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, 2019

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 formal 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, par value $0.00001 per share	**AKBA**	**The Nasdaq Global 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 the latest practicable date.

Outstanding at July 31, 2019
118,863,735

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our expectations with respect to (i) the anticipated financial impact and potential benefits to us related to our merger with Keryx Biopharmaceuticals, Inc., or Keryx, that was completed on December 12, 2018, or the Merger, (ii) integration of the businesses subsequent to the Merger, and (iii) other matters related to the Merger;
- the timing, investment and associated activities involved in commercializing Auryxia;
- the potential therapeutic applications of the hypoxia-inducible factor, or HIF, pathway;
- our pipeline, including its potential, and our research activities;
- the potential therapeutic benefits, safety profile, and effectiveness of our product candidates, including the potential for vadadustat to set a new standard of care in the treatment of anemia due to chronic kidney disease;
- the potential indications, demand and market potential and acceptance of our product and product candidates, including our estimates regarding the potential market opportunity for Auryxia, vadadustat or any other product candidates and the size of eligible patient populations;
- 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 costs, expenses, revenues, capital requirements, need for additional capital, financing our future cash needs, capital resources, cash flows, financial performance, profitability, tax obligations, liquidity, growth, contractual obligations, the period of time our cash resources and collaboration funding will fund our current operating plan, internal control over financial reporting, and disclosure controls and procedures;
- 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, commercialization, launch, marketing and sale of our product candidates, and the associated timing thereof;
- the designs of our studies, and the type of information and data expected from our studies and the expected benefits thereof;
- the timing of or likelihood of regulatory filings and approvals, including labeling or other restrictions;
- our ability to maintain any marketing authorizations we currently hold or will obtain, including our marketing authorizations for Auryxia and Fexeric 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 or any other product candidate that may be approved;
- the targeted timing of enrollment of our clinical trials;
- the timing of initiation of our clinical trials and plans to conduct preclinical and clinical studies 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, as well as Abbreviated New Drug Applications filed by generic drug manufacturers and potential U.S. Food and Drug Administration approval thereof, and associated patent infringement suits that we have filed or may file, or other actions that we may take against such companies, and the timing and resolution thereof;
- expected reliance on third parties, including with respect to the development, manufacturing, supply and commercialization of our product and product candidates;
- accounting standards and estimates, their impact, and their expected timing of completion;
- estimated periods of performance of key contracts;

- our facilities, lease commitments, and future availability of facilities;
- cybersecurity;
- insurance coverage;
- our employees, including our management team, employee compensation, employee relations, and our ability to attract 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; and
- the timing, outcome and impact of current and any future legal proceedings.

These forward-looking statements involve risks and uncertainties, including those that are described 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.

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 subsidiaries, including Keryx. The trademarks, trade names and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. All website addresses given in this Quarterly Report on Form 10-Q are for information only and are not intended to be an active link or to incorporate any website information into this document.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share data)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 87,212	$ 104,644
Available for sale securities	49,553	216,996
Inventory	122,137	114,245
Accounts receivable, net	28,888	16,666
Prepaid expenses and other current assets	28,606	15,724
Total current assets	316,396	468,275
Property and equipment, net	10,903	8,023
Operating lease assets	31,224	—
Goodwill	55,053	55,053
Other intangible assets, net	309,413	328,153
Other assets	100,539	137,036
Total assets	$ 823,528	$ 996,540
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 19,321	$ 42,796
Accrued expenses and other current liabilities	125,981	150,917
Debt	—	15,000
Short-term deferred revenue	40,316	56,980
Total current liabilities	185,618	265,693
Deferred rent, net of current portion	—	3,006
Deferred revenue, net of current portion	55,558	55,709
Operating lease liabilities, net of current portion	30,069	—
Deferred tax liabilities	3,029	6,631
Other non-current liabilities	29,898	29,573
Total liabilities	304,172	360,612
Commitments and contingencies (Note 15)		
Stockholders' equity:		
Preferred stock $0.00001 par value, 25,000,000 shares authorized; 0 shares issued and outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock $0.00001 par value; 175,000,000 shares authorized at June 30, 2019 and December 31, 2018; 118,787,301 and 116,887,518 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	1	1
Additional paid-in capital	1,164,318	1,150,583
Accumulated other comprehensive income (loss)	23	(261)
Accumulated deficit	(644,986)	(514,395)
Total stockholders' equity	519,356	635,928
Total liabilities and stockholders' equity	$ 823,528	$ 996,540

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	$ 29,089	$ —	$ 52,200	$ —
License, collaboration and other revenue	71,714	48,793	121,269	94,723
Total revenues	100,803	48,793	173,469	94,723
Cost of goods sold:				
Product	28,569	—	50,726	—
Amortization of intangibles	9,100	—	18,200	—
Total cost of goods sold	37,669	—	68,926	—
Operating expenses:				
Research and development	85,694	71,917	168,045	133,321
Selling, general and administrative	36,068	12,538	70,359	21,562
License expense	895	—	1,631	—
Total operating expenses	122,657	84,455	240,035	154,883
Operating loss	(59,523)	(35,662)	(135,492)	(60,160)
Other income:				
Interest income	485	1,561	1,354	2,637
Other income (expense)	23	32	(55)	36
Net loss before income taxes	(59,015)	(34,069)	(134,193)	(57,487)
Benefit from income taxes	(845)	—	(3,602)	—
Net loss	$ (58,170)	$ (34,069)	$ (130,591)	$ (57,487)
Net loss per share - basic and diluted	$ (0.49)	$ (0.60)	$ (1.11)	$ (1.09)
Weighted-average number of common shares - basic and diluted	118,268,832	56,890,295	117,669,422	52,774,794
Comprehensive loss:				
Net loss	$ (58,170)	$ (34,069)	$ (130,591)	$ (57,487)
Other comprehensive gain (loss) - unrealized gain (loss) on debt securities	59	91	284	(17)
Total comprehensive loss	$ (58,111)	$ (33,978)	$ (130,307)	$ (57,504)

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)
(in thousands, except share data)

	Common Stock		Additional			Total
	Number of Shares	$0.00001 Par Value	Paid-In Capital	Unrealized Gain/(Loss)	Accumulated Deficit	Stockholders' Equity
Balance at December 31, 2017	47,612,619	$ —	$ 493,823	$ (442)	$ (370,807)	$ 122,574
Issuance of common stock, net of issuance costs	9,194,306	—	95,416	—	—	95,416
Proceeds from sale of stock under employee stock purchase plan	17,569	—	218	—	—	218
Exercise of options	21,363	—	182	—	—	182
Share-based compensation expense	—	—	2,232	—	—	2,232
Restricted stock unit vesting	11,613	—	—	—	—	—
Unrealized gain/loss	—	—	—	(108)	—	(108)
Net income (loss)	—	—	—	—	(23,418)	(23,418)
Balance at March 31, 2018	56,857,470	$ —	$ 591,871	$ (550)	$ (394,225)	$ 197,096
Proceeds from sale of stock under employee stock purchase plan	—	—	(3)	—	—	(3)
Exercise of options	43,041	—	314	—	—	314
Share-based compensation expense	—	—	2,494	—	—	2,494
Restricted stock unit vesting	13,375	—	—	—	—	—
Unrealized gain/loss	—	—	—	91	—	91
Net income (loss)	—	—	—	—	(34,069)	(34,069)
Balance at June 30, 2018	56,913,886	$ —	$ 594,676	$ (459)	$ (428,294)	$ 165,923
Balance at December 31, 2018	116,887,518	$ 1	$ 1,150,583	$ (261)	$ (514,395)	$ 635,928
Proceeds from sale of stock under employee stock purchase plan	39,977	—	188	—	—	188
Exercise of options	62,204	—	365	—	—	365
Share-based compensation expense	—	—	2,094	—	—	2,094
Restricted stock unit vesting	132,563	—	—	—	—	—
Unrealized gain/loss	—	—	—	225	—	225
Net income (loss)	—	—	—	—	(72,421)	(72,421)
Balance at March 31, 2019	117,122,262	$ 1	$ 1,153,230	$ (36)	$ (586,816)	$ 566,379
Issuance of common stock, net of issuance costs	1,384,520	—	9,035	—	—	9,035
Exercise of options	300,592	—	195	—	—	195
Retired shares	(55,324)	—	(426)	—	—	(426)
Share-based compensation expense	—	—	2,284	—	—	2,284
Restricted stock unit vesting	35,251	—	—	—	—	—
Unrealized gain/loss	—	—	—	59	—	59
Net income (loss)	—	—	—	—	(58,170)	(58,170)
Balance at June 30, 2019	118,787,301	$ 1	$ 1,164,318	$ 23	$ (644,986)	$ 519,356

See accompanying notes to unaudited condensed consolidated financial statements

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Six Months Ended	
	June 30, 2019	June 30, 2018
Operating activities:		
Net loss	$ (130,591)	$ (57,487)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,026	413
Amortization of intangibles	18,200	—
Amortization of premium/discount on investments	(685)	(313)
Non-cash interest expense	339	—
Non-cash operating lease expense	(1,097)	—
Fair value write-up of inventory sold	33,587	—
Write-down of inventory to net realizable value	3,023	—
Stock-based compensation	4,378	4,725
Deferred income taxes	(3,602)	—
Changes in operating assets and liabilities:		
Accounts receivable	(12,222)	34,084
Inventory	(17,188)	—
Prepaid expenses and other current assets	(11,337)	1,186
Other long-term assets	3,371	(79)
Accounts payable	(19,628)	(2,203)
Accrued expense	(28,126)	28,547
Operating lease liabilities	1,072	—
Deferred revenue	(16,815)	(20,121)
Deferred rent	—	(86)
Net cash used in operating activities	(176,295)	(11,334)
Investing activities:		
Purchase of equipment	(3,906)	(469)
Proceeds from the maturities of available for sale securities	103,691	122,803
Proceeds from sales of available for sale securities	64,721	7,998
Purchase of available for sale securities	—	(121,466)
Net cash provided by investing activities	164,506	8,866
Financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	9,035	95,415
Proceeds from the sale of stock under employee stock purchase plan	188	217
Proceeds from the exercise of stock options	560	497
Retirement of treasury stock	(426)	—
Payments on debt	(15,000)	—
Payments on capital lease obligations	—	(6)
Net cash provided by (used in) financing activities	(5,643)	96,123
Increase (decrease) in cash, cash equivalents, and restricted cash	(17,432)	93,655
Cash, cash equivalents, and restricted cash at beginning of the period	107,099	71,437
Cash, cash equivalents, and restricted cash at end of the period	$ 89,667	$ 165,092

See accompanying notes to unaudited condensed consolidated financial statements

1. Nature of Organization and Operations

Akebia Therapeutics, Inc., referred to as Akebia or the Company, was incorporated in the State of Delaware in 2007. Akebia is a biopharmaceutical company focused on the development and commercialization of therapeutics for people with kidney disease. Akebia's commercial product, Auryxia® (ferric citrate) is currently approved by the United States Food and Drug Administration, or FDA, and marketed for two indications in the United States, or the U.S.: the control of serum phosphorus levels in adult patients with chronic kidney disease, or CKD, on dialysis, or DD-CKD, and the treatment of iron deficiency anemia, or IDA, in adult patients with CKD not on dialysis, or NDD-CKD. Ferric citrate is also approved and marketed in Japan as an oral treatment for the improvement of hyperphosphatemia in patients with DD-CKD and NDD-CKD under the trade name Riona® (ferric citrate hydrate) and is approved, but not currently marketed, in the European Union as an oral treatment for the control of hyperphosphatemia in adult patients with DD-CKD and NDD-CKD under the trade name Fexeric® (ferric citrate). The Company's lead investigational product candidate, vadadustat, is an oral therapy in Phase 3 development for two indications: anemia due to CKD in adult patients with DD-CKD and anemia due to CKD in adult patients with NDD-CKD. The Company believes vadadustat has the potential to set a new standard of care in the treatment of anemia due to CKD, acting via a novel hypoxia-inducible factor, or HIF, pathway. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body, as well as other important metabolic functions.

On December 12, 2018, the Company completed a merger with Keryx Biopharmaceuticals, Inc., or Keryx, or the Merger. Pursuant to the terms and conditions of the Agreement and Plan of Merger, or the Merger Agreement, each share of Keryx common stock, or Keryx Share, issued and outstanding immediately prior to the effective time of the Merger, or the Effective Time, was cancelled and converted into 0.37433, or the Exchange Multiplier, fully paid and non-assessable shares of Akebia common stock, or Akebia Shares, resulting in the issuance of an aggregate of 59,270,410 Akebia Shares.

Since inception, the Company has devoted most of its resources to research and development, including its preclinical and clinical development activities, raising capital, 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 to the Company's Japanese partners Japan Tobacco, Inc. and its subsidiary Torii Pharmaceutical Co., Ltd., collectively, JT and Torii, on December 12, 2018. The Company has not generated a profit to date and may never generate profits from product sales. The Company's 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 its product candidates. If the Company does not successfully commercialize any of its product candidates, it may be unable to achieve profitability.

We expect our cash resources, including committed research and development funding from collaborators, to fund our current operating plan beyond the next twelve months, into the third quarter of 2020. However, on a quarterly basis, we are required to conduct an accounting analysis under ASC 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or ASC 205-40. Under the accounting standards, a company is not permitted to include elements of its operating plan that are deemed to be "outside of the company's control" in an ASC 205-40 analysis, even though certain of those elements may be appropriately included in the company's cash runway analysis. For example, our cash runway includes receipt of a milestone payment from Mitsubishi Tanabe Pharma Corporation, or MTPC, upon manufacturing and marketing approval of vadadustat in Japan, but since receipt of that milestone payment is deemed to be "outside of our control" under the accounting standards, we are not permitted to include it in our ASC 205-40 analysis. The result of our ASC 205-40 analysis is that there is "substantial doubt" that we will have sufficient funds to satisfy our obligations through the next twelve months from the date of issuance of this Quarterly Report on Form 10-Q.

The Company will require additional capital for the further commercialization of Auryxia and continued development and potential commercialization of the Company's existing product candidates and would need to raise additional funds to pursue development activities related to any additional product candidates. If and until the Company can generate a sufficient amount of product revenue, the Company expects to finance future cash needs through public or private equity or debt offerings, payments from its collaborators, royalty transactions, strategic transactions, or a combination of these approaches. However, adequate additional financing may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise capital when needed or on attractive terms, it may be forced to delay, reduce or eliminate its research and development programs or any commercialization efforts.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the U.S., or 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 U.S. GAAP for complete financial statements. Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification, or ASC, and Accounting Standards Update, or ASU, of the Financial Accounting Standards Board, or FASB.

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, 2019 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2019 or any other future period.

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. Management has determined that the Company operates in one segment, which is the business of developing and commercializing novel therapeutics for patients with kidney disease. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the Company's consolidated financial statements and the accompanying notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 filed with the U.S. Securities and Exchange Commission on March 26, 2019, or the 2018 Annual Report on Form 10-K.

The significant accounting policies used in preparation of these unaudited condensed consolidated financial statements for the three and six months ended June 30, 2019 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's 2018 Annual Report on Form 10-K and are updated below as necessary.

New Accounting Pronouncements – Recently Adopted

In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires entities to recognize right-of-use assets and lease liabilities for leases with lease terms of more than 12 months on their balance sheets and provide enhanced disclosures. In 2018, the FASB issued additional ASUs related to Topic 842, or ASC 842, that clarified various aspects of the new lease guidance, including how to record certain transition adjustments, as well as other improvements and practical expedients. The Company adopted this new standard on January 1, 2019 using the modified retrospective approach for all leases existing at, or entered into after, the date of initial application, and has elected to use the following practical expedients that are permitted under the rules of the adoption:

- The Company elected the package of transition practical expedients, which allows it to retain the lease classification and initial direct costs for any leases that existed prior to the adoption of this new standard.
- The Company will not reassess whether any contracts completed prior to the adoption are leases.

The Company adopted ASC 842 using the modified retrospective approach, as of January 1, 2019, with no restatements of prior periods or a cumulative effect of the adoption of ASC 842 in retained earnings. On January 1, 2019, the Company recognized additional operating lease liabilities, net of deferred rent, of approximately $37.1 million based on the present value of the remaining minimum lease payments, a corresponding right of use assets of approximately $33.4 million, and $0.9 million to prepaid expenses and other current assets related to leasehold improvement allowances that had yet to be incurred as of the date of adoption, but for which the Company was reasonably certain to incur costs at least equal to the maximum level of leasehold improvement allowance. The adoption of ASC 842 did not have an impact on our unaudited condensed consolidated statement of operations. Prior periods are presented in accordance with ASC 840, *Leases*.

The Company made an accounting policy election not to recognize leases with an initial term of 12 months or less within its unaudited condensed consolidated balance sheets and to recognize those lease payments on a straight-line bases in its unaudited condensed consolidated statements of operations. The Company also made the accounting policy election not to separate the non-lease components from the lease components for its building leases and, rather, account for each non-lease component and lease component as a single component.

The Company determines if an arrangement is a lease at inception. An arrangement is determined to contain a lease if the contract conveys the right to control the use of an identified property, plant, or equipment for a period of time in exchange for consideration. If the Company can benefit from the various underlying assets of a lease on their own or together with other resources that are readily available, or if the various underlying assets are neither highly dependent on nor highly interrelated with other underlying assets in the arrangement, they are considered to be a separate lease component. In the event multiple underlying assets are identified, the lease consideration is allocated to the various components based on each of the component's relative fair value.

Operating lease assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent its obligation to make lease payments arising from the leasing arrangement. Operating lease assets and operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company uses the implicit rate when readily determinable and uses an estimate of its incremental borrowing rate when the implicit rate is not readily determinable based upon the available information at the commencement date of lease inception. The incremental borrowing rate is determined using a credit rating scoring model to estimate the Company's credit rating, adjusted for collateralization. The calculation of the operating lease assets includes any lease payments made and excludes any lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option.

Our operating leases are reflected in prepaid expenses and other current assets, operating lease assets, accrued expenses and operating lease liabilities, net of current portion in our condensed consolidated balance sheets. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term.

In January 2017, the FASB issued ASU 2017-04, *Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, which simplifies how companies calculate goodwill impairments by eliminating Step 2 of the impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. ASU 2017-04 requires companies to compare the fair value of a reporting unit to its carrying amount and recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to the related reporting unit. This ASU is effective for annual periods beginning after December 15, 2019, and is applicable to the Company in fiscal year 2020. Early adoption is allowed, and the Company adopted ASU 2017-04 in the first quarter of fiscal year 2019. The Company will conduct its initial goodwill impairment test as of October 1, 2019 and annually thereafter, or more frequently if indicators of impairment are present or changes in circumstances suggest that an impairment may exist.

New Accounting Pronouncements – Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires that financial assets measured at amortized cost be presented at the net amount expected to be collected. Currently, U.S. GAAP delays recognition of the full amount of credit losses until the loss is probable of occurring. Under this ASU, the income statement will reflect an entity's current estimate of all expected credit losses. The measurement of expected credit losses will be based upon historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down of the security. This ASU is effective for annual periods beginning after December 15, 2019, and is applicable to the Company in fiscal year 2020. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of ASU 2016-13 on its consolidated financial position and results of operations.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. 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. Estimates are used in the following areas, among others: prepaid and accrued research and development expense, operating lease assets and liabilities, other non-current liabilities, stock-based compensation expense, product and collaboration revenues including various rebates and reserves related to product sales, inventories, income taxes, intangible assets and goodwill.

Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents consist of all cash on hand, deposits and funds invested in available-for-sale securities with original maturities of three months or less at the time of purchase. At June 30, 2019, the Company's cash is primarily in money market funds. The Company may maintain balances with its banks in excess of federally insured limits.

Restricted cash represents amounts required for security deposits under the Company's office and lab space lease agreements and cash balances held as collateral for the Company's employee credit card program. Restricted cash is included in "prepaid expenses and other current assets" and "other assets" in the unaudited condensed consolidated balance sheets.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported in the unaudited condensed consolidated balance sheet that sum to the total of the amounts reported in the unaudited condensed consolidated statement of cash flows (in thousands):

	June 30, 2019	June 30, 2018
Cash and cash equivalents	$ 87,212	$ 163,526
Prepaid expenses and other current assets	363	—
Other assets	2,092	1,566
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 89,667	$ 165,092

Investments

Management determines the appropriate classification of securities at the time of purchase and reevaluates such designation as of each balance sheet date. Currently, the Company classifies all securities as available for sale which are included in current assets as they are intended to fund current operations. The Company carries available for sale securities at fair value. The Company conducts periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. When assessing whether a decline in the fair value of a security is other-than-temporary, the Company considers the fair market value of the security, the duration of the security's decline, and prospects for the underlying business. Based on these considerations, the Company did not identify any other-than-temporary unrealized losses at June 30, 2019. Unrealized losses on available for sale securities that are determined to be temporary, and not related to credit loss, are recorded in accumulated other comprehensive loss, a component of stockholders' equity. The amortized cost of debt securities in this category reflects amortization of premiums and accretion of discounts to maturity computed under the effective interest method. The Company includes this amortization in the caption "Interest income" within the unaudited condensed consolidated statements of operations and comprehensive loss. The Company also includes in net investment income, realized gains and losses and declines in value determined to be other than temporary. The Company bases the cost of securities sold upon the specific identification method and includes interest and dividends on securities in interest income.

Property and Equipment

Property and equipment is stated at cost, less accumulated depreciation. Assets under capital lease are included in property and equipment. Property and equipment is depreciated using the straight-line method over the estimated useful lives of the assets, generally three to seven years. Such costs are periodically reviewed for recoverability when impairment indicators are present. Such indicators include, among other factors, operating losses, unused capacity, market value declines and technological obsolescence. Recorded values of asset groups of equipment that are not expected to be recovered through undiscounted future net cash flows are written down to current fair value, which generally is determined from estimated discounted future net cash flows (assets held for use) or net realizable value (assets held for sale).

The following is the summary of property and equipment and related accumulated depreciation as of June 30, 2019 and December 31, 2018.

	Useful Life	June 30, 2019	December 31, 2018
		(in thousands)	
Computer equipment and software	3	$ 1,124	$ 1,593
Furniture and fixtures	5 - 7	1,663	1,170
Equipment	7	2,451	1,780
Leasehold improvements	Shorter of the useful life or remaining lease term (10 years)	8,649	5,324
Office equipment under capital lease	3	—	114
		13,887	9,981
Less accumulated depreciation		(2,984)	(1,958)
Net property and equipment		$ 10,903	$ 8,023

Depreciation expense was approximately $0.6 million and $0.2 million for the three months ended June 30, 2019 and 2018, respectively, and approximately $1.0 million and $0.4 million for the six months ended June 30, 2019 and 2018, respectively.

Inventory

The Company values its inventories at the lower-of-cost or net realizable value. The Company determines the cost of its inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. The Company classifies its inventory costs as long-term, in other assets in its unaudited condensed consolidated balance sheets, when it expects to utilize the inventory beyond their normal operating cycle.

Prior to the regulatory approval of its product candidates, the Company incurs expenses for the manufacture of material that could potentially be available to support the commercial launch of its products. Until the first reporting period when regulatory approval has been received or is otherwise considered probable and the future economic benefit is expected to be realized, the Company records all such costs as research and development expense. Inventory used in clinical trials is also expensed as research and development expense, when selected for such use. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in a clinical manufacturing campaign.

The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and writes down any excess and obsolete inventory to its net realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of cost of product sales in the unaudited condensed consolidated statements of operations and comprehensive loss. The determination of whether inventory costs will be realizable requires the use of estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required. Additionally, the Company's product is subject to strict quality control and monitoring throughout the manufacturing process. In the event that certain batches or units of product no longer meet quality specifications, the Company will record a charge to cost of product sales to write-down any unmarketable inventory to its estimated net realizable value. In all cases, product inventory is carried at the lower of cost or its estimated net realizable value.

Revenue Recognition

The Company generates revenues primarily from sales of Auryxia, see Note 3, and from its collaborations with MTPC and Otsuka, see Note 4. The Company recognizes revenue in accordance with ASC 606, which applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

The Company sells Auryxia in the U.S. primarily to wholesale distributors as well as certain specialty pharmacy providers, collectively, Customers. These Customers resell the Company's product to health care providers and patients. In addition to distribution agreements with Customers, the Company enters into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's product.

The Company recognizes revenue on product sales when the Customer obtains control of the Company's product, which occurs at a point in time, typically upon delivery to the Customer. The Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that it would have recognized is one year or less.

Reserves for Variable Consideration

Revenue from product sales is recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from discounts, returns, chargebacks, rebates, co-pay assistance and other allowances that are offered within contracts between the Company and its Customers, health care providers, payors and other indirect customers relating to the Company's sales of its products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount will be credited to the Customer) or as a current liability (if the amount is payable to a Customer or a party other than a Customer). When appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in ASC 606 for relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances: The Company generally provides Customers with discounts that include incentive fees that are explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, the Company compensates (through trade discounts and allowances) its Customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the Customer and, therefore, these payments have been recorded as a reduction of revenue within the unaudited condensed consolidated statement of operations and comprehensive loss through June 30, 2019. The Company records a corresponding reduction of accounts receivable (if the trade discount and/or allowance will be credited to the Customer) or an increase in accrued expense (if the trade discount and/or allowance is payable to a Customer) on the consolidated balance sheets.

Product Returns: Consistent with industry practice, the Company generally offers Customers a limited right of return which allows for the product to be returned when the product expiry is within an allowable window. This right of return lapses once the product is provided to a patient. The Company estimates the amount of its product sales that may be returned by its Customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates product return reserve using available industry data and its own historical sales information, including its visibility into the inventory remaining in the distribution channel.

Provider Chargebacks and Discounts: Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from the Company. Customers charge the Company for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's resale of the product. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel at each reporting period end that the Company expects will be sold to qualified healthcare providers, and chargebacks that Customers have claimed but for which the Company has not yet issued a credit.

Commercial and Medicare Part D Rebates: The Company contracts with various commercial payor organizations, primarily health insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of its products. The Company estimates the rebates for commercial and Medicare Part D payors based upon (i) its contracts with the payors and (ii) information obtained from its Customers and other third parties regarding the payor mix for Auryxia. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Other Government Rebates: The Company is subject to discount obligations under state Medicaid programs and other government programs. The Company estimates its Medicaid and other government programs rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel at the end of each reporting period.

Other Incentives: Other incentives that the Company offers include voluntary patient assistance programs such as the Company's co-pay assistance program, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on actual claims processed during a given period, as well as historical utilization data to estimate the amount the Company expects to receive associated with product that has been recognized as revenue, but remains in in the distribution channel at the end of each reporting period.

Collaboration Revenues

The Company enters into out-license and collaboration agreements which are within the scope of ASC 606, under which it licenses certain rights to its product candidates to third parties. The terms of these arrangements typically include payment to the Company of one or more of the following: non-refundable, up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services the Company provides through its contract manufacturers; and royalties on net sales of licensed products. Each of these payments may result in license, collaboration and other revenue, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under each of its agreements, the Company implements the five-step model noted above. As part of the accounting for these arrangements, the Company must develop assumptions that require judgment to determine whether the individual promises should be accounted for as separate performance obligations or as a combined performance obligation, and to determine the stand-alone selling price for each performance obligation identified in the contract. A deliverable represents a separate performance obligation if both of the following criteria are met: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer, and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. The Company uses key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success. With regard to the MTPC and Otsuka Agreements (each as defined in Note 4), the Company recognizes revenue related to amounts allocated to the identified performance obligation on a proportional performance basis as the underlying services are performed.

Licenses of Intellectual Property

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments

At the inception of each arrangement that includes development milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to assess the milestone as probable of being achieved. There is considerable judgment involved in determining whether a milestone is probable of being reached at each specific reporting period. Milestone payments that are not within the control of the Company or the customer, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenues as, or when, the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue in the period of adjustment.

Manufacturing Supply Services

Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee's discretion are generally considered as options. The Company assesses if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If the Company is entitled to additional payments when the licensee exercises these options, any additional payments are recorded in license, collaboration and other revenues when the licensee obtains control of the goods, which is upon delivery.

Royalties

The Company will recognize sales-based royalties, including milestone payments based on the level of sales, at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). The Company receives royalty payments from JT and Torii, based on net sales of Riona in Japan.

Collaborative Arrangements

The Company records the elements of its collaboration agreements that represent joint operating activities in accordance with ASC Topic 808, *Collaborative Arrangements* (ASC 808). Accordingly, the elements of the collaboration agreements that represent activities in which both parties are active participants and to which both parties are exposed to the significant risks and rewards that are dependent on the commercial success of the activities are recorded as collaborative arrangements. The Company considers the guidance in ASC 606-10-15, *Revenue from Contracts with Customers – Scope and Scope Exceptions*, in determining the appropriate treatment for the transactions between the Company and its collaborative partner and the transactions between the Company and third parties. Generally, the classification of transactions under the collaborative arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Therefore, the Company recognizes its allocation of the shared costs incurred with respect to the jointly conducted medical affairs and commercialization and non-promotional activities under the U.S. collaboration with Otsuka as a component of the related expense in the period incurred. During the three months ended June 30, 2019 and 2018, the Company incurred approximately $0.3 million and $0.2 million, respectively, of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, as defined below in Note 4, of which approximately $0.1 million are reimbursable by Otsuka and recorded as a reduction to research and development expense during each of the three months ended June 30, 2019 and 2018. During the three months ended June 30, 2019, Otsuka incurred approximately $0.1 million of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.1 million are reimbursable by the Company and recorded as an increase to research and development expense during the three months ended June 30, 2019. No costs were incurred by Otsuka related to the cost-sharing provisions of the Otsuka U.S. Agreement during the three months ended June 30, 2018. To the extent product revenue is generated from the collaboration, the Company recognizes its share of the net sales on a gross basis if it is deemed to be the principal in the transactions with customers, or on a net basis if it is instead deemed to be the agent in the transactions with customers, consistent with the guidance in ASC 606.

Intangible Assets

The Company maintains a definite-lived intangible asset related to developed product rights for Auryxia, which was acquired on December 12, 2018 as part of the Merger.

Intangible assets are initially recorded at fair value and stated net of accumulated amortization and impairments. The Company amortizes its intangible assets that have finite lives using either the straight-line method, or if reliably determinable, based on the pattern in which the economic benefit of the asset is expected to be utilized. Amortization for the Company's intangible asset is recorded over its estimated useful life of nine years.

The Company reviews intangible assets subject to amortization to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment or a change in the remaining useful life. If an impairment indicator exists, the Company performs a recoverability test by comparing the sum of the estimated undiscounted cash flows of the intangible asset to its carrying value on the unaudited condensed consolidated balance sheet. If the carrying value of the intangible asset exceeds the undiscounted cash flows used in the recoverability test, the Company will write the carrying value down to the fair value in the period identified. The Company calculates the fair value of intangible assets as the present value of estimated future cash flows expected to be generated from the intangible asset using a risk-adjusted discount rate. In determining estimated future cash flows associated with its intangible assets, the Company uses market participant assumptions pursuant to ASC Topic 820, *Fair Value Measurements and Disclosures* (ASC 820).

Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC 820 establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments, and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

- Level 1 – Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2 – Valuations based on quoted prices for similar assets or liabilities in markets that are not active, or for which all significant inputs are observable, either directly or indirectly.
- Level 3 – Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Items measured at fair value on a recurring basis include available for sale securities (see Note 7). The carrying amounts of prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to their short-term maturities.

Items measured at fair value on a nonrecurring basis include property and equipment, intangible assets and goodwill. The Company remeasures the fair value of these assets upon the occurrence of certain events. There were no such remeasurements to property and equipment for the three and six months ended June 30, 2019. There were no impairments to assets measured using Level 3 inputs during the three and six months ended June 30, 2019 and 2018, respectively.

Net Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, preferred stock, stock options, warrants, restricted stock and RSUs are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented. Diluted net income per share is calculated by dividing the net income by the weighted-average common shares outstanding for the period, including any dilutive effect from outstanding options, warrants, restricted stock and RSUs using the treasury stock method.

3. Product Revenue and Reserves for Variable Consideration

To date, the Company's only source of product revenue has been product revenue from the U.S. sales of Auryxia, which it began recording on December 12, 2018 following the consummation of the Merger. Total net product revenue was $29.1 million and $52.2 million for the three and six months ended June 30, 2019, respectively. The following table summarizes activity in each of the product revenue allowance and reserve categories for the six months ended June 30, 2019 (in thousands):

	Chargebacks and Discounts	Rebates, Fees and other Deductions	Returns	Total
Balance at December 31, 2018	$ 516	$ 22,861	$ 360	$ 23,737
Current provisions related to sales in current year	3,306	44,708	1,596	49,610
Adjustments related to prior period sales	(22)	479	—	457
Credits/payments made relating to sales in current year	(2,392)	(14,809)	—	(17,201)
Credits/payments made relating to prior period sales	(928)	(31,322)	(1,663)	(33,913)
Balance at June 30, 2019	$ 480	$ 21,917	$ 293	$ 22,690

Chargebacks, discounts and returns are recorded as a direct reduction of revenue on the unaudited condensed consolidated statement of operations with a corresponding reduction to accounts receivable on the unaudited condensed consolidated balance sheets. Rebates, distribution-related fees, and other sales-related deductions are recorded as a reduction in revenue on the unaudited condensed consolidated statement of operations with a corresponding increase to accrued liabilities or accounts payable on the unaudited condensed consolidated balance sheets.

4. License, Collaboration and Other Significant Agreements

During the three and six months ended June 30, 2019 and 2018, the Company recognized the following revenues from its license, collaboration and other significant agreements and had the following deferred revenue balances as of June 30, 2019:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
License, Collaboration and Other Revenue:	(in thousands)		(in thousands)	
MTPC Agreement	$ 10,000	$ 189	$ 10,000	$ 9,281
Otsuka U.S. Agreement	37,519	26,458	63,742	46,057
Otsuka International Agreement	22,467	22,087	44,423	39,061
Total Proportional Performance Revenue	$ 69,986	$ 48,734	$ 118,165	$ 94,399
JT and Torii	1,491	—	2,719	—
MTPC Stability Studies	237	59	385	324
Total License, Collaboration and Other Revenue	$ 71,714	$ 48,793	$ 121,269	$ 94,723

	June 30, 2019		
	Short-Term	Long-Term	Total
Deferred Revenue:	(in thousands)		
Otsuka U.S. Agreement	$ 23,673	$ 35,930	$ 59,603
Otsuka International Agreement	16,643	14,949	31,592
Vifor Agreement	—	4,679	4,679
Total	$ 40,316	$ 55,558	$ 95,874

The following table presents changes in the Company's contract assets and liabilities during the six months ended June 30, 2019 and 2018 (in thousands):

Six Months Ended June 30, 2019	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract assets:				
Other current assets	$ —	$ 10,000	$ —	$ 10,000
Accounts receivable(1)	$ 1,587	$ 81,830	$ (75,260)	$ 8,157
Contract liabilities:				
Deferred revenue	$ 112,689	$ 91,351	$ (108,166)	$ 95,874
Accounts payable	$ 13,492	$ —	$ (13,492)	$ —
Six Months Ended June 30, 2018				
Contract assets:				
Other current assets	$ —	$ 651	$ —	$ 651
Accounts receivable(1)	$ 34,186	$ 74,092	$ (108,278)	$ —
Contract liabilities:				
Deferred revenue	$ 179,624	$ 74,278	$ (94,399)	$ 159,503
Accounts payable	$ —	$ 1,040	$ —	$ 1,040

(1) Excludes accounts receivable from other services related to clinical and regulatory activities performed by the Company on behalf of MTPC that are not included in the performance obligations identified under the MTPC Agreement as of June 30, 2018 and 2019 and December 31, 2018 and 2019. Also excludes accounts receivable related to amounts due to the Company from product sales which are included in the accompanying unaudited condensed consolidated balance sheet as of June 30, 2019 and December 31, 2018.

During the three and six months ended June 30, 2019 and 2018, 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 from:	2019	2018	2019	2018
Amounts included in deferred revenue at the beginning of the period	$ 23,277	$ 48,545	$ 40,316	$ 89,340
Performance obligations satisfied in previous periods	$ —	$ 189	$ 1,254	$ 25,380

Mitsubishi Tanabe Pharma Corporation Collaboration Agreement

Summary of Agreement

On December 11, 2015, the Company and MTPC entered into a collaboration agreement, or the MTPC Agreement, providing MTPC with exclusive development and commercialization rights to vadadustat in Japan and certain other Asian countries, collectively, the MTPC Territory. In addition, the Company will supply vadadustat for both clinical and commercial use in the MTPC Territory, subject to MTPC's option to manufacture commercial drug product in the MTPC Territory.

The Company and MTPC agreed that, instead of including Japanese patients in the Company's global Phase 3 program for vadadustat, MTPC would be the sponsor of a Phase 3 program for vadadustat in Japan. Following consultation with the Japanese Pharmaceuticals and Medical Devices Agency, or the PMDA, MTPC initiated its Phase 3 development program for vadadustat in Japanese patients in Japan in the fourth quarter of 2017, and reported top-line data for the two Phase 3 pivotal trials and data from the two supportive Phase 3 studies in March 2019. MTPC is responsible for the costs of the Phase 3 program in Japan and other studies required there, and will make no funding payments for the global Phase 3 program. In July 2019, MTPC submitted a Japanese New Drug Application, or JNDA, to the Ministry of Health, Labor and Welfare in Japan for manufacturing and marketing approval of vadadustat, as a treatment for anemia due to CKD, which triggered a $10.0 million regulatory milestone payment due to the Company.

MTPC has sole responsibility for the commercialization of vadadustat in the MTPC Territory as well as for Medical Affairs (as defined in the MTPC Agreement) in the MTPC Territory. Akebia is responsible for manufacturing and supplying vadadustat for clinical use in the MTPC Territory. Akebia plans to enter into a supply agreement with MTPC for the commercial supply of vadadustat prior to commercial launch.

The Company and MTPC have established a joint steering committee pursuant to the MTPC Agreement to oversee development and commercialization of vadadustat in the MTPC Territory, including approval of any development or commercialization plans. Unless earlier terminated, the MTPC Agreement will continue in effect on a country-by-country basis until the later of the following: expiration of the last-to-expire patent covering vadadustat in such country in the MTPC Territory; expiration of marketing or regulatory exclusivity in such country in the MTPC Territory; or ten years after the first commercial sale of vadadustat in such country in the MTPC Territory. MTPC may terminate the MTPC Agreement upon twelve months' notice at any time after the second anniversary of the effective date of the MTPC Agreement. Either party may terminate the MTPC Agreement upon the material breach of the other party that is not cured within a specified time period or upon the insolvency of the other party.

MTPC is required to make certain milestone payments to the Company aggregating up to approximately $225.0 million upon the achievement of specified development, regulatory and commercial events. More specifically, the Company received $10.0 million in development milestone payments, and is eligible to receive up to $40.0 million in regulatory milestone payments, of which the Company received $10.0 million in the third quarter of 2019 in relation to the July 2019 JNDA filing, and up to $175.0 million in commercial milestone payments associated with aggregate sales of all products. In consideration for the exclusive license and other rights contained in the MTPC Agreement, MTPC was also obligated to make a $20.0 million upfront payment as well as a payment of $20.5 million for Phase 2 studies in Japanese patients completed by the Company and reimbursable by MTPC. Additionally, if vadadustat is commercialized, the Company would be entitled to receive tiered double-digit royalty payments of up to 20% on sales of vadadustat in the MTPC Territory. Royalty payments are subject to certain reductions, including upon the introduction of competitive products in certain instances. Royalties are due on a country-by-country basis from the date of first commercial sale of a licensed product in a country until the last to occur of: (i) the expiration of the last to expire valid claim within the intellectual property covering the licensed product, (ii) the expiration of marketing or regulatory exclusivity in such country, or (iii) the tenth anniversary of the first commercial sale of such licensed product in such country. Due to the uncertainty of pharmaceutical development and the high historical failure rates associated with drug development, although the Company has received $10.0 million in development milestones and earned a $10.0 million regulatory milestone, for which payment was received in the third quarter of 2019, no additional milestone or royalty payments may ever be received from MTPC.

