the word "or" will not be exclusive; (l) references to a particular person include such person's successors and assigns to the extent not prohibited by this Agreement; and (m) the section headings and

captions used herein are inserted for convenience of reference only and will not be construed to create obligations, benefits, or limitations.

17.16 **Counterparts**. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Each Party may execute this Agreement in Adobe™ Portable Document Format (PDF) sent by electronic mail. PDF signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Remainder of page intentionally left blank; Signature page follows.]

IN WITNESS WHEREOF, the Parties have executed this Agreement through their duly authorized representatives to be effective as of the Effective Date.

AKEBIA THERAPEUTICS, INC. AKEBIA THERAPEUTICS, INC.

By: /s/ John P. Butler By: /s/ David Spellman

Name: John P. Butler Name: David Spellman

Title: President & Chief Executive Officer Title: Senior Vice President, Chief Financial Officer & Treasurer

MEDICE Arzneimittel Pütter GmbH & Co. KG

By: /s/ Richard Ammer, MD, PhD

Name: Richard Ammer, MD, PhD

Title: CEO/Managing owner MEDICE

Exhibit 10.2

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

Execution Version

THIRD AMENDMENT TO LOAN AGREEMENT

This THIRD AMENDMENT TO LOAN AGREEMENT (this "Amendment"), dated and effective as of June 30, 2023 (the "Third Amendment Effective Date"), by and among AKEBIA THERAPEUTICS, INC., a Delaware corporation (as "Borrower"), BIOPHARMA CREDIT PLC, a public limited company incorporated under the laws of England and Wales (as the "Collateral Agent"), BPCR LIMITED PARTNERSHIP, a limited partnership established under the laws of England and Wales (as a "Lender"), and BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP, a Cayman Islands exempted limited partnership (as a "Lender").

Recitals

A. Collateral Agent, Lenders, Borrower and the other Credit Parties thereunder have entered into that certain Loan Agreement, dated as of November 11, 2019, and amended by that certain First Amendment and Waiver, dated as of February 18, 2022, and that certain Second Amendment and Waiver, dated as of July 15, 2022 (the "Loan Agreement").

B. In accordance with Section 11.5 of the Loan Agreement, Borrower (acting for its own behalf and on behalf of the other Credit Parties other than Parent), Collateral Agent and Lenders desire to amend the Loan Agreement on the terms and conditions set forth herein.

Agreement

Now, Therefore, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. All capitalized terms used in this Amendment (including in the recitals hereof) and not otherwise defined herein shall have the meanings assigned to them in the Loan Agreement. The rules of interpretation set forth in the first paragraph of Section 13.1 of the Loan Agreement shall be applicable to this Amendment and are incorporated herein by this reference.

2. **Amendments to Loan Agreement.** With immediate effect from and as of the Third Amendment Effective Date:

a. The Loan Agreement shall be amended by adding as the fourth paragraph in Section 1 of the Loan Agreement the following:

"The Collateral Agent does not warrant or accept responsibility for, and shall not have any liability with respect to (a) the continuation of, administration of, submission of, calculation of or any other matter related to the Term SOFR Reference Rate, Adjusted Term SOFR or Term SOFR, or any component definition thereof or rates referred to in the definition thereof, or any alternative, successor or replacement rate thereto (including any Benchmark Replacement), including whether the composition or characteristics of any such alternative, successor or replacement rate (including any Benchmark Replacement) will be similar to, or produce the same value or economic equivalence of, or have the same volume or liquidity as, the Term SOFR Reference Rate, Adjusted Term SOFR, Term SOFR or any other Benchmark prior to its discontinuance or unavailability, or (b) the effect, implementation or composition of any Conforming Changes. The Collateral Agent and its affiliates or other related entities may engage in transactions that affect the calculation of the Term SOFR Reference Rate, Adjusted Term SOFR, Term SOFR, any alternative, successor or replacement rate (including any Benchmark Replacement) or any relevant adjustments thereto, in each case, in a manner adverse to the Borrower. The Collateral Agent may select information sources or services in its reasonable

discretion to ascertain the Term SOFR Reference Rate, Adjusted Term SOFR, Term SOFR or any other Benchmark, in each case pursuant to the terms of this Agreement, and shall have no liability to Borrower, any Lender or any other Person for damages of any kind, including direct or indirect, special, punitive, incidental or consequential damages, costs, losses or expenses (whether in tort, contract or otherwise and whether at law or in equity), for any error or calculation of any such rate (or component thereof) provided by any such information source or service."

b. The Loan Agreement shall be amended by deleting in its entirety Section 2.2(c)(ii) of the Loan Agreement and replacing it as follows:

"(ii) Upon a Change in Control, Borrower shall promptly, and in any event no later than [**] after the consummation of such Change in Control, notify the Collateral Agent in writing of the occurrence of a Change in Control, which notice shall include [**] (such notice, a "**Change in Control Notice**"). Borrower shall prepay in full all of the Term Loans advanced by Lenders under this Agreement, no later than [**] after delivery to the Collateral Agent of such Change in Control Notice, in an amount equal to the sum of (A) all unpaid principal and any and all accrued and unpaid interest with respect to the Term Loans (such interest to be calculated based on Term SOFR for the Interest Period during which such Change in Control is consummated), and (B) any and all amounts payable with respect to the prepayment under this Section 2.2(c)(ii) pursuant to Section 2.2(e) or Section 2.2(f) (as applicable), together with any and all other amounts payable or accrued and not yet paid under this Agreement and the other Loan Documents (including pursuant to Section 2.4). The Collateral Agent will promptly notify each Lender of its receipt of the Change in Control Notice, and the amount of such Lender's Applicable Percentage of such prepayment."

c. The Loan Agreement shall be amended by adding as Section 2.2(g) of the Loan Agreement the following:

"(g) Any Makewhole Amount or Prepayment Premium payable as a result of any prepayment of the Term Loans pursuant to Section 2.2(c) or as a result of the acceleration of the maturity of the Term Loans pursuant to Section 8.1(a), shall be presumed to be the liquidated damages sustained by each applicable Lender as the result of the early redemption and repayment of such Term Loan Notes and Borrower agrees that it is reasonable under the circumstances currently existing. BORROWER EXPRESSLY WAIVES (TO THE FULLEST EXTENT IT MAY LAWFULLY DO SO) THE PROVISIONS OF ANY PRESENT OR FUTURE REQUIREMENTS OF LAW THAT PROHIBITS OR MAY PROHIBIT THE COLLECTION OF ANY MAKEWHOLE AMOUNT OR PREPAYMENT PREMIUM IN CONNECTION WITH ANY SUCH PREPAYMENT OR ACCELERATION OR OTHERWISE. Borrower expressly agrees that (to the fullest extent it may lawfully do so) that: (i) each Makewhole Amount and Prepayment Premium is reasonable and is the product of an arm's-length transaction among sophisticated business people, ably represented by counsel; (ii) each Makewhole Amount and Prepayment Premium shall be payable notwithstanding the then-prevailing market rates at the time payment thereof is made; (iii) there has been a course of conduct among Lenders and Borrower giving specific consideration in this transaction for such agreement to pay each Makewhole Amount and Prepayment Premium; and (iv) Borrower shall be estopped hereafter from claiming differently than as agreed to in this Section 2.2(g) and Section 8.6. Borrower expressly acknowledges that its agreement to pay the Makewhole Amount and Prepayment Premium, as the case may be, to applicable Lenders as herein described is a material inducement to such Lenders to make any Credit Extension. Without affecting any of any Lender's rights or remedies hereunder or in respect hereof, if Borrower fails to pay the applicable Makewhole Amount or Prepayment Premium when due, then the amount thereof shall thereafter bear interest until paid in full at the Default Rate."

d. The Loan Agreement shall be amended by deleting in its entirety Section 2.3(a)(i) of the Loan Agreement and replacing it as follows:

"(i) Subject to Section 2.3(b), the principal amount outstanding under each Term Loan shall accrue interest at a *per annum* rate equal to Adjusted Term SOFR for the Interest Period therefor *plus* the Applicable Margin (the "**Term Loan Rate**"), which interest shall be payable quarterly in arrears in accordance with this Section 2.3."

e. The Loan Agreement shall be amended by adding as Section 2.3(a)(iii) of the Loan Agreement the following:

"(iii) Interest is due and payable quarterly on each Interest Date, as calculated by the Collateral Agent (which calculations shall be deemed correct absent manifest error), commencing on the Interest Date occurring from and after the Third Amendment Effective Date; provided, however, that if any such date is not a Business Day, the applicable interest shall be due and payable on the first Business Day immediately after such Interest Date."

f. The Loan Agreement shall be amended by replacing the reference to [**] included in Section 2.3(d) of the Loan Agreement with "[**]."

g. The Loan Agreement shall be amended by deleting in its entirety Section 2.3(e) of the Loan Agreement and replacing it as follows:

"(e) Conforming Changes. In connection with the use or administration of Term SOFR, the Collateral Agent will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Loan Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Loan Document. The Collateral Agent will promptly notify Borrower and Lenders of the effectiveness of any Conforming Changes in connection with the use or administration of Term SOFR."

h. The Loan Agreement shall be amended by adding as Section 2.3(f) of the Loan Agreement the following:

"(f) Benchmark Replacement Setting.

(i) Benchmark Replacement. Notwithstanding anything to the contrary herein or in any other Loan Document, if a Benchmark Transition Event and its related Benchmark Replacement Date have occurred prior any setting of the then-current Benchmark, then (x) if a Benchmark Replacement is determined in accordance with clause (a) of the definition of "Benchmark Replacement" for such Benchmark Replacement Date, such Benchmark Replacement will replace such Benchmark for all purposes hereunder and under any Loan Document in respect of such Benchmark setting and subsequent Benchmark settings without any amendment to, or further action or consent of any other party to, this Agreement or any other Loan Document and (y) if a Benchmark Replacement is determined in accordance with clause (b) of the definition of "Benchmark Replacement" for such Benchmark Replacement Date, such Benchmark Replacement will replace such Benchmark for all purposes hereunder and under any Loan Document in respect of any Benchmark setting at or after [**] (New York City time) on the [**] after the date notice of such Benchmark Replacement is provided to Lenders without any amendment to, or further action or consent of any other party to, this Agreement or any other Loan Document so long as the Collateral Agent has not received, by such time, written notice of objection to such Benchmark Replacement from Lenders comprising the Required Lenders. If

the Benchmark Replacement is Daily Simple SOFR, all interest payments will be payable on a quarterly basis.

(ii) Conforming Changes. In connection with the implementation and administration of a Benchmark Replacement, the Collateral Agent will have the right to make Conforming Changes from time to time and, notwithstanding anything to the contrary herein or in any other Loan Document, any amendments implementing such Conforming Changes will become effective without any further action or consent of any other party to this Agreement or any other Loan Document.

(iii) Notices; Standards for Decisions and Determinations. The Collateral Agent will promptly notify Borrower and the Lenders of (A) the implementation of any Benchmark Replacement and (B) the effectiveness of any Conforming Changes in connection with the use, administration, adoption or implementation of a Benchmark Replacement. The Collateral Agent will notify Borrower of (x) the removal or reinstatement of any tenor of a Benchmark pursuant to sub-clause (iv) below and (y) the commencement of any Benchmark Unavailability Period. Any determination, decision or election that may be made by the Collateral Agent or, if applicable, any Lender (or group of Lenders) pursuant to this Section 2.3(f), including any determination with respect to a tenor, rate or adjustment or of the occurrence or non-occurrence of an event, circumstance or date and any decision to take or refrain from taking any action, will be conclusive and binding absent manifest error and may be made in its or their sole discretion and without consent from any other party to this Agreement or any other Loan Document, except, in each case, as expressly required pursuant to this Section 2.3(f).

(iv) Unavailability of Tenor of Benchmark. Notwithstanding anything to the contrary herein or in any other Loan Document, at any time (including in connection with the implementation of a Benchmark Replacement), (A) if the then-current Benchmark is a term rate (including the Term SOFR Reference Rate) and either (1) any tenor for such Benchmark is not displayed on a screen or other information service that publishes such rate from time to time as selected by the Collateral Agent in its reasonable discretion or (2) the regulatory supervisor for the administrator of such Benchmark has provided a public statement or publication of information announcing that any tenor for such Benchmark is not or will not be representative, then the Collateral Agent may modify the definition of "Interest Period" (or any similar or analogous definition) for any Benchmark settings at or after such time to remove such unavailable or non-representative tenor and (B) if a tenor that was removed pursuant to sub-clause (A) above either (1) is subsequently displayed on a screen or information service for a Benchmark (including a Benchmark Replacement) or (2) is not, or is no longer, subject to an announcement that it is not or will not be representative for a Benchmark (including a Benchmark Replacement), then the Collateral Agent may modify the definition of "Interest Period" (or any similar or analogous definition) for all Benchmark settings at or after such time to reinstate such previously removed tenor."

i. The Loan Agreement shall be amended by deleting the phrase "…the United States of America or any state thereof..." in Section 2.6(d)(i) of the Loan Agreement and replacing it with the phrase "…the United States…"

j. The Loan Agreement shall be amended by deleting in its entirety Section 8.1(f) of the Loan Agreement and replacing it as follows:

"(f) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. With respect to any and all Intellectual Property owned or held by any Credit Party and included in Collateral, each Credit Party hereby grants to the Collateral Agent, for the benefit of all Secured Parties, as of the Tranche A Closing Date: (i) an irrevocable, non-exclusive, assignable, royalty-free license or other right to use (and for its agents or

representatives to use), without charge, including the right to sublicense, use and practice, any and all such Intellectual Property in order to take possession of, collect, receive, assemble, process, appropriate, remove, realize upon, advertise for sale, sell, assign, license out, convey, transfer or grant options to purchase any Collateral, and access to all media in which any of the licensed items may be recorded or stored and to all Software and programs used for the compilation or printout thereof; and (ii) in connection with the Collateral Agent's exercise of its rights or remedies under this Section 8.1, each Credit Party's rights under all licenses and all franchise Contracts inure to the benefit of all Secured Parties;"

k. The Loan Agreement shall be amended by deleting in its entirety Section 8.6 of the Loan Agreement and replacing it as follows:

"**8.6 Demand Waiver; Makewhole Amount; Prepayment Premium.** Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by the Collateral Agent on which Borrower is liable. Borrower acknowledges and agrees that if the maturity of all Obligations shall be accelerated pursuant to Section 8.1(a) by reason of the occurrence of an Event of Default, the applicable Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, shall become due and payable by Borrower upon such acceleration, whether such acceleration is automatic or is effected by the Collateral Agent's or any Lender's declaration thereof, as provided in Section 8.1(a), and shall also become due and payable in the event the Obligations are satisfied or released by foreclosure (whether by power of judicial proceeding), deed in lieu of foreclosure or by any other similar means, and Borrower shall pay the applicable Makewhole Amount and Prepayment Premium that is payable pursuant to Section 2.2(e) and Section 2.2(f), as applicable, as compensation to Lenders for the loss of its investment opportunity and not as a penalty, and Borrower waives any right to object thereto in any voluntary or involuntary bankruptcy, insolvency or similar proceeding or otherwise."

l. The Loan Agreement shall be amended by deleting in its entirety the Collateral Agent's notice details in Section 9 of the Loan Agreement and replacing them as follows:

"BioPharma Credit Plc
c/o Link Group, Company Matters Ltd.
6th Floor
65 Gresham Street
London EC2V 7NQ
United Kingdom
Attn: Company Secretary
Tel: [**]
Fax: [**]
Email: [**]

with copies (which shall not constitute notice) to:

Pharmakon Advisors, LP
110 East 59th Street, #2800
New York, NY 10022
Attn: [**]
Phone: [**]
Fax: [**]
Email: [**]

and

Akin Gump Strauss Hauer & Feld LLP
One Bryant Park
New York, NY 10036-6745
Attn: [**]
Phone: [**]
Fax: [**]
Email: [**]"

m. The Loan Agreement shall be amended by deleting in its entirety Section 11.2(a) of the Loan Agreement and replacing it as follows:

"(a) Borrower agrees to indemnify and hold harmless each of the Collateral Agent, Lenders and its and their respective Affiliates (and its or their respective successors and assigns) and each manager, member, partner, controlling Person, director, officer, employee, agent or sub-agent, advisor and affiliate thereof (each such Person, an "**Indemnified Person**") from and against any and all Indemnified Liabilities; provided, however, that (i) Borrower shall have no obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities to the extent such Indemnified Liabilities arise from the bad faith, gross negligence or willful misconduct of such Indemnified Person (or any of such Indemnified Person's Affiliates or controlling Persons or any of their respective directors, officers, managers, partners, members, agents, sub-agents or advisors), in each case, as determined by a final, non-appealable judgment of a court of competent jurisdiction, (ii) Borrower shall have no obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities if and to the extent such Indemnified Liabilities arise from a material breach of any obligation of such Indemnified Person hereunder, and (iii) Borrower shall have no obligation to any Indemnified Person hereunder with respect to any Indemnified Liabilities if and to the extent such Indemnified Liabilities arise from any claim by one Indemnified Person against another Indemnified Person that does not relate to any act or omission of Borrower or any Credit Party (other than against the Collateral Agent or any intercreditor agent in their respective capacities as such), and (iv) no Credit Party shall be liable for any settlement of any claim or proceeding effected by any Indemnified Person without the prior written consent of such Credit Party (which consent shall not be unreasonably withheld, conditioned or delayed), but if settled with such consent or if there shall be a final judgment against an Indemnified Person, each of the Credit Parties shall, jointly and severally with each of the other Credit Parties, indemnify and hold harmless such Indemnified Person from and against any loss or liability by reason of such settlement or judgment in the manner set forth in this Agreement. This Section 11.2(a) shall not apply with respect to Taxes other than any Taxes that represent liabilities, obligations, losses, damages, penalties, claims, costs, expenses and disbursements arising from any non-Tax claim."

n. The Loan Agreement shall be amended by deleting in its entirety Section 11.12 of the Loan Agreement and replacing it as follows:

"11.12 Electronic Execution of Documents. The words "execution," "execute," "signed," "signature," and words of like import in this Agreement and the other Loan Documents shall be deemed to include electronic signatures or electronic records, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any Requirements of Law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act."

o. The Loan Agreement shall be amended by deleting in its entirety each of the definitions of Interest Date, Payment Date, Tranche A Closing Date and Tranche B Closing Date in Section 13.1 of the Loan Agreement and replacing them, in alphabetical order, as follows:

““**Interest Date**” means the last day of each calendar quarter, commencing with the last day of the calendar quarter during which the Third Amendment Effective Date occurs.”

““**Payment Date**” means, with respect to each Term Loan, (a) the Interest Date occurring on or immediately following each of the following dates: (i) the 33rd-month anniversary of the Closing Date applicable to such Term Loan, (ii) the 36th-month anniversary of such Closing Date, (iii) the 39th-month anniversary of such Closing Date, (iv) the 42nd-month anniversary of such Closing Date, (v) the 45th-month anniversary of such Closing Date, (vi) the 48th-month anniversary of such Closing Date, (vii) the 51st-month anniversary of such Closing Date, (viii) the 54th-month anniversary of such Closing Date, (ix) the 57th-month anniversary of such Closing Date, and (b) the Term Loan Maturity Date, as the context dictates; provided, however, that if any such date is not a Business Day, the applicable payment shall be due and payable on the first Business Day immediately after such Payment Date; provided, further, that in the event Borrower elects to delay amortization pursuant to and subject to the terms of Section 2.2(b)(ii) hereof, “Payment Date” shall mean each of the dates referred to clauses (a)(vi) through (ix) and clause (b) above. Notwithstanding the foregoing, “Payment Date” shall be subject to further adjustment in accordance with Section 2.2(b)(iii) hereof (in which case, for the avoidance of doubt, the first proviso above shall to apply to any such adjusted date).”

““**Tranche A Closing Date**” means the date on which the Tranche A Loan is advanced by Lenders, which is November 25, 2019.”

““**Tranche B Closing Date**” means the date on which the Tranche B Loan is advanced by Lenders, which is December 10, 2020.”

p. The Loan Agreement shall be amended by deleting in its entirety each of the definitions of Interest Rate Determination Date and LIBOR Rate in Section 13.1 of the Loan Agreement.

q. The Loan Agreement shall be amended by adding, in alphabetical order, each of the following definitions to Section 13.1 of the Loan Agreement:

““**Adjusted Term SOFR**” means, for purposes of any calculation, the rate per annum equal to (a) Term SOFR for such calculation plus (b) the Term SOFR Adjustment; provided, that, if Adjusted Term SOFR as so determined shall ever be less than the Floor, then Adjusted Term SOFR shall be deemed to be the Floor.”

““**Applicable Margin**” means, for any day, as to any Term Loan, a rate *per annum* equal to seven and one-half percent (7.50%).”

““**Available Tenor”** means, as of any date of determination and with respect to the then-current Benchmark, as applicable, (a) if such Benchmark is a term rate, any tenor for such Benchmark (or component thereof) that is or may be used for determining the length of an interest period pursuant to this Agreement or (b) otherwise, any payment period for interest calculated with reference to such Benchmark (or component thereof) that is or may be used for determining any frequency of making payments of interest calculated with reference to such Benchmark pursuant to this Agreement, in each case, as of such date and not including, for the avoidance of doubt, any tenor for such Benchmark that is then-removed from the definition of “Interest Period” pursuant to Section 2.3(e).”

““**Benchmark”** means, initially, the Term SOFR Reference Rate; provided, that, if a Benchmark Transition Event has occurred with respect to the Term SOFR Reference Rate or the then-current Benchmark, then “Benchmark” means the applicable Benchmark Replacement to the extent that such Benchmark Replacement has replaced such prior benchmark rate pursuant to Section 2.3(e).”

““**Benchmark Replacement**” means, with respect to any Benchmark Transition Event, the first alternative set forth in the order below that can be determined by the Collateral Agent for the applicable Benchmark Replacement Date:

(a) the sum of (i) Daily Simple SOFR and (ii) [**]; or

(b) the sum of: (i) the alternate benchmark rate that has been selected by the Collateral Agent giving due consideration to (A) any selection or recommendation of a replacement benchmark rate or the mechanism for determining such a rate by the Relevant Governmental Body or (B) any evolving or then-prevailing market convention for determining a benchmark rate as a replacement to the then-current Benchmark for Dollar-denominated syndicated credit facilities and (ii) the related Benchmark Replacement Adjustment;

provided, that, if the Benchmark Replacement as determined pursuant to clause (a) or (b) above would be less than the Floor, the Benchmark Replacement will be deemed to be the Floor for the purposes of this Agreement and the other Loan Documents.”

““**Benchmark Replacement Adjustment**” means, with respect to any replacement of the then-current Benchmark with an Unadjusted Benchmark Replacement, the spread adjustment, or method for calculating or determining such spread adjustment, (which may be a positive or negative value or zero) that has been selected by the Collateral Agent giving due consideration to (a) any selection or recommendation of a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of such Benchmark with the applicable Unadjusted Benchmark Replacement by the Relevant Governmental Body or (b) any evolving or then-prevailing market convention for determining a spread adjustment, or method for calculating or determining such spread adjustment, for the replacement of such Benchmark with the applicable Unadjusted Benchmark Replacement for Dollar-denominated syndicated credit facilities at such time.”

““**Benchmark Replacement Date**” means a date and time determined by the Collateral Agent in its reasonable discretion, which date shall be no later than the earliest to occur of the following events with respect to the then-current Benchmark:

(a) in the case of clause (a) or (b) of the definition of “Benchmark Transition Event,” the later of (i) the date of the public statement or publication of information referenced therein and (ii) the date on which the administrator of such Benchmark (or the published component used in the calculation thereof) permanently or indefinitely ceases to provide all Available Tenors of such Benchmark (or such component thereof); and

(b) in the case of clause (c) of the definition of “Benchmark Transition Event,” the first date on which such Benchmark (or the published component used in the calculation thereof) has been determined and announced by the regulatory supervisor for the administrator of such Benchmark (or such component thereof) to be non-representative; provided, that, such non-representativeness will be determined by reference to the most recent statement or publication referenced in such clause (c) and even if any Available Tenor of such Benchmark (or such component thereof) continues to be provided on such date.

For the avoidance of doubt, the “Benchmark Replacement Date” will be deemed to have occurred in the case of clause (a) or (b) above with respect to any Benchmark upon the occurrence of the applicable event or events set forth therein with respect to all then-current Available Tenors of such Benchmark (or the published component used in the calculation thereof).”

““**Benchmark Transition Event**” means the occurrence of one or more of the following events with respect to the then-current Benchmark:

(a) a public statement or publication of information by or on behalf of the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that such administrator has ceased or will cease to provide all Available Tenors of such Benchmark (or such component thereof), permanently or indefinitely; provided, that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof);

(b) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof), the Federal Reserve Board, the Federal Reserve Bank of New York, an insolvency official with jurisdiction over the administrator for such Benchmark (or such component), a resolution authority with jurisdiction over the administrator for such Benchmark (or such component) or a court or an entity with similar insolvency or resolution authority over the administrator for such Benchmark (or such component), which states that the administrator of such Benchmark (or such component) has ceased or will cease to provide all Available Tenors of such Benchmark (or such component thereof) permanently or indefinitely; provided, that, at the time of such statement or publication, there is no successor administrator that will continue to provide any Available Tenor of such Benchmark (or such component thereof); or

(c) a public statement or publication of information by the regulatory supervisor for the administrator of such Benchmark (or the published component used in the calculation thereof) announcing that all Available Tenors of such Benchmark (or such component thereof) are not, or as of a specified future date will not be, representative.

For the avoidance of doubt, a “Benchmark Transition Event” will be deemed to have occurred with respect to any Benchmark if a public statement or publication of information set forth above has occurred with respect to each then-current Available Tenor of such Benchmark (or the published component used in the calculation thereof).”

““**Benchmark Unavailability Period**” means, the period (if any) (a) beginning at the time that a Benchmark Replacement Date has occurred if, at such time, no Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Loan Document in accordance with Section 2.3(e) and (b) ending at the time that a Benchmark Replacement has replaced the then-current Benchmark for all purposes hereunder and under any Loan Document in accordance with Section 2.3(e).”

““**Conforming Changes**” means, with respect to either the use or administration of Term SOFR or the use, administration, adoption or implementation of any Benchmark Replacement, any technical, administrative or operational changes (including changes to the definition of “Business Day,” the definition of “U.S. Government Securities Business Day,” the definition of “Interest Period” or any similar or analogous definition (or the addition of a concept of “interest period”), timing and frequency of determining rates and making payments of interest, timing of borrowing requests or prepayment, conversion or continuation notices, the applicability and length of lookback periods and other technical, administrative or operational matters) that the Collateral Agent decides (after consultation with Borrower) may be appropriate to reflect the adoption and implementation of any such rate or to permit the use and administration thereof by the Collateral Agent in a manner substantially consistent with market practice (or, if the Collateral Agent decides that adoption of any portion of such market practice is not administratively feasible or if the Collateral Agent determines that no market practice for the administration of any such rate exists, in such other manner of administration as the Collateral Agent decides is reasonably

necessary in connection with the administration of this Agreement and the other Loan Documents)."

""**Daily Simple SOFR**" means, for any day, SOFR, with the conventions for this rate (which will include a lookback) being established by the Collateral Agent in accordance with the conventions for this rate recommended by the Relevant Governmental Body for determining "Daily Simple SOFR" for Dollar-denominated bilateral business loans; provided, that, if the Collateral Agent decides that any such convention is not administratively feasible for the Collateral Agent, then the Collateral Agent may establish another convention in its reasonable discretion."

""**Floor**" means a rate of interest equal to 2.00% *per annum*."

""**Periodic Term SOFR Determination Day**" has the meaning specified in the definition of Term SOFR."

""**Relevant Governmental Body**" means the Board of Governors of the Federal Reserve System or the Federal Reserve Bank of New York, or a committee officially endorsed or convened by the Board of Governors of the Federal Reserve System or the Federal Reserve Bank of New York, or any successor thereto."

""**SOFR**" means a rate equal to the secured overnight financing rate as administered by the SOFR Administrator."

""**SOFR Administrator**" means the Federal Reserve Bank of New York (or a successor administrator of the secured overnight financing rate)."

""**Term SOFR**" means, for any day in any calendar month, the Term SOFR Reference Rate for a tenor of three (3) months on the day (such day, the "**Periodic Term SOFR Determination Day**") that is [**] prior to the first day of such Interest Period, as such rate is published by the Term SOFR Administrator; provided, however, that if as of [**]. (New York City time) on any Periodic Term SOFR Determination Day the Term SOFR Reference Rate for the applicable tenor has not been published by the Term SOFR Administrator and a Benchmark Replacement Date with respect to the Term SOFR Reference Rate has not occurred, then Term SOFR will be the Term SOFR Reference Rate for such tenor as published by the Term SOFR Administrator on the first preceding U.S. Government Securities Business Day for which such Term SOFR Reference Rate for such tenor was published by the Term SOFR Administrator so long as such first preceding U.S. Government Securities Business Day is not more than [**] prior to such Periodic Term SOFR Determination Day; provided, however, that for purposes of calculating the Term Loan Rate, Term SOFR shall at all times be subject to a cap of 3.35%."

""**Term SOFR Adjustment**" means a percentage equal to [**]% *per annum*."

""**Term SOFR Administrator**" means CME Group Benchmark Administration Limited (CBA) (or a successor administrator of the Term SOFR Reference Rate selected by the Collateral Agent in its reasonable discretion)."

""**Term SOFR Reference Rate**" means the forward-looking term rate based on SOFR."

""**Third Amendment Effective Date**" means June 30, 2023."

""**U.S. Government Securities Business Day**" means any day except for (a) a Saturday, (b) a Sunday or (c) a day on which the Securities Industry and Financial Markets Association

recommends that the fixed income departments of its members be closed for the entire day for purposes of trading in United States government securities."

r. The Loan Agreement shall be amended by deleting in its entirety the notice details of each Lender in Exhibit D of the Loan Agreement and replacing them as follows:

"BPCR LIMITED PARTNERSHIP
c/o Link Group, Company Matters Ltd.
6th Floor
65 Gresham Street
London EC2V 7NQ
United Kingdom
Attn: Company Secretary
Tel: [**]
Fax: [**]
Email: [**]

with copies (which shall not constitute notice) to:

PHARMAKON ADVISORS, LP
110 East 59th Street, #2800
New York, NY 10022
Attn: [**]
Phone: [**]
Fax: [**]
Email: [**]

and

AKIN GUMP STRAUSS HAUER & FELD LLP
One Bryant Park
New York, NY 10036-6745
Attn: [**]
Phone: [**]
Fax: [**]
Email: [**]"

"BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP
c/o BioPharma Credit Investments V GP LLC
c/o Walkers Corporate Limited
190 Elgin Avenue,
George Town, Grand Cayman KY1-9008
Attn: [**]

with copies (which shall not constitute notice) to:

PHARMAKON ADVISORS, LP
110 East 59th Street, #2800
New York, NY 10022
Attn: [**]
Phone: [**]
Fax: [**]
Email: [**]

and

AKIN GUMP STRAUSS HAUER & FELD LLP
One Bryant Park
New York, NY 10036-6745
Attn: [**]
Phone: [**]
Fax: [**]
Email: [**]"

s. The Loan Agreement shall be amended by deleting in its entirety Exhibits B-1 and B-2 to the Loan Agreement and replacing them with Exhibits B-1 and B-2 attached to this Amendment.

3. Representations and Warranties; Reaffirmation; Covenant to Deliver.

a. Borrower hereby represents and warrants to each Lender and the Collateral Agent as follows:

i. Borrower has all requisite power and authority to enter into this Amendment and to carry out the transactions contemplated hereby.

ii. This Amendment has been duly executed and delivered by Borrower and is the legally valid and binding obligation of Borrower, enforceable against Borrower in accordance with its respective terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or limiting creditors' rights generally or by general principles of equity.

iii. The execution, delivery and performance by Borrower of this Amendment have been duly authorized and do not: (A) contravene the terms of any of Borrower's Operating Documents; (B) violate any Requirements of Law, except to the extent that such violation could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change; (C) conflict with or result in any breach or contravention of, or require any payment to be made under any provision of any security issued by Borrower or of any agreement, instrument or other undertaking to which Borrower is a party or affecting Borrower or the assets or properties of Borrower or any of its Subsidiaries or any

order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or any of its assets or properties are subject, except to the extent that such conflict, breach, contravention or payment could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change; (D) require any Governmental Approval, or other action by, or notice to, or filing with, any Governmental Authority (except such Governmental Approvals or other actions, notices and filings which have been duly obtained, taken, given or made on or before the Third Amendment Effective Date and are in full force and effect); (E) require any approval, consent, exemption or authorization, or other action by, or notice to, or filing with, any Person other than a Governmental Authority, including Borrower's stockholders, members or partners, (except such approvals, consents, exemptions, authorizations, actions, notices and filings which have been or will be duly obtained, taken, given or made on or before the Third Amendment Effective Date and are in full force and effect), except for those approvals, consents, exemptions, authorizations or other actions, notices or filings, the failure of which to obtain or make could not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Change; or (F) constitute a material breach of or a material default under (which such default has not been cured or waived) or an event of default (or the equivalent thereof, however described) under, or could reasonably be expected to give rise to the cancellation, termination or invalidation of or the acceleration of Borrower's or any Subsidiary's obligations under, any Material Contract.

iv. Both before and immediately after giving effect to this Amendment, no Event of Default or Default has occurred and is continuing.

b. Borrower hereby ratifies, confirms, reaffirms, and acknowledges its obligations under the Loan Documents to which it is a party and agrees that the Loan Documents remain in full force and effect, undiminished by this Amendment, except as expressly provided herein. By executing this Amendment, Borrower acknowledges that it has read, consulted with its attorneys regarding, and understands, this Amendment.

c. Borrower hereby confirms that all Tranche B Loans have been prepaid in full and acknowledges that neither such Term Loans nor any portion thereof may be re-borrowed.

d. Borrower hereby agrees to deliver to the Collateral Agent, within here (3) Business Days of the Third Amendment Effective Date, originally-signed copies of the Amended and Restated Tranche A Notes, in the form attached as Exhibit B-1 hereto, in replacement of the Tranche A Notes, dated November 25, 2019, issued by Borrower to each Lender (whereupon, the Tranche A Notes, dated November 25, 2019, issued by Borrower to the each Lender shall be treated as cancelled and of no further force or effect and the Lenders shall promptly destroy any and all copies or originals of such Tranche A Notes and confirm the same by email to Borrower), the failure of which such delivery constitutes an Event of Default for all purposes under the Loan Agreement.

4. References to and Effect on Loan Agreement. Except as specifically set forth herein, this Amendment shall not modify or in any way affect any of the terms, conditions, covenants, representations and warranties contained in the Loan Agreement, or any of the rights of the Lenders and the Collateral Agent therein, which shall remain in full force and effect and are hereby ratified and confirmed in all respects. Except as specifically set forth herein, the execution, delivery and effectiveness

of this Amendment shall not directly or indirectly (i) constitute a consent or waiver of any past, present or future breaches, violations or defaults of or under any provisions of the Loan Agreement nor constitute a novation of any of the Obligations under the Loan Agreement, (ii) amend, modify or operate as a waiver of any provision of the Loan Agreement or any right, power or remedy of any Lender or the Collateral Agent, or (iii) constitute a course of dealing or other basis for altering the Loan Agreement or any other Loan Document. Except as set forth herein, each of the Lenders and the Collateral Agent reserves all of its rights, powers, and remedies under the Loan Documents and Requirements of Law. On and after the Third Amendment Effective Date, all references in the Loan Agreement to "this Agreement," "hereto," "hereof," "hereunder," or words of like import shall mean the Loan Agreement as amended by this Amendment.

5. Successors and Assigns. This Amendment binds and is for the benefit of Borrower, the other Credit Parties, Lenders and Collateral Agent and each of their respective successors and permitted assigns.

6. Governing Law; Venue; Jury Trial Waiver. This Amendment shall be construed in accordance with and governed by the law of the State of New York. The provisions of Section 10 (*Choice of law, Venue and Jury Trial Waiver Etc*.) of the Loan Agreement shall apply hereto as if more fully set forth herein as if references therein to "this Agreement" were references to this Amendment.

7. Counterparts. This Amendment may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Amendment. Delivery of an executed counterpart of a signature page of this Amendment by facsimile or other electronic imaging means (e.g. "pdf" or "tif") shall be effective as delivery of a manually executed counterpart of this Amendment. The words "execution," "signed," "signature," and words of like import in this Amendment shall be deemed to include electronic signatures or electronic records, each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for under any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act, the New York State Electronic Signatures and Records Act, or any other similar state laws based on the Uniform Electronic Transactions Act..

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the undersigned hereto have caused this Amendment to be executed as of the date first written above by each of their officers thereunto duly authorized.

BORROWER (on its own behalf and on behalf of each other Credit Party):

AKEBIA THERAPEUTICS, INC.,
a Delaware corporation

By:/s/ David Spellman
Name: David Spellman
Title: Senior Vice President, Chief Financial Officer and Treasurer

BIOPHARMA CREDIT PLC,
as Collateral Agent

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BPCR LIMITED PARTNERSHIP,
as a Lender

By: Pharmakon Advisors, LP,
its Investment Manager

By: Pharmakon Management I, LLC,
its General Partner

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: Managing Member

BIOPHARMA CREDIT INVESTMENTS V (MASTER) LP,
as Lender

By: BioPharma Credit Investments V GP LLC,
its general partner

By: Pharmakon Advisors, LP,
its Investment Manager

By /s/ Pedro Gonzalez de Cosio
Name: Pedro Gonzalez de Cosio
Title: CEO and Managing Member

Exhibit 10.3

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

Execution Version
Confidential

PACKAGING VALIDATION TRANSFER AGREEMENT

This PACKAGING VALIDATION TRANSFER AGREEMENT (this "**Agreement**") is entered into as of April 20, 2023 (the "**Effective Date**"), by and between Akebia Therapeutics, Inc., a company organized and existing under the laws of the State of Delaware, United States of America with its principal offices at 245 First Street, Cambridge, MA 02142 ("**Akebia**"), and Otsuka Pharmaceutical Co. Ltd., a company organized and existing under the laws of Japan, having a registered office located at 2-9, Kanda Tsukasamachi, Chiyoda-ku, Tokyo 101-8535, Japan ("**Otsuka**"). Each of Akebia and Otsuka are sometimes referred to herein individually as a "**Party**" and together as the "**Parties**."

WHEREAS, the Parties entered into that certain Termination and Settlement Agreement dated as of June 30, 2022 (the "**Termination Agreement**") pursuant to which the Parties terminated the Collaboration Agreements (as defined in the Termination Agreement);

WHEREAS, Section 4(d) of the Termination Agreement provided that Otsuka would complete the packaging validation activities set forth in Exhibit B attached to the Termination Agreement (such activities, the "**Packaging Validation Activities**"), at Otsuka's sole cost and expense, and that Otsuka would have no responsibility for serialization validation, stability testing, physical testing or any other Packaging activities other than as set forth in Exhibit B to the Termination Agreement;

WHEREAS, Section 4(d) of the Termination Agreement further provided that the Packaging Validation Activities would be considered complete upon delivery of a validation report prepared by the packaging vendor and that, following delivery of such report, all Packaging activities related to the Licensed Product would transfer to Akebia; and

WHEREAS, as of the Effective Date, the Packaging Validation Activities have not been completed and the Parties have agreed that, in consideration of the payments to be made by Otsuka as set forth herein, the responsibility for all remaining Packaging Validation Activities shall transfer from Otsuka to Akebia.

NOW THEREFORE, in consideration of the foregoing and the premises and conditions set forth herein, the Parties agree as follows:

1. **Defined Terms**. Capitalized terms that are used in this Agreement have the meanings set forth in the Termination Agreement or the Collaboration Agreements, as applicable to the context in which such terms are used herein, unless otherwise defined in this Agreement.

2. **Transfer of Responsibilities; Release**. From and after the Effective Date, Akebia shall bear all responsibility, including all costs, for all Packaging Validation Activities and Otsuka shall have no further responsibilities, obligations or Liabilities under Section 4(d) of the Termination Agreement. Akebia acknowledges and agrees that Otsuka's payment of the amounts set forth herein are in full satisfaction of Otsuka's obligations under Section 4(d) of the Termination Agreement. Notwithstanding any provision to the contrary set forth in herein or in Section 4(d) of the Termination Agreement, from and

after Akebia's receipt of all payments from Otsuka prescribed herein, Akebia, on behalf of itself and each of the other Akebia Releasors, does hereby now and forever release, remise, hold harmless and forever discharge Otsuka and the other Licensee Releasees of and from any and all Actions and Liabilities, whether known or unknown, suspected or unsuspected, based on any act, fact, transaction, matter, or cause arising from, under or otherwise in connection with the Packaging Validation Activities or Otsuka's responsibilities as set forth under Section 4(d) of the Termination Agreement.

3. **Payments**. In consideration of the transfer from Otsuka to Akebia of the responsibility for all Packaging Validation Activities, including all costs and expenses thereof, Otsuka agrees to pay to Akebia the following amounts:

   (a) Otsuka shall pay Akebia USD $[**], representing USD $[**] to cover third party costs and USD $[**] to cover internal, consulting and other expenses to complete the Packaging Validation Activities; and

   (b) Otsuka shall pay Akebia USD $[**], representing the cost to purchase additional Licensed Product for Packaging Validation Activities in replacement of Licensed Product that had been intended for such activities ("**Replacement Product**").