In September 2017, the Company provided MTPC with an option to access data from the Company's global Phase 3 vadadustat program for payments to the Company of up to $25.0 million, which is in addition to the milestone payments described above.

Revenue Recognition

The Company evaluated the elements of the MTPC Agreement in accordance with the provisions of ASC 606 and concluded that the contract counterparty, MTPC, is a customer. The Company's arrangement with MTPC contains the following material promises under the contract at inception: (i) license under certain of the Company's intellectual property to develop and commercialize vadadustat (the License Deliverable) in the MTPC Territory, (ii) clinical supply of vadadustat (the Clinical Supply Deliverable), (iii) knowledge transfer, (iv) Phase 2 dosing study research services (the Research Deliverable), and (v) rights to future know-how.

The Company has 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*. Factors considered in making the assessment of which material promises will be accounted for as separate performance obligations included, among other things, the capabilities of the collaboration partner, whether any other vendor sells the item separately, whether the good or service is highly interdependent or highly interrelated to the other elements in the arrangement, and whether there are other vendors that can provide the items. Additionally, the MTPC Agreement does not include a general right of return.

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. The Company did not develop a best estimate of standalone selling price for the License, Research and Clinical Supply Performance Obligation because the estimate of standalone selling price associated with the Rights to Future Know-How Performance Obligation was determined to be immaterial. The Company has concluded that a change in the key assumptions used to determine the best estimate of standalone selling price for each performance obligation would not have a significant impact on the allocation of arrangement consideration. The deliverables associated with the License, Research and Clinical Supply Performance Obligation were satisfied as of June 30, 2018.

The transaction price at inception was comprised of: (i) the up-front payment, (ii) the estimated cost for the Phase 2 studies, (iii) a non-substantive milestone associated with the first patient enrolled in the NDD-CKD Phase 3 study, and (iv) the cost of all clinical supply provided to MTPC for the Phase 3 studies. No other development and no regulatory milestones were included in the transaction price at inception, as all other milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. The total aggregate amount of development milestones is $10.0 million and the total aggregate amount of the regulatory milestones is up to $40.0 million. The total aggregate amount of sales milestones is up to $175.0 million. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to MTPC and therefore have also been excluded from the transaction price. The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

As of June 30, 2019, the transaction price is 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, comprised of a $6.0 million and a $4.0 million development milestone, and (v) a $10.0 million regulatory milestone relating to the JNDA filing which, as of June 30, 2019, was deemed probable of being achieved. As of June 30, 2019, all development milestones have been achieved and, other than the $10.0 million regulatory milestone related to the filing of the JNDA no other regulatory milestones have been assessed as probable of being achieved and as a result have been fully constrained. Revenue for the License, Research and Clinical Supply Performance Obligation for the MTPC Agreement is being recognized using a proportional performance method. Accordingly, the Company recognized the $10.0 million regulatory milestone for the filing of the JNDA, as revenue during the three and six months ended June 30, 2019, as the regulatory milestone was both deemed probable of being achieved and the required performance obligations had been satisfied as of June 30, 2019. The payment for this $10.0 million regulatory milestone was received in the third quarter of 2019. The Company recognized approximately $0.2 million and $9.3 million during the three and six months ended June 30, 2018. The revenue is classified as collaboration revenue in the accompanying unaudited condensed consolidated statements of operations. As of June 30, 2019, there is no deferred revenue, no accounts receivable, and $10.0 million in contract assets (included in prepaid and other current assets). There were no asset or liability balances classified as long-term in the unaudited condensed consolidated balance sheet as of June 30, 2019.

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

Summary of Agreement

On December 18, 2016, the Company entered into a collaboration and license agreement with Otsuka, or the Otsuka U.S. Agreement. The collaboration is focused on the development and commercialization of vadadustat in the U.S. Under the terms of the Otsuka U.S. Agreement, the Company is responsible for leading the development of vadadustat, including the ongoing Phase 3 development program. The Company and Otsuka will co-commercialize vadadustat in the U.S., subject to the approval of vadadustat by the FDA.

Under the terms of the Otsuka U.S. Agreement, the Company granted to Otsuka a co-exclusive, non-sublicensable license under certain intellectual property controlled by the Company solely to perform medical affairs activities and to conduct non-promotional and commercialization activities related to vadadustat in accordance with the associated plans. The co-exclusive license relates to activities that will be jointly conducted by the Company and Otsuka pursuant to the terms of the Otsuka U.S. Agreement. Additionally, the parties agreed not to promote, market or sell any competing product in the territory covered by the agreement.

The Company is responsible for performing all activities related to the development of vadadustat as outlined in the current global development plan. The current global development plan encompasses all activities with respect to the ongoing PRO_2TECT and $INNO_2VATE$ clinical programs through the filing for marketing approval, as well as certain other studies. Under the Otsuka U.S. Agreement the Company controls and retains final decision-making authority with respect to certain matters. The Company's obligations related to the conduct of the current global development plan include the associated manufacturing and supply services for vadadustat.

Under the Otsuka U.S. Agreement, the parties jointly conduct, and have equal responsibility for, all medical affairs, commercialization and non-promotional activities pursuant to underlying plans as agreed to by the parties. If approved by the FDA, the Company plans to provide vadadustat to Otsuka for commercialization pursuant to a separate supply agreement to be negotiated.

The activities under the Otsuka U.S. Agreement are governed by a joint steering committee, or JSC, formed by an equal number of representatives from the Company and Otsuka. The JSC coordinates and monitors the parties' activities under the collaboration. Among other responsibilities, the JSC manages the overall strategic alignment between the parties, oversees the current global development plan and reviews other detailed plans setting forth the parties' activities under the arrangement, including the medical affairs plan and commercialization and non-promotional activities plan. Additionally, the parties established a joint development committee, or JDC, which is comprised of an equal number of representatives from the Company and Otsuka. Among other responsibilities, the JDC shares information related to, and reviews and discusses activities and progress under, the current global development plan and any other development that may be conducted pursuant to the collaboration. The Company and Otsuka also established a joint manufacturing committee, or JMC, which is comprised of an equal number of representatives from each of the parties. Among other responsibilities, the JMC oversees the manufacturing plan and related manufacturing activities. In support of the potential commercialization of vadadustat, the parties established a joint commercialization committee, or JCC, which is comprised of an equal number of representatives from the Company and Otsuka. Among other responsibilities, the JCC oversees the activities and progress under the commercialization and non-promotional activities plan and all other sales and marketing activities. The Company has retained final decision-making authority with respect to certain matters, including U.S. pricing strategy and certain other key commercialization matters.

Under the terms of the Otsuka U.S. Agreement, the Company received a $125.0 million up-front, non-refundable, non-creditable cash payment in December 2016. In March 2017, the Company received a payment of approximately $33.8 million, which represented reimbursement for Otsuka's share of costs previously incurred by the Company in implementing the current global development plan through December 31, 2016. Commencing in the third quarter of 2017, whereupon the Company had incurred a specified amount of incremental costs, Otsuka began to contribute, as required by the Otsuka U.S. Agreement, a percentage of the remaining costs incurred under the current global development plan. The Company estimates that Otsuka's funding of the current global development plan costs subsequent to December 31, 2016 will total $232.3 million or more, depending on the actual costs incurred toward the current global development plan. The $232.3 million estimate includes $168.6 million in base funding and $63.7 million in estimated additional funding that is expected to result from the Company's exercise of the Otsuka Funding Option, described below, or the Additional Funding. The costs associated with the performance of any development activities in addition to those outlined in the current global development plan will be subject to a cost sharing or reimbursement mechanism to be determined by the parties. Costs incurred with respect to medical affairs and commercialization and non-promotional activities will generally be shared equally by the parties. In addition, due to the costs incurred in completing the activities under the current global development plan exceeding a certain threshold in the second quarter of 2019, the Company elected to require Otsuka to increase the aggregate percentage of current global development costs it funds under the Otsuka U.S. Agreement and the Otsuka International Agreement, as defined below, from 52.5% to 80%, or the Otsuka Funding Option. The Company estimates that the Additional Funding is estimated to total $63.7 million or more, depending on the actual costs incurred toward the current global development plan. The Additional Funding is fully creditable against future payments due to the Company under the arrangement, provided that future payments due to the Company may not be reduced by more than 50% in any calendar year and any remaining creditable amount above 50% in any calendar year will be applied to subsequent future payments until fully credited. As of June 30, 2019, revenue earned under the Additional Funding provision totaled approximately $10.6 million.

In addition, Otsuka would be required to make certain milestone payments to the Company upon the achievement of specified development, regulatory and commercial events. More specifically, the Company is eligible to receive up to $125.0 million in development milestone payments and up to $65.0 million in regulatory milestone payments for the first product to achieve the associated event. Moreover, the Company is eligible for up to $575.0 million in commercial milestone payments associated with aggregate sales of licensed products, subject to reduction as a result of the Company's exercise of the Otsuka Funding Option, as described above, which as of June 30, 2019 totaled $10.6 million. Due to the uncertainty of pharmaceutical development and the high historical failure rates associated therewith, no milestone payments may ever be received from Otsuka.

Under the Otsuka U.S. Agreement, the Company and Otsuka share the costs of developing and commercializing vadadustat in the U.S. and the profits from the sales of vadadustat after approval by the FDA. In connection with the profit share calculation, net sales include gross sales to third-party customers net of discounts, rebates, chargebacks, taxes, freight and insurance charges and other applicable deductions. Shared costs generally include costs attributable or reasonably allocable to the manufacture of vadadustat for commercialization purposes and the performance of medical affairs activities, non-promotional activities and commercialization activities.

Unless earlier terminated, the Otsuka U.S. Agreement will expire in the U.S. on a product-by-product basis on the date that one or more generic versions of vadadustat first achieves 90% market penetration. Either party may terminate the Otsuka U.S. Agreement in its entirety upon an uncured breach or insolvency on the part of the other party. Otsuka may terminate the Otsuka U.S. Agreement in its entirety upon 12 months' prior written notice at any time after the release of the first topline data from the global Phase 3 development program for vadadustat. In the event of termination of the Otsuka U.S. Agreement, all rights and licensees granted to Otsuka under the Otsuka U.S. Agreement will automatically terminate and the licenses granted to the Company will become freely sublicensable. In addition, the upfront payment, all development costs and milestone payments received by the Company prior to such termination will not be refunded to Otsuka.

Revenue Recognition

The Company evaluated the elements of the Otsuka U.S. Agreement in accordance with the provisions of ASC 606 and concluded that the contract counterparty, Otsuka, is a customer. The Company's arrangement with Otsuka contains the following material promises under the contract at inception: (i) license under certain of the Company's intellectual property to develop, perform medical affairs activities with respect to and conduct non-promotional and commercialization activities related to vadadustat and products containing or comprising vadadustat (the License Deliverable), (ii) development services to be performed pursuant to the current global development plan (the Development Services Deliverable), (iii) rights to future intellectual property (the Future IP Deliverable), and (iv) joint committee services (the Committee Deliverable).

The Company has identified three performance obligations in connection with its obligations under the Otsuka U.S. Agreement. Factors considered in making the assessment of which material promises will be accounted for as separate performance obligations included, among other things, the capabilities of the collaboration partner, whether any other vendor sells the item separately, whether the good or service is highly interdependent or highly interrelated to the other elements in the arrangement, and whether there are other vendors that can provide the items. Additionally, the Otsuka U.S. Agreement does not include a general right of return. The three performance obligations identified in connection with the Company's obligations under the Otsuka U.S. Agreement are as follows:

(i) License and Development Services Combined (License Performance Obligation)

The License Deliverable is not distinct from the Development Services Deliverable, due to the limitations inherent in the license conveyed. More specifically, the license conveyed to Otsuka does not provide Otsuka with the right to manufacture vadadustat and products containing or comprising vadadustat. However, the manufacturing and supply services that are conducted as part of the services to be performed pursuant to the current global development plan are necessary for Otsuka to fully exploit the associated license for its intended purpose. The value of the rights provided through the license conveyed will be realized when the underlying products covered by the intellectual property progress through the development cycle, receive regulatory approval and are commercialized. Products containing or comprising vadadustat cannot be commercialized until the development services under the current global development plan are completed. Accordingly, Otsuka must obtain the manufacturing and supply of the associated products that are included within the development services to be performed pursuant to the current global development plan from the Company in order to derive benefit from the license, which significantly limits the ability for Otsuka to utilize the License Deliverable for its intended purpose in a way that generates economic benefits.

(ii) Rights to Future Intellectual Property (Future IP Performance Obligation)

The License and Development Services deliverables combined are distinct from the Future IP Deliverable because Otsuka can obtain the value of the license using the clinical trial materials implicit in the development services without the receipt of any other intellectual property that may be discovered or developed in the future. The Future IP Deliverable is distinct from the Committee Deliverable because the joint committee services have no bearing on the value to be derived from the rights to potential future intellectual property. As a result, the Future IP Deliverable qualifies as a separate performance obligation.

(iii) Joint Committee Services (Committee Performance Obligation)

The License and Development Services deliverables combined are distinct from the Committee Deliverable because Otsuka can obtain the value of the license using the clinical trial materials implicit in the development services without the joint committee services. The Committee Deliverable also is distinct from the rights to Future IP Deliverable because the joint committee services have no bearing on the value to be derived from the rights to potential future intellectual property. As a result, the Committee Deliverable qualifies as a separate 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 standalone selling price for the Committee Performance Obligation after considering the nature of the services to be performed and estimates of the associated effort and rates applicable to such services that would be expected to be realized under similar contracts. The Company developed a best estimate of standalone selling price for the Future IP 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. The Company did not develop a best estimate of standalone selling price for the License Performance Obligation due to the following: (i) the best estimates of standalone selling price associated with the Future IP Performance Obligation was determined to be immaterial and (ii) the period of performance and pattern of recognition for the License Performance Obligation and the Committee Performance Obligation was determined to be similar. The Company has concluded that a change in the key assumptions used to determine the best estimate of standalone selling price for each performance obligation would not have a significant impact on the allocation of arrangement consideration.

The transaction price at inception was comprised of: (i) the up-front payment, (ii) the cost share payment with respect to amounts incurred by the Company through December 31, 2016, and (iii) an estimate of the cost share payments to be received with respect to amounts incurred by the Company subsequent to December 31, 2016. No development or regulatory milestones were included in the transaction price at inception, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Otsuka and therefore have also been excluded from the transaction price. The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

No amounts were allocated to the Future IP Performance Obligation because the associated best estimate of standalone selling price was determined to be immaterial. Due to the similar performance period and recognition pattern between the License Performance Obligation and the Committee Performance Obligation, the transaction price has been allocated to the License Performance Obligation and the Committee Performance Obligation on a combined basis. Accordingly, the Company will recognize revenue related to the allocable arrangement consideration on a proportional performance basis as the underlying development services are performed pursuant to the current global development plan which is commensurate with the period and consistent with the pattern over which the Company's obligations are satisfied for both the License Performance Obligation and the Committee Performance Obligation. Effectively, the Company has treated the arrangement as if the License Performance Obligation and the Committee Performance Obligation are a single performance obligation.

As of June 30, 2019, the transaction price totaling $391.1 million is comprised of: (i) the up-front payment of $125.0 million, (ii) the cost share payment with respect to amounts incurred by the Company through December 31, 2016 of $33.8 million, (iii) the estimate of the base cost share payments to be received of approximately $168.6 million with respect to amounts incurred by the Company subsequent to December 31, 2016, and (iv) the estimate of the additional funding of approximately $63.7 million related to incremental cost share payments under the Otsuka Funding Option described above. As of June 30, 2019, no development or regulatory milestones have been assessed as probable of being reached and thus have been fully constrained.

During the three months ended June 30, 2019 and 2018, the Company recognized revenue totaling approximately $37.5 million and $26.5 million, respectively, and $63.7 million and $46.1 million during the six months ended June 30, 2019 and 2018, respectively, with respect to the Otsuka U.S. Agreement. The revenue is classified as collaboration revenue in the accompanying unaudited condensed consolidated statements of operations. As of June 30, 2019, there is approximately $59.6 million of deferred revenue related to the Otsuka U.S. Agreement of which $23.7 million is classified as current and $35.9 million is classified as long-term in the accompanying unaudited condensed consolidated balance sheet based on the performance period of the underlying obligations. Additionally, as of June 30, 2019, there is approximately $5.0 million in accounts receivable in the accompanying unaudited condensed consolidated balance sheet. As of December 31, 2018, there was approximately $7.2 million in contract liabilities (included in accounts payable) in the consolidated balance sheet.

The Company determined that the medical affairs, commercialization and non-promotional activities elements of the Otsuka U.S. 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, the Company is accounting for the joint medical affairs, commercialization and non-promotional activities in accordance with ASC No. 808, *Collaborative Arrangements* (ASC 808). Additionally, the Company has determined that in the context of the medical affairs, commercialization and non-promotional activities, Otsuka 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 the medical affairs, commercialization and non-promotional activities plans will be accounted for as a component of the related expense in the period incurred. During the three months ended June 30, 2019 and 2018, the Company incurred approximately $0.3 million and $0.2 million, respectively, of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement of which approximately $0.1 million are reimbursable by Otsuka and recorded as a reduction to research and development expense during each of the three months ended June 30, 2019 and 2018, respectively. During the three months ended June 30, 2019, Otsuka incurred approximately $0.1 million of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.1 million are reimbursable by the Company and recorded as an increase to research and development expense during the three months ended June 30, 2019. No costs were incurred by Otsuka related to the cost-sharing provisions of the Otsuka U.S. Agreement during the three months ended June 30, 2018.

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

Summary of Agreement

On April 25, 2017, the Company entered into a collaboration and license agreement with Otsuka, or the Otsuka International Agreement. The collaboration is 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. Under the terms of the Otsuka International Agreement, the Company is responsible for leading the development of vadadustat, including the ongoing global Phase 3 development program. Otsuka has the sole responsibility, at its own cost, for the commercialization of vadadustat in the Otsuka International Territory, subject to the approval by the relevant regulatory authorities.

Under the terms of the Otsuka International Agreement, the Company granted to Otsuka an exclusive, sublicensable license under certain intellectual property controlled by the Company to develop and commercialize vadadustat and products containing or comprising vadadustat in the Otsuka International Territory.

Pursuant to the terms of the Otsuka International Agreement, the Company is responsible for performing all activities related to the development of vadadustat as outlined in the current global development plan; however, the parties may agree to allocate certain responsibilities to Otsuka. Under the Otsuka International Agreement, the Company controls and retains final decision-making authority with respect to certain matters. Per the terms of the Otsuka International Agreement, Otsuka is generally responsible for the conduct of any development activities that may be required for marketing approvals in the Otsuka International Territory or otherwise performed with respect to the Otsuka International Territory that are incremental to those included in the current global development plan. The Company's obligations related to the conduct of the current global development plan include the associated manufacturing and supply services for vadadustat.

Under the Otsuka International Agreement, Otsuka is to be solely responsible for the conduct of all medical affairs and commercialization activities in the Otsuka International Territory pursuant to underlying plans as reviewed and discussed by the parties. If approved by the relevant jurisdictional regulatory health authorities in the Otsuka International Territory, the Company will provide vadadustat to Otsuka for commercialization pursuant to a separate supply agreement to be negotiated. Additionally, the parties agreed not to promote, market or sell any competing product in the territory covered by the agreement.

The activities under the Otsuka International Agreement are governed by a JSC formed by an equal number of representatives from the Company and Otsuka. The JSC coordinates and monitors the parties' activities under the collaboration. Among other responsibilities, the JSC manages the overall strategic alignment between the parties, oversees the current global development plan and reviews other detailed plans setting forth any other development activities that may be conducted under the arrangement. Additionally, the parties established a JDC, which is comprised of an equal number of representatives from the Company and Otsuka. Among other responsibilities, the JDC shares information related to, and reviews and discusses activities and progress under, the current global development plan and any other development that may be conducted pursuant to the collaboration. The Company and Otsuka also established a JMC, which is comprised of an equal number of representatives from each of the parties. Among other responsibilities, the JMC oversees the manufacturing plan and related manufacturing activities. In support of the potential commercialization of vadadustat, the parties established a JCC, which is comprised of an equal number of representatives from the Company and Otsuka. Among other responsibilities, the JCC manages the activities and progress under the commercialization and non-promotional activities plan and all other sales and marketing activities. The Company has retained final decision-making authority with respect to certain matters. Otsuka has retained final decision-making authority with respect to all commercialization matters, other than decisions related to certain marketing matters.

Under the terms of the Otsuka International Agreement, the Company received a $73.0 million up-front, non-refundable, non-creditable cash payment. The Company also received a payment of approximately $0.2 million which represents reimbursement for Otsuka's share of costs previously incurred by the Company in implementing the current global development plan in excess of a specified threshold during the quarter ended March 31, 2017. Commencing in the second quarter of 2017, Otsuka began to contribute, as required by the Otsuka International Agreement, a percentage of the remaining costs incurred under the current global development plan. The Company estimates that Otsuka's funding of the current global development plan costs subsequent to March 31, 2017 will total roughly $177.2 million or more, depending on the actual current global development plan costs incurred. The costs associated with the performance of any mutually agreed upon development activities in addition to those outlined in the current global development plan will be subject to a cost sharing or reimbursement mechanism to be determined by the parties. Otsuka may elect to conduct additional studies of vadadustat in the EU, subject to the Company's right to delay such studies based on its objectives outside the Otsuka International Territory. Otsuka will pay a percentage of the costs of any such studies, and the Company will pay its portion of the costs in the form of a credit against future amounts due to the Company under the Otsuka International Agreement. The costs incurred related to any other development activities, which are pursued solely for obtaining or maintaining marketing approval in the Otsuka International Territory or otherwise performed solely with respect to the Otsuka International Territory that are incremental to the development activities included in the current global development plan, will be borne in their entirety by Otsuka. Otsuka will pay costs incurred with respect to medical affairs and commercialization activities in the Otsuka International Territory.

In addition, Otsuka would be required to make certain milestone payments to the Company upon the achievement of specified development, regulatory and commercial events. More specifically, the Company is eligible to receive up to $80.0 million in development milestone payments and up to $52.0 million in regulatory milestone payments for the first licensed product to achieve the associated event. Moreover, the Company is eligible for up to $525.0 million in commercial milestone payments associated with aggregate sales of all licensed products. Additionally, to the extent vadadustat is commercialized, the Company would be entitled to receive tiered royalty payments ranging from the low double digits to the low thirties based on a percentage of net sales. Royalties are due on a country-by-country basis from the date of the first commercial sale of a licensed product in a country until the latest to occur of: (i) the expiration date in such country of the last to expire valid claim within the intellectual property covering the licensed product, (ii) the date of expiration of data or regulatory exclusivity in such country or (iii) the tenth anniversary of the first commercial sale of such licensed product in such country. Due to the uncertainty of pharmaceutical development and the high historical failure rates associated therewith, no milestone or royalty payments may ever be received from Otsuka. There are no cancellation, termination or refund provisions in the Otsuka International Agreement that contain material financial consequences to the Company.

Unless earlier terminated, the Otsuka International Agreement will expire upon the expiration of the royalty term in the last country in the Otsuka International Territory. Either party may terminate the Otsuka International Agreement in its entirety upon an uncured material breach or insolvency on the part of the other party. Otsuka may terminate the Otsuka International Agreement in its entirety or for a specific region in the Otsuka International Territory upon 12 months' prior written notice at any time after the release of the first topline data from either the PRO_2TECT Phase 3 development program or the $INNO_2VATE$ Phase 3 development program, whichever comes first. In the event of termination of the Otsuka International Agreement, all rights and licensees granted to Otsuka under the Otsuka International Agreement will automatically terminate, and the licenses granted to the Company will become freely sublicensable, but potentially subject to a future royalty. In addition, the upfront payment, all development costs and milestone payments received by the Company prior to such termination will not be eligible for refund to Otsuka.

Revenue Recognition

The Company has accounted for the Otsuka International Agreement separately from the collaboration arrangement with Otsuka with respect to the U.S. due to the lack of interrelationship and interdependence of the elements and payment terms within each of the contracts as they relate to the respective territories. Accordingly, the Company has applied the guidance in ASC 606 solely in reference to the terms and conditions of the Otsuka International Agreement, while the Otsuka U.S. Agreement has continued to be accounted for as a discrete agreement in its own right. The Company evaluated the Otsuka International Agreement in accordance with the provisions of ASC 606 and concluded that the contract counterparty, Otsuka, is a customer. The Company's arrangement with Otsuka related to the Otsuka International Territory contains the following material promises under the contract at inception: (i) license under certain of the Company's intellectual property to develop and commercialize (including the associated packaging) vadadustat and products containing or comprising vadadustat and development services to be performed pursuant to the current global development plan (the License and Development Services Deliverable), (ii) rights to future intellectual property (the Future IP Deliverable) and (iii) joint committee services (the Committee Deliverable).

The Company has identified three performance obligations in connection with its obligations under the Otsuka International Agreement. Factors considered in making this assessment of which material promises will be accounted for as a separate performance obligation included, among other things, the capabilities of the collaboration partner, whether any other vendor sells the item separately, whether the good or service is highly interdependent or highly interrelated to the other elements in the arrangement, and whether there are other vendors that can provide the items. Additionally, the Otsuka International Agreement does not include a general right of return. The three performance obligations identified in connection with the Company's obligations under the Otsuka International Agreement are as follows:

(i) *License and Development Services Combined (License Performance Obligation)*

The Company has determined that the license granted to Otsuka pursuant to the Otsuka International Agreement will be accounted for as component of the development services as opposed to a separately identified promise. Although the rights granted under the license are effective throughout the entire term of the arrangement, the Company will not be providing significant additional contributions of study data, regulatory submissions and regulatory approvals beyond the point that services under the current global development plan are conducted. Therefore, the period and pattern of recognition would be the same for both the license and the development services. Consequently, the Company has concluded that the license will effectively be treated as an inherent part of the associated development services promise instead of as a separate promise. As a result, the License and Development Services Deliverable will be treated as a single performance obligation (the License Performance Obligation).

(ii) *Rights to Future Intellectual Property (Future IP Performance Obligation)*

The License and Development Services Deliverable is distinct from the Future IP Deliverable because Otsuka can obtain the value of the license using the clinical trial materials implicit in the development services without the receipt of any other intellectual property that may be discovered or developed in the future. The Future IP Deliverable is distinct from the Committee Deliverable because the Committee Deliverable has no bearing on the value to be derived from the rights to potential future intellectual property. As a result, the Future IP Deliverable qualifies as a separate performance obligation.

(iii) *Joint Committee Services (Committee Performance Obligation)*

The License and Development Services Deliverable is distinct from the Committee Deliverable because Otsuka can obtain the value of the license using the clinical trial materials implicit in the development service without the joint committee services. The Committee Deliverable is distinct from the Future IP Deliverable because the Committee Deliverable has no bearing on the value to be derived from the rights to potential future intellectual property. As a result, the Committee Deliverable qualifies as a separate 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 standalone selling price for the Committee Performance Obligation after considering the nature of the services to be performed and estimates of the associated effort and rates applicable to such services that would be expected to be realized under similar contracts. The Company developed a best estimate of standalone selling price for the Future IP 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. The Company did not develop a best estimate of standalone selling price for the License Performance Obligation due to the following: (i) the best estimates of standalone selling price associated with the Future IP Performance Obligation was determined to be immaterial and (ii) the period of performance and pattern of recognition for the License Performance Obligation and the Committee Performance Obligation was determined to be similar. The Company has concluded that a change in the key assumptions used to determine the best estimate of standalone selling price for each performance obligation would not have a significant impact on the allocation of arrangement consideration.

The transaction price at inception was comprised of: (i) the up-front payment, (ii) the cost share payment with respect to amounts incurred by the Company during the quarter ended March 31, 2017, and (iii) an estimate of the cost share payments to be received with respect to amounts incurred by the Company subsequent to March 31, 2017. No development or regulatory milestones were included in the transaction price at inception, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including whether the receipt of the milestone payment is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones (including royalties) will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to Otsuka and therefore have also been excluded from the transaction price. The Company re-evaluates the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

No amounts were allocated to the Future IP Performance Obligation because the associated best estimate of standalone selling price was determined to be immaterial. Due to the similar performance period and recognition pattern between the License Performance Obligation and the Committee Performance Obligation, the transaction price has been allocated to the License Performance Obligation and the Committee Performance Obligation on a combined basis. Accordingly, the Company will recognize revenue related to the allocable arrangement consideration on a proportional performance basis as the underlying development services are performed pursuant to the current global development plan which is commensurate with the period and consistent with the pattern over which the Company's obligations are satisfied for both the License Performance Obligation and the Committee Performance Obligation. Effectively, the Company has treated the arrangement as if the License Performance Obligation and the Committee Performance Obligation are a single performance obligation.

As of June 30, 2019, the transaction price totaling $250.4 million is comprised of: (i) the up-front payment of $73.0 million, (ii) the cost share payment with respect to amounts incurred by the Company during the quarter ended March 31, 2017 of $0.2 million, and (iii) an estimate of the cost share payments to be received with respect to amounts incurred by the Company subsequent to March 31, 2017 of $177.2 million. As of June 30, 2019, no development or regulatory milestones have been assessed as probable of being reached and thus have been fully constrained.

During the three months ended June 30, 2019 and 2018, the Company recognized revenue totaling approximately $22.5 million and $22.1 million, respectively, and approximately $44.4 million and $39.1 million during the six months ended June 30, 2019 and 2018, respectively, with respect to the Otsuka International Agreement. The revenue is classified as collaboration revenue in the accompanying unaudited condensed consolidated statements of operations. As of June 30, 2019, there is approximately $31.6 million of deferred revenue related to the Otsuka International Agreement of which $16.6 million is classified as current and $14.9 million is classified as long-term in the accompanying unaudited condensed consolidated balance sheet based on the performance period of the underlying obligations. Additionally, as of June 30, 2019, there is approximately $1.6 million in accounts receivable in the accompanying unaudited condensed consolidated balance sheet. As of December 31, 2018, there was approximately $6.3 million in contract liabilities (included in accounts payable) in the consolidated balance sheet.

Janssen Pharmaceutica NV Research and License Agreement

Summary of Agreement

On February 9, 2017, the Company entered into a Research and License Agreement, the Janssen Agreement, with Janssen Pharmaceutica NV, or Janssen, a subsidiary of Johnson & Johnson, pursuant to which Janssen granted the Company an exclusive license under certain intellectual property rights to develop and commercialize worldwide certain HIF prolyl hydroxylase targeted compounds.

Under the terms of the Janssen Agreement, Janssen granted to the Company a license for a three-year research term to conduct research on the HIF compound portfolio, unless the Company elects to extend such research term for up to two additional one-year periods upon payment of an extension fee. During the research term, the Company may designate one or more compounds as candidates for development and commercialization. Once a compound is designated for development and commercialization, the Company will be solely responsible for the development and commercialization of the compound worldwide at its own cost and expense.

Under the terms of the Janssen Agreement, the Company made an upfront payment of $1.0 million in cash to Janssen and issued a warrant to purchase 509,611 shares of the Company's common stock. In addition, Janssen could be eligible to receive up to an aggregate of $16.5 million from the Company in specified development milestone payments on a product-by-product basis. Janssen will also be eligible to receive up to $215.0 million from the Company in specified commercial milestones as well as tiered, escalating royalties ranging from a low- to mid-single digit percentage of net sales, on a product-by-product basis, and subject to reduction upon expiration of patent rights or the launch of a generic product in the territory.

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

As discussed above, the Company issued a Common Stock Purchase Warrant, or the Warrant, to Johnson & Johnson Innovation – JJDC, Inc., or JJDC, an affiliate of Janssen, for 509,611 shares of the Company's common stock at an exercise price of $9.81 per share. The Warrant is exercisable by JJDC, in whole or in part, at any time prior to February 9, 2022. The Warrant and the shares issuable upon exercise of the Warrant will be sold and issued without registration under the Securities Act of 1933, as amended, or the Securities Act. The Company recorded the fair value of the Warrant in the amount of $3.4 million to additional paid-in capital and research and development expense in March 2017.

Vifor Pharma License Agreement

Summary of Agreement

On May 12, 2017, the Company entered into a License Agreement, or the Vifor Agreement, with Vifor (International) Ltd., or Vifor Pharma, pursuant to which the Company granted Vifor Pharma an exclusive license to sell vadadustat solely to Fresenius Kidney Care Group LLC, or FKC, an affiliate of Fresenius Medical Care North America, or FMCNA, in the U.S. On April 8, 2019, the Company and Vifor Pharma entered into an Amended and Restated License Agreement, or the Vifor Amended Agreement, which amends and restates in full the Vifor Agreement.

Pursuant to the Vifor Amended Agreement, the Company granted Vifor Pharma an exclusive license to sell vadadustat to FKC and to certain third party dialysis organizations approved by the Company, or Third Party Dialysis Organizations, in the U.S. The license granted under the Vifor Amended Agreement will become effective upon (i) the approval of vadadustat for DD-CKD patients by the FDA, (ii) the earlier of a determination by the Centers for Medicare & Medicaid Services that vadadustat will be included in Medicare's bundled reimbursement model or that vadadustat will be reimbursed using the Transitional Drug Add-On Payment Adjustment, and (iii) payment by Vifor Pharma of a $25.0 million milestone upon the occurrence of (i) and (ii).

The Vifor Amended Agreement is structured as a profit share arrangement between the Company and Vifor Pharma in which the Company will receive a majority of the profit, after deduction of certain amounts relating to Vifor Pharma's costs, from Vifor Pharma's sales of vadadustat to FKC and the Third Party Dialysis Organizations in the U.S. The Company will share the milestone payment and the revenue from the profit share with Otsuka pursuant to the Otsuka U.S. Agreement. The Company currently retains rights to commercialize vadadustat for use in the NDD-CKD market and in other dialysis organizations in the U.S., which will be done in collaboration with Otsuka following FDA approval.

The Vifor Amended Agreement provides that the Company and Vifor Pharma will enter into a commercial supply agreement for vadadustat pursuant to which the Company will supply all of Vifor Pharma's requirements for vadadustat in the U.S. In addition, Vifor Pharma will enter into supply arrangements with FKC and the Third Party Dialysis Organizations that will govern the terms pursuant to which Vifor Pharma will supply vadadustat to FKC and the Third Party Dialysis Organizations for use in patients at its dialysis centers in the U.S. During the term of the Vifor Amended Agreement, Vifor Pharma is not permitted to sell any HIF product that competes with vadadustat in the U.S. to FKC or its affiliates or to any Third Party Dialysis Organization, and the Company may not directly supply vadadustat to FKC or any other affiliate of FMCNA or any Third Party Dialysis Organization.

Unless earlier terminated, the Vifor 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 U.S. Vifor Pharma may terminate the Vifor Amended Agreement in its entirety upon 12 months' prior written notice after the release of the first topline data in the vadadustat global Phase 3 program for DD-CKD patients. In addition, either party may, subject to a cure period, terminate the Vifor Amended Agreement in the event of the other party's uncured material breach or bankruptcy. The Company may terminate the Vifor Amended Agreement (or suspend the license) upon the occurrence of certain events, such as for specific violations of the Vifor Amended Agreement, Vifor Pharma's failure to achieve certain sales levels, or if there are changes in Vifor Pharma's relationship with FKC or in applicable laws and regulations related to the reimbursement of drugs like vadadustat at dialysis clinics, or if Vifor Pharma contests the validity or enforceability of any patent controlled by the Company that covers vadadustat. The Vifor Amended Agreement also includes a standstill provision and customary representations and warranties.

Investment Agreement

In connection with the Vifor Agreement, in May 2017, the Company and Vifor Pharma entered into an investment agreement, or the Investment Agreement, pursuant to which the Company sold an aggregate of 3,571,429 shares of the Company's common stock, or the Shares, to Vifor Pharma 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. As the parties' rights under the Vifor Agreement are conditioned upon (a) the approval of vadadustat for DD-CKD patients by the FDA; (b) inclusion of vadadustat in a bundled reimbursement model; and (c) payment by Vifor Pharma of a $20.0 million milestone upon the occurrence of these two events, in accordance with ASC 606, the Company has determined that the full transaction price is fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including clinical and regulatory risks that must be overcome in order for the parties' rights to become effective and the probability of the $20.0 million milestone being achieved. Accordingly, the $4.7 million continues to be recorded as deferred revenue in the accompanying unaudited condensed consolidated balance sheets. Upon the satisfaction of the aforementioned conditions, revenue will be recognized as the Company supplies vadadustat to Vifor Pharma using a proportional performance method.

Vifor Pharma agreed to a lock-up restriction such that it agrees not to sell the Shares for a period of time following the effective date of the Investment Agreement as well as a customary standstill agreement. In addition, the Investment Agreement contains voting agreements made by Vifor Pharma with respect to the Shares. The 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 Rule 506 promulgated thereunder.

License Agreement with Panion & BF Biotech, Inc.

As a result of the Merger, the Company had a license agreement, which was amended from time to time, with Panion & BF Biotech, Inc., or Panion, under which Keryx, the Company's wholly owned subsidiary, was the contracting party, or the Panion License Agreement, Keryx in-licensed the exclusive worldwide rights, excluding certain Asian-Pacific countries, or the 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, or the 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 the Company with an exclusive license under Panion-owned know-how and patents covering the rights to sublicense, develop, make, use, sell, offer for sale, import and export ferric citrate worldwide, excluding the Licensor Territory. The Panion Amended License Agreement also provides Panion with an exclusive license under Keryx-owned patents covering the rights to sublicense (with the Company's written consent), develop, make, use, sell, offer for sale, import and export ferric citrate in certain countries in the Licensor Territory. Consistent with the Panion License Agreement, 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.

Pursuant to the terms of the Panion Amended License Agreement, a joint steering committee, or the Panion JSC, consisting of Panion and Company representatives was formed to oversee the development and commercialization of Fexeric in Europe. In accordance with the Panion Amended License Agreement, the Panion JSC reached consensus on a commercialization plan, which was subsequently agreed to by the parties for Europe in the second quarter of 2019. In addition, the Panion Amended License Agreement provides that each of the Company and Panion has the right, but not the obligation, to conduct litigation against any infringer of certain patent rights under the Panion Amended License Agreement in certain territories.

The Panion Amended License Agreement terminates upon the expiration of each of the Company's and Panion's obligations to pay royalties thereunder. In addition, the Company may terminate the Panion Amended License Agreement (i) in its entirety or (ii) with respect to one or more countries in the Company's licensed territory, in either case upon 90 days' notice. The Company and Panion also each have the right to terminate the Panion Amended License Agreement upon the occurrence of a material breach of the Panion Amended License Agreement by the other party, subject to certain cure provisions, or certain insolvency events. The Panion Amended License Agreement also provides that, on a country-by-country basis, until the second anniversary of the expiration of the obligation of the Company or Panion, as applicable, to pay royalties in a country in which such party has ferric citrate for sale on the date of such expiration, neither the other party nor its affiliates will, directly or indirectly, sell, distribute or otherwise commercialize or supply or cause to supply ferric citrate to a third party for sale or distribution in such country.