4. Payment Terms.

   (a) Within [**] after the Effective Date, Otsuka shall pay the amounts set forth in Sections 3(a) and 3(b), in the total amount of USD $[**], by wire transfer in accordance with the following wire instructions:

   Foreign Incoming Wires in USD
   Bank Name: [**]
   ABA #: [**] Swift: [**]

   Beneficiary:
   ABA #: [**] Swift: [**]
   Beneficiary: [**]
   Beneficiary Address: [**]
   Beneficiary Account #: [**]
   FFC Account Name: [**]
   FFC Account Number: [**].

   (b) The payment set forth in Section 3(a) is nonrefundable and non-creditable.

5. **Termination Agreement**. Except as expressly modified herein, all terms and conditions of the Termination Agreement shall remain in full force and effect. The Parties agree that the terms of Section 10(a) and Section 10(b) of the Termination Agreement apply to this Agreement, *mutatis mutandis*.

6. **Severability**. If any provision of this Agreement is declared invalid by a court of last resort or by any court or other governmental body from the decision of which an appeal is not taken within the time provided by law, then and in such event, this Agreement will be deemed to have been terminated only as to the portion thereof that relates to the provision

invalidated by that decision and only in the relevant jurisdiction, but this Agreement, in all other respects and all other jurisdictions, will remain in force.

7. **Governing Law**. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the Parties hereunder, will be construed under and governed by the laws of the state of New York, United States, exclusive of its conflicts of laws principles.

8. **English Language; Amendment**. This Agreement has been prepared in the English language and the English language will control its interpretation. All consents, notices, reports, and other written documents to be delivered or provided by a Party under this Agreement will be in the English language, and in the event of any conflict between the provisions of any document and the English language translation thereof, the terms of the English language translation will control. This Agreement may not be modified, or amended, except by an agreement in writing executed by the Parties

9. **Counterparts**. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. Each Party may execute this Agreement by electronically transmitted signatures, including in Adobe™ Portable Document Format (PDF) sent by electronic mail. PDF or other electronically transmitted signatures of authorized signatories of the Parties will be deemed to be original signatures, will be valid and binding upon the Parties, and, upon delivery, will constitute due execution of this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused their duly authorized representatives to sign this Agreement effective as of the Termination Effective Date.

AKEBIA THERAPEUTICS, INC.

By: /s/John Butler
Name: John Butler

Title: President & Chief Executive Officer

OTSUKA PHARMACEUTICAL CO., LTD.

By: /s/Keiso Yamasaki
Name: Keiso Yamasaki
Title: SVP, Associate General Manager (Pharmaceutical Division) and Head of Pharmaceutical Planning Dept.

[Signature Page to Packaging Validation Transfer Agreement]

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

Exhibit 10.4

[Akebia Letterhead]

May 3, 2023

By Email

[First Name Last Name]
[Address]

Dear [First Name Last Name]:

Upon your execution of this Amendment, the following amendments will be made to your Separation Agreement with Akebia Therapeutics, Inc. ("*Akebia*") dated May 5, 2022 (as previously amended, the "*Separation Agreement*")

A. Paragraph 1(ii) of the Separation Agreement shall be replaced in its entirety with the following:

(ii) Separation Date. Unless your employment is terminated by the Company for Cause or by you for Good Reason (as those terms are defined in your Executive Severance Agreement dated March 3, 2014, the "*ESA*"), you will remain employed until July 28, 2023; unless, [**], but in any event no later than January 26, 2024 (as applicable, the "*Separation Date*"). The Separation Date may be modified only upon mutual agreement between you and the Company.

B. Exhibit A of your Separation Agreement shall be replaced in its entirety with the Exhibit A in Appendix 1 attached hereto.

All other terms and conditions of the Separation Agreement shall remain in full force and effect.

Very truly yours,

AKEBIA THERAPEUTICS, INC.

John P. Butler
President and Chief Executive Officer

Accepted and Agreed to Under Seal:

[First Name Last Name]

Dated: _____, 2023

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

Exhibit 10.5

[Akebia Letterhead]

July 26, 2023

By Email

Michel Dahan
[Address]

Dear Michel:

Upon your execution of this Amendment, the following amendments will be made to your Separation Agreement with Akebia Therapeutics, Inc. ("*Akebia*") dated May 5, 2022 (as previously amended, the "*Separation Agreement*")

A. Paragraph 1(ii) of the Separation Agreement shall be replaced in its entirety with the following:

(ii) Separation Date. Unless your employment is terminated by the Company for Cause or by you for Good Reason (as those terms are defined in your Executive Severance Agreement dated March 3, 2014, the "*ESA*"), you will remain employed until March 22, 2024; unless, [**], but in any event no later than September 22, 2024 (as applicable, the "*Separation Date*"). The Separation Date may be modified only upon mutual agreement between you and the Company.

All other terms and conditions of the Separation Agreement shall remain in full force and effect.

Very truly yours,

AKEBIA THERAPEUTICS, INC.

/s/ John P. Butler

John P. Butler
President and Chief Executive Officer

Accepted and Agreed to Under Seal:

/s/ Michel Dahan

Michel Dahan

Dated: July 27, 2023

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

Exhibit 10.6

[Akebia Letterhead]

July 26, 2023

By Email

Nicole R. Hadas
[Address]

Dear Nikki:

Upon your execution of this Amendment, the following amendments will be made to your Separation Agreement with Akebia Therapeutics, Inc. ("*Akebia*") dated May 5, 2022 (as previously amended, the "*Separation Agreement*")

A. Paragraph 1(ii) of the Separation Agreement shall be replaced in its entirety with the following:

(ii) Separation Date. Unless your employment is terminated by the Company for Cause or by you for Good Reason (as those terms are defined in your Executive Severance Agreement dated March 3, 2014, the "*ESA*"), you will remain employed until October 6, 2023; unless, [**], but in any event no later than March 22, 2024 (as applicable, the "*Separation Date*"). The Separation Date may be modified only upon mutual agreement between you and the Company.

All other terms and conditions of the Separation Agreement shall remain in full force and effect.

Very truly yours,

AKEBIA THERAPEUTICS, INC.

/s/ John P. Butler

John P. Butler
President and Chief Executive Officer

Accepted and Agreed to Under Seal:

/s/ Nicole R. Hadas

Nicole R. Hadas

Dated: July 27, 2023

Exhibit 10.7

[Akebia Letterhead]

June 9, 2023

BY EMAIL

David Spellman

Dear Dave:

This letter agreement ("*Agreement*") confirms the terms of your separation from Akebia Therapeutics, Inc. ("*Akebia*" or the "*Company*").[1] Unless you rescind your assent as set forth in Section 5(viii) below, this Agreement shall be effective, final and binding upon the expiration of any applicable Revocation Period set forth in Section 5(viii) (the "*Effective Date*").

1. Separation Date; Final Payments; Benefits Cessation.

(i) Separation Date. Your employment with the Company shall terminate effective June 23, 2023 (the "*Separation Date*"). You agree that after the Separation Date, you will not represent yourself as an employee or agent of the Company.

(ii) Final Pay. On or about the Separation Date, the Company shall provide your final pay in accordance with applicable law ("*Final Pay*").

(iii) Benefits Cessation. As of the Separation Date, any entitlement you have or might have under a Company-provided benefit plan, program or practice shall terminate, except as required by law or under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("*COBRA*").

(iv) COBRA. Provided you timely complete the required election forms, you are eligible to continue receiving group medical, dental and/or vision insurance pursuant to COBRA. The "qualifying event" shall be deemed to have occurred on the Separation Date.

2. Consideration. In exchange for and in consideration of your executing this Agreement and complying with the terms of this Agreement and any other agreements between you and the Company, and as set forth in your Executive Severance Agreement with the Company dated June 29, 2020 (the "*ESA*"), the Company will do the following (the "*Consideration*"):

(i) continue paying your salary (less all applicable income and payroll taxes, deductions and withholdings) in accordance with its regular payroll cycle for twelve (12) months (the "*Severance Period*"), with the first payment beginning as soon as practicable after the Effective Date;

(ii) provided you remain eligible, pay that part of the COBRA premiums equivalent to the group insurance premiums it would have paid on your behalf had you remained employed by the Company during the Severance Period;

(iii) characterize your termination as a resignation for "Good Reason" (as defined in the ESA), and thereby not require you to repay any portion of the Signing Bonus as set forth in Exhibit A to your June 22, 2022 Retention Agreement (the "*Retention Agreement*"),

(iv) during the Severance Period, allow you to continue to vest in any other outstanding unvested options, restricted shares, restricted stock units or other equity-based awards in accordance with the terms of the applicable equity agreement(s) and plan(s); and

(v) forgive any obligation you otherwise would have to repay the Company for previously reimbursed tuition assistance or relocation expenses, and/or for any signing or similar bonus that is subject to repayment.

---

[1] Except for the obligations set forth in Section 2, which shall be the obligations solely of Akebia Therapeutics, Inc., whenever the terms "Akebia Therapeutics, Inc.," "Akebia" or the "Company" are used in this Agreement (including, without limitation, Section 5), they shall be deemed to include Akebia Therapeutics, Inc. and any and all of its divisions, affiliates and subsidiaries and all related entities, and its and their directors, officers, employees, agents, successors and assigns.

3. Acknowledgments. You acknowledge and agree that:

(i) this Agreement and the Consideration do not constitute a severance plan and shall confer no benefit on anyone other than Akebia and you;

(ii) the Consideration provided for herein is not otherwise due or owing to you unless you execute this Agreement;

(iii) except for the Final Pay, any amounts due under this Agreement and any vested monies due to you under any retirement programs in which you participate, you have been paid and provided all wages, vacation pay, holiday pay, earned paid sick time, bonuses (including, without limitation, any bonuses under the Retention Agreement), commissions, leaves of absence, family and medical leave, and any other form of compensation or benefit that may be due to you now or that would have become due in the future in connection with your employment with, or separation of employment from, Akebia; and

(iv) in order to be reimbursed for all outstanding business expenses that you may have incurred on behalf of the Company, all expense reports and supporting documentation must be submitted in accordance with the Company's *Travel & Expense Policy* within thirty (30) days after the Separation Date or such longer period as required by law.

4. Return of Company Property; Confidentiality; Trade Secrets; Non-Disparagement. As a condition of your receipt of the Consideration, you agree to:

(i) promptly return all property and documents (whether in hard copy or electronic form) of Akebia in your custody or possession;

(ii) abide by the terms of your Employee Agreement (confidentiality, non-solicitation, non-competition and/or developments agreement) with the Company. Without limiting the foregoing, consistent with Section 4(b) of the ESA, you agree that during the Non-Compete Period (as defined in the Employee Agreement), you will not, without the Company's prior written consent, directly or indirectly, take any of the actions described in Sections 5(a)(i) or 5(a)(ii) of the Employee Agreement. You understand that nothing in this Agreement prohibits you from reporting possible violations of federal law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal law or regulation. You understand that you do not need the prior authorization of the Company to make any such reports or disclosures and that you are not required to notify the Company that you have made such reports or disclosures;

(iii) abide by the Employee Agreement and any applicable common law and/or statutory obligations relating to the protection and non-disclosure of Akebia's trade secrets and/or confidential and proprietary documents and information, and you specifically agree that you will not disclose any confidential or proprietary information that you acquired as an employee of Akebia to any other person or entity, or use such information in any manner that is detrimental to the interests of Akebia. Further, notwithstanding your confidentiality and nondisclosure obligations, you are hereby advised as follows pursuant to the Defend Trade Secrets Act of 2016: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order";

(iv) keep confidential and not publicize or disclose the existence and terms of this Agreement, other than to (a) an immediate family member, legal counsel, accountant or financial advisor, provided that any such individual to whom disclosure is made aware of these confidentiality obligations; or (b) a state or federal tax authority or government agency to which disclosure is mandated by applicable state or federal law; and

(v) not make any statements (written or oral) that are false or disparaging about or adverse to the business interests of Akebia or that are intended to or do harm the reputation of Akebia, including, but not limited to, any statements that disparage any products, services, finances, employees, officers, directors, capabilities or any other aspect of the business of Akebia.

Your breach of this Section 4 will constitute a material breach of this Agreement and, in addition to any other legal or equitable remedy available to Akebia, will relieve Akebia of the obligation to provide any Consideration not already paid or provided and/or entitle Akebia to recover any Consideration already paid or provided.

5. Release of Claims.

(i) You hereby acknowledge and agree that by signing this Agreement and accepting the Consideration, you are waiving your right to assert any form of legal claim against Akebia (as defined in footnote number 1) of any kind whatsoever from the beginning of time through and including the Effective Date, except for claims related to the Company's failure to perform its obligations under this Agreement. Your waiver and release is intended to bar any form of legal claim, charge, complaint or any other form of action (jointly referred to as "*Claims*") against Akebia seeking any form of relief including, without limitation, equitable relief (whether declaratory, injunctive or otherwise), the recovery of any damages or any other form of monetary recovery whatsoever (including, without limitation, back pay, front pay, compensatory damages, emotional distress damages, punitive damages, attorneys' fees and any other costs) against Akebia up to and including the Effective Date. You understand that there could be unknown or unanticipated Claims resulting from your employment with Akebia and the termination thereof and agree that such Claims are intended to be, and are, included in this waiver and release.

(ii) Without limiting the foregoing general waiver and release, you specifically waive and release the Company from any Claims arising from or related to your employment relationship with the Company or the termination thereof, including without limitation:

(a) Claims under any local, state or federal discrimination, harassment, fair employment practices or other employment related statute, regulation or executive order, including, without limitation, the Massachusetts Fair Employment Practices Act (also known as Chapter 151B), the Pennsylvania Human Relations Act (43 P.S. § 951 *et seq.*), the New Jersey Law Against Discrimination (N.J.S.A. 10:5-1 *et seq.*), the New Jersey Conscientious Employee Protection Act (N.J.S.A. 34:19-1 *et seq.*), the Age Discrimination in Employment Act, the Older Workers Benefits Protection Act ("*OWBPA*"), the Americans with Disabilities Act, the Genetic Information Nondiscrimination Act, the Pregnancy Discrimination Act, the Worker Adjustment and Retraining Notification Act, the National Labor Relations Act, the Civil Rights Act of 1991, and Title VII of the Civil Rights Act of 1964, each as they may have been amended through the Effective Date;

(b) Claims under any local, state or federal employment related statute, regulation or executive order relating to wages, hours, whistleblowing, leaves of absence or any other terms and conditions of employment, including, without limitation, the Fair Labor Standards Act, the Equal Pay Act of 1963, the Family and Medical Leave Act, the Massachusetts Payment of Wages Law (Massachusetts General Laws Chapter 149, §§ 148, 150), Massachusetts General Laws Chapter 149 in its entirety and Massachusetts General Laws Chapter 151 in its entirety (including, without limitation, the sections concerning payment of wages, minimum wage and overtime), the New Jersey Family Leave Act (N.J.S.A. 34:11B-1 *et seq.*), the New Jersey Temporary Disability Leave Law (N.J.S.A. 43:21-25 *et seq.*), the New Jersey Equal Pay Act (N.J.S.A. 34:11-56.2 *et seq.*), the New Jersey Wage Payment Law (N.J.S.A. 34:11-4.1 *et seq.*), the New Jersey Wage and Hour Law (N.J.S.A. 34:11-56a *et seq.*), each as they may have been amended through the Effective Date. You specifically acknowledge that you are waiving any Claims for unpaid wages under these and other statutes, regulations and executive orders;

(c) Claims under any local, state or federal common law theory; and

(d) any other Claim arising under other local, state or federal law.

(iii) The general release in this Section 5 is not affected or limited by the recitation of the specific releases in this Section 5.

(iv) Consistent with federal and state discrimination laws, nothing in this release shall be deemed to prohibit you from challenging the validity of this release under federal or state discrimination laws or from filing a charge or complaint of age or other employment related discrimination with the Equal Employment Opportunity Commission ("*EEOC*") or similar state agency, or from participating in any investigation or proceeding conducted by the EEOC or similar state agency. Further, nothing in this release or Agreement shall be deemed to limit the Company's right to seek immediate dismissal of such charge or complaint on the basis that your signing of this Agreement constitutes a full release of any individual rights under federal or state discrimination laws, or the Company's right to seek restitution or other legal remedies to the extent permitted by law of the economic benefits provided to you under this Agreement in the event that you

successfully challenge the validity of this release and prevail in any claim under federal or state discrimination laws.

(v) The general release in this Section 5 shall not limit any right you may have to receive a whistleblower award or bounty for information provided to the Securities and Exchange Commission.

(vii) You have twenty (21) days to consider and accept the provisions of this Agreement. You agree that any changes to this Agreement, whether material or immaterial, will not restart the running of this 21-day period.

(viii) You may rescind your assent to this Agreement if, within seven (7) days after you sign it (the "*Revocation Period*")), you email a notice of rescission to Meredith Bowman at [**].

6. Cooperation.

(i) During the Severance Period, you agree to make yourself available to Akebia, upon reasonable notice (either by telephone, videoconference or, if Akebia believes necessary, in person) to assist Akebia in any matter relating to the services performed by you during your employment with Akebia including, but not limited to, transitioning your duties to others.

(ii) During the Severance Period and thereafter, you further agree to cooperate fully with Akebia in the defense or prosecution of any claims or actions now in existence or which may be brought or threatened in the future against or on behalf of Akebia or its successor(s), including any claim or action against its and their directors, officers and employees. Your cooperation in connection with such claims or actions shall include, without limitation, your being reasonably available (in a manner that does not unreasonably interfere with any employment obligations you may have) to speak or meet with Akebia to prepare for any proceeding, to provide truthful affidavits, to assist with any audit, inspection, proceeding or other inquiry, and to act as a witness in connection with any litigation or other legal proceeding affecting Akebia.

7. Miscellaneous.

(i) This Agreement supersedes any and all prior oral and/or written agreements (including, without limitation, the Retention Agreement and the ESA), and sets forth the entire agreement between Akebia and you with respect to your separation from Akebia, except for the Employee Agreement, which shall remain in full force and effect.

(ii) No variations or modifications of this Agreement shall be deemed valid unless in writing and signed by Akebia and you.

(iii) The provisions of this Agreement are severable, and if for any reason any part shall be found to be unenforceable, the remaining provisions shall be enforced in full.

(iv) Unless otherwise prohibited by law, the validity, interpretation and performance of this Agreement, and all other matters relating to your employment and separation of employment from Akebia, shall be governed by and construed in accordance with the internal laws of the Commonwealth of Massachusetts, without giving effect to conflict of law principles. Unless otherwise prohibited by law, both parties agree that any action, demand, claim or counterclaim relating to (a) your employment and separation of your employment, and (b) the terms and provisions of this Agreement or to its breach, shall be commenced in the Commonwealth of Massachusetts in a court of competent jurisdiction.

(v) Unless otherwise prohibited by law, both parties further agree that any such dispute shall be tried by a judge alone, and both parties hereby waive and forever renounce the right to a trial before a civil jury in any such dispute.

Akebia wants to ensure that you fully understand the terms and effects of this Agreement. To that end, you have been encouraged and given an opportunity to consult with legal counsel. By executing this Agreement, you are acknowledging that (a) you have been afforded sufficient time to understand this Agreement and consult with legal counsel; (b) your agreements and obligations under this Agreement are made voluntarily, knowingly and without duress; and (c) neither Akebia nor its agents or representatives have made any representations inconsistent with the provisions of this Agreement.

If the foregoing correctly sets forth our arrangement, please sign, date and return this Agreement to Meredith Bowman, [**], within the time frame set forth above.

Very truly yours,

AKEBIA THERAPEUTICS, INC.

/s/ John P. Butler
John P. Butler
President & CEO

Accepted and Agreed to Under Seal:

/s/ David Spellman
David Spellman

Dated: 20-Jun-2023

July 6, 2023

By Email

David Spellman

Dear Dave:

As discussed, we have agreed to amend your June 9, 2023 Separation Agreement (the "*Agreement*") with Akebia Therapeutics, Inc. (the "*Company*") to revise the Consideration in Section 2 of the agreement to add the following Section 2(vi):

> (vi) if a Change in Control (as defined in the ESA) occurs during the Severance Period, allow you to immediately vest in one hundred percent (100%) of any outstanding unvested options, restricted shares, restricted stock units or other equity-based awards in accordance with the terms of the applicable equity agreement(s) and plan(s);

All other terms and conditions of the Agreement shall remain in full force and effect.

Very truly yours,

AKEBIA THERAPEUTICS, INC.

/s/ John P. Butler
John P. Butler
President and Chief Executive Officer

Accepted and Agreed to Under Seal:

/s/ David Spellman
DAVID SPELLMAN

Dated: 08-Jul-2023

AKEBIA THERAPEUTICS, INC.
SECOND AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION PROGRAM

Effective June 6, 2023

Non-employee members of the Board of Directors (the "***Board***") of Akebia Therapeutics, Inc. (the "***Company***") shall be eligible to receive cash and equity compensation as set forth in this Second Amended and Restated Non-Employee Director Compensation Program (this "***Program***"). The cash and equity compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "***Non-Employee Director***") who is eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action of the Board. This Program shall be reviewed by the Board periodically and may be amended, modified or terminated by the Board at any time in its sole discretion and nothing herein should be construed as a guarantee to any Non-Employee Director of any particular level of cash or equity compensation. The terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors. This Program shall become effective on the date set forth above (the "***Effective Date***").

1. Cash Compensation.

(a) Annual Retainers. Each Non-Employee Director shall be eligible to receive an annual retainer of $45,000 for service on the Board.

(b) Additional Annual Retainers. In addition to the annual retainer payable pursuant to Section 1(a) above, a Non-Employee Director shall be eligible to receive the following annual retainers:

(i) Chairperson of the Board. A Non-Employee Director serving as Chairperson of the Board shall be eligible to receive an additional annual retainer of $35,000 for such service; provided, that, in the event that a Non-Employee Director is one of two concurrently serving Chairpersons of the Board, the additional annual retainer payable to such Non-Employee Director pursuant to this Section 1(b)(i) shall be $17,500.

(ii) Audit Committee. A Non-Employee Director serving as Chairperson of the Audit Committee of the Board (the "***Audit Committee***") shall be eligible to receive an additional annual retainer of $20,000 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson of the Audit Committee) shall be eligible to receive an additional annual retainer of $10,000 for such service.

(iii) Compensation Committee. A Non-Employee Director serving as Chairperson of the Compensation Committee of the Board (the "***Compensation Committee***") shall be eligible to receive an additional annual retainer of $15,000 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson of the Compensation Committee) shall be eligible to receive an additional annual retainer of $7,500 for such service.

(iv) Nominating and Corporate Governance Committee. A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee of the Board (the "***NCG Committee***") shall be eligible to receive an additional annual retainer of $10,000 for such service. A Non-Employee Director serving as a member of the NCG Committee (other than the Chairperson of the NCG Committee) shall be eligible to receive an additional annual retainer of $5,000 for such service.

(v) Research and Development Committee. A Non-Employee Director serving as Chairperson of the Research and Development Committee of the Board (the "***R&D Committee***") shall be eligible to receive an additional annual retainer of $10,000 for such service. A Non-Employee Director serving as a member of the R&D Committee (other than the Chairperson of the R&D Committee) shall be eligible to receive an additional annual retainer of $5,000 for such service.

(c) Payment of Retainers. The annual retainers described in Sections 1(a) and 1(b) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section 1(b), for an entire calendar quarter, the retainer paid to such Non-Employee Director shall be prorated for the portion of such calendar quarter actually served as a Non-Employee Director, or in such position, as applicable.

2. Equity Compensation. Non-Employee Directors shall be granted the equity awards described below. Each award described below shall be granted under and shall be subject to the terms and provisions of the Company's 2023 Stock Incentive Plan, as amended, or any other successor Company equity incentive plan under which awards are permitted to be made to Non-Employee Directors (the "***Equity Plan***") and (i) for option awards, a non-qualified stock option award agreement, including attached exhibits, in substantially the form of award agreement applicable to Non-Employee Directors most recently approved by the Board and/or the Compensation Committee, as applicable, and (ii) for restricted stock unit awards, a restricted stock unit award agreement, including attached exhibits, in substantially the form of award agreement applicable to Non-Employee Directors most recently approved by the Board and/or the Compensation Committee, as applicable. All applicable terms of the Equity Plan apply to this Program as if fully set forth herein. For the avoidance of doubt, if there is any conflict between the terms of the Equity Plan (including the applicable award agreements thereunder) and this Program, the Equity Plan (including the applicable award agreements thereunder) shall control.

(a) Initial Awards. Each Non-Employee Director who is initially elected or appointed to the Board after the Effective Date shall be eligible to receive, on the date of such initial election or appointment, an option to purchase 180,000 shares of the Company's common stock (subject to adjustment as provided in the Equity Plan). The awards described in this Section 2(a) shall be referred to as "***Initial Awards***." No Non-Employee Director shall be granted more than one Initial Award.

(b) Subsequent Awards. A Non-Employee Director who (i) has been serving on the Board for at least six months as of the date of any annual meeting of the Company's stockholders after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such meeting, shall be automatically granted, on the date of such annual meeting, an option to purchase 45,000 shares of the Company's common stock (subject to adjustment as provided in the Equity Plan) and 30,000 restricted stock units of the Company. The option awards described in this Section 2(b) shall be referred to as "***Subsequent Options***", the restricted stock unit awards described in this Section 2(b) shall be referred to as "***Subsequent RSUs***", and the Subsequent Options and Subsequent RSUs shall together be

referred to as the "***Subsequent Awards***." For the avoidance of doubt, a Non-Employee Director elected for the first time to the Board at an annual meeting of the Company's stockholders shall only receive an Initial Award in connection with such election, and shall not receive any Subsequent Awards on the date of such meeting as well.

(c) Termination of Service of Employee Directors. Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section 2(a) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Subsequent Awards as described in Section 2(b) above.

(d) Terms of Awards Granted to Non-Employee Directors.

(i) Purchase Price. The per share exercise price of each option granted to a Non-Employee Director shall equal the fair market value (as determined pursuant to the Equity Plan) of a share of the Company's common stock on the date the option is granted.

(ii) Vesting. Each Initial Award shall vest and become exercisable in accordance with the following schedule, subject to the Non-Employee Director remaining in continuous employment or other service relationship with the Company ("***Service***") through each such vesting date: 33 1/3% of the Initial Award shall vest on the one-year anniversary of the date of grant and 66 2/3% shall vest ratably on the first day of each calendar quarter between the one-year anniversary of the date of grant and the third anniversary of the date of grant. Each Subsequent Option shall vest and become exercisable in full on the first anniversary of the date of grant (or, if earlier, immediately prior to the first annual meeting of the Company's stockholders occurring after the date of grant), subject to the Non-Employee Director remaining in continuous Service through such vesting date. Each Subsequent RSU shall vest in full on the first anniversary of the date of grant (or, if earlier, immediately prior to the first annual meeting of the Company's stockholders occurring after the date of grant), subject to the Non-Employee Director remaining in continuous Service through such vesting date. Each Initial Award and Subsequent Award that is then-outstanding shall vest and become exercisable in full upon a change in control of the Company or termination of the Non-Employee Director's Service due to the Non-Employee Director's death or Disability. For purposes of the Program, "***Disability***" means Executive's inability by reason of physical or mental impairment to perform his/her job duties for a period exceeding twelve (12) consecutive weeks.

(iii) Term. The term of each option granted to a Non-Employee Director shall be ten (10) years from the date the option is granted.

3. Non-Employee Director Compensation Limit. Notwithstanding anything herein to the contrary, the cash compensation and equity compensation that each Non-Employee Director is entitled to receive under this Program shall be subject to any limits set forth in the applicable Equity Plan with respect to limits on awards to Non-Employee Directors.