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

During the three and six months ended June 30, 2019, the Company incurred approximately $2.6 million and $4.7 million, respectively, in royalty payments due to Panion relating to the Company's sales of Auryxia in the U.S. 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.

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

Summary of Agreement

In connection with the Merger, the Company now has a Sublicense Agreement with JT and Torii, and the Amended and Restated Sublicense Agreement with JT and Torii, collectively the JT and Torii Sublicense Agreement, under which Keryx, our 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.

Ferric citrate hydrate is currently approved by the Japanese Ministry of Health, Labour and Welfare for manufacturing and marketing in Japan for the treatment of hyperphosphatemia in patients with CKD. Ferric citrate hydrate is being marketed in Japan by Torii, under the brand name Riona. JT and Torii are currently conducting a Phase 3 clinical program evaluating Riona for the treatment of IDA in adult patients in Japan. JT and Torii have stated that, upon successful completion of its Phase 3 program, they expect to file an application for approval of IDA as an additional indication for Riona in Japan. The Company is eligible to receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, subject to certain reductions upon expiration or termination of the Amended and Restated License Agreement between Keryx and Panion, by which Keryx in-licensed the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and commercialization of ferric citrate. The Company is entitled to receive up to an additional $55.0 million upon the achievement of certain annual net sales milestones.

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

Revenue Recognition

The Company evaluated the elements of the JT and Torii Sublicense Agreement in accordance with the provisions of ASC 606 and concluded that the contract counterparty, JT and Torii, is a customer. The Company's arrangement with JT and Torii contains the following material promises under the contract at inception: (i) exclusive license to develop and commercialize ferric citrate hydrate in Japan (the License Deliverable), (ii) supply of ferric citrate hydrate until JT and Torii could secure their own source (the Supply Deliverable), (iii) knowledge transfer, and (iv) rights to future know-how.

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. Additionally, as of the consummation of the Merger, the services associated with the License and Supply Performance Obligation were completed and JT and Torii had secured their own source to manufacture ferric citrate hydrate. As such, any initial license fees as well as any development-based milestones and manufacturing fee revenue were received and recognized prior to the Merger. The Company determined that the remaining consideration that may be payable to the Company under the terms of the sublicense agreement are either quarterly royalties on net sales or payments due upon the achievement of sales-based milestones. In accordance with ASC 606, the Company recognizes sales-based royalties, including milestone payments based on the level of sales, when the related sales occur as these amounts have been determined to relate predominantly to the license granted to JT and Torii and therefore are recognized at the later of when the performance obligation is satisfied, or the related sales occur.

During the three and six months ended June 30, 2019, the Company recognized $1.5 million and $2.7 million, respectively, in license revenue 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.

5. Business Combination

On December 12, 2018, the Company completed the Merger with Keryx. Keryx focused on the development and commercialization of medicines for people with kidney disease. Keryx's proprietary product, Auryxia, is approved by the FDA for two indications: (1) the control of serum phosphorus levels in adult patients with DD-CKD and (2) the treatment of iron deficiency anemia in adult patients with NDD-CKD.

Pursuant to the terms and conditions of the Merger Agreement, each outstanding Keryx Share, excluding the Baupost Additional Shares, as defined below, and each outstanding Keryx equity award were converted into Akebia Shares and substantially similar Akebia equity awards, respectively, at an exchange ratio of 0.37433 for a total fair value consideration of $527.8 million consisting of the following (in thousands):

Fair value of 57,773,090 Akebia Shares	$	516,492
Fair value of 602,752 Akebia RSUs		304
Fair value of 3,967,290 Akebia stock options		10,958
Total consideration	$	527,754

Immediately prior to the Merger, Baupost Group Securities, L.L.C., or Baupost, agreed to convert its $164.7 million of Keryx's Convertible Notes into 35,582,335 Keryx Shares, in accordance with the terms of the governing indenture agreement, in exchange for an additional 4,000,000 Keryx Shares, or the Baupost Additional Shares. The aggregate 39.6 million Keryx Shares were then converted into Akebia Shares at the 0.37433 exchange ratio. The fair value of the Baupost Additional Shares, on an as-converted basis, of $13.4 million has been excluded from the purchase price and recorded within selling, general and administrative expenses in our consolidated financial statements, as the issuance of those shares by Keryx is considered to be a separate transaction under ASC 805, *Business Combinations*, since it was entered into by or on behalf of the acquirer or primarily for the benefit of the acquirer or the combined entity.

The Company has allocated the $527.8 million purchase price to the identifiable assets acquired and liabilities assumed in the business combination at their fair values as of December 12, 2018 as follows (in thousands):

Cash and cash equivalents	$	5,257
Inventory		235,597
Trade accounts receivable, net		15,834
Prepaid expenses and other current assets		8,399
Goodwill		55,053
Intangible assets:		
Developed product rights for Auryxia		329,130
Other intangible assets		545
Property and equipment, net		3,646
Other assets		14,441
Accounts payable		(17,570)
Accrued expenses		(42,972)
Deferred tax liability		(35,096)
Debt		(15,000)
Fair value of unfavorable executory contract		(29,510)
Total purchase price	$	527,754

In performing the purchase price allocation, the Company considered, among other factors, the intended future use of acquired assets, analysis of historical financial performance and estimates of future performance of Keryx's business.

As part of the purchase price allocation, the Company identified developed product rights for Auryxia as the primary intangible asset. The fair value of the developed product rights for Auryxia was determined using the multi-period excess earnings method which is a variation of the income approach, and is a valuation technique that provides an estimate of the fair value of an asset based on the principle that the value of an intangible asset is equal to the present value of the incremental after-tax cash flows attributable to the asset, after taking charges for the use of other assets employed by the business. Key estimates and assumptions used in this model were projected revenues and expenses related to the asset, estimated contributory asset charges, and a risk-adjusted discount rate of 20.0% used to calculate the present value of the future expected cash inflows from the asset. The intangible asset is being amortized on a straight-line basis over its estimated useful life, which for Auryxia is nine years.

The Company also identified an executory contract in the supply agreement between Keryx and BioVectra Inc., or BioVectra, which includes future firm purchase commitments. This executory contract was deemed to have an off-market element related to the amount of purchase commitments that exceed the current forecast and as such, the Company recorded a liability in purchase accounting. As of the acquisition date, the preliminary fair value of the off-market element was $29.5 million.

The preliminary goodwill represents the excess of the purchase price over the estimated fair value of net assets acquired. The factors contributing to the recognition of goodwill were based on several strategic and synergistic benefits that were expected to be realized from the Merger. These benefits included the expectation that the combined company would establish itself as a leading renal company with enhanced position and large market opportunity, synergistic utilization of Keryx's commercial organization, and strengthening the combined company's financial profile. Such goodwill is not deductible for tax purposes.

In connection with the Merger, the Company identified a preliminary deferred tax liability of $35.1 million as a result of the difference in the book basis and tax basis related to the identifiable inventory, other intangible assets, net and other liability. In determining the deferred tax liability to be recorded the Company elected to first consider the recoverability of the deferred tax assets acquired in the acquisition before considering the recoverability of the acquirer's existing deferred tax assets. The deferred tax liability recorded as part of purchase accounting creates a source of future income against which the Company can benefit its tax attributes. The use of the Company's tax attributes resulted in a release of the corresponding valuation allowance which was recorded as a benefit in the statement of operations. The fair values of deferred taxes may be subject to change as additional information becomes known and certain tax returns are finalized. Accordingly, the purchase price allocation is preliminary and remains subject to potential adjustments for the finalization of income taxes relating to purchase accounting. There can be no assurance that such finalizations will not result in material changes from the preliminary purchase price allocation. The Company's estimates and assumptions are subject to change during the measurement period, which is up to one year from the acquisition date, as the Company finalizes the valuations of assets acquired and liabilities assumed.

6. Available For Sale Securities

Available for sale securities at June 30, 2019 and December 31, 2018 consisted of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
June 30, 2019				
Cash and cash equivalents	$ 87,212	$ —	$ —	$ 87,212
Available for sale securities:				
Certificates of deposit	$ 245	$ —	$ —	$ 245
U.S. government debt securities	42,372	25	(3)	42,394
Corporate debt securities	6,913	1	—	6,914
Total available for sale securities	$ 49,530	$ 26	$ (3)	$ 49,553
Total cash, cash equivalents, and available for sale securities	$ 136,742	$ 26	$ (3)	$ 136,765

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
December 31, 2018				
Cash and cash equivalents	$ 104,644	$ —	$ —	$ 104,644
Available for sale securities:				
Certificates of deposit	$ 245	—	—	$ 245
U.S. government debt securities	158,518	1	(198)	158,321
Corporate debt securities	58,494	—	(64)	58,430
Total available for sale securities	$ 217,257	$ 1	$ (262)	$ 216,996
Total cash, cash equivalents, and available for sale securities	$ 321,901	$ 1	$ (262)	$ 321,640

The estimated fair value of the Company's available for sale securities balance at June 30, 2019, by contractual maturity, was as follows:

Due in one year or less	$ 49,553
Due after one year	—
Total available for sale securities	$ 49,553

There were no realized gains or losses on available for sale securities for the three and six months ended June 30, 2019 and 2018. The following table summarizes the Company's available for sale securities that were in a continuous unrealized loss position, but were not deemed to be other-than temporarily impaired, as of June 30, 2019 and December 31, 2018:

	Unrealized Loss for Less Than 12 Months		Unrealized Loss for 12 Months or More		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)					
June 30, 2019						
Available for sale securities:						
U.S. government debt securities	$ (1)	$ 245	$ (2)	$ 9,988	$ (3)	$ 10,233
Total	$ (1)	$ 245	$ (2)	$ 9,988	$ (3)	$ 10,233

	Unrealized Loss for Less Than 12 Months		Unrealized Loss for 12 Months or More		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)					
December 31, 2018						
Available for sale securities:						
U.S. government debt securities	$ (159)	$ 116,026	$ (39)	$ 29,934	$ (198)	$ 145,960
Corporate debt securities	(64)	58,430	—	—	(64)	58,430
Total	$ (223)	$ 174,456	$ (39)	$ 29,934	$ (262)	$ 204,390

There were 3 securities and 51 securities as of June 30, 2019 and December 31, 2018, respectively, that were in an unrealized loss position. The Company considered the decline in the market value of these securities to be primarily attributable to current economic conditions. The contractual terms of these securities do not permit the issuer to settle the securities at a price less than the amortized cost basis of the investment. As of June 30, 2019, the Company does not intend to sell these securities and it was not more likely than not that the Company would be required to sell these securities before the recovery of their amortized cost basis, which may be at maturity. As a result, the Company did not consider these investments to be other-than-temporarily impaired as of June 30, 2019.

7. Fair Value of Financial Instruments

The Company utilizes a portfolio management company for the valuation of the majority of its investments. This company is an independent, third-party vendor recognized to be an industry leader with access to market information that obtains or computes fair market values from quoted market prices, pricing for similar securities, recently executed transactions, cash flow models with yield curves and other pricing models. For valuations obtained from the pricing service, the Company performs due diligence to understand how the valuation was calculated or derived, focusing on the valuation technique used and the nature of the inputs.

Based on the fair value hierarchy, the Company classifies its cash equivalents and marketable securities within Level 1 or Level 2. This is because the Company values its cash equivalents and marketable securities using quoted market prices or alternative pricing sources and models utilizing market observable inputs.

Assets measured or disclosed at fair value on a recurring basis as of June 30, 2019 and December 31, 2018 are summarized below:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
June 30, 2019				
Assets:				
Cash and cash equivalents	$ 87,212	$ —	$ —	$ 87,212
Certificates of deposit	—	245	—	245
U.S. government debt securities	—	42,394	—	42,394
Corporate debt securities	—	6,914	—	6,914
	$ 87,212	$ 49,553	$ —	$ 136,765

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
December 31, 2018				
Assets:				
Cash and cash equivalents	$ 104,644	$ —	$ —	$ 104,644
Certificates of deposit	—	245	—	245
U.S. government debt securities	—	158,321	—	158,321
Corporate debt securities	—	58,430	—	58,430
	$ 104,644	$ 216,996	$ —	$ 321,640

The Company's corporate debt securities are all investment grade.

The Company had no assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) at June 30, 2019 and December 31, 2018.

Investment securities are exposed to various risks such as interest rate, market and credit risks. Due to the level of risk associated with certain investment securities and the level of uncertainty related to changes in the value of investment securities, it is at least reasonably possible that changes in risks in the near term would result in material changes in the fair value of investments.

8. Inventory

The components of inventory are summarized as follows:

	June 30, 2019	December 31, 2018
	(in thousands)	
Raw materials	$ 1,918	$ 1,880
Work in process	177,281	215,122
Finished goods	30,206	18,182
Total inventory	$ 209,405	$ 235,184

Long-term inventory, which primarily consists of raw materials and work in process, is included in other assets in the Company's consolidated balance sheets.

	June 30, 2019	December 31, 2018
	(in thousands)	
Balance Sheet Classification:		
Inventory	$ 122,137	$ 114,245
Other assets	87,268	120,939
Total inventory	$ 209,405	$ 235,184

Inventory amounts written down as a result of excess, obsolescence, scrap or other reasons and charged to cost of goods sold totaled $1.3 million and $3.0 million during the three and six months ended June 30, 2019. The Company did not have any inventory write-offs during the three and six months ended June 30, 2018, respectively, as there were no inventory amounts prior to the Merger on December 12, 2018. If future sales of Auryxia are lower than expected, the Company may be required to write-down the value of such inventories. Inventory write-downs and losses on purchase commitments are recorded as a component of cost of sales in the unaudited condensed consolidated statement of operations.

9. Intangible Assets and Goodwill

Intangible Assets

The following table presents the Company's intangible assets at June 30, 2019 and December 31, 2018 (in thousands):

	June 30, 2019				
	Gross Carrying Value	Accumulated Amortization	ASC 842 Adjustment	Total	Estimated useful life
Acquired intangible assets:					
Developed product rights for Auryxia	$ 329,130	$ (19,717)	$ —	$ 309,413	9 Years
Favorable lease	545	(5)	(540)	—	N/A
Total	$ 329,675	$ (19,722)	$ (540)	$ 309,413	

	December 31, 2018			
	Gross Carrying Value	Accumulated Amortization	Total	Estimated useful life
Acquired intangible assets:				
Developed product rights for Auryxia	$ 329,130	$ (1,517)	$ 327,613	9 Years
Favorable lease	545	(5)	540	4 Years
Total	$ 329,675	$ (1,522)	$ 328,153	

On December 12, 2018, the Company completed the Merger, whereby it acquired certain definite-lived intangible assets, including the developed product rights for Auryxia and a favorable lease. The Company amortizes its definite-lived intangible assets acquired as part of the Merger using the straight-line method, which is considered the best estimate of economic benefit, over its estimated useful life. As a result of the adoption of ASC 842 on January 1, 2019, the Company reclassed the remaining balance of the favorable lease intangible asset into the operating lease asset. The Company recorded $9.1 million and $18.2 million in amortization expense related to the developed product rights for Auryxia during the three and six months ended June 30, 2019, respectively. Estimated future amortization expense for the intangible asset as of June 30, 2019 is as follows (in thousands):

	Total
2019	$ 18,201
2020	36,402
2021	36,401
2022	36,402
2023	36,401
Thereafter	145,606
	$ 309,413

Goodwill

Goodwill was $55.1 million as of June 30, 2019 and December 31, 2018, derived as follows (in thousands):

Total Merger consideration	$ 527,754
Less: Fair value of identified acquired assets and liabilities, net	(472,701)
Goodwill	$ 55,053

Goodwill will be evaluated for impairment on an annual basis as of October 1, and more frequently if indicators are present or changes in circumstances suggest that an impairment may exist.

10. Accrued Expenses

Accrued expenses as of June 30, 2019 and December 31, 2018 are as follows:

	June 30, 2019	December 31, 2018
	(in thousands)	
Accrued clinical expenses	$ 68,821	$ 71,881
Product revenue allowances	21,917	22,861
Accrued bonus	5,635	9,537
Lease liability	4,780	—
Accrued commercial manufacturing	3,660	6,383
Royalties	2,646	2,430
Professional fees	2,620	2,367
Accrued payroll	2,047	2,255
Accrued vacation	1,017	1,088
Accrued severance	42	3,962
Merger costs	—	16,071
Accrued other	12,796	12,082
Total accrued expenses	$ 125,981	$ 150,917

11. Debt

Revolving Line of Credit

Keryx, our wholly owned subsidiary following the Merger, has a $40.0 million revolving line of credit, or the Line of Credit, under its Loan and Security Agreement with Silicon Valley Bank, or SVB. Availability under the Line of Credit is subject to a borrowing base comprised of eligible receivables and eligible inventory of Keryx as set forth in the Loan and Security Agreement. As of June 30, 2019 and December 31, 2018, there was $0 and $15.0 million outstanding, respectively, under the Line of Credit and the Company had approximately $23.9 million in available borrowing base as of June 30, 2019.

Proceeds from the Line of Credit may be used for working capital and general business purposes. The Line of Credit is secured by substantially all of Keryx's assets other than its intellectual property. The Line of Credit restricts Keryx's ability to grant any interest in its intellectual property other than certain permitted licenses and permitted encumbrances set forth in the Loan and Security Agreement.

The principal amount outstanding under the Loan and Security Agreement bears interest at a floating rate per annum equal to the greater of (i) 2.0% above the "prime rate," as reported in The Wall Street Journal and (ii) 6.75%, which interest is payable monthly. Principal amounts borrowed under the Line of Credit may be repaid and, prior to the maturity date, re-borrowed, subject to the terms and conditions set forth in the Loan and Security Agreement. The Line of Credit matures on the date that is the earlier of (i) two years after the effective date of the Loan and Security Agreement and (ii) ninety days prior to the maturity of any portion of any Permitted Convertible Debt, as defined under the Loan and Security Agreement. Upon entry into the Loan and Security Agreement (payable in installments and subject to certain conditions), and at the one year anniversary of the effective date of the Loan and Security Agreement (or, if earlier, upon termination of or an event of default under the Loan and Security Agreement), Keryx must pay to SVB a fee equal to 1.00% of the Line of Credit. Keryx is also required to pay on a quarterly basis a fee equal to 0.25% per annum of the average unused portion of the Line of Credit. Keryx must pay a termination fee of 2.00% of the Line of Credit, if the Loan and Security Agreement is terminated prior to the maturity date of July 18, 2020, subject to certain exceptions.

The Loan and Security Agreement contains customary covenants applicable to Keryx and its subsidiaries, including maintaining insurance on its business, achievement of minimum revenue amounts, the incurrence of additional indebtedness, and future encumbrances on Keryx's assets. In addition, the Keryx must maintain a liquidity ratio, defined as (i) the sum of unrestricted and unencumbered cash and cash equivalents maintained at SVB or its affiliates plus net billed accounts receivable divided by (ii) all outstanding obligations and liabilities of Keryx to SVB, including the aggregate amount of Keryx's obligations to SVB under any business credit cards, of at least 1.5 to 1.0, measured monthly.

Upon an event of default under the Loan and Security Agreement, SVB is entitled to accelerate and demand payment of all amounts outstanding under the Loan and Security Agreement, stop advancing money or extending credit to Keryx, demand that Keryx deposit at least 105% of the face amount of any letters of credit remaining undrawn to secure all obligations thereunder, and exercise other remedies available to SVB under the Loan and Security Agreement and at law or in equity. As of June 30, 2019 and December 31, 2018, the Company determined that events of default had occurred.

On July 31, 2019, Keryx entered into a Waiver and First Amendment to Loan and Security Agreement, or the Loan Amendment. Pursuant to the Loan Amendment, certain revisions were made to the Loan and Security Agreement, including requiring Keryx to maintain, from and after December 31, 2019, subject to certain exceptions, a certain amount of funds to which the Company has unrestricted access in one or more asset management accounts with SVB or SVB's affiliate and revising certain of the representations and warranties and covenants in the Loan and Security Agreement. In addition, pursuant to the Loan Amendment, SVB waived the then-existing events of default.

On August 7, 2019, the Company executed and delivered to SVB an Unconditional Guaranty, or the Guaranty, pursuant to which the Company guaranteed the prompt and complete payment and performance when due of all of the obligations and liabilities of Keryx under the Loan and Security Agreement, as amended by the Loan Amendment, or the Amended Loan Agreement. In addition, the Company entered into a Security Agreement with SVB effective August 7, 2019, or the Security Agreement, pursuant to which the Company granted to SVB a continuing first priority security interest in substantially all of the Company's personal property, other than the Company's intellectual property, to secure the payment and performance of the Company's obligations under the Guaranty. The Company's obligations under the Guaranty are independent of Keryx's obligations, and separate actions may be brought against the Company.

The Security Agreement contains customary representations and warranties and affirmative and negative covenants. The affirmative covenants include, among others, covenants requiring the Company to maintain its legal corporate existence and governmental approvals, maintain insurance coverage and protect our intellectual property rights. The negative covenants include, among others, restrictions on transferring the Company's assets, changing the Company's business, undergoing a change in control, engaging in mergers or acquisitions, incurring additional indebtedness, creating liens, paying dividends or making other distributions, making investments and transacting with affiliates, in each case subject to certain exceptions.

Upon an event of default under the Security Agreement, SVB is entitled to exercise several remedies, including accelerating and demanding payment of all the Company's liabilities under the Guaranty, ceasing to advance money or extend credit under the Amended Loan Agreement, demanding that the Company deposit cash with SVB in an amount equal to the aggregate amount of any letters of credit remaining undrawn to secure all obligations thereunder, and seeking to enforce security interests in the collateral securing the Amended Loan Agreement and the Guaranty.

During the three and six months ended June 30, 2019, the Company recognized approximately $37,000 and $0.3 million, respectively, of interest expense related to the Line of Credit. The Company did not incur any amortization expense related to the origination fee and other additional fees noted above as such fees were included in the fair value of the Line of Credit as of December 12, 2018, the date on which the Merger was consummated, in accordance with ASC 805.

12. Warrant

In connection with the Janssen Agreement, in February 2017 the Company issued a warrant to purchase 509,611 shares of the Company's common stock at an exercise price of $9.81 per share. The warrant was fully vested upon issuance and is exercisable in whole or in part, at any time prior to February 9, 2022. The warrant satisfied the equity classification criteria of ASC 815, and is therefore classified as an equity instrument. The fair value at issuance of $3.4 million was calculated using the Black Scholes option pricing model and was charged to research and development expense as it represented consideration for a license for which the underlying intellectual property was deemed to have no alternative future use. As of June 30, 2019, the warrant remains outstanding and expires on February 9, 2022.

13. Stockholders' Equity

Authorized and Outstanding Capital Stock

As of June 30, 2019, the authorized capital stock of the Company included 175,000,000 shares of common stock, par value $0.00001 per share, of which 118,787,301 and 116,887,518 shares were issued and outstanding at June 30, 2019 and December 31, 2018, respectively; and 25,000,000 shares of undesignated preferred stock, par value $0.00001 per share, of which 0 shares were issued and outstanding at June 30, 2019 and December 31, 2018.

At-the-Market Facility

In May 2016, the Company established an at-the-market, or ATM, equity offering program pursuant to which it was able to offer and sell up to $75.0 million of common stock at the then current market prices from time to time. Through December 31, 2018, the Company sold 1,775,214 shares of common stock under this program with net proceeds of $22.6 million, of which 694,306 shares were sold in the three months ended March 31, 2018 for net proceeds of approximately $10.5 million. The Company did not sell any additional shares in the three months ended June 30, 2018. Additionally, the Company sold 1,384,520 shares in the three months ended June 30, 2019 for net proceeds (after deducting commissions and other offering expenses) of approximately $9.4 million. During the three months ended March 31, 2019, the Company did not complete any sales of common stock under this program.

Retired Shares

In April 2019, the Company repurchased and retired 55,324 shares of common stock. The proceeds from the disposition of these shares were used by certain officers of the Company to cover tax liabilities associated with previously vested RSUs.

Equity Plans

On February 28, 2014, the Company's Board of Directors adopted its 2014 Incentive Plan and its 2014 Employee Stock Purchase Plan, or the 2014 ESPP, which were subsequently approved by its shareholders and became effective upon the closing of the Company's initial public offering on March 25, 2014. The Company's 2014 Incentive Plan was subsequently amended on December 11, 2018, which amendment did not require shareholder approval. The Company's 2014 Incentive Plan, as amended, is referred to as the 2014 Plan. The 2014 Plan replaced the Company's Amended and Restated 2008 Equity Incentive Plan, or the 2008 Plan; however, options or other awards granted under the 2008 Plan prior to the adoption of the 2014 Plan that have not been settled or forfeited remain outstanding and effective. On June 6, 2019, the Company's shareholders approved the Amended and Restated 2014 Employee Stock Purchase Plan, or the ESPP. In May 2016, the Company's Board of Directors approved an inducement award program that was separate from the Company's equity plans and which, consistent with Nasdaq Listing Rule 5635(c)(4), did not require shareholder approval, or the Inducement Award Program. For 2019, the Company authorized the issuance of up to 3,150,000 shares for the purpose of granting options to purchase shares of the Company's common stock to new hires under the Inducement Award Program, of which 787,700 options to purchase Akebia Shares were granted during the six months ended June 30, 2019, of which 774,700 options to purchase Akebia Shares remained outstanding at June 30, 2019.

The 2014 Plan allows for the granting of stock options, stock appreciation rights, or SARs, restricted stock, unrestricted stock, RSUs, performance awards and other awards convertible into or otherwise based on shares of the Company's common stock. Dividend equivalents may also be provided in connection with an award under the 2014 Plan. The Company's employees, officers, directors and consultants and advisors are eligible to receive awards under the 2014 Plan. The Company initially reserved 1,785,000 shares of its common stock for the issuance of awards under the 2014 Plan. The 2014 Plan provides that the number of shares reserved and available for issuance under the 2014 Plan will automatically increase annually on January 1 of each calendar year, by an amount equal to three percent (3%) of the number of Akebia Shares outstanding on a fully diluted basis as of the close of business on the immediately preceding December 31, or the 2014 Plan Evergreen Provision. The Company's Board of Directors may act prior to January 1 of any year to provide that there will be no automatic increase in the number of Akebia Shares available for grant under the 2014 Plan for that year (or that the increase will be less than the amount that would otherwise have automatically been made). On December 12, 2018, in connection with the consummation of the Merger, the Company assumed outstanding and unexercised options to purchase Keryx Shares, as adjusted by the Exchange Multiplier pursuant to the terms of the Merger Agreement, under the following Keryx equity plans, or the Keryx Equity Plans: the Keryx 1999 Share Option Plan, the Keryx 2004 Long-Term Incentive Plan, the Keryx 2007 Incentive Plan, the Keryx Amended and Restated 2013 Incentive Plan, and the Keryx 2018 Equity Incentive Plan, or the Keryx 2018 Plan. In addition, the number of Keryx Shares available for issuance under the Keryx 2018 Plan, as adjusted by the Exchange Multiplier pursuant to the terms of the Merger Agreement, may be used for awards granted by the Company under its 2014 Plan, or the Assumed Shares, provided that the Company uses the Assumed Shares for individuals who were not employees or directors of the Company prior to the consummation of the Merger. During the six months ended June 30, 2019, the Company granted 2,028,625 options to purchase Akebia Shares to employees under the 2014 Plan, 787,700 options to purchase Akebia Shares to employees under the Inducement Award Program, 1,432,200 Akebia RSUs to employees under the 2014 Plan, 180,900 options to purchase Akebia Shares to directors under the 2014 Plan, and 123,300 Akebia RSUs to directors under the 2014 Plan.

The ESPP provides for the issuance of options to purchase shares of the Company's common stock to participating employees at a discount to their fair market value. As noted above, the Company's stockholders approved the ESPP, which amended and restated the Company's 2014 ESPP, on June 6, 2019. The maximum aggregate number of shares at June 30, 2019 of the Company's common stock available for future issuance under the ESPP is 5,763,545. Under the ESPP, each offering period is six months, at the end of which employees may purchase shares of the Company's common stock through payroll deductions made over the term of the offering. The per-share purchase price at the end of each offering period is equal to the lesser of eighty-five percent (85%) of the closing price of the Company's common stock at the beginning or end of the offering period.

Shares Reserved for Future Issuance

The Company has reserved for future issuance the following number of shares of common stock:

	June 30, 2019	December 31, 2018
Common stock options and RSUs outstanding (1)	9,717,566	9,309,204
Shares available for issuance under Akebia equity plans (2)	7,874,513	4,526,563
Warrant to purchase common stock	509,611	509,611
Shares available for issuance under the ESPP (3)	5,763,545	603,522
Total	23,865,235	14,948,900

(1) Includes awards granted under the 2014 Plan and the Inducement Award Program and awards issued in connection with the Merger.

(2) On January 1, 2019, January 1, 2018 and January 1, 2017, the shares reserved for future grants under the 2014 Plan increased by 3,801,198, 1,575,329 and 1,265,863 shares, respectively, pursuant to the 2014 Plan Evergreen Provision. On December 12, 2018, the shares reserved for future grants under the 2014 Plan increased by 2,323,213 shares as a result of the Company's addition of the Assumed Shares to the 2014 Plan. On December 19, 2017, the Company's Board of Directors approved 750,000 shares for issuance as option awards in fiscal year 2018 under the Inducement Award Program. Additionally, on January 30, 2019, the Company's Board of Directors approved 3,150,000 shares for issuance as option awards in fiscal year 2019 under the Inducement Award Program, or the 2019 Inducement Shares.

(3) On June 6, 2019, the shares reserved for future issuance under the ESPP increased by 5,200,000 shares upon shareholder approval of the Amended and Restated 2014 Employee Stock Purchase Plan. On February 28, 2018 and February 28, 2017, the shares reserved for future issuance under the 2014 ESPP remained unchanged. There were no increases in the shares reserved for future issuance pursuant to the evergreen provision under the 2014 ESPP in 2017 and 2018 as the maximum aggregate number of shares available for purchase under the 2014 ESPP had reached its cap of 739,611 on February 28, 2016.

Stock-Based Compensation

Stock Options

Service-Based Stock Options

On February 28, 2019, as part of the Company's annual grant of equity, the Company issued 2,028,625 stock options to employees. 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 granted by the Company 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 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 generally expire ten years after the date of grant. The Company recorded approximately $1.1 million and $1.7 million of stock-based compensation expense related to stock options during the three months ended June 30, 2019 and 2018, respectively, and approximately $2.2 million and $3.6 million during the six months ended June 30, 2019 and 2018, respectively.

Performance-Based Stock Options

On December 12, 2018, pursuant to the Merger Agreement, each outstanding and unexercised performance-based option to acquire Keryx Shares granted under a Keryx equity plan converted into a service-based option or performance-based option to acquire Akebia Shares, with the number of shares and exercise price adjusted by the Exchange Multiplier. As a result, the Company issued 233,954 performance-based options related to the Merger. The Company did not have any performance-based options outstanding in fiscal year 2018 prior to the consummation of the Merger. The Company did not issue any performance-based options during the six months ended June 30, 2019 and 2018. As of June 30, 2019, the Company had 59,892 performance-based options outstanding. The potential range of shares issuable pursuant to the Company's outstanding performance-based options range from 0% to 100% of the target shares based on financial measures. Performance-based options vest up to 50% upon achievement of performance condition and up to 50% one year following achievement of the performance condition.

Restricted Stock Units

On February 28, 2019, as part of the Company's annual grant of equity, the Company issued 1,384,775 restricted stock units, or RSUs, to employees. In addition, the Company occasionally issues RSUs not in connection with the annual grant process to employees. RSUs granted by the Company vest in one of the following ways: 100% of each RSU grant vests on either the first or the third anniversary of the grant date, or one third of each RSU grant vests on the first, second and third anniversaries of the grant date, subject, in each case, to the individual's continued service through the applicable vesting date. 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 on a straight-line basis over the vesting period. The Company recorded approximately $1.2 million and $0.8 million of stock-based compensation expense related to the Akebia employee RSUs during the three months ended June 30, 2019 and 2018, respectively, and approximately $2.1 million and $1.0 million during the six months ended June 30, 2019 and 2018, respectively.

Employee Stock Purchase Plan

The first offering period under the ESPP opened on January 2, 2015. The Company issued 39,977 shares during the six months ended June 30, 2019. The Company recorded approximately $43,000 and $41,000 of stock-based compensation expense related to the ESPP during the three months ended June 30, 2019 and 2018, respectively, and approximately $91,000 and $101,000 during the six months ended June 30, 2019 and 2018, respectively.

Compensation Expense Summary

The Company has classified its stock-based compensation expense related to share-based awards as follows:

	Three Months Ended		Six Months Ended	
	June 30, 2019	June 30, 2018	June 30, 2019	June 30, 2018
	(in thousands)		(in thousands)	
Research and development	$ 684	$ 825	$ 1,562	$ 1,442
Selling, general and administrative	1,600	1,669	2,816	3,283
Total	$ 2,284	$ 2,494	$ 4,378	$ 4,725

Compensation expense by type of award:

	Three Months Ended		Six Months Ended	
	June 30, 2019	June 30, 2018	June 30, 2019	June 30, 2018
	(in thousands)		(in thousands)	
Stock options	$ 1,073	$ 1,673	$ 2,185	$ 3,615
Restricted stock units	1,168	780	2,102	1,009
Employee stock purchase plan	43	41	91	101
Total	$ 2,284	$ 2,494	$ 4,378	$ 4,725

14. Income Taxes

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax basis purposes. When realization of the deferred tax asset is more likely than not to occur, the benefit related to the deductible temporary differences attributable to operations is recognized as a reduction of income tax expense. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. The Company cannot be certain that future taxable income will be sufficient to realize its deferred tax assets. Accordingly, the Company has recorded a valuation allowance against the Company's otherwise recognizable net deferred tax assets. The Company continues to maintain the underlying tax benefits to offset future taxable income and to monitor the need for a valuation allowance based on the profitability of its future operations.

As of June 30, 2019 and December 31, 2018, the Company's net deferred tax liability was $3.0 million and $6.6 million, respectively. Deferred tax liabilities can be reduced by deferred tax assets generated by the Company. During the three and six months ended June 30, 2019, the Company reduced its net deferred tax liability by a portion of the deferred tax asset associated with the state net operating loss for the period. As a result, the Company reported a $0.8 million and $3.6 million tax benefit for the three and six months ended June 30, 2019, respectively.

15. Commitments and Contingencies

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 April 2018, collectively the Cambridge Lease. Under the Third Amendment to the Cambridge Lease, or the Third Amendment, executed in July 2016, total monthly lease payments under the initial base rent were approximately $242,000 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, or the 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 $135,000 commenced in February 2019 and are subject to annual rent escalations, commencing in September 2019.

Additionally, as a result of the Merger, the Company now has a lease for 27,300 square feet of office space in Boston, Massachusetts, or the Boston Lease, which expires in February 2023. The total monthly lease payments under the base rent are approximately $136,000 and are subject to annual rent escalations.

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 term of the Cambridge Lease with respect to the lab space expires on November 30, 2021, with an extension option for one additional period of two years. The term of the Boston Lease office space expires on February 28, 2023, with an extension option for one additional five year extension option available. The renewal options in the Company's real estate leases were not included in the calculation of the operating lease assets and operating lease liabilities as the renewal is not reasonably certain. The lease agreements do not contain residual value guarantees. Operating lease costs for the three and six months ended June 30, 2019 were $1.6 million and $3.3 million, respectively, and cash paid for amounts included in the measurement of operating lease liabilities for the three and six months ended June 30, 2019 were $1.7 million and $3.4 million, respectively.

We have not entered into any material short-term leases or financing leases as of June 30, 2019.

The total security deposit in connection with the Cambridge Lease is $1.6 million as of June 30, 2019. Additionally, the Company recorded $0.8 million for the security deposit under the Boston Lease. Both the Cambridge Lease and the Boston Lease have their security deposits in the form of a letter of credit, all of which are included in prepaid expenses and other current assets and in other assets in the Company's consolidated balance sheets as of June 30, 2019.

As of June 30, 2019, undiscounted minimum rental commitments under non-cancelable leases, for each of the next five years and total thereafter are as follows:

	Operating Leases
	(in thousands)
Remaining 2019	$ 3,026
2020	7,008
2021	7,064
2022	6,735
2023	5,347
Thereafter	13,934
Total	$ 43,114

In arriving at the operating lease liabilities as of June 30, 2019, we applied incremental borrowing rates ranging from 5.91% to 6.94% over remaining lease terms ranging from 2.91 years to 7.69 years. As of June 30, 2019, the following represents the difference between the remaining undiscounted minimum rental commitments under non-cancelable leases and the operating lease liabilities:

	Operating Leases
	(in thousands)
	Total
Undiscounted minimum rental commitments	$ 43,114
Present value adjustment using incremental borrowing rate	(8,265)
Operating lease liabilities	$ 34,849

At December 31, 2018, the Company's future minimum payments required under these leases are as follows:

	Operating Lease
	(in thousands)
2019	$ 6,777
2020	7,008
2021	7,064
2022	6,735
2023	5,347
Thereafter	13,934
Total	$ 46,865

Manufacturing Agreements

As part of the Merger, the Company retained Keryx's commercial supply agreements with BioVectra and Siegfried Evionnaz SA, or Siegfried, to supply commercial drug substance for Auryxia.

Pursuant to the BioVectra Manufacture and Supply Agreement and the Product Manufacture and Supply and Facility Construction Agreement, collectively the BioVectra Agreement, the Company has agreed to purchase a minimum quantity of drug substance of Auryxia at predetermined prices. The price per kilogram will decrease with an increase in quantity above the minimum purchase quantity. In addition, the BioVectra Agreement contained contingent milestone payments for capital developments in connection with construction of an expansion of the site of the BioVectra production facility for the manufacture of drug substance for Auryxia. These milestone payments were achieved by BioVectra and fully recorded prior to the Merger. These milestone payments are recorded in other assets and amortized into drug substance as inventory is released to the Company. The term of the BioVectra Agreement expires in late 2026, after which, it automatically renews for specified terms until terminated. The Company may terminate the BioVectra Agreement prior to the expiration of the contract term, which could result in early termination fee. As of June 30, 2019, the Company is required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $141.0 million through the end of the contract term.

As part of purchase accounting, the Company identified an executory contract in the BioVectra Agreement, which includes future firm purchase commitments. This executory contract was deemed to have an off-market element related to the amount of purchase commitments that exceed the current forecast. As a result, the Company recorded a liability of $29.5 million in purchase accounting, as of the acquisition date for the preliminary fair value of the off-market element. Through June 30, 2019, the Company recorded $0.4 million in accretion expense related to the present value discount associated with this liability.

Pursuant to the Siegfried Master Manufacturing Services and Supply Agreement, or the Siegfried Agreement, the Company has agreed to purchase a minimum quantity of drug substance of Auryxia at predetermined prices. The price per kilogram will decrease with an increase in quantity above the minimum purchase quantity. The term of the Siegfried Agreement expires on December 31, 2021, after which, it automatically renews for one-year terms until terminated. The Siegfried Agreement provides for certain termination rights prior to December 31, 2021 for the Company. As of June 30, 2019, the Company is required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $75.3 million through the year ending December 31, 2021.

Other Third Party Contracts

Under the Company's agreement with IQVIA, formerly known as Quintiles IMS, to provide contract research organization services for the PRO_2TECT and $INNO_2$VATE programs, the total remaining contract costs as of June 30, 2019 were approximately $111.8 million. The estimated period of substantive performance for the committed work with IQVIA is through the end of 2020. The Company also contracts with various other organizations to conduct research and development activities with remaining contract costs to the Company of approximately $55.5 million at June 30, 2019. 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.

16. Net Loss per Share

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:

	As of June 30,	
	2019	**2018**
Warrant	509,611	509,611
Outstanding stock options	7,779,744	4,060,361
Unvested restricted stock units	1,937,822	916,700
Total	10,227,177	5,486,672

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 the notes thereto included in this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2018, or the 2018 Annual Report, including the audited consolidated financial statements and notes thereto contained in our 2018 Annual Report. 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.

Operating Overview

We are a biopharmaceutical company focused on the development and commercialization of therapeutics for patients with kidney disease. On December 12, 2018, we completed a merger, or the Merger, with Keryx Biopharmaceuticals, Inc., or Keryx, combining a nephrology-focused commercial organization with our robust development organization. Following the Merger, Keryx is our wholly owned subsidiary, and we are integrating our business and Keryx's business with the goal of positioning Akebia to realize the potential growth opportunities and synergies from the Merger.

We now have a commercial product and a late-stage product candidate:

- ***Auryxia*® *(ferric citrate)*** is approved and marketed in the United States, or the U.S., for two indications: (1) the control of serum phosphorus levels in adult patients with chronic kidney disease, or CKD, on dialysis, or DD-CKD, or the Hyperphosphatemia Indication, and (2) the treatment of iron deficiency anemia, or IDA, in adult patients with CKD not on dialysis, or NDD-CKD, or the IDA Indication. Ferric citrate is also approved and marketed in Japan as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including DD-CKD and NDD-CKD, under the trade name Riona® (ferric citrate hydrate) and approved in the European Union, or the EU, for the control of hyperphosphatemia in adult patients with CKD under the trade name Fexeric® (ferric citrate).
- ***Vadadustat*** is an investigational, oral hypoxia-inducible factor prolyl hydroxylase inhibitor, or HIF-PHI, in global Phase 3 development for two indications: (1) anemia due to CKD in adult patients with DD-CKD, and (2) anemia due to CKD in adult patients with NDD-CKD. We believe vadadustat has the potential to set a new oral standard of care for patients with anemia due to CKD, subject to regulatory approval. Vadadustat's proposed mechanism of action is designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with increased production of hypoxia-inducible factor, or HIF, which coordinates the interdependent processes of iron mobilization and stimulates endogenous production of erythropoietin, or EPO, to increase red blood cell, or RBC, production and, ultimately, improve oxygen delivery.

We market Auryxia in the U.S. with our well-established, nephrology-focused commercial organization. Our Japanese sublicensee, Japan Tobacco, Inc., or JT, and its subsidiary, Torii Pharmaceutical Co., Ltd., or Torii, commercialize Riona in Japan. Fexeric is not currently marketed in the EU, and our EU marketing authorization for Fexeric will cease to be valid on December 23, 2019 unless we commence marketing Fexeric in the EU by that date. We are exploring commercialization opportunities with third parties for Fexeric.

We plan to commercialize vadadustat, subject to U.S. Food and Drug Administration, or FDA, approval, in the U.S. with our commercial organization, while also leveraging our collaboration with Otsuka Pharmaceutical Co. Ltd., or Otsuka, and its U.S. commercial organization. We also granted Otsuka exclusive rights to commercialize vadadustat in Europe, China and certain other markets, subject to marketing approvals. In Japan and certain other countries in Asia, we granted Mitsubishi Tanabe Pharma Corporation, or MTPC, exclusive rights to commercialize vadadustat, subject to marketing approvals. In July 2019, we announced that MTPC submitted a Japanese New Drug Application, or JNDA, for manufacturing and marketing approval of vadadustat as a treatment for anemia due to CKD in Japan. In addition, we granted Vifor (International) Ltd., or Vifor Pharma, an exclusive license to sell vadadustat to Fresenius Kidney Care Group LLC, or FKC, which manages approximately 40% of the dialysis patients in the U.S., and to certain third party dialysis organizations in the U.S., approved by us, which account for up to an additional 20% of the dialysis market in the U.S. The license granted to Vifor Pharma will be effective upon FDA approval of vadadustat in the DD-CKD indication, the earlier of a determination by the Centers for Medicare & Medicaid Services that vadadustat will be included in Medicare's bundled reimbursement model or that vadadustat will be reimbursed using the Transitional Drug Add-On Payment Adjustment, and a milestone payment by Vifor Pharma.

Since our incorporation as a Delaware corporation in 2007, we have devoted the largest portion of our resources to our development efforts relating to vadadustat, including preparing for and conducting clinical studies of vadadustat, providing general and administrative support for these operations and protecting our intellectual property. Auryxia is our only product approved for sale and it generated approximately $29.1 million and $52.2 million in revenue from product sales during the three and six months ended June 30, 2019, respectively. We have funded our operations primarily through equity offerings and strategic collaborations.

We have never been profitable and have incurred net losses in each year since inception. Our net losses were $58.2 million and $34.1 million for the three months ended June 30, 2019 and 2018, respectively, and $130.6 million and $57.5 million for the six months ended June 30, 2019 and 2018, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. The amount of our future net losses will depend, in part, on the rate of our future expenditures, and our financial position will depend, in part, on our product revenue from Auryxia and, if approved, vadadustat, and our ability to obtain additional funding. We expect to continue to incur significant expenses if and as we:

- conduct our development program of vadadustat for the treatment of anemia due to CKD, including PRO_2TECT, $INNO_2VATE$, FO_2RWARD-2, $TRILO_2GY$-2 and $EXPLO_2RE$, and develop plans for and conduct the preclinical and clinical development of any other potential product candidates;
- continue our commercialization activities for Auryxia and plan for the commercialization of vadadustat, if approved, and any other product candidate;
- continue our Merger-related integration activities;
- seek marketing approvals for our product candidates that successfully complete clinical studies, and maintain marketing approvals for Auryxia and any product candidate for which we obtain marketing approval, including complying with any post-marketing regulatory requirements;
- have our product candidates manufactured for clinical trials and for commercial sale;
- initiate additional preclinical, clinical or other studies for vadadustat and any other product candidates, or any post-marketing approval studies, Phase 4 studies or any other clinical trials for Auryxia and Fexeric;
- seek to discover and develop 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 other product candidates and technologies;
- make royalty, milestone or other payments under our license agreements and any future in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- continue to create additional infrastructure and expend additional resources to support our operations as a public company, including any additional infrastructure and resources necessary to support a transition from our status as an emerging growth company; and
- experience any delays or encounter issues with any of the above.

We have one product approved for commercial sale but have not generated, and may not generate, enough product revenue from the sale of Auryxia 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 any of our product candidates, and as we continue to commercialize Auryxia, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. If and until we can generate a sufficient amount of revenue from product sales, we expect to finance future cash needs through public or private equity or debt offerings, payments from our collaborators, royalty transactions, strategic transactions, or a combination of these approaches. 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 or commercialization of our product or one or more of our product candidates. Any of these events could significantly harm our business, financial condition and prospects.

From inception through June 30, 2019, we raised approximately $477.8 million of net proceeds from the sale of equity including $377.4 million from various underwritten public offerings, $50.4 million from at-the-market offerings, or ATM offerings, pursuant to sales agreements with Cantor Fitzgerald & Co and $50.0 million from the sale of 3,571,429 shares of common stock to Vifor Pharma. At inception of our collaboration agreements with Otsuka and MTPC, our collaborators committed to approximately $573.0 million or more in cost-share funding, which we generally continue to receive on a quarterly prepaid basis, and license payments. Of these commitments, we received approximately $272.0 million at the onset of the collaboration agreements.

Financial Overview

Revenue

To date, our revenues have been derived from collaboration revenues, which include license and milestone payments and cost-sharing revenue, generated through collaboration and license agreements with partners for the development and commercialization of vadadustat and, following the Merger, commercial sales of Auryxia and royalty revenue from sales of Riona in Japan. Cost-sharing revenue represents amounts reimbursed by our collaboration partners for expenses incurred by us for research and development activities and, potentially, co-promotion activities, under our collaboration agreements.

We expect our revenue to continue to be generated primarily from our commercial sales of Auryxia in the U.S., royalty revenue from JT and Torii, and collaborations with Otsuka and MTPC and any other collaborations into which we may enter.

Cost of Goods Sold

Cost of goods sold includes direct costs to manufacture commercial drug substance and drug product for Auryxia, as well as 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, and royalties due to the licensor of Auryxia related to the U.S. product sales recognized during the period.

As a result of the Merger and the application of purchase accounting, costs of goods sold also includes amortization expense associated with the fair value of the developed product rights for Auryxia, which is being amortized over nine years, as well as expense associated with the fair value inventory step-up, which we expect to incur over approximately two years.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- personnel-related expenses, including salaries, benefits, recruiting fees, travel and stock-based compensation expense of our research and development personnel;
- expenses incurred under agreements with CROs and investigative sites that conduct our clinical studies;
- the cost of acquiring, developing and manufacturing clinical study materials through contract manufacturing organizations, or CMOs;
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies; and
- costs associated with preclinical, clinical and regulatory activities.

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 studies of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain marketing approval. We may never succeed in achieving marketing approval for any of our product candidates.

The duration, costs and timing of clinical studies and development of our product candidates 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 a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, the European Medicines Agency, or the EMA, or other regulatory authorities were to require us to conduct clinical studies in addition to or different from those that we currently anticipate, or if we experience delays in any of our clinical studies, we could be required to expend significant additional financial resources and time on the completion of clinical development.

From inception through June 30, 2019, we have incurred $921.8 million in research and development expenses. We plan to increase our research and development expenditures for the foreseeable future as we continue the development of vadadustat and any other product candidates. Our current and/or planned research and development activities include the following:

- global development of vadadustat;
- post-marketing clinical trials of Auryxia;

- research and development of compounds in our HIF portfolio; and
- diversification of our pipeline in kidney disease.

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 studies, and drug substance and drug product manufacturing for clinical studies.

We currently have four clinical trials to which the majority of our research and development costs are attributable. We have not accumulated and tracked our research and development costs or our personnel and personnel-related costs on a program-by-program basis as our employee and infrastructure resources, and many of our costs, are directed broadly to applicable research endeavors. As a result, we are unable to specify precisely the costs incurred for each of our programs on a program-by-program basis.

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, accounting and legal services fees, recruiting fees and expenses associated with obtaining and maintaining patents.

We anticipate that our selling, general and administrative expenses will increase in the future as we increase our headcount to support continued commercialization of Auryxia and continued research and development and potential commercialization of our product candidates. We also anticipate increased expenses related to finance, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and U.S. Securities and Exchange Commission, or SEC, requirements, and our other costs associated with being a public company, particularly as our compliance obligations will increase once we are no longer an “emerging growth company” on December 31, 2019.

Results of Operations

Comparison of the Three Months Ended June 30, 2019 and 2018

	Three Months Ended		Increase
	June 30, 2019	June 30, 2018	(Decrease)
		(In Thousands)	
Revenues:			
Product revenue, net	$ 29,089	$ —	$ 29,089
License, collaboration and other revenue	71,714	48,793	22,921
Total revenues	100,803	48,793	52,010
Cost of goods sold:			
Product	28,569	—	28,569
Amortization of intangibles	9,100	—	9,100
Total cost of goods sold	37,669	—	37,669
Operating expenses:			
Research and development	85,694	71,917	13,777
Selling, general and administrative	36,068	12,538	23,530
License expense	895	—	895
Total operating expenses	122,657	84,455	38,202
Operating loss	(59,523)	(35,662)	23,861
Other income, net	508	1,593	(1,085)
Net loss before income taxes	(59,015)	(34,069)	24,946
Benefit from income taxes	(845)	—	845
Net loss	$ (58,170)	$ (34,069)	$ 24,101

Product Revenue, Net. Net product revenue is derived from sales of our sole commercial product, Auryxia. We distribute our product principally through a limited number of wholesale distributors as well as certain specialty pharmacy providers. We began recording product revenue on sales of Auryxia in the U.S. on December 12, 2018 following the consummation of the Merger. Net product revenue was $29.1 million for the three months ended June 30, 2019. During the three months ended June 30, 2019, the average net sales price per unit (after accounting for fees, rebates, chargebacks, and other discounts or reserves, or the gross-to-net adjustment) was approximately 52% of the wholesale acquisition cost, or WAC, which is the gross list price at which our direct customers purchase each unit.

Net U.S Auryxia product revenue for the three months ended June 30, 2018, as reported in the Keryx Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018 prior to the Merger, was $24.1 million. The increase in net product revenue for the three months ended June 30, 2019 as compared to the same period in 2018 was primarily driven by the increase in patient prescriptions and related units sold. In September 2018, the Centers for Medicare & Medicaid Services, or CMS, decided that Auryxia would not be covered by Medicare for the IDA Indication. While this decision does not impact CMS coverage of the Hyperphosphatemia Indication, it requires all Auryxia prescriptions for Medicare patients to undergo a prior authorization to ensure their use in the Hyperphosphatemia Indication. We are engaged in discussions with CMS with the goal of restoring coverage under Medicare for the IDA 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 prior authorization requirement had and may continue to have an adverse impact on the timing of prescriptions and Auryxia product revenue. Over the mid- to long-term, we believe that we are well positioned to grow Auryxia revenue in the hyperphosphatemia and IDA markets.

License, Collaboration and Other Revenue. License, collaboration and other revenue was $71.7 million for the three months ended June 30, 2019 compared to $48.8 million for the three months ended June 30, 2018. We recognized $70.0 million in collaboration revenue for the three months ended June 30, 2019 from our cost sharing arrangement under the Otsuka collaboration agreement for the U.S., or the Otsuka U.S. Agreement, the Otsuka collaboration agreement for certain territories outside the U.S., or the Otsuka International Agreement, and our collaboration agreement with MTPC, or the MTPC Agreement. We recognized $48.7 million in collaboration revenue for the three months ended June 30, 2018 from our cost sharing arrangement under the Otsuka U.S. Agreement, which commenced in December 2016, the Otsuka International Agreement, which commenced in April 2017, and the MTPC Agreement, for which the deliverables associated with the revenue recognition criteria, as required under ASC 606, were satisfied in the second quarter of 2018. The increase in revenue between the two periods was primarily attributable to an additional $11.1 million of revenue recognized under the Otsuka U.S. Agreement, primarily driven by $10.6 million in additional funding due to an increase Otsuka's funding percentage of the global development costs from 52.5% to 80% in the second quarter of 2019. Additionally, there was a $9.8 million increase in revenue in connection with the MTPC Agreement due to $10.0 million of revenue recognized related to the filing of the JNDA in the second quarter of 2019. The remaining variance is primarily due to an increase in license revenue relating to our sublicense agreement with JT and Torii and includes license fees and royalties on net product sales of Riona in Japan.

Cost of Goods Sold - Product. Cost of goods sold of $28.6 million for the three months ended June 30, 2019 consists primarily of costs associated with the manufacturing of Auryxia and a $19.0 million charge related to the fair-value inventory step-up from the application of purchase accounting. This increase as compared to the three months ended June 30, 2018 was due to costs associated with Auryxia, as there were no comparable costs in the second quarter of 2018.

Cost of Goods Sold - Amortization of Intangibles. Amortization of intangibles relates to the acquired developed product rights for Auryxia. This intangible asset is being amortized over its estimated useful life of approximately 9 years using a straight-line method. Amortization of intangibles for the three months ended June 30, 2019 was $9.1 million. This increase as compared to the three months ended June 30, 2018 was due to costs associated with Auryxia, as there were no comparable costs in the second quarter of 2018.

Research and Development Expenses. Research and development expenses were $85.7 million for the three months ended June 30, 2019, compared to $71.9 million for the three months ended June 30, 2018, an increase of $13.8 million. The increase was primarily due to the following:

	(in millions)
Other supporting clinical and preclinical activities and regulatory activities	$ 2.5
PRO$_2$TECT and INNO$_2$VATE Phase 3 program	2.1
FO$_2$RWARD-2 and TRILO$_2$GY-2 studies[1]	1.9
Japan Phase 2 studies	(0.8)
Manufacture of drug substance and drug product	(1.1)
Total increase related to the continued development of vadadustat	4.6
Headcount, consulting and facilities	5.2
Other research	2.6
Other	1.4
Total other increases	9.2
Total net increase	$ 13.8

(1) Includes costs from FO$_2$RWARD, FO$_2$RWARD-2, TRIL$_2$OGY, and TRILO$_2$GY-2 studies.

The increase in the costs related to the development of vadadustat is primarily attributable to an increase in external costs related to the continued advancement of the PRO$_2$TECT and INNO$_2$VATE Phase 3 program, including supporting clinical and preclinical activities as well as regulatory activities, ongoing enrollment, and increased costs related to FO$_2$RWARD-2 and TRILO$_2$GY-2, which replaced FO$_2$RWARD and TRILO$_2$GY, respectively. The aggregate increase in costs was partially offset by a decrease in costs related to Japan Phase 2 studies, which were completed in 2018, and manufacture of drug substance and drug product. The increase in research and development expenses were further impacted by increases in headcount and consulting costs to support our research and development programs. We expect to continue to incur significant research and development expenses in future periods in support of our global Phase 3 program and other studies for vadadustat and development of our other product candidates.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $36.1 million for the three months ended June 30, 2019, compared to $12.5 million for the three months ended June 30, 2018. The increase of $23.5 million was primarily due to commercialization costs associated with Auryxia as there were no comparable commercialization costs in the second quarter of 2018. We expect to continue to incur significant selling, general and administrative expenses in future periods to support our ongoing commercialization of Auryxia and our ongoing research and development and potential commercialization of vadadustat and other product candidates.

Other Income, Net. Other income, net, was $0.5 million for the three months ended June 30, 2019 and $1.6 million for the three months ended June 30, 2018. The decrease in other income, net was primarily due to lower interest income caused by lower average investment balances in the second quarter of 2019.

Benefit from Income Taxes. Benefit from income taxes was $0.8 million for the three months ended June 30, 2019 due to a decrease in our net deferred tax liabilities, or DTLs. During the three months ended June 30, 2019, there was an increase in deferred tax assets associated with the state net operating loss generated during the period. This increase in deferred tax assets reduced our net DTLs which created a benefit from income taxes for the three months ended June 30, 2019.

Comparison of the Six Months Ended June 30, 2019 and 2018

	Six Months Ended		Increase
	June 30, 2019	June 30, 2018	(Decrease)
	(In Thousands)		
Revenues:			
Product revenue, net	$ 52,200	$ —	$ 52,200
License, collaboration and other revenue	121,269	94,723	26,546
Total revenues	173,469	94,723	78,746
Cost of goods sold:			
Product	50,726	—	50,726
Amortization of intangibles	18,200	—	18,200
Total cost of goods sold	68,926	—	68,926
Operating expenses:			
Research and development	168,045	133,321	34,724
Selling, general and administrative	70,359	21,562	48,797
License expense	1,631	—	1,631
Total operating expenses	240,035	154,883	85,152
Operating loss	(135,492)	(60,160)	75,332
Other income, net	1,299	2,673	(1,374)
Net loss before income taxes	(134,193)	(57,487)	76,706
Benefit from income taxes	(3,602)	—	3,602
Net loss	$ (130,591)	$ (57,487)	$ 73,104

Product Revenue, Net. Net product revenue is derived from sales of our sole commercial product, Auryxia. We distribute our product principally through a limited number of wholesale distributors as well as certain specialty pharmacy providers. We began recording product revenue on sales of Auryxia in the U.S. on December 12, 2018 following the consummation of the Merger. Net product revenue was $52.2 million for the six months ended June 30, 2019. During the six months ended June 30, 2019, the average net sales price per unit (after accounting for fees, rebates, chargebacks, and other discounts or reserves, or the gross-to-net adjustment) was approximately 51% of the WAC, which is the gross list price at which our direct customers purchase each unit.

Net U.S Auryxia product revenue for the six months ended June 30, 2018, as reported in the Keryx Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2018 prior to the Merger, was $44.7 million. The increase in net product revenue for the six months ended June 30, 2019 as compared to the same period in 2018 was primarily driven by the increase in patient prescriptions and related units sold. In September 2018, CMS decided that Auryxia would not be covered by Medicare for the IDA Indication. While this decision does not impact CMS coverage of the Hyperphosphatemia Indication, it requires all Auryxia prescriptions for Medicare patients to undergo a prior authorization to ensure their use in the Hyperphosphatemia Indication. We are engaged in discussions with CMS with the goal of restoring coverage under Medicare for the IDA 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 prior authorization requirement had and may continue to have an adverse impact on the timing of prescriptions and Auryxia product revenue. Over the mid- to long-term, we believe that we are well positioned to grow Auryxia revenue in the hyperphosphatemia and IDA markets.

License, Collaboration and Other Revenue. License, collaboration and other revenue was $121.3 million for the six months ended June 30, 2019 compared to $94.7 million for the six months ended June 30, 2018. We recognized $118.2 million in collaboration revenue for the six months ended June 30, 2019 from our cost sharing arrangement under the Otsuka U.S. Agreement, the Otsuka International Agreement, and the MTPC Agreement. We recognized $94.4 million in collaboration revenue for the six months ended June 30, 2018 from our cost sharing arrangement under the Otsuka U.S. Agreement, which commenced in December 2016, the Otsuka International Agreement, which commenced in April 2017, and the MTPC Agreement. The increase in revenue between the two periods was primarily attributable to an additional $17.7 million of revenue recognized under the Otsuka U.S. Agreement, primarily driven by $10.6 million in additional funding due to an increase in Otsuka's funding percentage of the current global development costs for vadadustat from 52.5% to 80% in the second quarter of 2019, as described in Note 4 to our condensed consolidated financial statements in Part I, Item 1 – Financial Statements (unaudited), and increased expenses subject to reimbursement under the Otsuka U.S. Agreement and the Otsuka International Agreement compared to the same period in 2018. The remaining variance is primarily due to an increase in license revenue relating to our sublicense agreement with JT and Torii and includes license fees and royalties on net product sales of Riona in Japan.

Cost of Goods Sold - Product. Cost of goods sold of $50.7 million for the six months ended June 30, 2019 consists primarily of costs associated with the manufacturing of Auryxia and a $33.6 million charge related to the fair-value inventory step-up from the application of purchase accounting. This increase as compared to the six months ended June 30, 2018 was due to costs associated with Auryxia, as there were no comparable costs in the second quarter of 2018.

Cost of Goods Sold - Amortization of Intangibles. Amortization of intangibles relates to the acquired developed product rights for Auryxia. This intangible asset is being amortized over its estimated useful life of approximately 9 years using a straight-line method. Amortization of intangibles for the six months ended June 30, 2019 was $18.2 million. This increase as compared to the six months ended June 30, 2018 was due to costs associated with Auryxia, as there were no comparable costs in the second quarter of 2018.

Research and Development Expenses. Research and development expenses were $168.0 million for the six months ended June 30, 2019, compared to $133.3 million for the six months ended June 30, 2018, an increase of $34.7 million. The increase was primarily due to the following:

	(in millions)
PRO$_2$TECT and INNO$_2$VATE Phase 3 program	13.6
Other supporting clinical and preclinical activities and regulatory activities	2.8
FO$_2$RWARD-2 and TRILO$_2$GY-2 studies[1]	2.1
Manufacture of drug substance and drug product	0.6
Japan Phase 2 studies	(1.8)
Total increase related to the continued development of vadadustat	17.3
Headcount, consulting and facilities	9.7
Other research	5.2
Other	2.5
Total other increases	17.4
Total net increase	$ 34.7

(2) Includes costs from FO$_2$RWARD, FO$_2$RWARD-2, TRIL$_2$OGY, and TRILO$_2$GY-2 studies.

The increase in the costs related to the development of vadadustat is primarily attributable to an increase in external costs related to the continued advancement of the PRO$_2$TECT and INNO$_2$VATE Phase 3 program, including ongoing enrollment, other supporting clinical and preclinical activities, as well as regulatory activities, costs related to FO$_2$RWARD-2 and TRILO$_2$GY-2, which replaced FO$_2$RWARD and TRILO$_2$GY, respectively, and manufacture of drug substance and drug product, the aggregate which was partially offset by a decrease in costs related to Japan Phase 2 studies, which were completed in 2018. The increase in research and development expenses were further impacted by increases in headcount and consulting costs to support our research and development programs. We expect to continue to incur significant research and development expenses in future periods in support of our global Phase 3 program and other studies for vadadustat and development of our other product candidates.

Selling, General and Administrative Expenses. Selling, general and administrative expenses were $70.3 million for the six months ended June 30, 2019, compared to $21.6 million for the six months ended June 30, 2018. The increase of $48.8 million was primarily due to commercialization costs associated with Auryxia as there were no comparable commercialization costs in the first half of 2018. We expect to continue to incur significant selling, general and administrative expenses to in future periods to support our ongoing commercialization of Auryxia and our ongoing research and development and potential commercialization of vadadustat and other product candidates.

Other Income, Net. Other income, net, was $1.3 million for the six months ended June 30, 2019 and $2.7 million for the six months ended June 30, 2018. The decrease in other income, net was primarily due to lower interest income caused by lower average investment balances in the first half of 2019 and interest expense associated to our Line of Credit with SVB, which we did not have during the six months ended June 30, 2018.

Benefit from Income Taxes. Benefit from income taxes was $3.6 million for the six months ended June 30, 2019 due to a decrease in our net DTLs. During the six months ended June 30, 2019, there was an increase in deferred tax assets associated with the state net operating loss generated during the period. This increase in deferred tax assets reduced our net DTLs which created a benefit from income taxes for the six months ended June 30, 2019.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception in February 2007, and as of June 30, 2019, we had an accumulated deficit of $645.0 million. We anticipate that we will continue to incur losses for the foreseeable future. We expect to continue to incur additional research and development and selling, general and administrative expenses and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, royalty transactions, and other collaborations, strategic alliances and licensing arrangements.

We have funded our operations principally through sales of our common stock, payments received from our collaboration partners, and following the Merger, product sales. As of June 30, 2019, we had cash and cash equivalents and available for sale securities of approximately $136.8 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Accordingly, available for sale securities, consisting principally of corporate and government debt securities stated at fair value, are also available as a source of liquidity.

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below:

	Six Months Ended	
	June 30, 2019	**June 30, 2018**
	(In Thousands)	
Net cash provided by (used in):		
Operating activities	$ (176,295)	$ (11,334)
Investing activities	164,506	8,866
Financing activities	(5,643)	96,123
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (17,432)	$ 93,655

Operating Activities. Net cash used in operating activities of $176.3 million for the six months ended June 30, 2019 was largely driven by timing of payments on our Phase 3 development program for vadadustat, payments for inventory and merger-related liabilities. These payments were partially offset by adjustments for non-cash items, including the fair value write-up of inventory sold of $33.6 million, amortization of intangibles of $18.2 million, and stock-based compensation expense of $4.4 million.

The net cash used in operating activities of $11.3 million for the six months ended June 30, 2018 was largely driven by our Phase 3 development program for vadadustat, partially offset by receipt of cash from collaboration agreements, including a $4.0 million milestone payment under the MTPC Agreement and $103.7 million in cost-share reimbursements under the Otsuka U.S. Agreement and the Otsuka International Agreement. Additionally, there were adjustments for non-cash items, including stock-based compensation expense of $4.7 million.

Investing Activities. Net cash provided by investing activities for the six months ended June 30, 2019 was $164.5 million and was comprised primarily of proceeds from the maturities of available for sale securities of $103.7 million and proceeds from the sales of available for sale securities of $64.7 million, partially offset by purchases of equipment of $3.9 million.

Net cash provided by investing activities for the six months ended June 30, 2018 was $8.9 million and was comprised primarily of proceeds from the maturities of available for sale securities of $122.8 million and proceeds from the sales of available for sale securities of $8.0 million, offset by the purchases of available for sale securities of $121.5 million and purchases of equipment of $0.5 million.

Financing Activities. Net cash used in financing activities for the six months ended June 30, 2019 was $5.6 million and consisted primarily of payments on loans payable of $15.0 million, partially offset by proceeds from the public issuance of common stock, proceeds from the exercise of stock options and proceeds from the sale of stock under our employee stock purchase plan.

Net cash provided by financing activities for the six months ended June 30, 2018 was $96.1 million and consisted primarily of net proceeds from the public issuance of common stock, proceeds from the exercise of stock options and proceeds from the sale of stock under our employee stock purchase plan.

Operating Capital Requirements

As a result of the Merger, we have one product, Auryxia, approved for commercial sale, but have not generated, and may not generate, enough product revenue from the sale of Auryxia to realize net profits from product sales. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek marketing approvals for, our product candidates. We are subject to all risks incident to the development and commercialization of novel therapeutics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect to continue to incur additional costs associated with operating as a public company and we anticipate that we will need substantial additional funding in connection with our continuing operations.

We expect our cash resources, including committed research and development funding from collaborators, to fund our current operating plan beyond the next twelve months, into the third quarter of 2020. However, on a quarterly basis, we are required to conduct an accounting analysis under ASC 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or ASC 205-40. Under the accounting standards, a company is not permitted to include elements of its operating plan that are deemed to be "outside of the company's control" in an ASC 205-40 analysis, even though certain of those elements may be appropriately included in the company's cash runway analysis. For example, our cash runway includes receipt of a milestone payment from MTPC upon manufacturing and marketing approval of vadadustat in Japan, but since receipt of that milestone payment is deemed to be "outside of our control" under the accounting standards, we are not permitted to include it in our ASC 205-40 analysis. The result of our ASC 205-40 analysis is that there is "substantial doubt" that we will have sufficient funds to satisfy our obligations through the next twelve months from the date of issuance of this Quarterly Report on Form 10-Q.

We will require additional capital for the further commercialization of Auryxia, development and potential commercialization of our existing product candidates and will need to raise additional funds to pursue development activities related to additional product candidates. If and until we can generate a sufficient amount of product revenue, we expect to finance future cash needs through public or private equity or debt offerings, payments from our collaborators, royalty transactions, strategic transactions, or a combination of these approaches. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Furthermore, our development and regulatory milestones may not be achieved, we may not receive the anticipated funding from our collaboration partners, and we may not secure other sources of financing. Additional funds may not be available to us on acceptable terms or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the commercialization of our product or the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders or increased fixed payment obligations, and any such securities may have rights senior to those of our common stock. Any of these events could significantly harm our business, financial condition and prospects.

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 risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may be substantially different than actual results, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near- and long-term, will depend on many factors including, but not limited to, those described under Part II, Item 1A. Risk Factors.

If we cannot expand our operations or otherwise capitalize on our business opportunities because we lack sufficient capital, our business, financial condition and results of operations could be materially adversely affected.

Contractual Obligations and Commitments

Leases

We lease approximately 65,167 square feet of office and lab space in Cambridge, Massachusetts under a lease which was most recently amended in April 2018, collectively the Cambridge Lease. Under the Third Amendment to the Cambridge Lease, or the Third Amendment, executed in July 2016, total monthly lease payments under the initial base rent were approximately $242,000 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 us and did not impact rent payments. In April 2018, we entered into a Fifth Amendment to the Cambridge Lease, or the 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 us was delivered in September 2018 and additional monthly lease payments of approximately $135,000 commenced in February 2019 and are subject to annual rent escalations, commencing in September 2019.

Additionally, as a result of the Merger, we have a lease for 27,300 square feet of office space in Boston, Massachusetts, or the Boston Lease, which expires in February 2023. The total monthly lease payments under the base rent are approximately $136,000 and are subject to annual rent escalations. By the end of 2019, we plan to move employees based in our Boston office to our Cambridge office and to sublet our Boston office.

Debt

Keryx, our wholly owned subsidiary following the Merger, has a $40.0 million revolving line of credit, or the Line of Credit, under its Loan and Security Agreement with Silicon Valley Bank, or SVB. Availability under the Line of Credit is subject to a borrowing base comprised of eligible receivables and eligible inventory of Keryx as set forth in the Loan and Security Agreement. As of June 30, 2019 and December 31, 2018, there was $0 and $15.0 million outstanding, respectively, under the Line of Credit and we had approximately $23.9 million in available borrowing base as of June 30, 2019.

Proceeds from the Line of Credit may be used for working capital and general business purposes. The Line of Credit is secured by substantially all of Keryx's assets other than intellectual property. The Line of Credit restricts Keryx's ability to grant any interest in its intellectual property other than certain permitted licenses and permitted encumbrances set forth in the Loan and Security Agreement.

The principal amount outstanding under the revolving line bears interest at a floating rate per annum equal to the greater of (i) 2.0% above the "prime rate," as reported in The Wall Street Journal and (ii) 6.75%, which interest is payable monthly. Principal amounts borrowed under the Line of Credit may be repaid and, prior to the maturity date, re-borrowed, subject to the terms and conditions set forth in the Loan and Security Agreement. The Line of Credit will mature on the date that is the earlier of (i) two years after the effective date of the Loan and Security Agreement and (ii) ninety days prior to the maturity of any portion of any Permitted Convertible Debt, as defined under the Loan and Security Agreement. Upon entry into the Loan and Security Agreement (payable in installments and subject to certain conditions), Keryx paid to SVB an initial commitment fee of $149,000, upon the consummation of the Merger, we paid to SVB an additional commitment fee of approximately $251,000, and at the one year anniversary of the effective date of the Loan and Security Agreement (or, if earlier, upon termination of or an event of default under the Loan and Security Agreement), Keryx must pay to SVB a fee equal to 1.00% of the Line of Credit. Keryx is also required to pay on a quarterly basis a fee equal to 0.25% per annum of the average unused portion of the revolving line. Keryx must pay a termination fee of 2.00% of the Line of Credit, if the revolving line is terminated prior to the maturity date of July 18, 2020, subject to certain exceptions.

The Loan and Security Agreement contains customary covenants applicable to Keryx and its subsidiaries, including maintaining insurance on Keryx's business, achievement of minimum revenue amounts, the incurrence of additional indebtedness, and future encumbrances on the Keryx's assets. In addition, Keryx must maintain a liquidity ratio, defined as (i) the sum of unrestricted and unencumbered cash and cash equivalents maintained at SVB or its affiliates plus net billed accounts receivable divided by (ii) all Keryx's outstanding obligations and liabilities to SVB, including the aggregate amount of our obligations to SVB under any business credit cards, of at least 1.5 to 1.0, measured monthly.

Upon an event of default under the Loan and Security Agreement, SVB is entitled to accelerate and demand payment of all amounts outstanding under the Loan and Security Agreement, stop advancing money or extending credit to Keryx, demand that Keryx deposit at least 105% of the face amount of any letters of credit remaining undrawn to secure all obligations thereunder, and exercise other remedies available to SVB under the Loan and Security Agreement and at law or in equity. As of June 30, 2019, and December 31, 2018, Akebia determined that events of default had occurred.

On July 31, 2019, Keryx entered into a Waiver and First Amendment to Loan and Security Agreement, or the Loan Amendment. Pursuant to the Loan Amendment, certain revisions were made to the Loan and Security Agreement, including requiring Keryx to maintain, from and after December 31, 2019, subject to certain exceptions, a certain amount of funds to which we have unrestricted access in one or more asset management accounts with SVB or SVB's affiliate and revising certain of the representations and warranties and covenants in the Loan and Security Agreement. In addition, pursuant to the Loan Amendment, SVB waived the then-existing events of default.

On August 7, 2019, we executed and delivered to SVB an Unconditional Guaranty, or the Guaranty, pursuant to which we guaranteed the prompt and complete payment and performance when due of all of the obligations and liabilities of Keryx under the Loan and Security Agreement, as amended by the Loan Amendment, or the Amended Loan Agreement. In addition, we entered into a Security Agreement with SVB effective August 7, 2019, or the Security Agreement, pursuant to which we granted to SVB a continuing first priority security interest in substantially all of our personal property, other than our intellectual property, to secure the payment and performance of our obligations under the Guaranty. Our obligations under the Guaranty are independent of Keryx's obligations, and separate actions may be brought against us.

The Security Agreement contains customary representations and warranties and affirmative and negative covenants. The affirmative covenants include, among others, covenants requiring us to maintain its legal corporate existence and governmental approvals, maintain insurance coverage and protect our intellectual property rights. The negative covenants include, among others, restrictions on transferring our assets, changing our business, undergoing a change in control, engaging in mergers or acquisitions, incurring additional indebtedness, creating liens, paying dividends or making other distributions, making investments and transacting with affiliates, in each case subject to certain exceptions.

Upon an event of default under the Security Agreement, SVB is entitled to exercise several remedies, including accelerating and demanding payment of all our liabilities under the Guaranty, ceasing to advance money or extend credit under the Amended Loan Agreement, demanding that we deposit cash with SVB in an amount equal to the aggregate amount of any letters of credit remaining undrawn to secure all obligations thereunder, and seeking to enforce security interests in the collateral securing the Amended Loan Agreement and the Guaranty.

Manufacturing Agreements

As a result of the Merger, our contractual obligations now include Keryx's commercial supply agreements with BioVectra Inc., or BioVectra, and Siegfried Evionnaz SA, or Siegfried, to supply commercial drug substance for Auryxia.

Pursuant to the BioVectra Manufacture and Supply Agreement and the Product Manufacture and Supply and Facility Construction Agreement, collectively, the BioVectra Agreement, we have agreed to purchase a minimum quantity of drug substance of Auryxia at predetermined prices. The price per kilogram will decrease with an increase in quantity above the minimum purchase quantity. In addition, the BioVectra Agreement contained contingent milestone payments for capital developments in connection with construction of an expansion of the site of the BioVectra production facility for the manufacture of drug substance for Auryxia. These milestone payments were achieved by BioVectra and paid and fully recorded prior to the Merger. The term of the BioVectra Agreement expires in late 2026, after which, it automatically renews for specified terms until terminated. We have the right to terminate the BioVectra Agreement prior to the contract term, which could result in an early termination fee. As of June 30, 2019, we are required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $141.0 million through the year ended December 31, 2026.

As part of purchase accounting, we identified an executory contract in the supply agreement between Keryx and BioVectra, which includes future firm purchase commitments. This executory contract was deemed to have an off-market element related to the amount of purchase commitments that exceed the current forecast. As a result, we recorded a liability of $29.5 million in purchase accounting as of the acquisition date for the preliminary fair value of the off-market element. Through June 30, 2019, we recorded $0.4 million in accretion expense related to the present value discount associated with this liability.

Pursuant to the Siegfried Master Manufacturing Services and Supply Agreement, or the Siegfried Agreement, we have agreed to purchase a minimum quantity of drug substance of Auryxia at predetermined prices. The price per kilogram will decrease with an increase in quantity above the minimum purchase quantity. The term of the Siegfried Agreement expires on December 31, 2021, after which, it automatically renews for one-year terms until terminated. The Siegfried Agreement provides us with certain termination rights prior to December 31, 2021. As of June 30, 2019, we are required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $75.3 million through the year ended December 31, 2021.