4. Reimbursements. The Company shall reimburse each Non-Employee Director for all reasonable, documented, out-of-pocket travel and other business expenses incurred by such Non-Employee Director in the performance of such Non-Employee Director's duties to the Company in accordance with the Company's applicable expense reimbursement policies and procedures, as in effect from time to time. To the extent that any reimbursement under this Program provides for a deferral of compensation under Section 409A of the Internal Revenue Code of 1986, as amended: (a) the amount eligible for reimbursement in one calendar year may not affect the amount eligible for reimbursement in any other calendar year; (b) the right to

reimbursement is not subject to liquidation or exchange for another benefit; and (c) any such reimbursement of an expense must be made on or before the last day of the calendar year following the calendar year in which the expense was incurred.

AKEBIA THERAPEUTICS, INC.
STOCK OPTION AGREEMENT FOR NON-EMPLOYEE DIRECTORS
2023 STOCK INCENTIVE PLAN

Akebia Therapeutics, Inc. (the "Company") hereby grants the following stock option pursuant to its 2023 Stock Incentive Plan (the "Plan"). The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of optionee (the "Participant"):	
Grant Date:	
Incentive Stock Option or Nonstatutory Stock Option:	Nonstatutory Stock Option
Number of shares of the Company's Common Stock subject to this option ("Shares"):	
Option exercise price per Share:[1]	
Number, if any, of Shares that vest immediately on the Grant Date:	
Shares that are subject to vesting schedule:	
Vesting Start Date:	
Final Exercise Date: [2]	

Vesting Schedule:

[Insert Applicable Vesting Schedule]
All vesting is dependent on the Participant remaining an Eligible Participant, as provided herein.

This option satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

Akebia Therapeutics, Inc.

_____
Signature of Participant

_____
Street Address

_____
City/State/Zip Code

By:_____
Name of Officer
Title:

[1] This must be at least 100% of the Grant Date Fair Market Value (as defined in the Plan) of the Common Stock on the date of grant.
[2] The Final Exercise Date must be no more than 10 years from the date of grant. The correct approach to calculate the final exercise date is to use the day immediately prior to the date ten years out from the date of the stock option award grant.

Akebia Therapeutics, Inc.

Stock Option Agreement
Incorporated Terms and Conditions

1. Grant of Option.

This agreement evidences the grant by the Company, on the grant date (the "Grant Date") set forth in the Notice of Grant that forms part of this agreement (the "Notice of Grant"), to the Participant of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2023 Stock Incentive Plan (the "Plan"), the number of Shares set forth in the Notice of Grant of common stock, $0.00001 par value per share, of the Company ("Common Stock"), at the exercise price per Share set forth in the Notice of Grant. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the Final Exercise Date set forth in the Notice of Grant (the "Final Exercise Date").

The option evidenced by this agreement is not intended to be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

(a) General. This option will become exercisable ("vest") in accordance with the vesting schedule set forth in the Notice of Grant.

(b) Change in Control.

(1) Treatment of Option in a Change in Control. If, in connection with a Change in Control, this option is not assumed or continued, nor is a new award granted in substitution thereof in accordance with the provisions of Section 10 of the Plan, the option, to the extent outstanding immediately prior to such Change in Control but not then vested in full, shall automatically become fully vested and exercisable upon such Change in Control.

(2) Definitions.

(i) "Change in Control" means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company's securities: (A) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; (B) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (C) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or

by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (D) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (I) its sole purpose is to change the domicile of the Company's incorporation; or (II) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.

(ii) "Incumbent Directors" means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).

(c) Exercisability. The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, in the form of the Stock Option Exercise Notice attached as Annex A, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, or in such other form (which may be electronic) as is approved by the Company, together with payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share or for fewer than ten whole shares.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee, officer, or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in paragraphs (d) and (e) below, the right to exercise this option shall terminate six months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the restrictive covenants (including, without limitation, the non-competition, non-solicitation, or confidentiality provisions) of any employment contract, any non-competition, non-solicitation, confidentiality or assignment agreement to which the Participant is a party, or any other agreement between the

Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death. If the Participant dies prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death of the Participant, by an authorized transferee of the Participant, provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment, consulting, director or advisor relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination. If, prior to the Final Exercise Date, the Participant is given notice by the Company of the termination of his or her service by the Company for Cause, and the effective date of such termination is subsequent to the date of delivery of such notice, the right to exercise this option shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's service shall not be terminated for Cause as provided in such notice or (ii) the effective date of such termination (in which case the right to exercise this option shall, pursuant to the preceding sentence, terminate upon the effective date of such termination). If the Participant is subject to an Executive Severance Agreement or other written agreement with the Company, in any case which agreement contains a definition of "cause" for termination of service, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any fiduciary duty or of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

4. Tax Matters.

No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

5. Transfer Restrictions; Clawback.

(a) This option may not be sold, assigned, transferred, pledged, encumbered or otherwise disposed of by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

(b) In accepting this option, the Participant agrees to be bound by any clawback policy that the Company has in place or may adopt in the future.

6. Provisions of the Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is furnished to the Participant with this option.

ANNEX A

Akebia Therapeutics, Inc.

Stock Option Exercise Notice

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142

Dear Sir or Madam:

I, _____(the "Participant"), hereby irrevocably exercise the right to purchase ____ shares of the Common Stock, $0.00001 par value per share (the "Shares"), of Akebia Therapeutics, Inc. (the "Company") at $___per share pursuant to the Company's 2023 Stock Incentive Plan and a stock option agreement with the Company dated __ (the "Option Agreement"). Enclosed herewith is a payment of $____, the aggregate purchase price for the Shares. The Shares should be registered in my name as it appears below or, if so indicated below, jointly in my name and the name of the person designated below, with right of survivorship.

Dated: _____

_____
Signature
Print Name:

Address:
_____
_____

Name and address of persons in whose name the Shares are to be jointly registered (if applicable):

_____

AKEBIA THERAPEUTICS, INC.
STOCK OPTION AGREEMENT FOR OFFICERS
2023 STOCK INCENTIVE PLAN

Akebia Therapeutics, Inc. (the "Company") hereby grants the following stock option pursuant to its 2023 Stock Incentive Plan (the "Plan"). The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of optionee (the "Participant"):	
Grant Date:	
Incentive Stock Option or Nonstatutory Stock Option:	
Number of shares of the Company's Common Stock subject to this option ("Shares"):	
Option exercise price per Share:[1]	
Number, if any, of Shares that vest immediately on the grant date:	
Shares that are subject to vesting schedule:	
Vesting Start Date:	
Final Exercise Date: [2]	

Vesting Schedule:

Vesting Date:	Number of Options that Vest:
All vesting is dependent on the Participant remaining an Eligible Participant, as provided herein.	

This option satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

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[1] This must be at least 100% of the Grant Date Fair Market Value (as defined in the Plan) of the Common Stock on the date of grant (110% in the case of a Participant that owns more than 10% of the total combined voting power of all classes of stock of the Company or its parent or subsidiary (a "10% Shareholder") when the option is intended to qualify as an incentive stock option (an "ISO") under Section 422 of the Internal Revenue Code).

[2] The Final Exercise Date must be no more than 10 years (5 years in the case of a 10% Shareholder for an option intended to qualify as an ISO) from the date of grant. The correct approach to calculate the final exercise date is to use the day immediately prior to the date ten years out from the date of the stock option award grant (or 5 years, as applicable).

Akebia Therapeutics, Inc.

_____
Signature of Participant

_____
Street Address

_____
City/State/Zip Code

By:_____
Name of Officer
Title:

Akebia Therapeutics, Inc.

Stock Option Agreement for Officers
Incorporated Terms and Conditions

1. Grant of Option.

This agreement evidences the grant by the Company, on the grant date (the "Grant Date") set forth in the Notice of Grant that forms part of this agreement (the "Notice of Grant"), to the Participant of an option to purchase, in whole or in part, on the terms provided herein and in the Company's 2023 Stock Incentive Plan (the "Plan"), the number of Shares set forth in the Notice of Grant of common stock, $0.00001 par value per share, of the Company ("Common Stock"), at the exercise price per Share set forth in the Notice of Grant. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the Final Exercise Date set forth in the Notice of Grant (the "Final Exercise Date").

The option evidenced by this agreement is intended to be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code") to the maximum extent permitted by law, solely to the extent designated as an incentive stock option in the Notice of Grant. Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

(a) General. Subject to this Agreement and the terms of any Executive Severance Agreement or other written agreement between the Participant and the Company, this option will become exercisable ("vest") in accordance with the vesting schedule set forth in the Notice of Grant.

(b) Change in Control.

(1) Treatment of Option in a Change in Control. The option, to the extent outstanding immediately prior to a Change in Control but not then vested in full, shall automatically become fully vested and exercisable upon such Change in Control.

(2) Definitions.

(i) "Change in Control" means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company's securities: (A) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; (B) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (C) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately

prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (D) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (I) its sole purpose is to change the domicile of the Company's incorporation; or (II) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.

(ii) "Incumbent Directors" means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).

(c) Exercisability. The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, in the form of the Stock Option Exercise Notice attached as Annex A, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, or in such other form (which may be electronic) as is approved by the Company, together with payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share or for fewer than ten whole shares.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee, officer, or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in this paragraph or in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation; and, provided, further, that to the extent the Participant is a party to an Executive Severance Agreement or other written agreement with the Company that provides for the option to remain outstanding and continue to vest during a specified period of time following the Participant's cessation of status as an Eligible Participant (such period, the "Severance

Period"), the option shall remain outstanding and shall continue to vest in accordance with the terms of this Agreement during the Severance Period as if the Participant had remained an Eligible Participant during such period, subject to any conditions on continued vesting as may be contained in such Executive Severance Agreement or other written agreement. Any portion of this option that vests during such Severance Period will remain exercisable until the earlier of (A) the date that is three (3) months following the date that is the last day of such Severance Period, or (B) the Final Exercise Date, and except to the extent previously exercised as permitted by this Section 3(c) will thereupon immediately terminate. For the avoidance of doubt, any portion of the option that fails to vest during the Severance Period will immediately be forfeited on the last day of such period. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the restrictive covenants (including, without limitation, the non-competition, non-solicitation, or confidentiality provisions) of any employment contract, any non-competition, non-solicitation, confidentiality or assignment agreement to which the Participant is a party, or any other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death. If the Participant dies prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death of the Participant, by an authorized transferee of the Participant, provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment, consulting, director or advisor relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination. If, prior to the Final Exercise Date, the Participant is given notice by the Company of the termination of his or her service by the Company for Cause, and the effective date of such termination is subsequent to the date of delivery of such notice, the right to exercise this option shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's service shall not be terminated for Cause as provided in such notice or (ii) the effective date of such termination (in which case the right to exercise this option shall, pursuant to the preceding sentence, terminate upon the effective date of such termination). If the Participant is a party to an Executive Severance Agreement or other written agreement with the Company, in any case which agreement contains a definition of "cause" for termination of service, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any fiduciary duty or of any provision of any employment, consulting, advisory, nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

4. Tax Matters.

(a) Withholding. No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

(b) Disqualifying Disposition. If this option is an incentive stock option and the Participant disposes of Shares acquired upon exercise of this option within two years from the Grant Date or one year after such Shares were acquired pursuant to exercise of this option, the Participant shall notify the Company in writing of such disposition.

5. Transfer Restrictions; Clawback.

(a) This option may not be sold, assigned, transferred, pledged, encumbered or otherwise disposed of by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

(b) In accepting this option, the Participant agrees to be bound by any clawback policy that the Company has in place or may adopt in the future.

6. Provisions of the Plan.

This option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is furnished to the Participant with this option. Notwithstanding the foregoing, to the extent the Participant has entered in to an Executive Severance Agreement with the Company, for so long as such Executive Severance Agreement remains in effect, the terms of such Executive Severance Agreement as they relate to the option shall control in the event of a conflict with this Agreement or the Plan.

ANNEX A

Akebia Therapeutics, Inc.

Stock Option Exercise Notice

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142

Dear Sir or Madam:

I, _____(the "Participant"), hereby irrevocably exercise the right to purchase ____ shares of the Common Stock, $0.00001 par value per share (the "Shares"), of Akebia Therapeutics, Inc. (the "Company") at $___per share pursuant to the Company's 2023 Stock Incentive Plan and a stock option agreement with the Company dated __ (the "Option Agreement"). Enclosed herewith is a payment of $____, the aggregate purchase price for the Shares. The Shares should be registered in my name as it appears below or, if so indicated below, jointly in my name and the name of the person designated below, with right of survivorship.

Dated: _____

_____
Signature
Print Name:

Address:
_____
_____

Name and address of persons in whose name the Shares are to be jointly registered (if applicable):

_____

AKEBIA THERAPEUTICS, INC.
RESTRICTED STOCK UNIT AGREEMENT FOR NON-EMPLOYEE DIRECTORS
2023 STOCK INCENTIVE PLAN

Akebia Therapeutics, Inc. (the "Company") hereby grants the following restricted stock units pursuant to its 2023 Stock Incentive Plan (the "Plan"). The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of recipient (the "Participant"):	
Grant Date:	
Number of restricted stock units ("RSUs") granted:	
Vesting Start Date:	

Vesting Schedule:

Vesting Date:	Number of RSUs that Vest:
All vesting is dependent on the Participant remaining an Eligible Participant, as provided herein.	

This grant of RSUs satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

Akebia Therapeutics, Inc.

_____
Signature of Participant

_____
Street Address

_____
City/State/Zip Code

By:_____
Name of Officer
Title:

Akebia Therapeutics, Inc.

Restricted Stock Unit Agreement for Non-Employee Directors
Incorporated Terms and Conditions

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Award of Restricted Stock Units.

The Company has granted to the Participant, subject to the terms and conditions set forth in this Restricted Stock Unit Agreement (this "Agreement") and in the Company's 2023 Stock Incentive Plan (the "Plan"), an award with respect to the number of RSUs set forth in the Notice of Grant that forms part of this Agreement (the "Notice of Grant"). Each RSU represents the right to receive one share of common stock, $0.00001 par value per share, of the Company (the "Common Stock") upon vesting of the RSU, subject to the terms and conditions set forth herein.