Other Third Party Contracts

Under our agreement with IQVIA, formerly known as Quintiles IMS, to provide contract research organization services for the PRO_2TECT and $INNO_2$VATE programs, the total remaining contract costs as of June 30, 2019 were approximately $111.8 million. The estimated period of performance for the committed work with IQVIA is through the end of 2020. We also contract with various other organizations to conduct research and development activities with remaining contract costs to us of approximately $55.5 million as of June 30, 2019. The scope of the services under these research and development contracts can be modified and the contracts cancelled by us upon written notice, and therefore not included in the table of contractual obligations and commitments. In some instances, the contracts may be cancelled by the third party upon written notice.

Off-Balance Sheet Arrangements

As of June 30, 2019, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, 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, prepaid and accrued research and development expenses and stock-based compensation. 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, 2019, there were no material changes to our critical accounting policies, other than as described below, as reported in our Annual Report on Form 10-K for the year ended December 31, 2018, which was filed with the SEC on March 26, 2019.

Inventory

We value our inventories at the lower-of-cost or net realizable value. We determine the cost of our inventories, which includes amounts related to materials and manufacturing overhead, on a first-in, first-out basis. We classify inventory costs as long-term, in other assets in our unaudited condensed consolidated balance sheets, when we expect to utilize the inventory beyond our normal operating cycle.

Prior to the regulatory approval of our product candidates, we incur expenses for the manufacture of material that could potentially be available to support the commercial launch of our products. Until the first reporting period when regulatory approval has been received or is otherwise considered probable and the future economic benefit is expected to be realized, we record all such costs as research and development expense. Inventory used in clinical trials is also expensed as research and development expense, when selected for such use. Inventory that can be used in either the production of clinical or commercial products is expensed as research and development costs when identified for use in a clinical manufacturing campaign.

We perform an assessment of the recoverability of capitalized inventory during each reporting period, and write down any excess and obsolete inventory to our net realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded as a component of cost of product sales in the unaudited condensed consolidated statements of operations and comprehensive loss. The determination of whether inventory costs will be realizable requires the use of estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required. Additionally, our product is subject to strict quality control and monitoring that we perform throughout the manufacturing process. In the event that certain batches or units of product no longer meet quality specifications, we will record a charge to cost of product sales to write-down any unmarketable inventory to its estimated net realizable value. In all cases, product inventory is carried at the lower of cost or its estimated net realizable value.

Revenue

We generate revenues primarily from sales of Auryxia, see Note 3 to our condensed consolidated financial statements in Part I, Item 1. Financial Statements (unaudited), and from our collaborations with MTPC and Otsuka, see Note 4 to our condensed consolidated financial statements in Part I, Item 1 – Financial Statements (unaudited). We recognize revenue in accordance with ASC 606, which applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

(i) identify the contract(s) with a customer;

(ii) identify the performance obligations in the contract;

(iii) determine the transaction price;

(iv) allocate the transaction price to the performance obligations in the contract; and

(v) recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when it is probable that the entity will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

We sell Auryxia in the U.S., primarily to wholesale distributors as well as certain specialty pharmacy providers, collectively the Customers. These Customers resell our product to health care providers and patients. In addition to distribution agreements with Customers, we enter into arrangements with health care providers and payors that provide for government-mandated and/or privately-negotiated rebates, chargebacks, and discounts with respect to the purchase of our product.

We recognize revenue on product sales when the Customer obtains control of our product, which occurs at a point in time, typically upon delivery to the Customer. We expense incremental costs of obtaining a contract as and when incurred if the expected amortization period of the asset that we would have recognized is one year or less.

Reserves for Variable Consideration

Revenue from product sales is recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from discounts, returns, chargebacks, rebates, co-pay assistance and other allowances that are offered within contracts between us and our Customers, health care providers, payors and other indirect customers relating to our sales of our products. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount will be credited to the Customer) or a current liability (if the amount is payable to a Customer or a party other than a Customer). When appropriate, these estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in ASC 606 for relevant factors such as our historical experience, current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the respective underlying contracts.

The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product revenue and earnings in the period such variances become known.

Trade Discounts and Allowances: We generally provide Customers with discounts that include incentive fees that are explicitly stated in our contracts and are recorded as a reduction of revenue in the period the related product revenue is recognized. In addition, we compensate (through trade discounts and allowances) our Customers for sales order management, data, and distribution services. However, we have determined such services received to date are not distinct from our sale of products to the Customer and, therefore, these payments have been recorded as a reduction of revenue within the unaudited condensed consolidated statement of operations and comprehensive loss through June 30, 2019. We record a corresponding reduction to accounts receivable (if the trade discount and/or allowance will be credited to the Customer) or an increase to accrued expense (if the trade discount and/or allowance is payable to a Customer) on the consolidated balance sheets.

Product Returns: Consistent with industry practice, we generally offer Customers a limited right of return which allows for product return when the product expiry is within an allowable window. This right of return lapses once provided to a patient. We estimate the amount of our product sales that may be returned by our Customers and record this estimate as a reduction of revenue in the period the related product revenue is recognized. We currently estimate product return reserve using available industry data and our own historical sales information, including our visibility into the inventory remaining in the distribution channel.

Provider Chargebacks and Discounts: Chargebacks for fees and discounts to providers represent the estimated obligations resulting from contractual commitments to sell products to qualified healthcare providers at prices lower than the list prices charged to Customers who directly purchase the product from us. Customers charge us for the difference between what they pay for the product and the ultimate selling price to the qualified healthcare providers. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargeback amounts are generally determined at the time of resale to the qualified healthcare provider by Customers, and we generally issue credits for such amounts within a few weeks of the Customer's resale of the product. Reserves for chargebacks consist of credits that we expect to issue for units that remain in the distribution channel at each reporting period end that we expect will be sold to qualified healthcare providers, and chargebacks that Customers have claimed but for which we have not yet issued a credit.

Commercial and Medicare Part D Rebates: We contract with various commercial payor organizations, primarily health insurance companies and pharmacy benefit managers, for the payment of rebates with respect to utilization of our products. We estimate the rebates for commercial and Medicare Part D payors based upon (i) our contracts with the payors and (ii) information obtained from our Customers and other third parties regarding the payor mix for Auryxia. We estimate these rebates and record such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Other Government Rebates: We are subject to discount obligations under state Medicaid programs and other government programs. We estimate Medicaid and other government programs rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the consolidated balance sheets. For Medicare, we also estimate the number of patients in the prescription drug coverage gap for whom we will owe an additional liability under the Medicare Part D program. Our liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel at the end of each reporting period.

Other Incentives: Other incentives that we offer include voluntary patient assistance programs such as our co-pay assistance program, which are intended to provide financial assistance to qualified commercially insured patients with prescription drug co-payments required by payors. The calculation of the accrual for co-pay assistance is based on actual claims processed during a given period, as well as historical utilization data to estimate the amount we expect to receive associated with product that has been recognized as revenue, but remains in in the distribution channel at the end of each reporting period.

Collaboration Revenues

We enter into out-license and collaboration agreements which are within the scope of ASC 606, under which we license certain rights to our product candidates to third parties. The terms of these arrangements typically include payment to us of one or more of the following: non-refundable, up-front license fees; development, regulatory, and commercial milestone payments; payments for manufacturing supply services we provide through our contract manufacturers; and royalties on net sales of licensed products. Each of these payments may result in license, collaboration and other revenue, except for revenues from royalties on net sales of licensed products, which are classified as royalty revenues.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of our agreements, we implement the five-step model noted above. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine whether the individual promises represent separate performance obligations or as a combined performance obligation, and to determine the stand-alone selling price for each performance obligation identified in the contract. A deliverable represents a separate performance obligation if both of the following criteria are met: (i) the customer can benefit from the good or service either on our own or together with other resources that are readily available to the customer, and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. We use key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success. With regard to the MTPC and Otsuka collaboration agreements, we recognize revenue related to amounts allocated to the identified performance obligation on a proportional performance basis as the underlying services are performed.

Licenses of Intellectual Property

If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments

At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. We evaluate factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to assess the milestone as probable of being achieved. There is considerable judgment involved in determining whether a milestone is probable of being reached at each specific reporting period. Milestone payments that are not within our control or the customer, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. The transaction price is then allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenues as, or when, the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenue in the period of adjustment.

Manufacturing Supply Services

Arrangements that include a promise for future supply of drug substance or drug product for either clinical development or commercial supply at the licensee’s discretion are generally considered as options. We assess if these options provide a material right to the licensee and if so, they are accounted for as separate performance obligations. If we are entitled to additional payments when the licensee exercises these options, any additional payments are recorded in license, collaboration and other revenues when the licensee obtains control of the goods, which is upon delivery.

Royalties

We will recognize sales-based royalties, including milestone payments based on the level of sales, at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). We receive royalty payments from JT and Torii, based on net sales of Riona in Japan.

Collaborative Arrangements

We record the elements of our collaboration agreements that represent joint operating activities in accordance with ASC Topic 808, *Collaborative Arrangements* (ASC 808). Accordingly, the elements of the collaboration agreements that represent activities in which both parties are active participants and to which both parties are exposed to the significant risks and rewards that are dependent on the commercial success of the activities are recorded as collaborative arrangements. We consider the guidance in ASC 606-10-15, *Revenue from Contracts with Customers – Scope and Scope Exceptions*, in determining the appropriate treatment for the transactions between us and our collaborative partner and the transactions between us and third parties. Generally, the classification of transactions under the collaborative arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Therefore, we recognize our allocation of the shared costs incurred with respect to the jointly conducted medical affairs and commercialization and non-promotional activities under the Otsuka U.S. Agreement as a component of the related expense in the period incurred. During the three months ended June 30, 2019 and 2018, we incurred approximately $0.3 million and $0.2 million, respectively, of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, as defined in Note 4 to our consolidated financial statements in Part I, Item I. Financial Statements (unaudited), of which approximately $0.1 million are reimbursable by Otsuka and recorded as a reduction to research and development expense during each of the three months ended June 30, 2019 and 2018. During the three months ended June 30, 2019, Otsuka incurred approximately $0.1 million of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.1 million are reimbursable by us and recorded as an increase to research and development expense. No costs were incurred by Otsuka related to the cost-sharing provisions of the Otsuka U.S. Agreement during the three months ended June 30, 2018. To the extent product revenue is generated from the collaboration, we recognize our share of the net sales on a gross basis if it is deemed to be the principal in the transactions with customers, or on a net basis if it is instead deemed to be the agent in the transactions with customers, consistent with the guidance in ASC 606.

Recent Accounting Pronouncements

For additional discussion of recent accounting pronouncements, please refer to *New Accounting Pronouncements – Recently Adopted* and *New Accounting Pronouncements – Not Yet Adopted* included within Note 2 to our condensed consolidated financial statements in Part I, Item 1 – Financial Statements (unaudited).

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, 2019, and December 31, 2018, we had cash and cash equivalents and available-for-sale securities of $136.8 million and $321.6 million, respectively, consisting primarily of money market mutual funds consisting of U.S. government debt securities, certificates of deposit and corporate debt securities. Our primary exposure to market risk is interest rate sensitivity, which 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. Currently, we do not hedge our interest rate exposures.

Item 4. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended, is (1) recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of June 30, 2019, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving such control objectives. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of June 30, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended June 30, 2019, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Shareholder Litigation

Shareholder Litigation Relating to our Merger with Keryx

On June 28, 2018, we entered into an Agreement and Plan of Merger with Keryx Biopharmaceuticals, Inc., or Keryx, and Alpha Therapeutics Merger Sub, Inc., or the Merger Sub, pursuant to which the Merger Sub would merge with and into Keryx, with Keryx becoming a wholly owned subsidiary of ours, or the Merger. On December 12, 2018, we completed the Merger. In October and November 2018, four purported shareholders of Keryx filed four separate putative class actions, or the Merger Securities Actions, against Keryx, a former officer and director of Keryx (Jodie P. Morrison, who is now a director of ours), former directors of Keryx (Kevin J. Cameron, Mark J. Enyedy, Steven C. Gilman, Michael T. Heffernan, Daniel P. Regan and Michael Rogers, some of whom are current members of our Board of Directors), and, with respect to the Rosenblatt action discussed below, the Merger Sub and Akebia, challenging the disclosures made in connection with the Merger.

Three of the Merger Securities Actions were filed in the United States District Court for the District of Delaware, or the Delaware District Court: Corwin v. Keryx Biopharmaceuticals, Inc., et al. (filed October 16, 2018); Van Hulst v. Keryx Biopharmaceuticals, Inc., et al. (filed October 24, 2018); and Andreula v. Keryx Biopharmaceuticals, Inc., et al. (filed November 1, 2018). The fourth Merger Securities Action was filed in the United States District Court for the District of Massachusetts, or the Massachusetts District Court: Rosenblatt v. Keryx Biopharmaceuticals, Inc., et al. (filed October 23, 2018). On February 19, 2019, the plaintiff in the Rosenblatt action filed a notice of voluntary dismissal of the action without prejudice. On March 27, 2019, the plaintiff in the Van Hulst action filed a notice of voluntary dismissal of the action without prejudice.

On April 2, 2019, the Delaware District Court granted Abraham Kiswani, a member of the putative class in both the Andreula and Corwin actions, and plaintiff John Andreula's motion to consolidate the remaining two Merger Securities Actions pending in the Delaware District Court and consolidated the Corwin and Andreula cases under the caption In re Keryx Biopharmaceuticals, Inc., or the Consolidated Action. The Delaware District Court also appointed Kiswani and plaintiff Andreula as lead plaintiffs for the Consolidated Action. On June 3, 2019, the lead plaintiffs filed a consolidated amended complaint in the Consolidated Action, or the Consolidated Complaint. The Consolidated Complaint generally 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 14(a) and 20(a) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 14a-9 promulgated thereunder. The alleged misstatements or omissions relate to (i) certain financial projections for Keryx and Akebia and certain financial analyses performed by our advisors and (ii) any alleged negotiations that may have taken place regarding the conversion of certain convertible notes of Keryx in connection with the Merger. The Consolidated Complaint seeks compensatory and/or rescissory damages, a declaration that the defendants violated Sections 14(a) and 20(a) of the Exchange Act and Rule 14a-9 thereunder, and an award of lead plaintiffs' costs, including reasonable allowance for attorneys' fees and experts' fees. The defendants in the Consolidated Action moved to dismiss the Consolidated Complaint in its entirety on August 2, 2019. Under the scheduling order applicable to the Consolidated Action, briefing on the defendants' motion to dismiss will be completed by November 15, 2019.

On December 10, 2018, a purported stockholder of Keryx, Michael J. Donnelly, filed a complaint against Keryx pursuant to Section 220 of the Delaware General Corporation Law in the Delaware Court of Chancery, captioned Donnelly v. Keryx Biopharmaceuticals, Inc., or the Donnelly Action. The Donnelly Action seeks inspection of various Keryx books and records, purportedly to investigate "possible wrongdoing," in connection with Keryx's negotiation and approval of the Merger, as well as the independence of former members of Keryx's Board of Directors, some of whom are current members of our Board of Directors. In addition to the production of books and records, the Donnelly Action seeks costs and expenses incurred in the action, including reasonable attorneys' fees. On January 31, 2019, Keryx answered the complaint in the Donnelly Action. The Delaware Court of Chancery entered a scheduling order to govern the Donnelly Action on March 28, 2019. The trial for the Donnelly Action took place on July 10, 2019, and a decision has not yet been issued.

Shareholder Litigation Relating to Auryxia Supply

Four putative class action lawsuits have been filed against Keryx and certain of its former officers (Gregory P. Madison, Scott A. Holmes, Ron Bentsur, and James Oliviero) and consolidated in the Massachusetts District Court, captioned Karth v. Keryx Biopharmaceuticals, Inc., et al. (filed October 26, 2016, with an amended complaint filed on February 27, 2017). Plaintiff seeks to represent all stockholders who purchased shares of Keryx common stock between May 8, 2013 and August 1, 2016. The complaint alleges that Keryx and the named individual defendants violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning Keryx, its supplier relationships, and future prospects, and that the allegedly misleading statements were not made known to the market until Keryx's August 1, 2016 announcement of an interruption in its supply of Auryxia. By order dated July 19, 2018, the Massachusetts District Court granted in part and denied in part the defendants' motion to dismiss the complaint. On February 27, 2019, defendants filed a motion for judgment on the pleadings. On April 30, 2019, plaintiff filed a motion to further amend his complaint, and also moved for class certification. The Massachusetts District Court heard oral argument on the motions for judgment on the pleadings and class certification on June 19, 2019. The court took the motions (as well as plaintiff's motion to further amend the complaint) under advisement. The parties are presently engaged in discovery. No trial date has been set.

Two stockholder derivative complaints also were filed on December 16, 2016 against Keryx and certain of its former officers (Gregory P. Madison, Scott A. Holmes, Ron Bentsur and James Oliviero) certain of its former directors (Kevin J. Cameron, Daniel P. Regan, Steven C. Gilman, Michael Rogers Michael P. Tarnok, Joseph Feczko, Jack Kaye Wyche Fowler, Jr. and John P. Butler), some of whom are current directors and officers of ours, in the Superior Court of Massachusetts, one captioned Venkat Vara Prasad Malledi v. Keryx Biopharmaceuticals, Inc., et al., and one captioned James Anderson v. Keryx Biopharmaceuticals, Inc., et al. Each of these two complaints generally alleges breach of fiduciary duty, unjust enrichment, abuse of control, mismanagement and corporate waste. On June 27, 2017, the Superior Court of Massachusetts granted the parties' motion to consolidate and stay the derivative litigations. All of the complaints seek unspecified damages, interest, attorneys' fees, and other costs.

We deny any allegations of wrongdoing and intend to vigorously defend against the shareholder lawsuits described in this section. There is no assurance, however, that we will be successful in the defense of these lawsuits or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of these actions. Moreover, we are unable to predict the outcome or reasonably estimate a range of possible losses at this time. A resolution of these lawsuits 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 a particular lawsuit is resolved.

Legal Proceedings Relating to Auryxia

ANDA Litigation

On October 31, 2018, November 6, 2018, December 24, 2018 and February 4, 2019, Keryx received Paragraph IV certification notice letters regarding Abbreviated New Drug Applications, or ANDAs, submitted to the U.S. Food and Drug Administration, or FDA, by Lupin Atlantis Holdings SA, or Lupin, Teva Pharmaceuticals USA, Inc., or Teva, Chemo Research S.L., or Chemo, and Mylan Pharmaceuticals Inc., or Mylan, respectively, requesting approval for generic versions of Auryxia tablets (210 mg iron per tablet). On December 13, 2018, Keryx and its licensors, Panion & BF Biotech, Inc., or Panion, and Chen Hsing Hsu, M.D., filed a complaint for patent infringement against Lupin and Lupin Ltd., or the Lupin Defendants, in the Delaware District Court, arising from Lupin's ANDA filing with the FDA. On December 19, 2018, Keryx and Panion filed a complaint for patent infringement against Teva and Teva Pharmaceutical Industries Limited, or the Teva Defendants, in the Delaware District Court arising from Teva's ANDA filing with the FDA. On February 1, 2019, Keryx, Panion and Dr. Hsu filed a complaint for patent infringement against Chemo and Insud Pharma S.A., or the Chemo Defendants, in the Delaware District Court arising from Chemo's ANDA filing with the FDA. On March 15, 2019, Keryx, Panion and Dr. Hsu filed a complaint for patent infringement against Mylan in the United States District Court for the Northern District of West Virginia of arising from Mylan's ANDA filing with the FDA. On April 18, 2019, Keryx, Panion and Dr. Hsu filed a motion with the Judicial Panel on Multidistrict Litigation seeking to consolidate these four cases in the Delaware District Court for pretrial proceedings.

On March 29, 2019, April 2, 2019, and April 12, 2019, Keryx received Paragraph IV certification notice letters regarding ANDAs submitted to the FDA by Lupin Ltd., Watson Laboratories, Inc., or Watson, a wholly-owned, indirect subsidiary of Teva, and Par Pharmaceutical, Inc., or Par, an Endo International company, or Endo, respectively, requesting approval for generic versions of Auryxia tablets (210 mg iron per tablet). On May 10, 2019, Keryx, Panion and Dr. Hsu filed a complaint for patent infringement against Lupin Ltd. in the Delaware District Court arising from Lupin Ltd.'s ANDA filing with the FDA. On May 10, 2019, Keryx and Panion filed a complaint for patent infringement against Watson and Teva, or the Watson Defendants, in the Delaware District Court arising from Watson's ANDA filing with the FDA. On May 15, 2019, Keryx and Panion filed a complaint for patent infringement against the Watson Defendants in the United States District Court for the District of Nevada, or the Nevada District Court, from Watson's ANDA filing with the FDA. On May 23, 2019, Keryx and Panion filed a complaint for patent infringement against Par in the Delaware District Court arising from Par's ANDA filing with the FDA. On May 24, 2019, Keryx and Panion filed a complaint for patent infringement against Par, in the United States District Court for the Southern District of New York, or the Southern New York District Court, arising from Par's ANDA filing with the FDA. On June 4, 2019, Keryx and Panion filed a notice of voluntary dismissal to dismiss the suit in the Nevada District Court in view of the Watson Defendants' consent to venue of the Delaware District Court. On June 26, 2019, Keryx, Panion and Dr. Hsu notified the Judicial Panel on Multidistrict Litigation of additional actions in the Delaware District Court against the Lupin Defendants and the Watson Defendants. On July 31, 2019, the Judicial Panel on Multidistrict Litigation issued an order to consolidate all of our ANDA cases in Delaware District Court for pretrial proceedings.

As a result of the timely filing of these lawsuits in accordance with the relevant statute, a 30-month stay of approval will be imposed by the FDA on Lupin's ANDA, Teva's ANDA, Chemo's ANDA, Mylan's ANDA, Lupin Ltd.'s ANDA, Watson's ANDA, and Par's ANDA, which stays are expected to remain in effect until April 2021, May 2021, June 2021, August 2021, September 2021, October 2021 and October 2021, respectively, absent an earlier judgment by the court in each of these lawsuits finding the patents at issue invalid, unenforceable or not infringed. We and the other plaintiffs in each of these lawsuits are seeking, among other relief, an order that the effective date of FDA approval of the ANDA be a date no earlier than the expiration of each of the patents at issue and equitable relief enjoining the Lupin Defendants, the Teva Defendants, the Chemo Defendants, Mylan, the Watson Defendants and Par from infringing these patents.

On July 22, 2019, Keryx received from Teva a supplemental Paragraph IV certification notice letter regarding its ANDA. On July 22, 2019, Keryx received from Watson a supplemental Paragraph IV certification notice letter regarding its ANDA. On July 31, 2019, Keryx received from Lupin a supplemental Paragraph IV certification notice letter regarding its ANDA. On July 31, 2019, Keryx received from Lupin Ltd. a supplemental Paragraph IV certification notice letter regarding its ANDA.

On August 2, 2019, Keryx and Panion entered into a settlement and license agreement with Par resolving patent litigation brought by Keryx and Panion in response to Par's ANDA seeking approval to market a generic version of Auryxia tablets prior to the expiration of the applicable patents. Pursuant to the terms of the settlement, Keryx and Panion will grant Par 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 agreement, the parties will terminate all ongoing litigation between Keryx and Panion and Par regarding Auryxia patents pending in the Delaware District Court and the Southern New York 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 August 5, 2019, the parties filed a request to stay the litigation pending a review of the settlement and license agreement by these regulatory authorities.

Opposition Proceedings Against Patents Covering Auryxia

On November 25, 2015, a third party filed an opposition to our issued European Patent No. 1 931 689, or the '689 EP Patent, in the European Patent Office, or the EPO. During the oral proceedings, which took place on June 27, 2017, the Opposition Division of the EPO revoked the '689 EP Patent. On December 6, 2017, we filed an appeal of the decision of the Opposition Division of the EPO, which is presently pending. According to European practice, the revocation of the patent is stayed until an appeal is finally resolved. We anticipate the appeal will take a few years to resolve, during which time the patent will remain in force.

On December 23, 2016, a third party filed an opposition to our issued European Patent No. 1 978 807, or the '807 EP Patent, in the EPO. During the oral proceedings, which took place on June 8, 2018, the Opposition Division of the EPO maintained the '807 EP Patent as granted. This decision resulted in the maintenance of all of the claims of the patent, including claims directed to the use of ferric citrate for preventing, reversing, maintaining or delaying progression of chronic kidney disease, or CKD. On November 16, 2018, the third party filed an appeal of the decision of the Opposition Division of the EPO, which is presently pending. On June 7, 2019, the third party withdrew the appeal. As a result, the Opposition Division's decision is final, and the '807 EP Patent will be maintained as granted.

Legal Proceedings Relating to Vadadustat

Opposition Proceedings Against Patents Covering Vadadustat

In July 2011, a third party filed an opposition to our issued European Patent No. 2044005, or the '005 EP Patent, in the EPO. During the oral proceedings, which took place on April 10, 2013, the Opposition Division of the EPO maintained the '005 EP Patent. This decision resulted in the maintenance of a claim directed to a compound chosen from a group of eight compounds, including vadadustat, as well as claims to compositions and methods for treating various diseases, including, but not limited to, anemia. Both parties appealed the decision of the Opposition Division of the EPO. On February 27, 2018, we withdrew the '005 EP Patent from appeal and filed a divisional patent application to pursue a focused claim set that includes claims for vadadustat, as well as pharmaceutical compositions and methods of treating anemia.

In September 2018, Dr. Reddy's Laboratories Limited filed an opposition to our issued Indian Patent No. 287720, or the '720 IN Patent, in the Indian Patent Office.

Opposition and Invalidity Proceedings Against FibroGen, Inc.

We filed an opposition in the EPO against FibroGen, Inc.'s, or FibroGen's, European Patent No. 1463823, or the '823 EP Patent on December 5, 2013, and an oral proceeding took place March 8 and 9, 2016. Following the oral proceeding, the Opposition Division of EPO ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. FibroGen has appealed that decision. Likewise, we also filed an invalidity proceeding before the Japan Patent Office, or JPO, on June 2, 2014 against certain claims of FibroGen's Japanese Patent No. 4804131, or the '131 JP Patent, which is the Japanese counterpart to the '823 EP Patent, and the JPO issued a preliminary decision finding all of the challenged claims to be invalid. FibroGen subsequently amended the claims and the JPO accepted the amendments. The resulting '131 JP Patent does not cover vadadustat or any pyridine carboxamide compounds. To date, FibroGen has been unsuccessful in its attempts to obtain a patent in the United States covering the same claim scope as it obtained initially in Europe and Japan in the '823 EP Patent and '131 JP Patent. In the event FibroGen were to obtain such a patent in the United States, we may decide to challenge the patent as we have done in Europe and Japan.

On May 13, 2015, May 20, 2015 and July 6, 2015, we filed oppositions to FibroGen's European Patent Nos. 2322155, or the '155 EP Patent, 1633333, or the '333 EP Patent, and 2322153, or the '153 EP Patent in the EPO, respectively, requesting the patents be revoked in their entirety. These related patents claim, among other things, various compounds that either stabilize HIFα or inhibit a HIF hydroxylase or a HIF prolyl hydroxylase, or HIF-PH, for treating or preventing various conditions, including, among other things, iron deficiency, microcytosis associated with iron deficiency, anemia of chronic disease, anemia wherein the subject has a transferrin saturation of less than 20%, anemia refractory to treatment with exogenously administered erythropoietin and microcytosis in microcytic anemia. Such method of use patents do not prevent persons from using the compound for other uses, including any previously known use of the compound. In particular, these patents do not claim methods of using any of our product candidates for purposes of inhibiting HIF-PH for the treatment of anemia due to CKD. While we do not believe these patents will prevent us from commercializing vadadustat for the treatment of anemia due to CKD, we filed these oppositions to provide us and our collaborators with maximum flexibility for developing vadadustat and our pipeline of HIF-PHI compounds.

Oppositions to the '155 EP Patent and the '153 EP Patent were also filed in the EPO by Glaxo Group Limited, or Glaxo, and by Bayer Intellectual Property GmbH, Bayer Pharma Aktiengesellschaft, and Bayer Animal Health GmbH, or, collectively, Bayer.

With regard to the opposition that we filed in Europe against the '333 EP Patent, an oral proceeding took place on December 8 and 9, 2016. Following the oral proceeding, the Opposition Division of the EPO ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. On December 9, 2016, FibroGen filed a notice to appeal the decision to revoke the '333 EP Patent.

In oral proceedings held on May 29, 2017, regarding the '155 EP Patent, the European Opposition Division ruled that the '155 EP Patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. FibroGen filed a notice to appeal the decision to revoke the '155 EP Patent on May 29, 2017.

Subsequently, in related oral proceedings held on May 31, 2017 and June 1, 2017 for the '153 EP Patent, the Opposition Division of the EPO maintained the patent after FibroGen significantly narrowed the claims to an indication for which vadadustat is not intended to be developed. We and Glaxo separately filed notices to appeal the decision to maintain the '153 EP Patent on November 9, 2017. Bayer filed a notice to appeal the decision on November 14, 2017.

On April 3, 2019, we filed oppositions to FibroGen's European Patent Nos. 2289531, or the '531 EP Patent, and 2298301, or the '301 EP Patent in the EPO, respectively, requesting the patents be revoked in their entirety.

On May 21, 2018, we filed a Statement of Claim in Canadian Federal Court to challenge the validity of three of FibroGen's HIF-related patents in Canada: CA 2467689, CA 2468083, and CA 2526496.

On June 22, 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 one of FibroGen's HIF-related patents in Japan, JP4845728. On July 20, 2018 and August 13, 2018, we and MTPC jointly filed a Request for Trial before the JPO to challenge the validity of two additional FibroGen HIF-related patents in Japan, JP5474872 and JP5474741, respectively.

On December 13, 2018, we and our collaboration partner, Otsuka Pharmaceutical Co. Ltd., or Otsuka, filed Particulars of Claim in the Patents Court of the United Kingdom, or the UK, to challenge the validity of FibroGen, Inc.'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 March 2019, Astellas Pharma Inc., or Astellas, the exclusive licensee of FibroGen's HIF-related patents, sued Akebia and Otsuka for patent infringement in the Patents Court of the UK. On December 21, 2018, GlaxoSmithKline UK Limited and GlaxoSmithKline Intellectual Property (No. 2) Limited, or, collectively, Glaxo UK, also filed Particulars of Claim in the Patents Court of the UK to challenge the validity of the '153 EP Patent (UK) and the '155 EP Patent (UK). In March 2019, Astellas sued Glaxo UK for patent infringement in the Patents Court of the UK.

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. If any of the following risks occurs, our business, financial statements and future growth prospects could be materially and adversely affected.

Risks Related to our Merger with Keryx

We may fail to realize the anticipated benefits of our merger with Keryx, those benefits may take longer to realize than expected, and we may encounter significant integration difficulties and liabilities, which may have a material adverse effect on our business and financial position.

On December 12, 2018, we completed a merger, or the Merger, whereby Keryx Biopharmaceuticals, Inc., or Keryx, became a wholly owned subsidiary of ours. There can be no assurance that we will realize the full benefit of the anticipated synergies and cost savings relating to the Merger or that these benefits will be realized within the expected time frames or at all. Our ability to realize the anticipated benefits of the Merger will depend, to a large extent, on our ability to continue to integrate our business and Keryx's business and realize anticipated growth opportunities and synergies. If we are unable to successfully integrate the businesses, or integrate them in a timely fashion, we may face material adverse effects including, but not limited to (i) diversion of the attention of management and key personnel and potential disruption of our ongoing business, (ii) the loss of employees, (iii) challenges of managing a larger company, including challenges of conforming standards, controls, procedures and accounting and other policies and compensation structures, (iv) difficulties in achieving anticipated cost savings, (v) declines in our results of operations, financial condition or cash flows, (vi) a decline in the market price of our common stock, and (vii) potential liabilities, adverse consequences, increased expenses or other problems associated with our company following completion of the Merger. Many of these factors are outside of our control, and any one of them could result in increased costs, decreased expected revenues and further diversion of management time and energy, which could materially impact our business, financial statements and prospects.

In addition, following the Merger, we have become responsible for Keryx's liabilities and obligations, including with respect to legal, financial, regulatory and compliance matters, including certain post-approval regulatory requirements with respect to Auryxia and Fexeric, and obligations under collaboration, license, supply and manufacturing agreements. These obligations will result in additional cost and investment by us and, if we have underestimated the amount of these costs and investments or if we fail to satisfy any such obligations, we may not realize the anticipated benefits of the transaction. Also, due to the Merger and ongoing integration, we may forego or delay pursuit of other opportunities that may have proven to have greater commercial potential.

Further, it is possible that there may be unknown, contingent or other liabilities or problems that may arise in the future, the existence and/or magnitude of which we were previously unaware. Any such liabilities or problems could have an adverse effect on our business, financial condition or results of operations.

Lawsuits have been filed challenging the Merger and additional lawsuits may be filed in the future. Any monetary damages, or other adverse judgment could have a material adverse effect on us.

There is an ongoing putative class action lawsuit filed by purported Keryx shareholders challenging the disclosures made in connection with the Merger. In addition, a purported stockholder of Keryx filed a complaint against Keryx pursuant to Section 220 of the Delaware General Corporation Law, which seeks inspection of various Keryx books and records, purportedly to investigate "possible wrongdoing," in connection with Keryx's negotiation and approval of the Merger, as well as the independence of former members of Keryx's Board of Directors (some of whom are current members of our Board of Directors). See Part II, Item 1. Legal Proceedings for further information relating to the lawsuits. Additional lawsuits arising out of the Merger may be filed in the future. We could be forced to expend significant resources in the defense of these lawsuits, including but not limited to, costs associated with the indemnification of Keryx and Akebia directors and officers, and the lawsuits, regardless of outcome, could have a negative effect on our reputation, stock price and results of operations. In addition, monetary damages or other adverse judgment would have a material adverse effect on our business and financial position.

Our financial statements include goodwill and other intangible assets as a result of the Merger. These assets could become impaired in the future under certain conditions.

Accounting standards in the United States require that one party to the Merger be identified as the acquirer. In accordance with these standards, the Merger was accounted for as an acquisition of all outstanding shares of Keryx common stock by us, as the acquirer, and followed the acquisition method of accounting for business combinations. Our assets and liabilities were consolidated with those of Keryx in our financial statements. We measured Keryx's assets acquired and liabilities assumed by us at their fair values, including net tangible and identifiable intangible assets acquired and liabilities assumed, as of the consummation of the Merger. The excess of the purchase price over the fair value of Keryx's assets and liabilities was recorded as goodwill. The Merger added approximately $384.7 million of goodwill and definite lived intangible assets to our financial statements as of December 12, 2018. Our definite lived intangible assets are amortized over their estimated useful lives. In accordance with generally accepted accounting principles, or GAAP, we will be required at least annually to review the carrying value of our goodwill, and for definite lived intangible assets when indicators of impairment are present, to determine if any adverse conditions exist or a change in circumstances has occurred that would indicate impairment of the value of these assets. Conditions that could indicate impairment and necessitate an evaluation of these assets include, but are not limited to, a significant adverse change in the business climate or the legal or regulatory environment within which we operate. In addition, the deterioration of a company's market capitalization significantly below its net book value is an indicator of impairment. To the extent goodwill or other intangible assets become impaired, we may be required to incur material charges relating to such impairment. Such a potential impairment charge could have a material impact on our future operating results and financial position.

Risks Related to our Financial Position and Need for Additional Capital

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 entails upfront capital expenditures and 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 and, following the Merger, commercialization. We have financed our operations primarily through sales of equity securities, our strategic collaborations and, following the Merger, product revenues. Prior to the Merger, 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 have incurred net losses each year since our inception, including net losses of $130.6 million for the six months ended June 30, 2019. As of June 30, 2019, we had an accumulated deficit of $645.0 million. We cannot guarantee when, if ever, we will become profitable. Our ability to generate product revenue and achieve profitability depends significantly on our success in many areas, including the following:

- developing, commercializing and marketing Auryxia, vadadustat, if approved, or any other product or product candidate, including those that may be in-licensed or acquired;
- completing preclinical and clinical development of our product candidates;
- seeking and obtaining and, if approved, maintaining marketing approvals for our product candidates after completion of clinical studies and the timing of such approvals, and maintaining marketing approvals for Auryxia;
- developing sustainable and scalable manufacturing processes for Auryxia, vadadustat and any other product or product candidate, including those that may be in-licensed or acquired;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate products that are compliant with good manufacturing practices, or GMPs, and services to support the clinical development and the market demand for our products and product candidates, including those that may be in-licensed or acquired;
- launching and commercializing our product candidates, either directly or with a collaborator or distributor;
- obtaining sufficient pricing and reimbursement for Auryxia, vadadustat and any other product or product candidate, including those that may be in-licensed or acquired, from private and governmental payors;
- obtaining market acceptance of Auryxia, vadadustat and any other product candidate, including those that may be in-licensed or acquired, as viable treatment options;
- 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, receive approval and obtaining adequate market share in those markets;
- addressing any competing products;
- identifying, assessing, acquiring and/or developing new product candidates;

- negotiating favorable terms in any transaction into which we may enter, including collaboration, merger, acquisition and licensing arrangements;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how;
- integrating following the Merger; and
- attracting, hiring and retaining qualified personnel.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. The amount of our future net losses will depend, in part, on the rate of our future expenditures, and our financial position will depend, in part, on our product revenue from Auryxia and, if approved, vadadustat, and our ability to obtain additional funding. We expect to continue to incur significant expenses if and as we:

- conduct our development program of vadadustat for the treatment of anemia due to chronic kidney disease, or CKD, including PRO_2TECT, $INNO_2VATE$, FO_2RWARD-2, $TRILO_2GY$-2 and $EXPLO_2RE$, and develop plans for and conduct the preclinical and clinical development of any other potential product candidates;
- continue our commercialization activities for Auryxia and plan for the commercialization of vadadustat, if approved, and any other product candidate;
- continue our Merger-related integration activities;
- seek marketing approvals for our product candidates that successfully complete clinical studies, and maintain marketing approvals for Auryxia and any product candidate for which we obtain marketing approval, including complying with any post-marketing regulatory requirements;
- have our product candidates manufactured for clinical trials and for commercial sale;
- initiate additional preclinical, clinical or other studies for vadadustat and any other product candidates, or any post-marketing approval studies, Phase 4 studies or any other clinical trials for Auryxia and Fexeric;
- seek to discover and develop 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;
- make royalty, milestone or other payments under our license agreements and any future in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- continue to create additional infrastructure and expend additional resources to support our operations as a public company, including any additional infrastructure and resources necessary to support a transition from our status as an emerging growth company; and
- experience any delays or encounter issues with any of the above.

We also could be forced to expend significant resources in the defense of the pending securities class action and shareholder derivative lawsuits brought against Keryx and certain of Keryx's former directors and officers, some of whom are current directors and officers of ours, and other legal proceedings, as described under Part II, Item 1. Legal Proceedings, or any other such lawsuits brought 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.

Even if we succeed in receiving marketing approval for and are able to commercialize vadadustat, we will continue to incur substantial research and development and other expenditures to develop and market, if approved, any other product candidates as well as any costs relating to continued commercialization and post-marketing requirements for Auryxia, vadadustat and any other product candidates that may receive marketing approval. 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 U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or 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 repeat any of our clinical trials, to perform studies in addition to, different from or larger than those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing Auryxia, vadadustat, if approved, and any other approved product candidate. 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 expect, 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 may generate revenues from the sale of any product candidates that may be approved in the future, we may never generate revenue that is significant enough to become and remain profitable, and we may need to obtain additional funding to continue operations.

Under our ASC 205-40 analysis, there is "substantial doubt" that we will have sufficient funds to satisfy our obligations through the next twelve months from the date of issuance of this Quarterly Report on Form 10-Q

We expect our cash resources, including committed research and development funding from collaborators, to fund our current operating plan beyond the next twelve months, into the third quarter of 2020. However, on a quarterly basis, we are required to conduct an accounting analysis under ASC 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or ASC 205-40. Under the accounting standards, a company is not permitted to include elements of its operating plan that are deemed to be "outside of the company's control" in an ASC 205-40 analysis, even though certain of those elements may be appropriately included in the company's cash runway analysis. For example, our cash runway includes receipt of a milestone payment from MTPC upon manufacturing and marketing approval of vadadustat in Japan, but since receipt of that milestone payment is deemed to be "outside of our control" under the accounting standards, we are not permitted to include it in our ASC 205-40 analysis. The result of our ASC 205-40 analysis is that there is "substantial doubt" that we will have sufficient funds to satisfy our obligations through the next twelve months from the date of issuance of this Quarterly Report on Form 10-Q. If we are unable to raise sufficient capital when needed, our business, financial condition and results of operations will be materially and adversely affected, and we will need to significantly modify our operational plans. Our conclusion, in accordance with ASC 205-40, that there is "substantial doubt" that we will have sufficient funds to satisfy our obligations through the next twelve months from the date of issuance of this Quarterly Report on Form 10-Q may materially adversely affect our share price and our ability to raise capital or to enter into agreements with third parties that may be beneficial to us.

We will require substantial additional financing to achieve our goals. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

As of June 30, 2019, our cash and cash equivalents and available for sale securities were $136.8 million. We expect to continue to expend substantial amounts for the foreseeable future continuing to commercialize Auryxia and developing and commercializing vadadustat, if approved, and any other product candidates. These expenditures will include costs associated with research and development, potentially obtaining marketing approvals and having our products manufactured, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise, including as a result of our decision to include certain elements in our development programs. Because the outcome of our current and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amount of funding necessary to successfully complete the development and commercialization of our product candidates. Our future capital requirements depend on many factors, including:

- significant costs associated with our global Phase 3 development program for vadadustat for the treatment of anemia due to CKD. As of June 30, 2019, we expect the remaining external aggregate contract research organization, or CRO, costs of PRO_2TECT and $INNO_2$VATE, which are designed to enroll up to approximately 7,900 subjects, to be in the range of $125.0 million to $150.0 million; the estimated costs for PRO_2TECT and $INNO_2$VATE could increase significantly due to a number of factors, including changes in target enrollment and enrollment rates, accrual of major adverse cardiovascular events, or MACE, detection of unexpected safety signals, the addition of new investigative sites, modification of clinical trial protocols, performing other studies in support of the Phase 3 program, choosing to add third party vendors to support the program, and any other factor that could delay completion of PRO_2TECT and $INNO_2$VATE;
- the cost and timing of commercialization activities for Auryxia and our product candidates, if approved for marketing, including product manufacturing, marketing, sales and distribution costs;

- the results of our meetings with the FDA, the EMA and other regulatory authorities and any consequential effects, including on study design, study size and resulting operating costs;
- difficulties or delays in enrolling patients in our clinical trials;
- the timing of, and the costs involved in obtaining, and, if approved, maintaining marketing approvals for vadadustat and any other product candidates that we may develop or acquire, including to fund the preparation and filing of regulatory submissions with the FDA, the EMA and other regulatory authorities, if clinical studies are successful, and the costs of maintaining marketing approvals for Auryxia;
- the cost of conducting the FO_2RWARD-2, TRILO_2GY-2 and EXPLO_2RE clinical studies or any post-marketing approval studies, Phase 4 studies or any other clinical trials for Auryxia and Fexeric;
- the cost, timing and outcome of our efforts to obtain marketing approval for vadadustat in the United States, Europe and in other jurisdictions;
- the scope, progress, results and costs of additional preclinical, clinical, or other studies for vadadustat and Auryxia, as well as any studies of any other product candidates;
- the cost of securing and validating commercial manufacturing of vadadustat and maintaining our manufacturing arrangements for Auryxia, 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;
- Merger-related integration costs;
- our ability to attract, hire and retain qualified personnel; and
- the extent to which we engage in transactions, including collaboration, merger, acquisition and licensing transactions, pursuant to which we would develop and market commercial products, or develop other product candidates and technologies.

Furthermore, we expect to continue to incur additional costs associated with operating as a larger company following the Merger and as a public company, including any additional infrastructure and resources necessary to support a transition from our status as an emerging growth company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. 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 expect our cash resources, including the timing of committed research and development funding from our collaborators, to fund our current operating plan beyond the next twelve months, into the third quarter of 2020. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Furthermore, our development milestones may not be achieved, we may not receive the anticipated funding from our collaboration partners, and we may not secure other sources of financing. If and until we can generate a sufficient amount of product revenues, we expect to finance future cash needs through public or private equity or debt offerings, payments from our collaborators, royalty transactions, strategic transactions, or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic objectives.

Our wholly owned subsidiary, Keryx, also has a $40.0 million revolving loan facility, or the Line of Credit, with Silicon Valley Bank, or SVB. The borrowing base under the Line of Credit, or any other asset-based credit facility into which we may enter in the future, may be significantly lower than the total commitment under any such facility and therefore may limit the total amount we may be able to borrow. As of June 30, 2019, there were no borrowings outstanding and we had approximately $23.9 million in available borrowing base under the Line of Credit. We expect our cash resources to fund our current operating plan beyond the next twelve months, into the third quarter of 2020, which assumes no future borrowings under the Line of Credit. We cannot assure that we will be able to obtain alternative sources of financing on favorable terms 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, vadadustat and any other product candidates. 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 or commercialization of Auryxia, vadadustat and any other product candidates. Any of these events could significantly harm our business, financial condition and prospects.

Our obligations in connection with the Line of Credit with SVB could adversely affect our financial condition and restrict our operations.

In connection with the Line of Credit, Keryx entered into a Loan and Security Agreement with SVB (which was subsequently amended), we executed and delivered to SVB an Unconditional Guaranty, and we entered into a Security Agreement with SVB, collectively referred to as the SVB Agreements. See Note 11 to our condensed consolidated financial statements in Part I, Item 1 – Financial Statements (unaudited) for additional information regarding our and Keryx's obligations under the SVB Agreements.

There are currently no borrowings outstanding under the Line of Credit; however, in the event we draw down the Line of Credit in the future, and there is an acceleration of our and Keryx's liabilities under the SVB Agreements as a result of an event of default, 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 SVB could seek to enforce security interests in the collateral securing the Line of Credit and the Guaranty, which could have a material adverse effect on our business, financial condition and results of operations.

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

- obligating us to negative covenants restricting our activities, including limitations on transferring our assets, changing our business, undergoing a change in control, engaging in mergers or acquisitions, incurring additional indebtedness, creating liens, paying dividends or making other distributions, making investments and transacting with our affiliates;
- limiting our flexibility in planning for, or reacting to, changes in our business and our industry;
- placing us at a competitive disadvantage compared to our competitors who have less 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.

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 our cash needs through product revenues, public or private equity or debt offerings, payments from our collaborators, royalty transactions, strategic 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. 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 royalty 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 be required to delay, limit, reduce or terminate our product development or commercialization efforts for Auryxia, vadadustat, or any other product candidates that we develop or acquire, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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 acquisition of assets, businesses, or rights to products, product candidates or technologies or through strategic alliances or collaborations, similar to the Merger and our collaboration and license arrangements. We may not identify suitable strategic transactions, or complete such transactions in a timely manner, 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, may incur additional debt or assume unknown or contingent liabilities in connection therewith, 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 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.

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

- incurrence of substantial debt, dilutive issuances of securities or depletion of cash to pay for acquisitions;
- exposure to known and unknown liabilities, including possible intellectual property infringement claims, violations of laws, tax liabilities and commercial disputes;
- higher than expected acquisition and integration costs;
- difficulty in integrating operations and personnel of any acquired business;
- increased amortization expenses or, in the event that we write-down the value of acquired assets, impairment losses;
- 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 direct prior development or commercial experience and where competitors in such markets have stronger market positions; and
- other challenges associated with managing an increasingly diversified business.

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

Risks Related to Commercialization

Our ability to successfully commercialize our product, Auryxia, our late-stage product candidate, vadadustat, if approved, and any other product or product candidate, including our ability to achieve their widespread market acceptance, is critical to the success of our business.

Our ability to generate significant product revenue will depend almost entirely on our ability to execute on our commercialization plans, the level of market adoption for, and the availability of and continued use of our product, Auryxia, and, if approved, our late-stage product candidate, vadadustat, by physicians, hospitals, dialysis clinics, wholesalers, patients, and/or healthcare payors, including government payors, consumers, managed care organizations, pharmacy benefit managers, and pharmacies. If we are not successful in commercializing Auryxia and vadadustat, if approved, including achieving and maintaining an adequate level of market adoption, our profitability and our future business prospects will be adversely impacted. Market acceptance of Auryxia and any other product candidate that may be approved, including vadadustat, depends on a number of other factors, including:

- the availability of adequate coverage and reimbursement by third party payors and governmental authorities;
- the safety and efficacy of the product, as demonstrated in clinical trials and in the post-marketing setting;
- the prevalence of the disease treated by our 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 collaborators are able to make regarding the safety and efficacy of our products;
- 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 prevalence and severity of adverse side effects;
- adverse publicity about our products or favorable or adverse publicity about competing products;
- the availability of discounts, rebates, and price concessions;
- the effectiveness of our and our collaborators' sales, marketing and distribution efforts; and
- the restrictions on the use of our products together with other medications, if any.

Market acceptance is critical to our ability to generate significant product revenue. In addition, any product or product candidate, if approved and commercialized, may achieve only limited market acceptance or none at all. If any of our approved products is not accepted by the market to the extent that we expect, we may not be able to generate product revenue and our business would suffer.

Generic competitors are seeking approval of generic versions of Auryxia and the market entry of one or more generic competitors would limit Auryxia sales and have an adverse impact on our business and results of operation.

Although composition and use of Auryxia are currently claimed by 15 issued patents that are listed in the FDA's Orange Book, we cannot assure that we will be successful in defending against third parties attempting to invalidate or design around our patents or assert 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 future products.

The Hatch-Waxman Act allows applicants seeking to market a generic equivalent of a drug that relies, in whole or in part, on the FDA's prior approval of a patented brand name drug, to provide notice to the holder of the New Drug Application for the brand name drug of its application, called a Paragraph IV certification notice, if the applicant is seeking to market its product prior to the expiration of the patents with claims directed to the brand name drug. After the introduction of a generic competitor, a significant percentage of the prescriptions written for a product may be filled with the generic version, resulting in a loss in sales of the branded product. We have received Paragraph IV certification notice letters regarding Abbreviated New Drug Applications, or ANDAs, submitted to the FDA requesting approval for generic versions of Auryxia tablets (210 mg iron per tablet) and have filed certain complaints for patent infringement relating to such ANDAs. See Part II, Item 1. Legal Proceedings for further information relating to the ANDAs and lawsuits. Generic competition for Auryxia or any of our future products could have a material adverse effect on our sales, results of operations and financial condition.

In addition, litigation to enforce or defend intellectual property rights is complex, costly and involves significant management time. If our Orange Book listed patents are successfully challenged by a third party and a generic version of Auryxia is approved and launched, revenue from Auryxia could decline significantly which would have a material adverse effect on our sales, results of operations and financial condition.

If we are unable to maintain sales, marketing and distribution capabilities or to enter into additional agreements with third parties, we may not be successful in commercializing Auryxia or any of our product candidates if they are approved.

In order to market Auryxia, we intend to continue to invest in sales and marketing, which will require substantial effort and significant management and financial resources. We will need to 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.

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

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

If we are unable to maintain our own sales, marketing and distribution capabilities and our arrangements with third parties with respect to sales, marketing and distribution, or we are unsuccessful in entering into additional arrangements with third parties to sell, market and distribute our product candidates or are unable to do so on terms that are favorable to us, we will not be successful in commercializing our product candidates.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product and product candidates, if approved, which could make it difficult for us to sell any approved products profitably.

Market acceptance and sales of any approved products will depend significantly on the availability of adequate coverage and reimbursement from third party payors and may be affected by existing and future healthcare reform measures. Government authorities and third party payors decide which drugs they will cover, as well as establish formularies or implement other mechanisms to manage utilization of products and determine reimbursement levels. Coverage and reimbursement by a third party payor may depend upon a number of factors, including the third party payor's determination that use of a product is:

- a covered benefit under its 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 government or other 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 government and private third party payors with varying coverage and reimbursement levels for pharmaceutical products. Within Medicare, for oral drugs dispensed by pharmacies and also administered in facilities, coverage and reimbursement may vary depending on the setting. The Centers for Medicare & Medicaid Services, or CMS, local Medicare administrative contractors and/or 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 only under Part D. In September 2018, CMS communicated to Medicare Part D sponsors that CMS does not consider Auryxia to be covered under Part D when it is used solely for the treatment of iron deficiency anemia in patients with CKD not on dialysis, or the IDA Indication. CMS does, however, consider Auryxia to be a covered Part D drug when it is used for its other FDA-approved indication, the control of serum phosphorus levels in CKD patients on dialysis, or the Hyperphosphatemia Indication. As a result, Part D sponsors now require a prior authorization for all Auryxia prescriptions for Medicare beneficiaries to ensure that Auryxia is being used for the Part D covered indication. We continue to engage in discussions with CMS and Part D sponsors on this matter as we believe that Auryxia should qualify for coverage under Part D of the CMS regulations when it is used for the IDA Indication. If we are unsuccessful in our efforts to obtain Part D coverage for the IDA Indication, our ability to commercialize Auryxia for this indication will continue to be adversely impacted. While we believe that the vast majority of the Part D prescriptions written for Auryxia today are for the Hyperphosphatemia Indication and therefore will continue to be covered by Part D plans with prior authorization, the prior authorization requirement has had and may continue to have an adverse impact on market acceptance of Auryxia and may influence physicians' prescribing decisions. We cannot predict the future impact of the CMS determination or prior authorization changes on our operations and they could have a material adverse effect on our revenue and results of operations going forward.

Medicaid reimbursement of drugs will also vary by state. Private third party payor reimbursement policies may 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 offering rebates or discounts on our products in order to obtain favorable formulary status. We may not be able to agree upon commercially reasonable terms with such third party payors 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. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Even if we obtain coverage for any 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 products. If reimbursement is not available or is limited, we may not be able to commercialize certain of our products. In addition, in the United States third party payors are increasingly attempting to contain healthcare costs by limiting both coverage and reimbursement levels for new drugs. As a result, significant uncertainty exists as to whether and how much reimbursement third party payors will provide for newly approved drugs which, in turn, will put downward pressure on the pricing of drugs.

If we are unable to obtain or maintain contracts with key distribution partners, our business could be materially harmed.

As we disclosed in our Annual Report on Form 10-K for the year ended December 31, 2018, we had four third party payors, Fresenius Medical Care Rx, McKesson Corporation, Cardinal Health, Inc. and Amerisource Bergen Drug Corporation, that, in the aggregate, accounted for a significant percentage of our gross accounts receivable as of December 31, 2018. If we are not able to maintain our contracts with these key third party payors on favorable terms, on a timely basis or at all, or if there is any adverse change one or more of these payors' business practices or financial condition, it would adversely impact the market opportunity for Auryxia and our revenues and operating results.

Further, if vadadustat is approved 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 third party payors, which we believe could be challenging. The dialysis market is unique and is dominated by two providers: DaVita, Inc., or DaVita, and Fresenius Medical Care, or Fresenius, which account for nearly 80% of the dialysis population in the United States. In May 2017, we entered into a license agreement, which was amended and restated in April 2019, pursuant to which we granted Vifor (International) Ltd., or Vifor Pharma, an exclusive license to sell vadadustat to Fresenius Kidney Care Group LLC, or FKC, and certain third party dialysis organizations, or the Third Party Dialysis Organizations, approved by us, in the United States. The license will be effective upon the following: FDA approval of vadadustat for anemia due to CKD in adult patients with the dialysis-dependent CKD, the earlier of CMS's determination that vadadustat will be reimbursed using the Transitional Drug Add-On Payment Adjustment, or the TDAPA, and inclusion in a bundled reimbursement model; and a milestone payment by Vifor Pharma. Under this amended license agreement with Vifor Pharma, or the Vifor Agreement, FKC and the Third Party Dialysis Organizations are not obligated to utilize vadadustat in its clinics. In addition, even if FKC and the Third Party Dialysis Organizations choose to utilize vadadustat in their clinics in the United States, they are not restricted from utilizing other therapies for anemia due to CKD. The Vifor Agreement restricts us from directly supplying vadadustat to FKC or any other affiliate of Fresenius Medical Care North America and the Third Party Dialysis Organizations. The Vifor Agreement does not restrict us from entering into supply agreements with other dialysis clinics, such as DaVita; however, these dialysis clinics may choose not to contract with us for vadadustat or they may choose to contract with us for a limited supply of vadadustat. If vadadustat is approved and we are not able to maintain the Vifor Agreement or enter into a supply agreement with DaVita, our business may be materially harmed.

Although we currently believe it is likely that vadadustat will be reimbursed using the TDAPA and/or included in the bundle, if vadadustat is not reimbursed using the TDAPA or included in the bundle, then the Vifor Agreement will not become effective, and patients would 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, if there are updates to the TDAPA rule that decrease the basis for reimbursement during the transition period or if the TDAPA is eliminated, then our profitability may be adversely affected.

In addition, we may be unable to sell 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 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.

Price controls may be imposed, which may adversely affect our future profitability.

In some countries, including member states of the European Union, or 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.

Recently, there has been considerable public and government scrutiny in the United States of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. There have also been several recent state legislative efforts to address drug costs, which generally have focused on increasing transparency around drug costs or limiting drug prices or price increases. Adoption of new legislation at the federal or state level could affect demand for, or pricing of, our product candidates, if approved, and could diminish our ability to establish what we believe is a fair price for our products, ultimately diminishing our revenue for our products if they are approved.

Approval of Fexeric in the EU does not ensure successful commercialization and reimbursement.

On September 23, 2015, the European Commission, or EC, approved Fexeric for the control of hyperphosphatemia, in adult patients with CKD. The EC also considered ferric citrate coordination complex as a New Active Substance, or NAS, which provides 10 years of data and marketing exclusivity in the EU.

Fexeric has never been marketed in the EU, and we do not intend to commercialize Fexeric in the EU on our own. We have not been successful in finding a suitable commercialization partner for Fexeric in the EU to date. We cannot assure that we will be able to find a suitable commercialization partner in the EU or otherwise create value from our European rights. The EC's approval of Fexeric in the EU was contingent on, among other things, our commencing marketing of Fexeric by September 23, 2018; however, we received an extension to March 25, 2019, and a subsequent extension to December 23, 2019. If we are unable to commence marketing Fexeric in the EU by December 23, 2019, the Fexeric approval in the EU will cease to be valid. We are working with Panion & BF Biotech, Inc., or Panion, the licensor of our rights to ferric citrate to formulate a commercial plan for Fexeric in Europe. See below for additional information about our arrangements with Panion. There can be no assurances that we will successfully work with Panion with respect to the European commercialization of Fexeric in a timely manner or at all, or that the EC will not revoke its approval of Fexeric if we fail to market Fexeric by the deadline or for any other reason.

The commercial success of Fexeric is subject to the same types of risks we face with commercializing Auryxia in the United States. In addition, in European countries, pricing and payment of prescription pharmaceuticals is subject to more extensive governmental control than in the United States. Pricing negotiations with European governmental authorities can take six to twelve months, or longer, after the receipt of regulatory approval and product launch. If reimbursement for Fexeric is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at or reduced to unsatisfactory levels, our ability or any potential partner's ability to successfully commercialize Fexeric in such a country would be impacted negatively. Furthermore, if these measures prevent us or any potential partner from selling Fexeric on a profitable basis in a particular country, they could prevent the commercial launch or continued sale of Fexeric in that country. We may never commercialize Fexeric in the EU or reach or maintain profitability with respect to Fexeric in the EU.

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 our product and product candidates. Our objective is to continue to commercialize Auryxia and develop and commercialize new products with superior 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 Genzyme Corporation (a wholly-owned subsidiary of 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 phosphate binders are in development, including OPKO Health Inc.'s Alpharen™ Tablets (fermagate tablets) and Ardelyx, Inc.'s tenapanor, 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 IV 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 are in development for the treatment of IDA that may impact the market for Auryxia, such as Shield Therapeutics' Ferracru® (ferric maltol), which is currently approved in Europe for IDA and is seeking FDA approval in the United States.

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

If vadadustat is approved and launched commercially, competing drugs may 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 Vifor Pharma in the United States and Roche Holding Ltd. outside the United States. We may also face competition from potential new anemia therapies. There are several other HIF-PHI 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 such companies as FibroGen, Japan Tobacco International, GlaxoSmithKline plc and Bayer HealthCare AG. FibroGen, together with its collaboration partners, Astellas Pharma Inc. and AstraZeneca PLC, is currently in global Phase 3 clinical development of its product candidate, roxadustat. GlaxoSmithKline plc is currently in global Phase 3 clinical development of its product candidate, daprodustat. Japan Tobacco International and Bayer HealthCare AG are currently in Phase 3 clinical development of their product candidates in Japan. Some of these product candidates may launch in certain Asian markets as early as 2019. In addition, certain companies are developing potential new therapies for renal-related diseases that could potentially reduce injectable 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.

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 our product. Several biosimilar versions of injectable ESAs are available for sale in the EU. 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.

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 and Roche, 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 in Japan, our efforts with respect to the potential commercialization of Fexeric in the EU and our current and 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, Japan Tobacco, Inc., or 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 in Japan. While Fexeric is not currently marked in the EU, Fexeric has received conditional marketing approval in the EU as an oral treatment for the control of hyperphosphatemia in adult patients with CKD, and we are continuing efforts to find a suitable commercialization partner for Fexeric in the EU. We also granted Otsuka Pharmaceutical Co. Ltd., or Otsuka, exclusive rights to commercialize vadadustat in Europe, China and certain other markets, subject to marketing approvals. In Japan and certain other countries in Asia, we granted Mitsubishi Tanabe Pharma Corporation, or MTPC, exclusive rights to commercialize vadadustat, subject to marketing approvals. We are also conducting our global Phase 3 development with respect to vadadustat for the treatment of anemia due to CKD, and MTPC is carrying out development efforts for vadadustat in Japan. As a result of these and other activities, we are or may become subject to additional risks in developing and commercializing our product and product candidates outside the United States, including:

- political, regulatory, compliance and economic developments that could restrict our ability to manufacture, market and sell our products;
- changes in international medical reimbursement policies and programs;
- changes in health care policies of foreign jurisdictions;
- trade protection measures, including import or export licensing requirements and tariffs;
- our ability to develop relationships with qualified local distributors and trading companies;
- political and economic instability in particular foreign economies and markets;
- diminished protection of intellectual property in some countries outside of the United States;
- differing labor regulations and business practices;
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' and service providers' activities that may fall within the purview of the U.S. Foreign Corrupt Practices Act, or FCPA, the UK Bribery Act or similar local regulation;
- compliance with the EU General Data Protection Regulation, or GDPR;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- potentially negative consequences from changes in or interpretations of tax laws;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- 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 or natural disasters including earthquakes, typhoons, floods and fires.

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 the Clinical Development of Vadadustat and our Other Product Candidates

In addition to Auryxia, we will continue to depend heavily on the success of our product candidate, vadadustat, which is currently in Phase 3 development. Clinical drug development involves a lengthy and expensive process with an uncertain outcome. We will incur additional costs in connection with, and may experience delays in completing, or ultimately be unable to complete, the development and commercialization of vadadustat and any other product candidates.

The risk of failure in drug development is high. We currently have only one commercial product, Auryxia, and one product candidate, vadadustat, in clinical development, and we depend heavily on the successful commercialization of Auryxia and the successful clinical development, marketing approval and commercialization of vadadustat, which may never occur. 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. 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 clinical trial process. 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, and interim results of a clinical trial do not necessarily predict final results. 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. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive or maintain marketing approval or commercialize our product candidates. Our 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 for a variety of other reasons, such as:

- the costs are greater than we anticipate;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- enrollment in our clinical trials and accrual of MACE events 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, international 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, 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;
- failure 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 Japanese Pharmaceuticals and Medical Devices Agency, or PMDA, or other regulatory authorities, or for other reasons;
- 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;
- delay or failure in having subjects complete a clinical trial or return for post-treatment follow-up;
- delay or failure in recruiting and enrolling suitable subjects to participate in a clinical trial;
- 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;

- 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;
- 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;
- 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;
- the design of our clinical trials;
- failure to comply with good practice quality guidelines and regulations, or GXP, including good laboratory practice, or GLP, good clinical practice, or GCP, and current good manufacturing practice, or cGMP; or
- changes in governmental regulations or administrative actions.

If we are unable to successfully complete clinical trials of our product candidates or other studies, 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, or if any of the factors listed above occur, the following may occur:

- regulators may require that we conduct additional clinical trials, repeat clinical trials or conduct other studies of our product candidates beyond those that we currently contemplate;
- we may be delayed in obtaining marketing approval for our product candidates;
- we may not obtain marketing approval for our product candidates at all;
- we may obtain approval for indications or patient populations that are not as broad as intended or desired;
- we may obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for our products or inhibit our ability to successfully commercialize our products;
- 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 will also increase if we experience delays in preclinical and clinical development or 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 our product candidates 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.

Even if we obtain favorable clinical results in our Phase 3 studies, we may not be able to obtain marketing approval for, or successfully commercialize, vadadustat, or we may experience significant delays in doing so, any of which would materially harm our business.

The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous governmental authorities in the United States, and in other countries where we and our collaborators intend to test and, if approved, market any product candidates. 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 programs, we may be unable to successfully develop or commercialize vadadustat or any other product candidates.

We and Otsuka, our collaboration partner, are not permitted to market vadadustat in the United States until we receive approval from the FDA, in the EU until we receive approval from the EMA, or in any other jurisdiction until the requisite approval from regulatory authorities in such jurisdiction is received. MTPC, our collaboration partner in Asia, will not be permitted to market vadadustat in Japan without approval from the PMDA 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 must complete Phase 3 studies and any additional preclinical or clinical studies required by the FDA, the EMA, the PMDA or other regulatory authorities. Vadadustat may not be successful in clinical trials or receive marketing approval. Further, vadadustat may not receive marketing approval even if it is successful in clinical trials.

Obtaining marketing approval in the United States and other jurisdictions is a complex, lengthy, expensive and uncertain process that typically takes many years and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Even if our product candidates demonstrate safety and efficacy in clinical studies, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain marketing approval. In addition, the safety concerns associated with injectable ESAs may affect the FDA's, the EMA's, the PMDA's or other regulatory authorities' review of the safety results of compounds in development for treatment of the same indications as injectable ESAs, including vadadustat. 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 and any other product candidates will never obtain marketing approval. The FDA may delay, limit or deny approval of vadadustat or any other product candidates for many reasons including, among others:

- we may not be able to demonstrate that vadadustat is safe and effective in treating anemia due to CKD or that any other product candidate is safe and effective for its proposed indication(s) to the satisfaction of the FDA;
- 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 FDA may require us to complete both the INNO$_2$VATE clinical program and the PRO$_2$TECT clinical program for vadadustat prior to filing our NDA even if one of these programs finishes in advance of the other;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may not approve the formulation, labeling or specifications we request for vadadustat or any other product candidate;
- the FDA 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 FDA may require that we conduct additional clinical trials or repeat one or more clinical trials;
- the FDA may grant approval contingent on the performance of costly post-marketing clinical trials;
- we, or our CROs or vendors, may fail to comply with GXP;
- the CROs that we retain to conduct our clinical trials may not perform effectively or take actions that adversely impact our clinical trials, or we may fail to communicate effectively or provide the appropriate level of oversight of our CROs;
- we or our third party manufacturers may fail to perform in accordance with the FDA's cGMP requirements;
- 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 FDA may disagree with our interpretation of data from our preclinical studies and clinical trials;
- the FDA 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;
- an FDA Advisory Committee or other regulatory advisory group or authority could recommend non-approval or restrictions on approval;
- the FDA's decision-making regarding vadadustat and any other product candidates may be impacted by the results of 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 candidates are being developed;
- the FDA may not approve the manufacturing processes or facilities of third party manufacturers with whom we contract; or
- the policies or regulations of the FDA may significantly change in a manner that renders our clinical data insufficient for approval, or requires us to amend or submit new clinical protocols.

In addition, similar reasons may cause the EMA or the PMDA or other regulatory authorities to delay, limit or deny approval of vadadustat or any other product candidate outside the United States.

If we experience delays in obtaining approval, or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired, which could have a material adverse effect on our business.

We may find it difficult to enroll patients in our clinical studies, which could delay or prevent clinical studies of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends, in part, on the speed at which we can recruit patients to participate in testing our product candidates. Patients may be unwilling to participate in our clinical studies of vadadustat or other product candidates because of concerns about adverse events observed with injectable ESAs, other investigational agents and commercial products in CKD or for other reasons, including competitive clinical studies for similar patient populations. In addition, patients currently receiving treatment with injectable ESAs may be reluctant to participate in a clinical trial with an investigational drug. Finally, competition for clinical trial sites may limit our access to subjects appropriate for studies of vadadustat and any other product candidates. As a result, the timeline for recruiting patients, conducting studies and obtaining marketing approval of vadadustat and any other product candidates may be delayed. These delays could result in increased costs, delays in advancing our development of vadadustat and any other product candidates, or termination of the clinical studies 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 studies 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;
- perceived risks and benefits of the product candidate under study, including as a result of adverse effects observed in similar or competing therapies;
- proximity and availability of clinical study sites for prospective patients;
- availability of competing therapies and clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to available therapies or other product candidates in development;
- efforts to facilitate timely enrollment in clinical studies;
- clinical trial sites and investigators failing to perform effectively;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical studies if we cannot enroll a sufficient number of eligible patients to participate in the clinical studies required by regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit or terminate ongoing or planned clinical studies, any of which could have a material adverse effect on our business.

We may not be able to conduct clinical trials in some jurisdictions outside of the United States.

We and our collaboration partners currently expect to seek marketing approval of vadadustat for the treatment of anemia due to CKD in markets outside the United States, including the EU and Japan. Our ability to successfully initiate, enroll and complete a clinical study 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;
- different local standards for the conduct of clinical studies;
- 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. For example, in Japan, MTPC is conducting a Phase 3 program of vadadustat, which is separate from our global Phase 3 program of vadadustat.

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

Positive results from preclinical and clinical studies are not necessarily predictive of the results of any future clinical studies.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies may not be predictive of similar results in humans during clinical trials, successful results from early or small clinical trials may not be replicated in later and larger clinical trials, and successful interim results from ongoing clinical studies may not be indicative of results obtained when those studies are completed. For example, our encouraging preclinical and clinical results for vadadustat thus far do not ensure that the results of any future clinical trials will demonstrate similar results. Our global Phase 3 development program for vadadustat is enrolling a larger number of subjects and will treat subjects for longer periods than our prior trials, which will result in a greater likelihood that adverse events may be observed. Due to these and other differences between our global Phase 3 development program for vadadustat and our prior trials, our positive results from preclinical and clinical studies may not be replicated in our global Phase 3 development program for vadadustat. 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. If the results of our ongoing or future clinical trials for vadadustat or any other product candidates are inconclusive with respect to efficacy, if we do not meet our clinical endpoints with statistical significance, or if there are safety concerns or adverse events, we may be prevented from or delayed in obtaining marketing approval for vadadustat or any other product candidates.

We may not be successful in our efforts to identify, acquire, discover, develop and commercialize additional products or product candidates, which could impair our ability to grow.

Although we continue to focus a substantial amount of our efforts on the commercialization of Auryxia and the development and potential commercialization of vadadustat, a key element of our long-term growth strategy is to acquire, 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 otherwise does not meet applicable regulatory criteria;
- 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 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 occurs, 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 would have a material adverse effect on our business.

Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Because our internal research capabilities are limited, we may be dependent upon other pharmaceutical and biotechnology companies, academic scientists, and other researchers to sell or license 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 proposing, 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, including, for example, with respect to the Merger. 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 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 products that we develop or approved products that we acquire will be manufactured profitably, 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 additional therapeutic opportunities for our product candidates or to acquire or develop suitable potential product candidates or approved products, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other programs that ultimately prove to be unsuccessful.

Auryxia, vadadustat or other products and product candidates may cause undesirable side effects or have other properties that delay or limit their commercial potential, or in the case of our product candidates, prevent their marketing approval.

Undesirable side effects caused by our product or product candidates or competing products 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. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

If we or others identify undesirable side effects caused by Auryxia, vadadustat, or other products or product candidates, either before or after receipt of marketing approval, a number of potentially significant negative consequences could result, including:

- our clinical trials may be put on hold;
- patient recruitment could be slowed, and enrolled patients may not want to complete the clinical trial;
- we may be unable to obtain marketing approval for our product candidates or regulatory authorities may withdraw approvals of products;
- regulatory authorities may require warnings on the label such as the warning on Auryxia’s label regarding iron overload;
- Risk Evaluation and Mitigation Strategies, or REMS, or FDA-imposed risk management plans that use risk minimization strategies to ensure that the benefits of certain prescription drugs outweigh their risks, may be required;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining marketing approval and, ultimately, market acceptance of Auryxia, vadadustat or other products or product candidates, could substantially increase our costs, and could significantly impact our ability to successfully commercialize Auryxia, vadadustat, or other products and product candidates and generate revenues.

The patient populations treated with Auryxia and the subjects in our clinical studies for vadadustat, have CKD, a serious disease that increases the risk of cardiovascular disease including heart attacks and stroke and, ultimately, may cause kidney failure. Many patients with CKD are elderly with comorbidities making them susceptible to significant health risks. Therefore, the likelihood of these subjects having adverse events, including serious adverse events, while participating in our studies is high.

In our Phase 1 and Phase 2 studies of vadadustat, adverse events were reported. For example, in our Phase 2b study of vadadustat in non-dialysis subjects with anemia due to CKD, one subject with multiple co-morbidities and concomitant medications, including chlorthalidone, had a serious adverse event of liver function test abnormal, considered a case of drug induced liver injury meeting the biochemical criteria of Hy’s Law, which was assessed as probably related to vadadustat. Serious adverse events considered related to vadadustat and any other product candidates could have a material adverse effect on the development of such 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, and additional unexpected adverse events may be observed in future clinical trials.

The most commonly reported adverse reactions in the clinical trials that supported the approval of Auryxia for the Hyperphosphatemia Indication in the United States included diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%), and cough (6%). Gastrointestinal adverse reactions were the most common reason for discontinuing Auryxia (14%) in clinical trials for the Hyperphosphatemia Indication. The most commonly reported adverse reactions in the clinical trials that supported the approval of Auryxia in the United States for the IDA Indication included discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%). Diarrhea was the most common reason for discontinuing Auryxia (2.6%) in clinical trials for the IDA Indication.

Furthermore, any post-marketing clinical trials conducted, if successful, may expand the patient populations treated with Auryxia. or any other products 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 side effects, increased frequency or severity of known side effects, or detection of unexpected safety signals. In addition, as Auryxia and any other products are commercialized, they will be used in larger patient populations and in less rigorously controlled environments than in clinical studies. As a result, regulatory authorities, healthcare practitioners, third party payors or patients may perceive or conclude that the use of Auryxia or any other products are associated with serious adverse effects, undermining our commercialization efforts.

Further, if we or others identify previously unknown side effects, if known side effects are more frequent or severe than in the past, if we or others detect unexpected safety signals for our products or product candidates, including Auryxia, vadadustat, or any product or product candidate perceived to be similar to Auryxia, vadadustat, or our other product candidates, 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:

- sales may be impaired;
- regulatory approvals may be restricted or withdrawn;
- we may decide to, or be required to, send drug warnings or safety alerts to physicians, pharmacists and hospitals (or the FDA or other regulatory authorities may choose to issue such alerts), or we may decide to conduct a product recall or be requested to do so by the FDA or other regulatory authority;
- reformulation of the product, additional nonclinical or clinical studies, 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
- government investigations or lawsuits, including class action suits, may be brought against us.

Any of the above occurrences could delay or prevent us from achieving or maintaining marketing approval, harm or prevent sales of Auryxia or, if approved, vadadustat or other product candidates, increase our expenses and impair or prevent our ability to successfully commercialize Auryxia, vadadustat or other product candidates

Risks Related to Regulatory Approval of Our Product Candidates

We may be delayed in obtaining, or be unable to obtain, marketing approval or reimbursement for vadadustat or any other product candidate in certain countries outside of the United States.

Regulatory authorities outside of the United States will require compliance with numerous and varying requirements. The approval procedures vary among jurisdictions and may involve requirements for additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. In addition, in many countries outside the United States, a drug product 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 FDA does not ensure approval by regulatory or reimbursement authorities outside the United States, and approval by one regulatory or reimbursement authority outside the United States does not ensure approval by the FDA or any other regulatory or reimbursement authorities. However, the failure to obtain approval or reimbursement in one jurisdiction may negatively impact our ability to obtain approval or reimbursement in another jurisdiction. The marketing approval process in countries outside of the United States may include all of the risks associated with obtaining FDA approval and, in some cases, additional risks. We may not obtain such regulatory or reimbursement approvals on a timely basis, if at all. We may not be able to file for marketing approvals and may not receive the necessary approvals to commercialize our product candidates in any market. Also, favorable pricing in certain countries depends on a number of factors, some of which are outside of our control.

Additionally, on June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU, commonly referred to as Brexit. On March 29, 2017, the United Kingdom formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom has a period of a maximum of two years from the date of its formal notification to negotiate the terms of its withdrawal from, and future relationship with, the EU. If no formal withdrawal agreement is reached between the United Kingdom and the EU, then it is expected that the United Kingdom's membership of the European Union will automatically terminate on the deadline, which was initially March 29, 2019 (two years after the submission of the notification of the United Kingdom's intention to withdraw from the European Union) and has been extended to October 31, 2019. Discussions between the United Kingdom and the EU focused on finalizing withdrawal issues and transition agreements are ongoing. However, limited progress to date in these negotiations and ongoing uncertainty within the UK Government and Parliament sustains the possibility of the United Kingdom leaving the EU on the given deadline without a withdrawal agreement and associated transition period in place, which is likely to cause significant market and economic disruption.

Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, the withdrawal could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the EU. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occurs, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or EU for our product candidates, which could significantly and 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 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 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. With regard to our Hyperphosphatemia Indication, we committed to completing the post-approval pediatric study and submitting a final report to the FDA by December 31, 2019, which was extended to July 2022 by the FDA in response to our request. With regards to our IDA Indication, we committed to completing the post-approval pediatric study and submitting a final report to the FDA by January 2023. We cannot guarantee that we will be able to complete these studies and submit the final reports in a timely manner. If we are unable to complete these studies successfully, our marketing approval could be suspended or revoked, 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, and any other product for which we receive regulatory approval, will be subject to extensive and ongoing regulatory requirements. These requirements include 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.

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 our products beyond their 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 FD&C Act, 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, third party payor actions, shareholder 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.

Non-compliance with 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.

Additional Legal and Compliance Risks

We are subject to a complex regulatory scheme that requires significant resources to ensure compliance. Failure to comply with applicable laws could subject us to government scrutiny or government enforcement, potentially resulting in costly investigations and/or fines or sanctions, or impacting our relationships with key regulatory agencies such as the FDA, SEC or the EMA.