2. Vesting; Delivery.

(a) Vesting. The RSUs shall vest in accordance with the Vesting Schedule set forth in the Notice of Grant (the "Vesting Schedule"). Any fractional shares resulting from the application of any percentages used in the Vesting Schedule shall be rounded down to the nearest whole number of RSUs.

(b) Change in Control.

(1) Treatment of RSUs in a Change in Control. If, in connection with a Change in Control, this RSUs are not assumed or continued, nor is a new award granted in substitution thereof in accordance with the provisions of Section 10 of the Plan, the RSUs, to the extent outstanding immediately prior to such Change in Control but not then vested in full, shall automatically become fully vested and exercisable upon such Change in Control.

(2) Definitions.

(i) "Change in Control" means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company's securities: (A) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; (B) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (C) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the

voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (D) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (I) its sole purpose is to change the domicile of the Company's incorporation; or (II) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.

(ii) "Incumbent Directors" means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).

(c) Delivery. Upon the vesting of the RSU, the Company will deliver to the Participant, for each RSU that becomes vested, one share of Common Stock, subject to the payment of any taxes pursuant to Section 7. The Common Stock will be delivered to the Participant as soon as practicable following each vesting date, but in any event within 30 days of such date.

3. Forfeiture of Unvested RSUs Upon Cessation of Service.

In the event that the Participant ceases to be an employee, officer, or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive awards under the Plan (an "Eligible Participant") for any reason or no reason, with or without cause, all of the RSUs that are unvested as of the time of such cessation shall be forfeited immediately and automatically to the Company, without the payment of any consideration to the Participant, effective as of such cessation. The Participant shall have no further rights with respect to the unvested RSUs or any Common Stock that may have been issuable with respect thereto. If the Participant provides services to a subsidiary of the Company, any references in this Agreement to provision of services to the Company shall instead be deemed to refer to service with such subsidiary.

4. Restrictions on Transfer.

The Participant shall not sell, assign, transfer, pledge, hypothecate, encumber or otherwise dispose of, by operation of law or otherwise (collectively "transfer") any RSUs, or any interest therein. The Company shall not be required to treat as the owner of any RSUs or issue any Common Stock to any transferee to whom such RSUs have been transferred in violation of any of the provisions of this Agreement.

5. Rights as a Stockholder.

The Participant shall have no rights as a stockholder of the Company with respect to any shares of Common Stock that may be issuable with respect to the RSUs until the issuance of the shares of Common Stock to the Participant following the vesting of the RSUs.

6. Provisions of the Plan.

This Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Agreement.

7. Tax Matters.

(a) Acknowledgments; No Section 83(b) Election. The Participant acknowledges that he or she is responsible for obtaining the advice of the Participant's own tax advisors with respect to the award of RSUs and the Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating to the RSUs. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's tax liability that may arise in connection with the acquisition, vesting and/or disposition of the RSUs. The Participant acknowledges that no election under Section 83(b) of the Internal Revenue Code of 1986, as amended (the "Code"), is available with respect to RSUs.

(b) Withholding. The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state, local or other taxes of any kind required by law to be withheld with respect to the vesting of the RSUs. The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

8. Miscellaneous.

(a) No Right to Continued Service. The Participant acknowledges and agrees that, notwithstanding the fact that the vesting of the RSUs is contingent upon his or her continued service to the Company, this Agreement does not constitute an express or implied promise of continued service relationship with the Participant or confer upon the Participant any rights with respect to a continued service relationship with the Company or any affiliate of the Company.

(b) Section 409A. The RSUs awarded pursuant to this Agreement are intended to be exempt from or comply with the requirements of Section 409A of the Code and the Treasury Regulations issued thereunder ("Section 409A"). The delivery of shares of Common Stock on the vesting of the RSUs may not be accelerated or deferred unless permitted or required by Section 409A.

(c) Participant's Acknowledgments. The Participant acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; (iv) is agreeing, in accepting this award, to be bound by any clawback policy that the Company has in place or may adopt in the future; and (v) is fully aware of the legal and binding effect of this Agreement.

(d) Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflicts of laws provisions.

AKEBIA THERAPEUTICS, INC.
RESTRICTED STOCK UNIT AGREEMENT FOR OFFICERS
2023 STOCK INCENTIVE PLAN

Akebia Therapeutics, Inc. (the "Company") hereby grants the following restricted stock units pursuant to its 2023 Stock Incentive Plan (the "Plan"). The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of recipient (the "Participant"):	
Grant Date:	
Number of restricted stock units ("RSUs") granted:	
Vesting Start Date:	

Vesting Schedule:

Vesting Date:	Number of RSUs that Vest:
All vesting is dependent on the Participant remaining an Eligible Participant, as provided herein.	

This grant of RSUs satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

Akebia Therapeutics, Inc.

_____
Signature of Participant

_____
Street Address

_____
City/State/Zip Code

By:_____
Name of Officer
Title:

Akebia Therapeutics, Inc.

Restricted Stock Unit Agreement for Officers
Incorporated Terms and Conditions

For valuable consideration, receipt of which is acknowledged, the parties hereto agree as follows:

1. Award of Restricted Stock Units.

The Company has granted to the Participant, subject to the terms and conditions set forth in this Restricted Stock Unit Agreement (this "Agreement") and in the Company's 2023 Stock Incentive Plan (the "Plan"), an award with respect to the number of RSUs set forth in the Notice of Grant that forms part of this Agreement (the "Notice of Grant"). Each RSU represents the right to receive one share of common stock, $0.00001 par value per share, of the Company (the "Common Stock") upon vesting of the RSU, subject to the terms and conditions set forth herein.

2. Vesting; Delivery.

(a) General. The RSUs shall vest in accordance with the Vesting Schedule set forth in the Notice of Grant (the "Vesting Schedule"), subject to the terms of any Executive Severance Agreement or other written agreement between the Participant and the Company. Any fractional shares resulting from the application of any percentages used in the Vesting Schedule shall be rounded down to the nearest whole number of RSUs.

(b) Change in Control.

i. Treatment of RSUs in a Change in Control. The RSUs, to the extent outstanding immediately prior to a Change in Control but not then vested in full, will automatically and immediately become fully vested upon such Change in Control.

ii. Definitions.

(A) "Change in Control" means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company's securities: (A) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; (B) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (C) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more

than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (D) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (I) its sole purpose is to change the domicile of the Company's incorporation; or (II) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.

(B) "Incumbent Directors" means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).

(c) Delivery. Upon the vesting of the RSU, the Company will deliver to the Participant, for each RSU that becomes vested, one share of Common Stock, subject to the payment of any taxes pursuant to Section 7. The Common Stock will be delivered to the Participant as soon as practicable following each vesting date, but in any event within 30 days of such date.

3. Forfeiture of Unvested RSUs Upon Cessation of Service.

In the event that the Participant ceases to be an employee, officer, or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive awards under the Plan (an "Eligible Participant") for any reason or no reason, with or without cause, all of the RSUs that are unvested as of the time of such cessation shall be forfeited immediately and automatically to the Company, without the payment of any consideration to the Participant, effective as of such cessation. The Participant shall have no further rights with respect to the unvested RSUs or any Common Stock that may have been issuable with respect thereto. If the Participant provides services to a subsidiary of the Company, any references in this Agreement to provision of services to the Company shall instead be deemed to refer to service with such subsidiary.

Notwithstanding the foregoing, to the extent the Participant is a party to an Executive Severance Agreement or other written employment agreement with the Company that provides for the RSUs to remain outstanding and continue to vest during a specified period of time following Participant's cessation of status as an Eligible Participant (such period, the "Severance Period"), the RSUs will remain outstanding and will continue to vest, and the Shares will be delivered upon such vesting, in accordance with the terms of this Agreement during the Severance Period as if the Participant had continued to be an Eligible Participant during such period, subject to any conditions on the vesting and delivery as may be contained in such Executive Severance Agreement or other written agreement. For the avoidance of doubt, any portion of the RSUs that fails to vest during the Severance Period will immediately be forfeited on the last day of such period.

4. Restrictions on Transfer.

The Participant shall not sell, assign, transfer, pledge, hypothecate, encumber or otherwise dispose of, by operation of law or otherwise (collectively "transfer") any RSUs, or any interest therein. The Company shall not be required to treat as the owner of any RSUs or issue any Common Stock to any transferee to whom such RSUs have been transferred in violation of any of the provisions of this Agreement.

5. Rights as a Stockholder.

The Participant shall have no rights as a stockholder of the Company with respect to any shares of Common Stock that may be issuable with respect to the RSUs until the issuance of the shares of Common Stock to the Participant following the vesting of the RSUs.

6. Provisions of the Plan.

This Agreement is subject to the provisions of the Plan, a copy of which is furnished to the Participant with this Agreement.

7. Tax Matters.

(a) Acknowledgments; No Section 83(b) Election. The Participant acknowledges that he or she is responsible for obtaining the advice of the Participant's own tax advisors with respect to the award of RSUs and the Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents with respect to the tax consequences relating to the RSUs. The Participant understands that the Participant (and not the Company) shall be responsible for the Participant's tax liability that may arise in connection with the acquisition, vesting and/or disposition of the RSUs. The Participant acknowledges that no election under Section 83(b) of the Internal Revenue Code of 1986, as amended (the "Code"), is available with respect to RSUs.

(b) Withholding. The Participant acknowledges and agrees that the Company has the right to deduct from payments of any kind otherwise due to the Participant any federal, state, local or other taxes of any kind required by law to be withheld with respect to the vesting of the RSUs. At such time as the Participant is not aware of any material nonpublic information about the Company or the Common Stock and is not prohibited from doing so by the Company's insider trading policy or otherwise, the Participant shall execute the instructions set forth in Schedule A attached hereto (the "Durable Automatic Sell-to-Cover Instruction") as the means of satisfying such tax obligation unless the Participant has already executed such instruction, as determined by the Company. If the Participant does not execute the Durable Automatic Sell-to-Cover Instruction prior to an applicable vesting date, then the Participant agrees that if under applicable law the Participant will owe taxes at such vesting date on the portion of the award then vested the Company shall be entitled to immediate payment from the Participant of the amount of any tax required to be withheld by the Company. The Company shall not deliver any shares of Common Stock to the Participant until it is satisfied that all required withholdings have been made.

8. Miscellaneous.

(a) No Right to Continued Service. The Participant acknowledges and agrees that, notwithstanding the fact that the vesting of the RSUs is contingent upon his or her continued service to the Company, this Agreement does not constitute an express or implied promise of continued service relationship with the Participant or confer upon the Participant any rights with respect to a continued service relationship with the Company or any affiliate of the Company.

(b) Section 409A. The RSUs awarded pursuant to this Agreement are intended to be exempt from or comply with the requirements of Section 409A of the Code and the Treasury Regulations issued thereunder ("Section 409A"). The delivery of shares of Common Stock on the vesting of the RSUs may not be accelerated or deferred unless permitted or required by Section 409A.

(c) Participant's Acknowledgments. The Participant acknowledges that he or she: (i) has read this Agreement; (ii) has been represented in the preparation, negotiation and execution of this Agreement by legal counsel of the Participant's own choice or has voluntarily declined to seek such counsel; (iii) understands the terms and consequences of this Agreement; (iv) is agreeing, in accepting this award, to be bound by any clawback policy that the Company has in place or may adopt in the future; and (v) is fully aware of the legal and binding effect of this Agreement.

(d) Governing Law. This Agreement shall be construed, interpreted and enforced in accordance with the internal laws of the State of Delaware without regard to any applicable conflicts of laws provisions.

Schedule A

Durable Automatic Sell-to-Cover Instruction

This Durable Automatic Sell-to-Cover Instruction (this "Instruction"), which is being delivered to Akebia Therapeutics, Inc. (the "Company") by the undersigned on the date set forth below (the "Adoption Date"), relates to the Covered RSUs (as defined following my signature below). This Instruction provides for "eligible sell-to-cover transactions" (as described in Rule 10b5-1(c)(1)(ii)(D)(3) under the Securities Exchange Act of 1934 (the "Exchange Act")) and is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c)(1) under the Exchange Act.

I acknowledge that upon vesting and settlement of any Covered RSUs in accordance with the applicable RSU's terms, whether vesting is based on the passage of time or the achievement of performance goals, I will have compensation income equal to the fair market value of the shares of the Company's common stock subject to the RSUs that are settled on such settlement date and that the Company is required to withhold income and employment taxes in respect of that compensation income.

I desire to establish a plan and process to satisfy such withholding obligation in respect of all Covered RSUs through an automatic sale of a portion of the shares of the Company's common stock that would otherwise be issuable to me on each applicable settlement date, such portion to be in an amount sufficient to satisfy such withholding obligation, with the proceeds of such sale delivered to the Company in satisfaction of such withholding obligation.

I understand that the Company has arranged for the administration and execution of its equity incentive programs and the sale of securities by participants thereunder pursuant to a platform administered by a third party (the "Administrator") and the Administrator's designated brokerage partner.

Upon the settlement of any of my Covered RSUs after the 30th day following the Adoption Date (or if I am an officer of the Company on the Adoption Date, after the 120th day following the Adoption Date), I hereby appoint the Administrator (or any successor administrator) to automatically sell such number of shares of the Company's common stock issuable with respect to such RSUs that vested and settled as is sufficient to generate net proceeds sufficient to satisfy the Company's minimum statutory withholding obligations with respect to the income recognized by me in connection with the vesting and settlement of such RSUs (based on minimum statutory withholding rates for all tax purposes, including payroll and social security taxes, that are applicable to such income), and the Company shall receive such net proceeds in satisfaction of such tax withholding obligation.

I hereby appoint the Chief Executive Officer, Chief Financial Officer, General Counsel and Secretary of the Company to serve as my attorneys in fact to arrange for the sale of shares of the Company's common stock in accordance with this Instruction. I agree to execute and deliver such documents, instruments and certificates as may reasonably be required in connection with the sale of the shares of common stock pursuant to this Instruction.

Unless the last box in the definition of Covered RSUs below is checked, if I have previously adopted an automatic sale or sell-to-cover instruction relating to Covered RSUs, this Instruction shall be void *ab initio*.

I hereby certify that, as of the Adoption Date:

(i) I am not prohibited from entering into this Instruction by the Company's insider trading policy or otherwise;

(ii) I am not aware of any material nonpublic information about the Company or its common stock; and

(iii) I am adopting this Instruction in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5 under the Exchange Act.

_____

Print Name: _____

Date: _____

Covered RSUs:
The following restricted stock units ("RSUs") are covered by this Instruction.

Check all applicable boxes:

The first award of RSUs granted to me on or after _____ [*insert date of grant of current RSUs the grant of which is triggering the execution of this Instruction; if Instruction is being executed in advance of a grant of RSUs, insert the Adoption Date*] and any RSUs that may, from time to time following such date, be granted to me by the Company, other than any future granted RSUs which by the terms of the applicable award agreement require the Company to withhold shares for tax withholding obligations in connection with the vesting and settlement of such RSUs, and therefore do not permit sell-to-cover transactions.

Any outstanding RSUs that were granted to me by the Company prior to the Adoption Date that (1) are not subject to any prior automatic sale or sell-to-cover instruction and (2) for which the next vesting date is after the cooling-off period referred to above, other than any previously granted RSUs which by the terms of the applicable award agreement require the Company to withhold shares for tax withholding obligations in connection with the vesting and settlement of such RSUs, and therefore do not permit sell-to-cover transactions.

With respect to any RSUs, whether or not granted to me by the Company prior to the Adoption Date, that already are subject to an automatic sale or sell-to-cover instruction (a "Prior Instruction"), I elect to have such sales effected pursuant to this Instruction and confirm that doing so does not modify or change the amount, price, or timing of such sales from those provided by the Prior Instruction (and, as a result the cooling-off period referred to above is not applicable to sales pursuant to this Instruction that were previously subject to the Prior Instruction).

AKEBIA THERAPEUTICS, INC.
OFFICER INDUCEMENT AWARD
STOCK OPTION AGREEMENT

Akebia Therapeutics, Inc. (the "Company") hereby grants the following inducement non-statutory stock option award. The terms and conditions attached hereto are also a part hereof.

Notice of Grant

Name of optionee (the "Participant"):	
Grant Date:	
Number of shares of the Company's Common Stock subject to this option ("Shares"):	
Option exercise price per Share:[1]	
Number, if any, of Shares that vest immediately on the grant date:	
Shares that are subject to vesting schedule:	
Vesting Start Date:	
Final Exercise Date: [2]	

Vesting Schedule:

Vesting Date:	Number of Options that Vest:
All vesting is dependent on the Participant remaining an Eligible Participant, as provided herein.	

This option satisfies in full all commitments that the Company has to the Participant with respect to the issuance of stock, stock options or other equity securities.

Akebia Therapeutics, Inc.

_____
Signature of Participant

_____
Street Address

_____
City/State/Zip Code

By:_____
Name of Officer
Title:

[1] This must be at least 100% of the Grant Date Fair Market Value (as defined in the Plan) of the Common Stock on the date of grant.
[2] The Final Exercise Date must be no more than 10 years from the date of grant. The correct approach to calculate the final exercise date is to use the day immediately prior to the date ten years out from the date of the stock option award grant.

Akebia Therapeutics, Inc.

Officer Inducement Award
Non-Statutory Stock Option Agreement

Incorporated Terms and Conditions

1. Grant of Option.

This agreement evidences the grant by the Company, on the grant date (the "Grant Date") set forth in the Notice of Grant that forms part of this agreement (the "Notice of Grant"), to the Participant of an option to purchase, in whole or in part, on the terms provided herein, the number of Shares set forth in the Notice of Grant of common stock, $0.00001 par value per share, of the Company ("Common Stock"), at the exercise price per Share set forth in the Notice of Grant. Unless earlier terminated, this option shall expire at 5:00 p.m., Eastern time, on the Final Exercise Date set forth in the Notice of Grant (the "Final Exercise Date").

The option evidenced by this agreement is being granted to the Participant pursuant to the inducement grant exception under Nasdaq Stock Market Rule 5635(c)(4) as an inducement that is material to the Participant's employment with the Company, and not pursuant to the Company's 2023 Stock Incentive Plan (the "Plan"), or any equity incentive plan of the Company. Notwithstanding the foregoing, the option shall be subject to, and governed by, and shall be construed and administered in accordance with, the terms of the Plan, which terms and conditions are incorporated herein by reference, but any shares of Common Stock issued hereunder shall not reduce the number of shares of Common Stock available under the Plan.

The option evidenced by this agreement is not intended to be an incentive stock option as defined in Section 422 of the Internal Revenue Code of 1986, as amended, and any regulations promulgated thereunder (the "Code"). Except as otherwise indicated by the context, the term "Participant", as used in this option, shall be deemed to include any person who acquires the right to exercise this option validly under its terms.

2. Vesting Schedule.

(a) General. Subject to this Agreement and the terms of any Executive Severance Agreement or other written agreement between the Participant and the Company, this option will become exercisable ("vest") in accordance with the vesting schedule set forth in the Notice of Grant.

(b) Change in Control.

(1) Treatment of Option in a Change in Control. The option, to the extent outstanding immediately prior to a Change in Control but not then vested in full, shall automatically become fully vested and exercisable upon such Change in Control.

(2) Definitions.

(i) "Change in Control" means the occurrence of any of the following events other than in connection with the consummation of an initial public offering of the Company's securities: (A) any "person" (as such term is used in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934,

as amended) who is not a shareholder of the Company as of the date of this Agreement or an affiliate thereof is or becomes the "beneficial owner" (as defined in Rule 13d-3 under said Act), directly or indirectly, of securities of the Company representing 50% or more of the total voting power represented by the Company's then outstanding voting securities; (B) a change in the composition of the Board occurring within a two-year period, as a result of which less than a majority of the directors are Incumbent Directors; (C) the date of the consummation of a merger, scheme of arrangement or consolidation of the Company with any other corporation that has been approved by the stockholders of the Company, other than a merger, scheme of arrangement or consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity outstanding immediately after such merger or consolidation; or (D) the date of the consummation of the sale or disposition by the Company of all or substantially all the Company's assets. Notwithstanding the foregoing, a transaction will not constitute a Change in Control if: (I) its sole purpose is to change the domicile of the Company's incorporation; or (II) its sole purpose is to create a holding company that will be owned in substantially the same proportions by the persons who held the Company's securities immediately before such transaction. In all respects, the definition of Change in Control shall be interpreted to comply with Section 409A of the Code, and any successor statute, regulation and guidance thereto.

(ii) "Incumbent Directors" means directors who either (A) are directors of the Company as of the date hereof, or (B) are elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the remaining Incumbent Directors at the time of such election or nomination (but will not include an individual whose election or nomination is in connection with an actual or threatened proxy contest relating to the election of directors to the Company).

(c) Exercisability. The right of exercise shall be cumulative so that to the extent the option is not exercised in any period to the maximum extent permissible it shall continue to be exercisable, in whole or in part, with respect to all Shares for which it is vested until the earlier of the Final Exercise Date or the termination of this option under Section 3 hereof or the Plan.

3. Exercise of Option.

(a) Form of Exercise. Each election to exercise this option shall be in writing, in the form of the Stock Option Exercise Notice attached as Annex A, signed by the Participant, and received by the Company at its principal office, accompanied by this agreement, or in such other form (which may be electronic) as is approved by the Company, together with payment in full in the manner provided in the Plan. The Participant may purchase less than the number of shares covered hereby, provided that no partial exercise of this option may be for any fractional share or for fewer than ten whole shares.

(b) Continuous Relationship with the Company Required. Except as otherwise provided in this Section 3, this option may not be exercised unless the Participant, at the time he or she exercises this option, is, and has been at all times since the Grant Date, an employee,

officer, or director of, or consultant or advisor to, the Company or any other entity the employees, officers, directors, consultants, or advisors of which are eligible to receive option grants under the Plan (an "Eligible Participant").

(c) Termination of Relationship with the Company. If the Participant ceases to be an Eligible Participant for any reason, then, except as provided in this paragraph or in paragraphs (d) and (e) below, the right to exercise this option shall terminate three months after such cessation (but in no event after the Final Exercise Date), provided that this option shall be exercisable only to the extent that the Participant was entitled to exercise this option on the date of such cessation; and, provided, further, that to the extent the Participant is a party to an Executive Severance Agreement or other written agreement with the Company that provides for the option to remain outstanding and continue to vest during a specified period of time following the Participant's cessation of status as an Eligible Participant (such period, the "Severance Period"), the option shall remain outstanding and shall continue to vest in accordance with the terms of this Agreement during the Severance Period as if the Participant had remained an Eligible Participant during such period, subject to any conditions on continued vesting as may be contained in such Executive Severance Agreement or other written agreement. Any portion of this option that vests during such Severance Period will remain exercisable until the earlier of (A) the date that is three (3) months following the date that is the last day of such Severance Period, or (B) the Final Exercise Date, and except to the extent previously exercised as permitted by this Section 3(c) will thereupon immediately terminate. For the avoidance of doubt, any portion of the option that fails to vest during the Severance Period will immediately be forfeited on the last day of such period. Notwithstanding the foregoing, if the Participant, prior to the Final Exercise Date, violates the restrictive covenants (including, without limitation, the non-competition, non-solicitation, or confidentiality provisions) of any employment contract, any non-competition, non-solicitation, confidentiality or assignment agreement to which the Participant is a party, or any other agreement between the Participant and the Company, the right to exercise this option shall terminate immediately upon such violation.

(d) Exercise Period Upon Death. If the Participant dies prior to the Final Exercise Date while he or she is an Eligible Participant and the Company has not terminated such relationship for "cause" as specified in paragraph (e) below, this option shall be exercisable, within the period of one year following the date of death of the Participant, by an authorized transferee of the Participant, provided that this option shall be exercisable only to the extent that this option was exercisable by the Participant on the date of his or her death, and further provided that this option shall not be exercisable after the Final Exercise Date.

(e) Termination for Cause. If, prior to the Final Exercise Date, the Participant's employment, consulting, director or advisor relationship with the Company is terminated by the Company for Cause (as defined below), the right to exercise this option shall terminate immediately upon the effective date of such termination. If, prior to the Final Exercise Date, the Participant is given notice by the Company of the termination of his or her service by the Company for Cause, and the effective date of such termination is subsequent to the date of delivery of such notice, the right to exercise this option shall be suspended from the time of the delivery of such notice until the earlier of (i) such time as it is determined or otherwise agreed that the Participant's service shall not be terminated for Cause as provided in such notice or (ii) the effective date of such termination (in which case the right to exercise this option shall, pursuant to the preceding sentence, terminate upon the effective date of such termination). If the Participant is subject to an Executive Severance Agreement or other written agreement with the Company, in any case which agreement contains a definition of "cause" for termination of service, "Cause" shall have the meaning ascribed to such term in such agreement. Otherwise, "Cause" shall mean willful misconduct by the Participant or willful failure by the Participant to perform his or her responsibilities to the Company (including, without limitation, breach by the Participant of any fiduciary duty or of any provision of any employment, consulting, advisory,

nondisclosure, non-competition or other similar agreement between the Participant and the Company), as determined by the Company, which determination shall be conclusive. The Participant shall be considered to have been terminated for Cause if the Company determines, within 30 days after the Participant's resignation, that termination for Cause was warranted.

4. Tax Matters.

No Shares will be issued pursuant to the exercise of this option unless and until the Participant pays to the Company, or makes provision satisfactory to the Company for payment of, any federal, state or local withholding taxes required by law to be withheld in respect of this option.

5. Transfer Restrictions; Clawback.

(a) This option may not be sold, assigned, transferred, pledged, encumbered or otherwise disposed of by the Participant, either voluntarily or by operation of law, except by will or the laws of descent and distribution, and, during the lifetime of the Participant, this option shall be exercisable only by the Participant.

(b) In accepting this option, the Participant agrees to be bound by any clawback policy that the Company has in place or may adopt in the future.

6. Provisions of the Plan.

As described in Section 1 of this Agreement, this option is subject to the provisions of the Plan (including the provisions relating to amendments to the Plan), a copy of which is furnished to the Participant with this option. Notwithstanding the foregoing, to the extent the Participant has entered in to an Executive Severance Agreement with the Company, for so long as such Executive Severance Agreement remains in effect, the terms of such Executive Severance Agreement as they relate to the option shall control in the event of a conflict with this Agreement or the Plan.

ANNEX A

Akebia Therapeutics, Inc.

Stock Option Exercise Notice

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142

Dear Sir or Madam:

I, _____(the "Participant"), hereby irrevocably exercise the right to purchase ____ shares of the Common Stock, $0.00001 par value per share (the "Shares"), of Akebia Therapeutics, Inc. (the "Company") at $___per share pursuant to a stock option agreement with the Company dated ____ (the "Option Agreement"). Enclosed herewith is a payment of $____, the aggregate purchase price for the Shares. The Shares should be registered in my name as it appears below or, if so indicated below, jointly in my name and the name of the person designated below, with right of survivorship.

Dated: _____

_____
Signature
Print Name:

Address:
_____
_____

Name and address of persons in whose name the Shares are to be jointly registered (if applicable):

_____

Exhibit 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: August 28, 2023

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, Ellen Snow, 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: August 28, 2023

By: /s/ Ellen Snow

Ellen Snow

Senior Vice President, Chief Financial Officer and Treasurer

(Principal Financial Officer and Principal Accounting 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 June 30, 2023 (the "Report"), I, John P. Butler, as Chief Executive Officer and President of the Company, and I, Ellen Snow, as Senior Vice President, Chief Financial 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; 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: August 28, 2023

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

Date: August 28, 2023

By: /s/ Ellen Snow
Ellen Snow
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer and Principal Accounting Officer)