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

- laws and regulations governing the conduct of preclinical and clinical studies in the United States and other countries in which we are conducting such studies;
- laws and regulations in the United States and in countries in which we are interacting with health care providers, patients, patient organizations and other constituencies that prohibit promoting a drug prior to approval and/or reimbursement;
- laws and regulations of countries outside the United States that prohibit pharmaceutical companies from promoting prescription drugs to the general public;
- laws, regulations and industry codes that vary from country to country and govern our relationships with health care providers, patients, patient organizations, and other constituencies, prohibit certain types of gifts and entertainment, establish codes of conduct and, in some instances, require disclosure to, or approval by, regulatory authorities for us to engage in arrangements with such constituencies;
- 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 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, the GDPR, and state privacy and data protection laws, as well as state consumer protection laws;
- federal securities laws restricting the purchase or sale of any securities while in possession of material, non-public information; 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.

Compliance with these and other applicable laws and regulations requires us to expend significant resources. Failure to comply with these laws and regulations may subject us to government investigations, penalties, damages, fines, the restructuring of our operations, or the imposition of a clinical hold, any of which could materially adversely affect our business and would result in increased costs and diversion of management attention and could delay or prevent the development, regulatory approval and commercialization of our product candidates, any of which could have a material adverse effect on our business.

We will incur significant liability if it is determined that we are promoting any "off-label" use of Auryxia 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 FD&C Act 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 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 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 U.S. 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.

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 guidances 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, Auryxia is our first commercial product so our implementation of our compliance program in connection with commercialization activities is still relatively new.

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 and other representatives could be subject to significant fines and criminal sanctions, imprisonment, and potential exclusion from Medicare and Medicaid.

Recent efforts to pursue regulatory reform may limit the FDA's ability to engage in oversight and implementation activities in the normal course, and that could negatively impact our business.

Recently, there have been several executive actions taken, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. On January 30, 2017, an executive order, applicable to all executive agencies including the FDA, was issued that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This executive order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the executive order requires agencies to identify regulations to offset any incremental cost of a new regulation. Interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and Budget on February 2, 2017, indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

We are conducting global clinical trials in countries where corruption is prevalent. In addition, we are subject to a variety of import and export trade laws. 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 purposes of obtaining or keeping business or to obtain 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 U.S. Securities and Exchange Commission 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 are conducting clinical trials 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 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 are conducting 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 sanctions 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 people and products among certain countries is subject to maintaining required licenses and complying with these laws and regulations.

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 our 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 Global Market. In addition, we may incur significant costs in implementing sufficient systems, controls and processes to ensure compliance with the aforementioned laws.

Compliance with global 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 European Economic Area, or EEA, in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, 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 with respect to clinical trials conducted 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 subjects and investigators. In addition, 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 clinical trial sites located in the EEA 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. 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.

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. Similarly, failure to comply with federal and state laws regarding privacy and security of personal information could expose us to fines and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Our relationships with healthcare providers, physicians and third party payors are subject to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security, and other healthcare laws and regulations, which, in the event of a violation, could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers, physicians and third party payors play a primary role in the recommendation and prescription of Auryxia and any other product candidates for which we obtain marketing approval. Our arrangements with healthcare providers, physicians and third party payors expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute Auryxia and any other product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by federal and state governments and by governments in foreign jurisdictions in which we conduct our business. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the FD&C Act 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 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 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, currently set at $5,500 to $11,000 per false claim;
- HIPAA 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 requires applicable manufacturers of covered drugs to report payments and other transfers of value to physicians and teaching hospitals;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws and gift ban and transparency statutes, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by 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.

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, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. 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. 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.

Recently enacted and future legislation 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 our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell Auryxia and any product candidates for which we obtain marketing approval. The pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by legislative initiatives. Current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any FDA approved product, such as Auryxia.

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. Among the provisions of the ACA of potential importance to our business including, without limitation, our ability to commercialize and the prices we obtain for Auryxia and may obtain for any of our product candidates that are approved for sale, are the following:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the civil False Claims Act and the federal anti-kickback statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes and regulatory 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 2027 unless additional congressional action is taken, and 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 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 any product candidates for which we may obtain regulatory approval or the frequency with which Auryxia and any such product candidate is prescribed or used. Further, there have been several recent U.S. congressional inquiries and proposed 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.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

With the enactment of the Tax Cuts and Jobs Act of 2017, Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, will become effective in 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause an estimated 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Additionally, on January 22, 2018, the President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, among other things, amended the ACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole”. Further, each chamber of the U.S. Congress has put forth multiple bills designed to repeal or repeal and replace portions of the ACA. Although none of these measures has been enacted by Congress to date, Congress may consider other legislation to repeal and replace elements of the ACA.

The current administration has also taken executive actions to undermine or delay implementation of the ACA. Since January 2017, the President has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third party payors who argued that such payments were owed to them. The effects of this gap in reimbursement on third party payors, providers, and potentially our business, are not yet known.

Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA and, therefore, because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. The current administration and CMS have both stated that the ruling will have no immediate effect, and on December 30, 2018 the same judge issued an order staying the judgment pending appeal. The current administration has recently represented to the court of appeals considering this judgment that it does not oppose the lower court's ruling. On July 10, 2019, the Court of Appeals for the Fifth Circuit heard oral argument in this case. In those arguments, the current administration argued in support of upholding the lower court decision. It is unclear how this decision and any subsequent appeals and other efforts to repeal and replace the ACA will impact the ACA and our business. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States, and members of U.S. Congress and the current administration have stated that they will address such costs through new legislative and administrative measures. 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. Including measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Specifically, there have been several recent U.S. congressional inquiries and proposed federal and proposed and enacted state 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, on May 11, 2018, the current administration issued a plan to lower drug prices. Under this blueprint for action, the current administration indicated that the Department of Health and Human Services, or HHS, will take steps to end the gaming of regulatory and patent processes by drug makers to unfairly protect monopolies, advance biosimilars and generics to boost price competition, evaluate the inclusion of prices in drug makers' ads to enhance price competition, speed access to and lower the cost of new drugs by clarifying policies for sharing information between insurers and drug makers, avoid excessive pricing by relying more on value-based pricing by expanding outcome-based payments in Medicare and Medicaid, work to give Medicare Part D plan sponsors more negotiation power with drug makers, examine which Medicare Part B drug prices could be negotiated by Medicare Part D plans, improve the design of the Medicare Part B Competitive Acquisition Program, update Medicare's drug-pricing dashboard to increase transparency, prohibit Medicare Part D contracts that include "gag rules" that prevent pharmacists from informing patients when they could pay less out-of-pocket by not using insurance, and require that Medicare Part D plan members be provided with an annual statement of plan payments, out-of-pocket spending, and drug price increases. More recently, on January 31, 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations.

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. In addition, regional health care 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 health care 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.

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

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 the rights to our product, Auryxia. We have licensed and sublicensed the rights, patent or otherwise, to Auryxia from a third party, Panion, who in turn licenses certain rights to Auryxia from one of the inventors of Auryxia. The license agreement with Panion, or the Panion License Agreement, requires us to meet development milestones and imposes development and commercialization due diligence requirements on us. In addition, under the 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 our 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 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 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 execute an amendment to the 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 4 to the Condensed Consolidated Financial Statements (unaudited) contained in 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.

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

We do not have the ability to independently conduct preclinical and clinical trials. We are currently relying, and expect to continue to rely, on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our current and future preclinical studies and our clinical trials, including our global Phase 3 development program for vadadustat. The third parties on whom we rely may fail to perform effectively, or terminate their engagement with us, for a number of reasons, including the following:

- if the quantity or accuracy of the data obtained by the third parties is compromised due to their failure to adhere to clinical trial protocols or to regulatory requirements, or if the third parties otherwise fail to comply with clinical trial protocols, perform effectively or meet expected deadlines;
- if third parties experience staffing difficulties;
- if we fail to communicate effectively or provide the appropriate level of oversight;
- if third parties undergo changes in priorities or corporate structure or become financially distressed; or
- if they form relationships with other entities, some of which may be our competitors.

Any of these events could cause our preclinical 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 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 approved products, any of which would adversely affect our business operations. In addition, if the third parties on 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 continued commercialization of Auryxia and the development and commercialization of vadadustat and any other product candidates.

Even though we do not directly control the third parties on whom we rely to conduct our preclinical 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 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 trial sites fail to comply with applicable GXP requirements, the clinical data generated in our clinical trials may be deemed unreliable or insufficient, our clinical trials could be put on hold, and/or the FDA, the EMA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials 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 on third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, resulting in additional costs and depriving us of potential product revenue. In addition, we are using an active comparator in our PRO_2TECT and $INNO_2$VATE clinical programs for vadadustat. If our distributors are unable to obtain sufficient supply of the active comparator for any reason, or supply active comparator to clinical trial sites in a timely manner, our clinical trials may be extended, delayed, suspended or terminated.

We rely on third parties to conduct all aspects of our product manufacturing. If they do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to continue commercializing Auryxia or obtain marketing approval for or commercialize vadadustat or any other product candidates, and our business could be substantially harmed.

We do not have any manufacturing facilities and do not expect to independently manufacture any product or product candidates. We currently rely on third party manufacturers to produce all of our commercial, preclinical and clinical material supply. We expect to continue to rely on existing or alternative third party manufacturers to supply our ongoing and planned preclinical and clinical trials and for commercial production. We currently have multiple suppliers of Auryxia's drug substance and one supplier with three approved sites for the supply of Auryxia drug product. If any of our suppliers were to limit or terminate production, or otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at adequate levels, we could experience losses of revenue which could materially and adversely impact our results of operations. We have entered into a supply agreement with Esteve Química, S.A. for the manufacture of vadadustat drug substance for commercial use. We intend to put additional supply arrangements in place for commercial manufacturing of vadadustat; however, we may not be able to negotiate these agreements at commercially reasonable terms. For example, a contract manufacturer may require a substantial financial commitment, including but not limited to a commitment to fund the purchase of a new facility or equipment. Our reliance on third party manufacturers increases the risk that we will not have sufficient quantities of our product and product candidates or the ability to obtain such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

As a result of the large quantity of materials required for Auryxia production and the large quantities of Auryxia tablets that are required for our commercial success, the continued commercial viability of Auryxia will also depend on adequate supply of starting materials that meet quality, quantity and cost standards and the ability of our contract manufacturers to continually produce drug substance and finished drug product on a commercial scale. Failure to achieve and maintain these levels of supply can jeopardize and prevent the successful continued commercialization of Auryxia. Moreover, issues that may arise in our scale-up and technology transfer of Auryxia and continued commercial scale manufacture of Auryxia may lead to significant delays in our development 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. Although this supply interruption was resolved and actions designed to prevent future interruptions in the supply of Auryxia have been taken, any future supply interruptions for Auryxia or any of our product candidates for which we receive marketing approval would negatively and materially impact our reputation and financial condition.

If any of our third party manufacturers cannot perform as agreed, including a misappropriation of our proprietary information, or if they terminate their engagements with us, 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 on favorable or reasonable terms, if at all. 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 such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture Auryxia or our product candidates. 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 associated with the verification of a new manufacturer could negatively affect our ability to continue to commercialize or satisfy patient demand for Auryxia or any other product candidate for which we receive marketing approval, or develop and receive marketing approval for our product candidates in a timely manner or within budget.

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 our product candidates will be inspected by the FDA, the EMA and other regulatory authorities prior to or after we submit our marketing application. We do not control the manufacturing processes of, and are completely dependent on, our third party manufacturers for compliance with cGMP requirements for manufacture of certain starting materials, drug substance and finished drug product. If our third party manufacturers cannot successfully manufacture material that conforms to our specifications and regulatory requirements, we will not be able to maintain marketing approval for Auryxia or secure and/or maintain marketing approval for our product candidates. In addition, we have no control over the ability of our third party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, the EMA or other regulatory authorities do not approve the facilities being used to manufacture of our product candidates, or if they withdraw any approval of the facilities being used to manufacture Auryxia or any other product candidates for which we receive marketing approval, we may need to find alternative manufacturing facilities, which would significantly impact our ability to continue commercializing Auryxia or develop, obtain marketing approval for or market our product candidates, if approved. Moreover, the failure of our third party manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of Auryxia or our product candidates operating restrictions or criminal prosecutions, any of which could significantly and adversely affect the supply of Auryxia or our product candidates. Also, if our starting materials, drug substance or drug product are damaged or lost while in our third party manufacturers' control, it may impact our ability to supply our products or product candidates and we may incur significant financial harm. In addition, Auryxia and our product candidates may compete with other products and product candidates for access to third party manufacturing facilities. A third party manufacturer may also encounter delays brought on by sudden internal resource constraints, labor disputes, or shifting regulatory protocols. Certain of these third party manufacturing facilities may be contractually prohibited from manufacturing our product candidates or products, due to exclusivity provisions in agreements with our competitors. There are a limited number of manufacturers that operate under cGMP regulations and are capable of manufacturing Auryxia and our product candidates for us.

Our current and anticipated future dependence on third parties for the manufacture of Auryxia and our product candidates may adversely affect our ability to continue to commercialize Auryxia or any product candidates that receive marketing approval on a timely and competitive basis and any future profit margins.

Third party manufacturers may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products.

In order to complete our development of and commercialize, if approved, vadadustat and any other product candidates, we will need to work with third party manufacturers to manufacture them in large quantities. Our current and future third party manufacturers may be unable to successfully achieve commercial scale production of vadadustat or increase the manufacturing capacity of any other product candidates for the conduct of clinical trials and commercialization in a timely or cost-effective manner, if at all. In addition, quality issues may arise during scale-up activities. Any changes in our manufacturing processes as a result of scaling up may result in the need to obtain additional marketing approvals. If our third party manufacturers are unable to achieve commercial scale production or there is a need for additional marketing approvals of vadadustat or any other product candidates, or if there are difficulties in increasing the manufacturing capacity for any other product candidates, the development, marketing approval and commercialization of that product candidate may be delayed or infeasible, or ongoing commercialization may be unsuccessful, any of which could significantly harm our business.

The loss of any of our manufacturers could materially harm our business.

We currently have redundant supply arrangements in place for the commercial supply of Auryxia and the preclinical and clinical supply of vadadustat. We have entered into a supply agreement with Esteve Química, S.A. for the manufacture of vadadustat drug substance for commercial use. While we intend to put additional supply arrangements in place for commercial manufacturing of vadadustat, we may be unsuccessful in doing so or achieving sufficient redundancy due to a number of factors, including that we may not be able to negotiate binding agreements at commercially reasonable terms. Even if we are ultimately successful in entering into redundant supply arrangements for commercial manufacturing of vadadustat, the timing of such additional arrangements is uncertain.

We do not know whether our third party manufacturers will be able to meet our demand, either because of the nature of our agreements with those third party manufacturers, or, in some cases, our limited experience with those third party manufacturers or our relative importance as a customer to those third party manufacturers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our current third party manufacturers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

If we are unsuccessful in implementing redundant supply arrangements for commercial quantities of vadadustat or if our commercial supply arrangements for Auryxia are terminated, or if any of our third party manufacturers is unable to fulfill the terms of their agreements with us, are subject to regulatory review, or cease their operations for any reason, it could result in delays to our marketing approval and risk that we would not have sufficient quantities of our product candidates and products for clinical trials and commercialization.

We depend on collaborations with third parties for the development and commercialization of vadadustat and Auryxia. If our 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 and vadadustat, and our business could be materially harmed.

We sublicensed the rights to commercialize Riona to JT and Torii in Japan. We entered into collaboration agreements with Otsuka to develop and commercialize vadadustat in the United States, Europe, China and certain other territories. We also entered into a collaboration agreement with MTPC to develop and commercialize vadadustat in Japan and certain other Asian countries. 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 commercialization efforts with respect to Auryxia and our development and commercialization efforts with respect to vadadustat and any other product candidates. Our likely collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

We may not be able to maintain our collaborations and our 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 collaborations 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 collaborations, 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 collaborations, 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 our products may not commit sufficient resources to their marketing and distribution;
- if permitted by the terms of the collaboration, we and our collaborator may have a difference of opinion regarding the development or commercialization strategy for a particular product, 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 or commercialization of Auryxia, vadadustat and any other product candidates, 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 in the most efficient manner or at all;
- 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 requirements.

If any of these events occurs, the market potential of our products and product candidates could be reduced, and our business could be materially harmed. We also cannot be certain that, following a collaboration, 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, 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 vadadustat and any other product candidates. We may decide to enter into additional collaborations for the development and commercialization of vadadustat or Auryxia. 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, or disrupt our management and 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;
- inability to negotiate collaborations on acceptable terms;
- inability to negotiate collaborations on a timely basis;
- a potential collaborator’s evaluation of our product or product candidates;
- a potential collaborator’s resources and expertise; and
- restrictions due to an existing collaboration agreement.

If we are unable to enter into additional collaborations, we may have to curtail the commercialization of the product or the development of the product candidate on which we are seeking to collaborate, reduce or delay its development program or other of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further commercialize Auryxia or develop or commercialize our product candidates.

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

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(s) 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, thus reducing any advantage of the patent. 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.

Additionally, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. For example, claims in a patent application directed to methods of treatment of the human body are not patentable or are restricted in many non-U.S. countries. Further, we may not pursue or obtain patent protection in all major markets. In addition, in jurisdictions outside the United States where we own or license patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our proprietary technology.

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, or the Act, 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.

On November 25, 2015, a third party filed an opposition to our issued European Patent No. 1 931 689, or the ‘689 EP Patent, which covers Fexeric. During the oral proceedings, which took place on June 27, 2017, the Opposition Division of the European Patent Office, or EPO, revoked the ‘689 EP Patent. On December 6, 2017, we filed an appeal of the decision of the Opposition Division, which is presently pending. According to European practice, the revocation of the patent is stayed until an appeal is finally resolved. We anticipate the appeal will take a few years to resolve, during which time the patent will remain in force.

On December 23, 2016, a third party filed an opposition to our issued European Patent No. 1 978 807, or the ’807 EP Patent, which covers Fexeric. During the oral proceedings, which took place on June 8, 2018, the Opposition Division of the EPO maintained the ’807 EP Patent as granted. This decision resulted in the maintenance of all of the claims of the patent, including claims directed to the use of ferric citrate for preventing, reversing, maintaining or delaying progression of chronic kidney disease. On November 16, 2018, the third party filed an appeal of the decision of the Opposition Division. On June 7, 2019, the third party withdrew the appeal. As a result, the Opposition Division’s decision is final, and the ’807 EP Patent will be maintained as granted.

In July 2011, a third party filed an opposition to our issued European patents, European Patent No. 2044005, or the ’005 EP Patent, which covers vadadustat. During the oral proceedings, which took place on April 10, 2013, the Opposition Division of the European Patent Office decided to maintain certain claims of the patent directed to a compound chosen from a group of eight compounds, including vadadustat, as well as claims to compositions and methods for treating various diseases including, but not limited to, anemia. Both parties appealed the decision of the Opposition Division. On February 27, 2018, we withdrew the ’005 EP Patent from appeal and filed a divisional patent application to pursue a focused claim set that includes claims for vadadustat, as well as pharmaceutical compositions and methods of treating anemia. We cannot be assured that such claims in the divisional application will be granted by the European Patent Office. If such claims are not granted, or the scope of the claims is significantly narrowed, we may not be able to adequately protect our rights, provide sufficient exclusivity, or preserve our competitive advantage.

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.

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, we share ownership and publication rights to data relating to our drug product and technologies with our research collaborators and scientific advisors. 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.

The intellectual property and related non-patent exclusivity that we own or have licensed relating to our product, Auryxia, is 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 not market a product for methods of use 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. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction, which could prevent us from making or selling Auryxia. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

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 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.

In addition to patent protection, we may utilize, if granted by the FDA, pediatric exclusivity or other provisions of the FDCA such as new chemical entity, or NCE, exclusivity, or exclusivity for a new use or new formulation, to provide non-patent exclusivity for a drug product. The FDCA provides a five-year period of non-patent exclusivity within the United States to the first applicant to gain approval of a new drug application, or 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 applicant does not own or have a legal right of reference to all the data

required for approval. However, an ANDA or 505(b)(2) NDA 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, 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 applicant 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, an applicant 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 applicant.

On August 23, 2018, Keryx submitted a Citizen Petition requesting, *inter alia*, that FDA recognize that Auryxia is eligible for five years of new chemical entity, or NCE, exclusivity based on its novel active ingredient and for three years exclusivity for the IDA Indication. On January 19, 2019, FDA responded that Auryxia is eligible for a three-year exclusivity period for the IDA Indication, which expires on November 6, 2020. FDA, however, denied the NCE exclusivity based on its determination that Auryxia contains a previously-approved active moiety (ferric cation). FDA's decision on the Citizen Petition is subject to further review both within FDA and in the courts. On February 21, 2019, we filed a Petition for Reconsideration of FDA's decision on the NCE determination for Auryxia.

The FDA's determination as to whether to grant NCE exclusivity to Auryxia may also affect the timing of the 30 month stay barring FDA from granting final approval to generic versions of Auryxia. When an ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days after the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent, or a decision in the infringement case that is favorable to the ANDA applicant. We have received Paragraph IV certification notice letters regarding Abbreviated New Drug Applications, or ANDAs, submitted to the FDA, from generic drug manufacturers requesting approval for generic versions of Auryxia tablets (210 mg iron per tablet) and have filed certain complaints for patent infringement relating to such ANDAs. See Part II, Item 1. Legal Proceedings for further information relating to the ANDAs and lawsuits.

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 7.5 years 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 applicant.

We cannot assure that Auryxia or any drug candidates we may acquire or in-license 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 that Auryxia or any drug candidates we may acquire or in-license will obtain patent term extension.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to assist with research, development and manufacture of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, services agreements, material transfer agreements, consulting agreements, research agreements or other similar agreements with our advisors, employees, third party contractors, collaborators and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such information becomes known by our competitors, is inadvertently incorporated into the technology of others, or is disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third party contractors, and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution with which we may collaborate will usually expect to be granted rights to publish data arising out of such collaboration. We often grant such rights, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration and remove confidential or trade secret information from any such publication. In the future, we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties or independent development or disclosure or publication of information by any of our employees, advisors, consultants, third party contractors or collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

Litigation or third party claims of intellectual property infringement 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. In addition, third parties may have or may obtain patents in the future and claim that our product or any 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 or us that seeks damages or an injunction of our commercial activities relating to our product or other technologies could subject us to monetary liability, a temporary or permanent injunction preventing the development, marketing and sale of our product or such technologies, and/or require our licensor or us to obtain a license to continue to use our product or other technologies. We cannot predict whether our licensor 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. 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 drug 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. As a result of the Merger, our portfolio now includes a commercial product, Auryxia. Consequently, there is an increased possibility of a patent infringement claim against us. We attempt to ensure that our 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.

Third parties may hold or obtain patents or other intellectual property rights and allege in the future that the use of our products or product candidates infringes these patents or intellectual property rights, or that we are employing their proprietary technology without authorization. We do not believe that there are any currently issued U.S. patents that will prevent us from commercializing Auryxia or vadadustat; nor do we make any admission that any of such patents are valid, enforceable or infringed. Under U.S. law, a party may be able to patent a discovery of a new way to use a previously known compound, even if such compound itself is patented, provided the newly discovered use is novel and nonobvious. Such a method-of-use patent, however, if valid, only protects the use of a claimed compound for the specified methods claimed in the patent. This type of patent does not prevent persons from using the compound for any previously known use of the compound. Further, this type of patent does not prevent persons from making and marketing the compound for an indication that is outside the scope of the patented method. We are not aware of any valid U.S. patents issued to FibroGen, or any other person, that claim methods of using any of our product candidates for purposes of inhibiting hypoxia-inducible factor prolyl hydroxylases, or HIF-PHs, for the treatment of anemia due to CKD. For example, we are aware of certain patents that have been acquired by FibroGen directed to certain heterocyclic carboxamide compounds that are described as inhibitors of prolyl-4-hydroxylase. Those patents, however, are believed to have expired as of December 2014.

FibroGen has also filed other patent applications in the U.S. and other countries directed to purportedly new methods of using such previously known heterocyclic carboxamide compounds for purposes of treating or affecting specified conditions, and some of these applications have since issued as patents. To the extent any such patents issue or have been issued, we may initiate opposition or other legal proceedings with respect to such patents. We discuss the status of the opposition and/or invalidation proceedings against certain FibroGen patents in Part II, Item 1. Legal Proceedings of this Quarterly Report on Form 10-Q.

There may be other patents of FibroGen or patents of other 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 drug 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.

Third parties, including FibroGen, may in the future claim that our product candidates and other technologies infringe upon their patents and may challenge our ability to commercialize vadadustat. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to continue to commercialize Auryxia or further develop and commercialize vadadustat or any other product candidates. 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, including patient selection methods, 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 products or product candidates 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.

We are currently involved in patent infringement lawsuits and opposition and invalidity proceedings and may in the future be involved in additional lawsuits or administrative proceedings to challenge the patents of our competitors or to protect or enforce our patents, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our patents or misappropriate our trade secrets or confidential information. To counter infringement or unauthorized use, we may be required to file infringement or misappropriation claims, which can be expensive and time-consuming. 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, 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. An adverse result in any litigation or 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, 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. 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.

For example, we are currently involved in patent infringement lawsuits against several generic companies in the federal district courts. In addition, we are currently involved in opposition or invalidation proceedings in the European Patent Office, the Japan Patent Office, the Canadian Federal Court and the United Kingdom Patents Court. 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" and Part II, Item 1. Legal Proceedings of this Quarterly Report on Form 10-Q.

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.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

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, which would have a material adverse effect on our business.

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.

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

Filing, prosecuting and defending patents on our 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 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 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 from the intellectual property that we develop or license.

Risks Related to our Business and Industry

If we fail to attract, keep and motivate senior management and key personnel, we may be unable to successfully develop vadadustat and commercialize Auryxia.

Recruiting and retaining qualified scientific, clinical, medical, manufacturing and sales and marketing 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 key employees, including employees in our commercial organization, could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. 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, gain marketing approval of and commercialize products. We may be unable to hire, train, retain or motivate these key 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 we are unable to continue to attract and retain high quality personnel, our ability to grow and pursue our business strategy will be limited.

We may expend our limited resources to pursue a particular product, product candidate or indication and fail to capitalize on products, product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, 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 that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Security breaches and unauthorized use of our IT systems and information, or the IT systems or information in the possession of our collaborators and other third-parties, could damage the integrity of our clinical studies, 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 cyber security 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 some 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 subjects 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, cyber-attack 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 discussed elsewhere in these risk factors and the privacy or security rules under federal, state, or other international laws protecting confidential information, that could be expensive to defend and could result in significant fines or other penalties. Cyber-attacks 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 cyber-attacks. 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.

Likewise, 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 vulnerable to attacks against our collaborators, vendors or service providers, and we may not have adequate contractual remedies against such collaborators, vendors and service providers in 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. In the recent past, 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, divert the attention of our management and key information technology resources, disrupt key business operations, harm our reputation and deter business partners from working with us. A compromise with respect to our information security could lead to public exposure of personal information of our clinical trial subjects, Auryxia patients and others, and publicity about information security. Publicity about vulnerabilities and attempted or successful incursions could damage the integrity of our studies or delay their completion. If a compromise to our information security were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, any loss of clinical trial data could result in delays in our regulatory approval efforts for our product candidates and significantly increase our costs to recover or reproduce the data. In addition, such attacks could compromise our ability to protect our trade secrets and proprietary information from unauthorized access or misappropriation and a loss of, or damage to, our data or marketing applications. Inappropriate public disclosure of confidential or proprietary information could subject us to liability and cause delays in our product research, development and commercialization efforts. We currently do not maintain cybersecurity insurance to protect against losses due to security breaches.

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, harm our competitive position and delay the further development and commercialization of our products and product candidates, or impact our relationships with Auryxia patients.

Our employees, independent contractors, principal investigators, CROs, consultants and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, 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:

- the 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. securities laws and regulations and their non-U.S. equivalents.

These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. 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 unknown or unmanaged risks or 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, 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.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we commercialize Auryxia and advance our product candidates through clinical trials and commercialization, we have expanded and may need to further expand our clinical, medical, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. In addition, we may encounter difficulties in managing the expanded operations of a larger and more complex company following the Merger as well as challenges associated with managing an increasingly diversified business.

We have strategic collaborations for the commercialization of Riona and the development and commercialization of vadadustat. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, consultants, vendors, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management.

In addition, in connection with the Merger, we have experienced and may to continue to experience significant growth in our employee base for sales, marketing, operational, managerial, financial, human resources, compliance, drug development, quality, regulatory and medical affairs and other areas. This growth has imposed and will continue to impose significant added responsibilities on members of management, including the need to recruit, hire, retain, motivate and integrate additional employees, including employees who joined us in connection with the Merger. Also, our management may have 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 activities, including the integration of Keryx's business with our business.

Our future financial performance and our ability to commercialize Auryxia and vadadustat or any other product candidate, if approved, and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To manage our recent and anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. In addition, we may need to adjust the size of our workforce as a result of changes to our expectations for our business, which can result in diversion of management attention, disruptions to our business, and related expenses. The physical 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 growing our company or realizing the anticipated benefits of the Merger.

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

We face an inherent risk of product liability as a result of the use of our product commercially, and clinical testing of our product candidates, and we will face an even greater risk if we commercialize any additional products in the future. For example, we may be sued if our product or any of our product candidates allegedly causes injury or is found to be otherwise unsuitable during product testing, 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 our products and product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for any product or product candidates;
- 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 a product candidate;
- 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 a product or product candidate;
- loss of revenue;
- the inability to commercialize any product or product candidates; 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 product liability risks that may arise. Consequently, a product liability claim may result in losses that could be material to our business.

Risks Related to our Common Stock

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. As a result, we take advantage of certain reduced disclosure requirements.

We are an "emerging growth company", as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and will remain an emerging growth company until December 31, 2019. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and obtaining shareholder approval of any golden parachute payments not previously approved.

Investors may find our common stock less attractive if we continue to rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, therefore, we are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

If we are unable to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act or our internal control over financial reporting is not effective, the reliability of our financial statements may be questioned and our stock price may suffer.

Section 404 of the Sarbanes-Oxley Act requires any company subject to the reporting requirements of the U.S. securities laws to do a comprehensive evaluation of its and its consolidated subsidiaries' internal controls over financial reporting. Additionally, Section 404(b), which is applicable to us as of December 31, 2019, requires our independent auditors to opine on the design and operating effectiveness of our internal controls over financial reporting. The rules governing the standards that must be met for management to assess our internal controls over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. If our management cannot favorably assess the effectiveness of our internal controls over financial reporting or our auditors identify material weaknesses in our internal controls, investor confidence in our financial results may weaken and our stock price may suffer.

Our stock price has been and may continue to be volatile, which could result in substantial losses for 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 smaller pharmaceutical and biotechnology companies in particular 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 Global Market has ranged from a low of $3.50 on August 6, 2019 to a high of $31.00 on June 20, 2014. 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, developments related to and results of our clinical studies, developments related to our regulatory submissions, developments related to our ability to commercialize Auryxia and any other approved product candidates, announcements by us or our competitors of significant mergers, acquisitions, licenses, strategic collaborations, joint ventures, collaborations or capital commitments, negative publicity around Auryxia, vadadustat or any other product or product candidate, the results of competitive clinical trials, products or technologies, regulatory or legal developments in the United States and other countries, developments or disputes concerning patent applications, issued patents or other proprietary rights, the recruitment or departure of key personnel, the level of expenses related to Auryxia, vadadustat or any other product or product candidate or clinical development programs, actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts, variations in our financial results or those of companies that are perceived to be similar to us, changes in the structure of healthcare payment systems, market conditions in the pharmaceutical and biotechnology sectors, general economic, industry and market conditions and others beyond our control. As a result of this volatility, our shareholders 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 for information concerning securities class action and shareholder derivative lawsuits 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 shareholders will dilute our shareholders' ownership interest in Akebia and may cause the market price of our common stock to decline.

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

As of December 31, 2018, Baupost Group Securities, L.L.C., or Baupost, beneficially owned approximately 21% of our outstanding common stock, and our former, director Muneer Satter, beneficially owned approximately 3% of our outstanding common stock. Subject to certain restrictions, Baupost and Mr. Satter are able to sell their shares of common stock in the public market from time to time without registering them, subject to certain limitations on the timing, amount and method of those sales imposed by Rule 144 under the Securities Act of 1933, as amended. In addition, pursuant to our registration rights agreement with Baupost and our Fourth Amended and Restated Investors' Rights Agreement, as amended, with Mr. Satter, Baupost and Mr. Satter have the right, subject to certain conditions and with certain exceptions, to require us to file registration statements covering the shares common stock they own or to include their shares in registration statements that we may file or in public offerings of our shares of common stock. Following their registration and sale under the applicable registration statement, those shares would become freely tradable. By exercising their registration rights and selling a large number of shares of common stock, Baupost and Mr. Satter could cause the price of our common stock to decline.

We have a significant number of shares that are subject to outstanding options, restricted stock units and a warrant, and in the future we may issue additional options, restricted stock units, warrants or other derivative securities convertible into our common stock. The exercise or vesting of any such options, restricted stock units, warrants 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. Also, the Merger was financed by the issuance of shares of our common stock to shareholders of Keryx, comprising approximately 50.6% of our issued and outstanding shares of common stock, calculated based on our fully diluted market capitalization as of the date of signing the Agreement and Plan of Merger relating to the Merger. Keryx shareholders may decide not to hold the shares of our common stock they received in the Merger. Other Keryx shareholders, such as funds with limitations on the amount of stock they are permitted to hold in individual issuers, may be required to sell the shares of our common stock they received in the Merger. 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 universal shelf registration statement, which allows us to offer and sell certain registered securities, such as common stock, preferred stock, 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.

Sales of substantial amounts of shares of our common stock or other securities by our employees or our other shareholders or by us under our universal shelf registration statement 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.

Insiders and significant stockholders could cause us to take actions that may not be, or refrain from taking actions that may be, in our best interest or in the best interest of all of our stockholders.

As of June 30, 2019, we believe that our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, approximately 3% of our outstanding common stock. In addition, we have certain significant stockholders, including Baupost, which beneficially owned approximately 21% of our outstanding common stock as of December 31, 2018. As a result, if certain significant stockholders were to choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs, such as:

- the composition of our Board of Directors;
- the adoption of amendments to our Ninth Amended and Restated Certificate of Incorporation and Amended and Restated By-Laws;
- the approval of mergers or sales of substantially all of our assets;
- our capital structure and financing; and
- the approval of contracts between us and these shareholders or their affiliates, which could involve conflicts of interest.

This concentration of ownership could harm the market price of our common stock by:

- delaying, deferring or preventing a change in control of our company and making some transactions more difficult or impossible without the support of these stockholders, even if such transactions are beneficial to other stockholders;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- entrenching our management or our Board of Directors.

Moreover, the interests of these stockholders may conflict with the interests of other stockholders, and we may be required to engage in transactions that may not be agreeable to or in the best interest of us or other stockholders.

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, and particularly on December 31, 2019 when we will no longer be an "emerging growth company", we will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, or the SOX Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global 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 corporate governance practices. Our management and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and make some activities more time-consuming and costly, especially since we will no longer be an "emerging growth company" on December 31, 2019 and we will therefore no longer be able to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are "emerging growth companies".

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.

If we 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. As a result, stockholders could lose confidence in our financial and other public reporting which would harm our business and the trading price of our common stock.

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 implement required new or improved controls, or difficulties encountered in their 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 SOX Act, or Section 404, or any subsequent testing by our independent registered public accounting firm, which will be required as of December 31, 2019, 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. As a larger company following the Merger, implementing and maintaining effective controls may require more resources, and we may encounter internal control integration difficulties. 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.

Pursuant to Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, as an "emerging growth company", we have not been required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm until we are no longer an emerging growth company as of December 31, 2019. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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 Ninth Amended and Restated Certificate of Incorporation, Amended and Restated By-Laws 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 Amended and Restated By-Laws; 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 Ninth Amended and Restated Certificate of Incorporation.

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 Delaware General Corporation Law 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.

Any provision of our Ninth Amended and Restated Certificate of Incorporation, our Amended and Restated By-Laws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

Under Section 382 of the Code, 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 a change in control under Section 382 of the Code, or Section 382. Future changes in our stock ownership, many of which are outside of our control, could result in an additional ownership change under Section 382. As a result, if we earn net 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. In addition, at the state level, 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 and Need for Additional Capital," 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. A valuation allowance has been provided for the entire amount of our NOLs.

Our Ninth Amended and Restated Certificate of Incorporation designates the state or federal courts located in 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 Ninth Amended and Restated Certificate of Incorporation provides that, subject to limited exceptions, the state and federal courts located in the State of Delaware will be the sole and exclusive forum for (1) any derivative action or proceeding brought on our behalf, (2) 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, (3) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our Ninth Amended and Restated Certificate of Incorporation or our Amended and Restated By-Laws, or (4) any other action asserting a claim against us that is governed by the internal affairs doctrine. Under our Ninth Amended and Restated Certificate of Incorporation, this exclusive forum provision will not apply to claims that are vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery of the State of Delaware, or for which the Court of Chancery of the State of Delaware does not have subject matter jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended, or the 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 Ninth Amended and Restated Certificate of Incorporation 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 Ninth Amended and Restated Certificate of Incorporation 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 securities class action litigation and other legal proceedings, which could result in substantial costs and divert management's attention, and we could be subject to additional securities class actions, shareholder derivative lawsuits and other legal proceedings.

We are currently subject to securities class action litigation and other legal proceedings as described in Part II, Item 1. Legal Proceedings. 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. 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. We could also suffer an adverse impact on our reputation and a diversion of management's attention and resources, which could have a material adverse effect on our business.

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. We currently intend to retain all of our future earnings, if any, to finance the development and growth of our business. In addition, the terms of our current or future debt agreements may preclude us from paying 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, 2019, we did not have any sales of unregistered securities.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

The following table summarizes repurchases of shares of our common stock on April 11, 2019 pursuant to a share repurchase authorized by our Board of Directors.

Period	(a) Total number of shares (or units) purchased (1)	(b) Average price paid per share (or unit)	(c) Total number of shares (or units) purchased as part of publicly announced plans or programs	(d) Maximum number (or approximate dollar value) of shares (or units) that may yet be purchased under the plans or programs
April 1 - April 30, 2019	55,324	$ 7.70	—	$ —
May 1 - May 31, 2019	—	—	—	—
June 1 - June 30, 2019	—	—	—	—
Total	55,324	$ 7.70	—	$ —

(1) The proceeds from the disposition of these shares on April 11, 2019 were used by certain of our officers to cover tax liabilities associated with previously vested restricted stock units.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

As previously disclosed, prior to the consummation of our merger with Keryx Biopharmaceuticals, Inc., or Keryx, Keryx entered into a Loan and Security Agreement with Silicon Valley Bank, or SVB, dated July 18, 2018, for a $40 million Line of Credit, or the Loan and Security Agreement. On August 7, 2019, we executed and delivered to SVB an Unconditional Guaranty, or the Guaranty, pursuant to which we guaranteed the prompt and complete payment and performance when due of all of the obligations and liabilities of Keryx under the Loan and Security Agreement, as it was subsequently amended on July 31, 2019, or the Amended Loan Agreement, as described below. In addition, we entered into a Security Agreement with SVB effective August 7, 2019, or the Security Agreement, pursuant to which we granted to SVB a continuing first priority security interest in substantially all of our personal property, other than our intellectual property, to secure the payment and performance of our obligations under the Guaranty. Our obligations under the Guaranty are independent of Keryx's obligations, and separate actions may be brought against us.

The Security Agreement contains customary representations and warranties and affirmative and negative covenants. The affirmative covenants include, among others, covenants requiring us to maintain our legal corporate existence and governmental approvals, maintain insurance coverage and protect our intellectual property rights. The negative covenants include, among others, restrictions on transferring our assets, changing our business, undergoing a change in control, engaging in mergers or acquisitions, incurring additional indebtedness, creating liens, paying dividends or making other distributions, making investments and transacting with affiliates, in each case subject to certain exceptions.

Upon an event of default under the Security Agreement, SVB is entitled to exercise several remedies, including accelerating and demanding payment of all liabilities of ours under the Guaranty, ceasing to advance money or extend credit under the Amended Loan Agreement, demanding that we deposit cash with SVB in an amount equal to the aggregate amount of any letters of credit remaining undrawn to secure all obligations thereunder, and seeking to enforce security interests in the collateral securing the Amended Loan Agreement and the Guaranty.

The foregoing information is included for the purpose of providing the disclosures required under “Item 1.01 – Entry into a Material Definitive Agreement” and “Item 2.03 – Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant” of Form 8-K.

In addition, on July 31, 2019, Keryx entered into a Waiver and First Amendment to Loan and Security Agreement, or the Loan Amendment. Pursuant to the Loan Amendment, certain revisions were made to the Loan and Security Agreement, including requiring Keryx to maintain, from and after December 31, 2019, subject to certain exceptions, a certain amount of funds to which we have unrestricted access in one or more asset management accounts with SVB or SVB’s affiliate and revising certain of the representations and warranties and covenants in the Loan and Security Agreement. In addition, pursuant to the Loan Amendment, SVB waived then-existing events of default.

The foregoing descriptions of the agreements do not purport to be complete and are qualified in their entirety by reference to such agreements, copies of which we expect to file as exhibits to our Quarterly Report on Form 10-Q for the quarter ending September 30, 2019.

The representations, warranties and covenants contained in the Guaranty, the Security Agreement and the Amended Loan Agreement were made only for purposes of such agreements and as of specific dates, were solely for the benefit of the parties to such agreements, and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures exchanged between the parties in connection with the execution of such agreements. The representations and warranties may have been made for the purposes of allocating contractual risk between the parties to such agreements instead of establishing these matters as facts, and may be subject to standards of materiality applicable to the contracting parties that differ from those applicable to investors. Investors are not third-party beneficiaries under such agreements and should not rely on the representations, warranties and covenants or any descriptions thereof as characterizations of the actual state of facts or condition of the Company or any of our subsidiaries or affiliates. Moreover, information concerning the subject matter of the representations and warranties may change after the date of such agreements, and this subsequent information may or may not be fully reflected in our public disclosure.

Item 6. Exhibits.

Exhibits

2.1	Agreement and Plan of Merger, dated as of June 28, 2018, by and among Akebia Therapeutics, Inc., Alpha Therapeutics Merger Sub, Inc., and Keryx Biopharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed on June 28, 2018).
2.2	First Amendment to Agreement and Plan of Merger, dated as of October 1, 2018, by and among Akebia Therapeutics, Inc., Alpha Therapeutics Merger Sub, Inc. and Keryx Biopharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 1, 2018).
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	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed on March 28, 2014).
10.1*#	Second Amended and Restated License Agreement, dated as of April 17, 2019, by and between Akebia Therapeutics, Inc. and Panion & BF Biotech, Inc.
10.2*#	Amended and Restated License Agreement, dated as of April 8, 2019, by and between Akebia Therapeutics, Inc. and Vifor (International) Ltd.
10.3*#	Supply Agreement, dated as of April 9, 2019, by and between Akebia Therapeutics, Inc. and Esteve Química, S.A.
10.4*	Master Consulting Services Agreement, dated as of June 10, 2019, by and between Akebia Therapeutics, Inc. and Scott A. Canute.
10.5	Amended and Restated 2014 Employee Stock Purchase Plan (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement, filed with the Securities and Exchange Commission on April 26, 2019).
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*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed, or submitted electronically, herewith

\# Indicates portions of the exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AKEBIA THERAPEUTICS, INC.

Date: August 8, 2019

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

Date: August 8, 2019

By: /s/ Jason A. Amello
Jason A. Amello
Senior Vice President, Chief Financial Officer and Treasurer

Exhibit 10.1

Execution Version

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

SECOND AMENDED AND RESTATED LICENSE AGREEMENT

THIS SECOND AMENDED AND RESTATED LICENSE AGREEMENT (this "Agreement"), effective as of this 17th day of April, 2019 (the "Second Amendment Effective Date"), by and between Panion & BF Biotech, Inc., with offices at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan, ROC (hereinafter "Licensor"), and Akebia Therapeutics, Inc., with offices at 245 First Street, Cambridge, MA as successor-in-interest to Keryx Biopharmaceuticals, Inc. (hereinafter "Licensee").

WHEREAS, Dr. Chen Hsing Hsu (the "Inventor"), an employee of the University of Michigan (the "Institution"), is the named inventor on U.S. Patent No. 5,753,706, issued May 19th, 1998 ("the '706 Patent"), which is part of Licensed Patent Property (defined below),

WHEREAS, the Institution has transferred to the Inventor all of the Institution's right, title, and interest in and to the Licensed Patent Property (subject to certain noncommercial applications, specified below), by an Agreement for the Reassignment of Intellectual Property, with a last-signed date of August 16, 2000,

WHEREAS, the Inventor has granted the Licensor the exclusive license, throughout the world (except the People's Republic of China) to make, use, and sell products embodying the inventions described in the '706 Patent and Taiwan Patent No. 108,931, entitled "Compound For Treating Renal Failure," issued on November 11, 1999,

WHEREAS, Licensor has developed certain Licensor Know-How (as hereinafter defined),

WHEREAS, by operation of this exclusive license, Licensor is the sole and exclusive licensee of the entire right, title and interest in the '706 Patent within the Licensee Territory (defined below) and Licensor Know-How claimed in the '706 Patent,

WHEREAS, effective November 7, 2005 (the "Effective Date"), Licensor and Keryx Biopharmaceuticals, Inc. (Licensee's predecessor-in-interest) entered into an Original License Agreement ("Original License Agreement"), as amended and restated by the Amended and Restated Licensed Agreement with an effective date of March 17, 2008 (the "A&R License Agreement"), under which Keryx Biopharmaceuticals, Inc. obtained an exclusive license under such Licensor Patent Property and Licensor Know-How to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold, import and export the Compound and Product in the Licensee Territory (as hereinafter defined),

WHEREAS, Licensor is the assignee and/or owner of the entire right, title and interest in the remaining assets that fall within the scope of the Licensor Patent Rights and Licensor Know-How.

WHEREAS, on or about September 26, 2007 Keryx Biopharmaceuticals, Inc. entered into a sublicense agreement with Japan Tobacco Inc. and Torii Pharmaceutical Co., Ltd ("Japan Sublicense"),

WHEREAS, on December 18, 2018 Keryx Biopharmaceuticals, Inc. merged with Akebia Therapeutics, Inc. ("Akebia") with Akebia continuing as the surviving corporation, and pursuant to such merger, Akebia assumed all of Keryx's rights and obligations under the A&R License Agreement,

WHEREAS, Licensor continues to have the authority and is willing to grant such license to Licensee, and Licensee is willing to accept such license from Licensor, under the terms and conditions set forth in this Second Amended and Restated License Agreement, and

WHEREAS, the parties now wish to amend and restate the A&R License Agreement in its entirety on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties hereto agree to amend and restate the A&R Agreement to read in its entirety as follows:

ARTICLE 1. DEFINITIONS

As used in this Agreement, the following terms, whether used in the singular or the plural, shall have the following meanings:

1.1 "Affiliate" means any corporation or non-corporate business entity, that controls, is controlled by, or is under common control with a party to this Agreement. A corporation or non-corporate business entity shall be regarded as in control of another corporation if it owns or directly or indirectly controls at least fifty-one percent (51%) of the voting stock of the other corporation, or (i) in the absence of the ownership of at least fifty-one percent (51%) of the voting stock of a corporation, or (ii) in the case of a noncorporate business entity, if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or non-corporate business entity, as applicable.

1.2 "Combination Product" means a Product containing one or more therapeutically active ingredients in addition to the Compound.

1.3 "Commercially Reasonable Efforts" means, with respect to the Development, manufacture and Commercialization of a Product by Licensee, those efforts and resources, including reasonably necessary personnel, equivalent to [**].

1.4 "Compound" means ferric citrate or any other iron-based compound that falls within the scope of the Licensed Patent Property.

1.5 "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. Notwithstanding the foregoing, no know-how, patent right or other intellectual property right will be "Controlled" by either party hereunder if such know-how, patent right or other intellectual property right is owned or in-licensed by a Third Party that becomes an Affiliate of such Party after the Second Amendment Effective Date as a result of such party being acquired by such Third Party, whether by merger, stock purchase, or purchase of assets and prior to the date of such transaction and neither such party nor any of its Affiliates had any rights to any such know-how, patent right or other intellectual property right. However, any such know-how, patent right or other intellectual property right that is owned or in-licensed by such an acquiring Third Party and that is used by such acquiring Third Party (or acquired party) following the date of such transaction in connection with the development, manufacture, or commercialization of the Compound or any Product will be "Controlled" by such Third Party (as an Affiliate) or acquired Party for purposes of this Agreement.

1.6 "EU" means the European Union.

1.7 "FDA" means the United States Food and Drug Administration.

1.8 "First Commercial Sale" means with respect to a Product, the first sale for end use or consumption of such Product in a country after all Registrations in such country have been obtained.

1.9 "IND" means an Investigational New Drug Application in the United States.

1.10 "Indication" means any therapeutic application for a Product that is covered by the Licensor Patent Rights.

1.11 "Improvements" means any and all improvements, materials, technical data and information whether patented or unpatented, including any changes to the Compound, to the Product or to the Licensor Know-How or Licensee Know-How including any analogues, or derivatives of the Compound, and changes in the manufacturing process for the Compound or the Product, in each case, that are conceived or reduced to practice during the term of this Agreement.

1.12 "Licensed Patent Property" means U.S. Patent No. 5,753,706, issued May 19, 1998 and entitled "Methods for Treating Renal Failure" together with all patents and patent applications listed under the heading "Licensed Patent Property" on **Exhibit 1** (which Licensor shall update from time to time), including any and all divisionals, continuations, continuations-in-part, extensions, substitutions, renewals, registrations, supplementary protection certificates, revalidations, reissues or additions of or to any of the aforesaid patents and patent applications, and any and all patents that may issue from any of the foregoing.

1.13 "Licensee Development Data" means and includes all data relating to the Compound or the Product and all chemistry, manufacturing and control data relating to the development and manufacture of the Compound or the Product, results of pre-clinical and clinical studies and all other documentation containing or embodying any pre clinical, clinical, chemistry, manufacturing and control data relating to any application for Registrations for a Product, in each case, that is generated by Licensee, its agents or any Sublicensees during the term of this Agreement.

1.14 "Licensee Know-How" means all information and materials, including discoveries, processes, instructions, formulas, data, inventions, knowhow and trade secrets, patentable or otherwise, in each case, Controlled by Licensee that arise out of the development, manufacture or commercialization by Licensee of the Compound or the Product, including all biological, chemical, pharmacological, toxicological, pharmaceutical, physical, analytical, clinical, safety, manufacturing and quality control data and information related thereto, and all applications, registrations, licenses authorizations, documents, approvals and correspondence relating to the Compound or the Product, including correspondence submitted to Regulatory Authorities and all information and data contained in Registrations. Licensee Know-How shall also include Licensee's interest in Improvements.

1.15 "Licensee Patent Rights" means (a) any and all patents and patent applications that are directed to or otherwise pertain to the Compound or the Product or its manufacture or use and in which Licensee holds rights (at any time during the term of this Agreement), including those patents and patent applications that cover or claim Licensee's interest in Improvements.

1.16 "Licensee Territory" means the entire world, other than the Licensor Territory.

1.17 "Licensor Development Data" means and includes all data to which Licensor has rights relating to the Compound or the Product and all chemistry, manufacturing and control data relating to the development and manufacture of the Compound or the Product, results of pre-clinical and clinical studies and all other documentation containing or embodying any pre-clinical, clinical, chemistry, manufacturing and control data relating to any application for Registrations for the Product, whether such Licensor Development Data is in existence as of the Effective Date or generated by Licensor during the term of this Agreement.

1.18 "Licensor Know-How" means all information and materials to which Licensor has rights, including discoveries, processes, formulas, instructions, data, inventions, know-how and trade secrets, patentable or otherwise, in each case, Controlled by Licensor as of the Effective Date or during the term of this Agreement and that are necessary or useful to Licensee in connection with the development, registration, manufacture, marketing, use or sale of any Product. Licensor Know-How shall also include all biological, chemical, pharmacological, toxicological, pharmaceutical, physical, analytical, clinical, safety, manufacturing and quality control data and information related thereto and all applications, registrations, licenses, authorizations, documents, approvals and correspondence relating to a Compound or a Product. Licensor Know-How shall also include Licensor's interest in Improvements.

1.19 "Licensor Patent Rights" means (a) the Licensed Patent Property, (b) all patents and patent applications listed under the heading "Other Licensor Patent Rights" on **Exhibit 1** (which Licensor shall update from time to time), (c) any and all divisionals, continuations, continuations-in-part, extensions, substitutions, renewals, registrations, supplementary protection certificates, revalidations, reissues or additions of or to any of the aforesaid patents and patent applications listed in clause (b), and any and all patents that may issue from any of the foregoing listed in clause (b), and (d) all other patents and patent applications that are directed to or otherwise pertain to the Compound or Product or its manufacture or use and in which Licensor holds rights (at any time during the term of this Agreement), including those patents and patent applications that cover or claim Licensor's interest in Improvements.

1.20 "Licensor Territory" means [**] in the Asian Pacific Region, [**].

1.21 "NDA" means a New Drug Application in the United States.

1.22 "Net Sales" with respect to any Product other than a Combination Product means the gross sales (*i.e.*, gross invoice prices) of such Product billed by Licensee or Licensor, as applicable, or their respective Sublicensees to Third Party customers on all sales of a Product and exclusive of intercompany transfer or sales, less the reasonable and customary deductions from such gross sales, including:

(i) actual credited allowances to such Third Party customers for spoiled, damaged, outdated, recalled or returned Product and for retroactive price reductions or billing corrections,

(ii) the amounts of trade, cash discounts and rebates, to the extent such discounts and rebates were not deducted by Licensee or Licensor, as applicable, or their respective Sublicensees at the time of invoice in order to arrive at the gross invoice prices,

(iii) all transportation, handling charges and freight insurance, sales taxes, excise taxes, use taxes, import/export duties paid or distribution fees paid to third parties,

(iv) invoiced amounts from a prior period that have not been collected and have been written off by Licensor 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 Sale 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

(v) 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 U.S. generally accepted accounting principles (U.S. GAAP) or international financial reporting standards (IFRS), as applicable, consistently applied.

If Licensor, Licensee or a Sublicensee receives non-cash consideration for a Product sold to a Third Party, then the Net Sales amount for such Product will be calculated based on the average arms-length cash selling price for such Product over the immediately prior four calendar quarters in the relevant countries.

The sale of a Product between Licensee or Licensor, as applicable, and any of their respective Sublicensees solely for the research or clinical testing of such Product shall be excluded from the computation of Net Sales of such Product, provided that Licensee's or Licensor's (as applicable) sale of the Product was at cost and such Product was used for research or clinical testing.

"Net Sales" with respect to any Combination Product means the gross sales of such Product billed by Licensee or Licensor, as applicable, or their respective Sublicensees to Third Party customers on all sales of a Combination Product, exclusive of inter-company transfer or sales, less all the allowances, adjustment, reductions, discounts, taxes, duties and other charges referred to in Section 1.22 multiplied by a fraction to be determined by Licensor and Licensee at such time when the Combination Product becomes available.

The sale of a Combination Product between Licensee or Licensor, as applicable, and any of their respective Sublicensees solely for the research or clinical testing of such Product shall be excluded from the computation of Net Sales for such Combination Product, *provided* that Licensee's or Licensor's (as applicable) sale of the Combination Product was at cost and such Combination Product was used for research or clinical testing.

1.23 "Payment Default" means (i) Licensee's failure to pay Licensor the license fee and milestone payments in accordance with Article 4 and (ii) Licensee's or Licensor's (as applicable) failure to pay the royalties in accordance with Section 6.1 or Section 6.2, in each case ((i) and (ii)), for more than ninety (90) days past the date on which these amounts are due.

1.24 "Product" means the Compound or any pharmaceutical product containing the Compound as an active ingredient, either alone or in combination with other active ingredients.

1.25 "Proprietary Information" means all information, including all Licensee Know-How, Licensor Know-How and all other scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, orally or electronically, in each case, that is provided by one party to the other party in connection with this Agreement.

1.26 "Registration" in relation to any Product means such approvals by a Regulatory Authority in a country or community or association of countries as may be legally required before such Product may be commercialized in such country or community or association of countries.

1.27 "Regulatory Authority" means the applicable government regulatory authority in each country in the Territory involved in granting regulatory approval for the Product. Such term includes the FDA and any successor agency thereto and the European Medicines Agency and any successor agency thereto.

1.28 "Sublicensee" means a Third Party to which Licensee or Licensor (as applicable) has granted sublicense rights under the license granted to Licensee or Licensor (as applicable) hereunder, which rights include at least the right to sell the Product. Third Parties that are permitted to manufacture the Compound or the Product for supply only to Licensee or Licensor (as applicable) or only to Sublicensees are not "Sublicensees" and such transaction shall be deemed a transfer and not a sale of the Product.

1.29 "Territory" means the Licensee Territory or the Licensor Territory, collectively or individually (as applicable).

1.30 "Third Party" means any party other than Licensor or Licensee or their respective Affiliates or Sublicensees of Licensee or its Sublicensees.

1.31 "Valid Claim" means a claim of an issued and unexpired patent included within the Licensor Patent Rights or Licensee Patent Rights (as applicable) that has not been held unenforceable or invalid in the applicable jurisdiction by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that has not been admitted to be invalid or unenforceable through dedication, disclaimer or otherwise.

ARTICLE 2. REPRESENTATIONS AND WARRANTIES

2.1 Each party represents and warrants to the other party as of the Second Amendment Effective Date that it has the full right and authority to enter into this Agreement, and that, to the best of its knowledge, there are no prior agreements, commitments or other obstacles that could prevent it from carrying out all of its obligations hereunder.

2.2 Licensor represents to Licensee that, as of the Second Amendment Effective Date:

(a) it is the exclusive licensee, owner or assignee of the entire right, title and interest in and to the Licensor Patent Rights in the Licensee Territory, and to the best of its knowledge, there are no charges, encumbrances, licenses, options, restrictions, liens, rights of others, disputes, proceedings or claims relating to, affecting, or limiting its rights or the rights granted to Licensee under this Agreement, with the exception of non-commercial uses of the '706 Patent reserved to the Institution;

(b) except as disclosed in writing to or known by Licensee prior to the Second Amendment Effective Date, there is no claim, pending or threatened, of infringement, interference or invalidity regarding any part or all of the Licensor Patent Rights and their use as contemplated in this Agreement, and it has no present knowledge from which Licensor can infer that the Licensor Patent Rights are invalid or that their exercise would infringe the patent rights of any Third Party;

(c) it has the right to enter into this Agreement and to grant the licenses granted herein and there is nothing in any Third Party agreement Licensor has entered into as of the Effective Date that in any way will limit the ability of Licensor to perform any and all of the obligations undertaken by Licensor hereunder;

(d) it will not enter into any agreement after the Second Amendment Effective Date that will limit its ability to perform any and all of the obligations undertaken by Licensor hereunder;

(e) it has delivered to Licensee all Licensor Development Data and Licensor Know-How; and

(f) to the best of its knowledge neither this Agreement, nor any document or piece of Licensor Development Data, Licensor Know-How or Licensor Patent Rights contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained herein or therein misleading.

2.3 Licensee represents to Licensor that, as of the Second Amendment Effective Date:

(a) it is the exclusive licensee, owner or assignee of the entire right, title and interest in and to the Licensee Patent Rights in the Licensor Territory, and to the best of its knowledge, there are no charges, encumbrances, licenses, options, restrictions, liens, rights of others, disputes, proceedings or claims relating to, affecting, or limiting its rights or the rights granted to Licensor under this Agreement;

(b) it has no present knowledge from which Licensee can infer that the Licensee Patent Rights are invalid or that their exercise would infringe the patent rights of any Third Party;

(c) it has the right to enter into this Agreement and to the best of its knowledge, there is nothing in any Third Party agreement Licensee has entered into as of the Effective Date that in any way will limit the ability of Licensee to perform any and all of the obligations undertaken by Licensee hereunder, and

(d) it will not enter into any agreement after the Second Amendment Effective Date that will limit its ability to perform any and all of the obligations undertaken by Licensee hereunder; and

(e) to the best of its knowledge neither this Agreement, nor any document or piece of Licensee Know-How or Licensee Patent Rights contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained herein or therein misleading.

ARTICLE 3. LICENSE GRANTS

3.1 Grant to Licensee. Subject to the terms and conditions of this Agreement, Licensor hereby grants to Licensee an exclusive license, in the Licensee Territory, with the right to sublicense, to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold and import and export the Product in the Licensee Territory under the Licensor Know-How and the Licensor Patent Rights for all Indications.

3.2 Sublicensing by Licensee. Sublicensees of Licensee shall be entitled to sublicense to Third Parties the right to manufacture the Product, provided such Third Party manufacturers are permitted to sell only to Licensee or its immediate Sublicensees. Sublicensees of Licensee may not grant sublicenses of the rights granted by Licensor under this Agreement without the written consent of Licensor, which consent shall not be unreasonably withheld or delayed. Should Licensee or any Sublicensee of Licensee grant any sublicenses, the terms and conditions of such sublicenses and the identity of Sublicensees shall be at the sole discretion of Licensee and no consent shall be required from Licensor in connection with the terms and conditions of such sublicenses or the identity of Sublicensees.

3.3 Grant to Licensor. Subject to the terms and conditions of this Agreement, Licensee hereby grants to Licensor an exclusive license, in the Licensor Territory, with the right to sublicense (solely in accordance with Section 3.4), to develop, have developed, make, have made, use, have used, offer to sell, sell, have sold and import and export the Product in the Licensor Territory under the Licensee Patent Rights for all Indications.

3.4 Sublicensing by Licensor. Licensor may not grant sublicenses of the rights granted by Licensee under this Agreement without the written consent of Licensee, which consent shall not be unreasonably withheld or delayed. Licensee shall use good faith efforts to respond to approve or disapprove a request for consent from Licensor within [**] of receipt of the request.

3.5 Consent of Inventor. The Inventor has provided his written consent to the terms and conditions of the licenses granted to Licensee under this Agreement and the terms and conditions of the Original License Agreement. The Written Consent of the Inventor is set forth in **Exhibit 2** hereto.

ARTICLE 4. GOVERNANCE

4.1 Formation and Purpose of the JSC. The EU Joint Steering Committee ("JSC") will coordinate and oversee or monitor the parties' development and commercialization activities hereunder for the Products in accordance with this Article 4. The parties will establish the JSC no later than [**] after the Second Amendment Effective Date. The JSC will establish a charter that will include details regarding the operation of the JSC consistent with this Article 4 and the JSC will have the responsibilities set forth under this Agreement. The JSC will dissolve upon the First Commercial Sale of the first Product in the EU.

4.2 Membership. Each party will designate up to two (2) 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. The parties' representatives will prepare and circulate an agreed agenda in advance of each meeting, and prepare and issue minutes of each meeting no later than [**] after each meeting. Such minutes will not be finalized until all JSC members have had an adequate opportunity to review and confirm the accuracy of such minutes.

4.3 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. The JSC will meet at such locations as the parties may agree. Meetings of the JSC may be held

by audio or video teleconference with the consent of each party. Each party will be responsible for all of its own expenses of participating in any JSC meeting.

4.4 Specific Responsibilities of the JSC. Other than as set forth in Section 8.1 with respect to approval of the Commercialization Plan, the JSC's responsibilities will be limited to oversight and information sharing with respect to development and commercialization of the Products in the EU.

4.5 Additional Participants. At the request of either party, other employees or consultants of such party or any of its Affiliates involved in the development, manufacturing or commercialization of the Products may attend meetings of the JSC as non-voting participants; provided, however, that such Third Party participants must be under written obligations of confidentiality and non-use applicable to the Proprietary Information of each party that are at least as stringent as those set forth in Article 12.

ARTICLE 5. SUBLICENSE PAYMENTS

5.1 Sublicense Payments. In the event that Licensee enters into a sublicense agreement other than the Japan Sublicense, Licensee shall pay to Licensor a sublicense payment in an amount equal to [**] of any Sublicense Income within thirty (30) days of receipt thereof by Licensee. For purposes of this Section 5.1, Sublicense Income shall mean consideration in any form received by Licensee or an Affiliate of Licensee in connection with a grant to one or more Third Parties of a sublicense or other right, license, privilege or immunity to make, have made, use, sell, have sold, distribute, import or export Products or to practice licensed methods. Sublicense Income shall mean any license signing fee, license maintenance fee, unearned portion of any minimum royalty payment received by Licensee, equity, distribution or joint marketing fee, research and development funding in excess of Licensee's cost of performing such research and development and any consideration received for an equity interest in, extension of credit to or other investment in Licensee to the extent such consideration exceeds the fair market value of the equity or other interest received as determined by agreement of the parties or by an independent appraiser mutually agreeable to the parties. Notwithstanding the foregoing, Sublicense Income shall not include (i) sales-based milestones; (ii) payments based on sales of the Products (including royalty payments and profit share payments); (iii) sublicense income received by Licensee under the Japan Sublicense; or (iv) consideration received in connection with a sale of Licensee.

ARTICLE 6. ROYALTIES

6.1 Royalties Payable by Licensee. In consideration of the license rights granted to Licensee hereunder, on a country-by-country basis in the Licensee Territory, Licensee shall pay or cause any Sublicensee to pay to Licensor a royalty on their respective Net Sales of each Product in a country as follows: for each Product where the manufacture, use or sale of such Product in such would, but for the license granted hereunder, infringe a Valid Claim of a Licensor Patent Right in such country, a royalty of [**] on Net Sales of such Product in such country.

6.2 Royalties Payable by Licensor. In consideration of the license rights granted to Licensor hereunder, on a country-by-country basis in the Licensor Territory, Licensor shall pay or cause any Sublicensee to pay to Licensee a royalty on their respective Net Sales of each Product

in a country as follows: for each Product where the manufacture, use or sale of such Product in such would, but for the license granted hereunder, infringe a Valid Claim of a Licensee Patent Right in such country, a royalty of [**] on Net Sales of such Product in such country.

6.3 Limitation. If the laws of any country where royalties are payable under Section 6.1 or Section 6.2 limit the amount of royalty or the duration of such royalty payments to less than the amount specified herein, then the royalty payment to Licensor or Licensee (as applicable) shall be limited to that permitted by law.

6.4 Accrual of Royalties. No royalty shall be payable on a Product made, sold or used for testing or development purposes or distributed as samples, provided such samples are sold by Licensee or Licensor (as applicable) or their respective Sublicensee at cost. No royalties shall be payable on sales among Licensee or Licensor (as applicable) and their respective Sublicensees, but royalties shall be payable on subsequent sales by Licensee or its Sublicensees to a Third Party. No multiple royalty shall be payable because the manufacture, use, or sale of a Product is covered by more than one Valid Claim.

6.5 Royalty Withheld due to Invalid Claims. In the event that (i) all applicable claims of a patent included within the Licensor Patent Rights under which Licensee is paying a royalty according to Section 6.1 shall be held invalid or unenforceable by a court of competent jurisdiction in a given country of the Licensee Territory, or (ii) all applicable claims of a patent included within the Licensee Patent Rights under which Licensor is paying a royalty according to Section 6.2 shall be held invalid or unenforceable by a court of competent jurisdiction in a given country of the Licensor Territory, in each case ((i) or (ii)), Licensor or Licensee (as applicable) may withhold payments of royalties that would otherwise have been due on Net Sales in that country by reason of Section 6.1 or Section 6.2 (as applicable) until such judgment shall be finally reviewed by an unappealed or unappealable decree of a higher court of competent jurisdiction in such country. Licensee shall promptly pay Licensor any withheld royalty payments upon a final adjudication that at least one applicable claim of a patent included within the Licensor Patent Rights under which Licensee is paying a royalty under Section 6.1 is valid and enforceable. Licensor shall promptly pay Licensee any withheld royalty payments upon a final adjudication that at least one applicable claim of a patent included within the Licensee Patent Rights under which Licensor is paying a royalty under Section 6.2 is valid and enforceable.

6.6 Compulsory Licenses. If Licensee is caused to grant a compulsory license to any Third Party with respect to a Product in any country in the Licensee Territory, then the royalty rate to be paid by Licensee on Net Sales due on such Product in that country under Section 6.1 shall be reduced to the rate paid by such Third Party compulsory licensee on such Product in such country. If Licensor is caused to grant a compulsory license to any Third Party with respect to a Product in any country in the Licensor Territory, then the royalty rate to be paid by Licensor on Net Sales due on such Product in that country under Section 6.2 shall be reduced to the rate paid by such Third Party compulsory licensee on such Product in such country.

ARTICLE 7. ROYALTY REPORTS AND ACCOUNTING

7.1 Flash Reports. No later than [**] after the end of each calendar quarter during the Term, the Selling Party will provide to the non-Selling Party a “flash” report that will set forth (i)

for the first and second month of such calendar quarter: (a) the actual gross sales of the Products sold by the Selling Party and its Affiliates and Sublicensees in the applicable Territory in such months; and (b) the actual total aggregate Net Sales of the Products sold by the Selling Party and its Affiliates and Sublicensees in the applicable Territory in such months, and (ii) for the third month of such calendar quarter, the Selling Party's good faith estimate of the amounts set forth in the foregoing clauses (i)(a) and (i)(b) of this Section 7.1.

7.2 Royalty Reports and Records. In addition to the "flash" reports to be provided in accordance with Section 7.1, beginning with the First Commercial Sale (i) by Licensee or any Sublicensee, as the case may be, of a Product in any country of the Licensee Territory or (ii) by Licensor or any Sublicensee, as the case may be, of a Product in any country of the Licensor Territory (each of Licensee in the Licensee Territory or Licensor in the Licensor Territory, as applicable, the "Selling Party"), and continuing thereafter during the term of this Agreement, the Selling Party shall furnish, and shall cause any Sublicensee to furnish, to the non-Selling Party a written report covering each calendar quarter (the "Reporting Period") showing (a) the Net Sales of each Product in each country of the applicable Territory where royalties are payable under Section 6.1 or Section 6.2 (as applicable) during the Reporting Period; (b) the royalties, payable in United States Dollars, that shall have accrued hereunder in respect of such sales with a summary computation of such royalties during the Reporting Period; (c) withholding taxes, if any required by law to be deducted in respect of such sales in such Reporting Period; and (d) the exchange rates used in determining the amount of United States Dollars payable in respect of sales outside the United States. With respect to sales of a Product invoiced in a currency other than United States Dollars, the Net Sales and royalty payable shall be expressed in the domestic currency of the party making the sale together with the United States Dollars equivalent of the royalty payable, calculated using the simple average of the exchange rate published in the Wall Street Journal on the last day of each month of the Reporting Period. If any Sublicensee makes any sale invoiced in a currency other than its domestic currency, then the Net Sales shall be converted to its domestic currency in accordance with its normal accounting principles. The Selling Party's Sublicensees shall have the option of making any royalty payment directly to the non-Selling Party. However, notwithstanding anything to the contrary, the Selling Party shall continue to be liable for all royalties due under Section 6.1 or Section 6.2 (as applicable) until they are paid. The Selling Party or its Sublicensee shall furnish to the non-Selling Party appropriate evidence of payment of, and itemize any tax, credits or specific amount deducted from any royalty payment.

7.3 Royalty Reports and Payments. Royalty reports and payments shall be due sixty (60) days after the close of each Reporting Period. Payment of royalties in whole or in part may be made in advance of such due date. In case no royalty is due for any given Reporting Period, then the Selling Party shall so report to the non-Selling Party. The Selling Party and its Sublicensees shall keep accurate records in sufficient detail to enable the royalty payable hereunder to be determined and confirmed. The Selling Party shall be responsible for all royalties, late payments and interest that are due but have not been paid by the Selling Party's Sublicensees.

7.4 Right to Audit. Upon written request of the non-Selling Party, but not more than once in each calendar year nor more than once in respect to any given calendar year, the Selling Party shall permit an independent public accountant, selected by the non-Selling Party and acceptable to the Selling Party, which acceptance shall not be unreasonable withheld, to have access during normal business hours to those records of the Selling Party as may be reasonably necessary to verify the accuracy of the royalty reports hereunder in respect of any calendar year ending not more than thirty-six (36) months prior to the date of such request. The Selling Party shall include in each Sublicense granted by it pursuant to this Agreement a provision requiring the Sublicensee to keep and maintain records of sales made pursuant to such sublicense and to grant the same right of access to such records to the non-Selling Party's independent accountant. Upon the expiration of thirty-six (36) months following the end of any calendar year, the calculation of royalties payable with respect to such calendar year shall be binding and conclusive upon the parties, and the Selling Party and its Sublicensees shall be released from any liability or accountability with respect to royalties (and the non-Selling Party for an overpayment of royalties) for such calendar year, unless (a) an audit requested by the non-Selling Party prior to expiration of such thirty-six (36) months period has not yet been completed, or (b) the non-Selling Party has notified the Selling Party prior to the expiration of such thirty-six (36) months period that such audit has revealed a discrepancy regarding such calculation. The report prepared by such independent public accountant, a copy of which promptly shall be provided to the Selling Party, shall disclose only the amount of any underpayment or overpayment of royalties, if any, without disclosure of or reference to supporting documentation. If such independent accountant's report shows any underpayment of royalties, the Selling Party shall remit or shall cause its Sublicensees to remit to the non-Selling Party the amount of such underpayment within thirty (30) days after the Selling Party's receipt of such report, and if such underpayment exceeds five percent (5%) of the royalty due, then the Selling Party shall reimburse the non-Selling Party for its reasonable out-of-pocket expenses for the audit, upon submission of supporting documentation. Any overpayment of royalties shall be creditable against future royalties payable in subsequent royalty periods, allocated evenly over the next-following two (2) Reporting Periods. In the event this Agreement is terminated or expires before such overpayment is fully credited, then the non-Selling Party shall pay the Selling Party the portion of such overpayment not credited within one hundred twenty (120) days after the date of such termination or expiration.

7.5 Confidentiality of Records. The non-Selling Party agrees that all information subject to review under Section 7.4 or under any sublicense agreement shall be deemed the Proprietary Information of the Selling Party.

7.6 Late Payment Interest. Royalties and other payments required to be paid by the Selling Party pursuant to this Agreement shall, if overdue, bear interest at the rate equal to two percent (2%) over the prime rate as quoted by Citibank NA and not to exceed ten percent (10%) per annum until paid. The payment of such interest shall not preclude the non-Selling Party from exercising any other rights it may have because any payment is overdue.

ARTICLE 8. COMMERCIALIZATION PROGRAM

8.1 Commercialization in the EU. The JSC will use Commercially Reasonable Efforts to develop, discuss and, no later than [**] after the Second Amendment Effective Date, reach consensus on a written plan for the commercialization of the Product in the EU (the "Commercialization Plan"). If the JSC has not reached consensus on such a Commercialization Plan within [**] after the Second Amendment Effective Date, then Licensee, at its sole discretion, will either (i) launch (itself or through a Sublicensee) the Product in at least one of [**] no later than [**] after the Second Amendment Effective Date, (ii) agree to pay to Licensor a license maintenance fee equal to $[**] for the first calendar year after the Second Amendment Effective Date (which amount will be pro rated based on the remaining portion of such calendar year), $[**] for the second calendar year after the Second Amendment Effective Date and $[**] for each subsequent calendar year after the Second Amendment Effective Date or (iii) expand the Licensor Territory to include the EU on commercially reasonable terms to be negotiated by the parties; provided that in such case (iii), Licensor will not be required to pay to Licensee any upfront payment in connection with such an expansion of the Licensor Territory. If Licensee elects to agree to pay to Licensor the license maintenance fee pursuant to the foregoing clause (ii), then Licensee will have no further obligation with respect to the development or commercialization of the Product in the EU.

8.2 Suspension of Diligence Obligations. Licensee's obligation to satisfy its obligations under Section 8.1(i) to launch (itself or through a Sublicensee) the Product in at least one of [**] no later than [**] after the Second Amendment Effective Date is expressly conditioned on the continuing absence of any event or condition (such as a regulatory action affecting the Product or the existence of an issue relating to the safety or efficacy of the Product, the introduction of a generic form of the Product or a therapy that has superior safety or efficacy in the EU, or the existence of any circumstances, economic or otherwise, that make the development or marketing of the Product, in Licensee's judgment, commercially unrewarding) that would suggest to Licensee, in exercising prudent and justifiable business judgment, that the activities described in Section 8.1(i) should be suspended or stopped altogether, and Licensee's obligation thereunder may be suspended for up to six (6) months, after which time Licensee must resume the activities described in Section 8.1(i) or elect to take one of the actions set forth in Section 8.1(ii) or Section 8.1(iii), and if Licensee does not so resume such activities or make such an election, then Licensor may elect, in its sole discretion, to terminate this Agreement pursuant to Section 13.3.1(a).

8.3 Mutual Assistance.

(a) Licensor Development Data. As soon as practical after the Second Amendment Effective Date, Licensor will make available to Licensee all Licensor Development Data in the possession of Licensor that is not already in the possession of Licensee and will cooperate with and provide reasonable assistance to Licensee in its evaluation of such Licensor Development Data. On a continuing basis during the term of this Agreement, Licensor shall make available to Licensee all additional Licensor Development Data generated by Licensor or any Third Party on behalf of Licensor. Licensor shall provide Licensee with a right of reference to all such Licensor Development data and Licensee shall have the right to include such Licensor Development Data in any of its applications for Registrations. All such Licensor Development Data shall be deemed the Proprietary Information of Licensor, and all rights, title and interests in and to such Licensor Development Data shall remain vested in Licensor.

(b) Licensee Development Data. On a continuing basis during the term of this Agreement, Licensee shall make available to Licensor all Licensee Development Data generated by Licensee or any Third Party on behalf of Licensee. Licensee shall provide Licensor with a right of reference to all such Licensee Development data and, subject to the terms of this Agreement. Licensee will provide to Licensor free of charge [**] per calendar year of assistance in connection with Licensee's delivery of such Licensee Development Data to Licensor pursuant to this Section 8.3(b), and if Licensor requests additional assistance beyond such [**] per year, then Licensor will be responsible for all internal costs (at a rate to be agreed by the Parties in advance of Licensee providing any such additional assistance) and in any event all out-of-pocket costs, in each case reasonably incurred by Licensee in connection with such assistance. Licensor shall reimburse Licensee for its reasonable costs and expenses incurred in connection with providing any Licensee Development Data, upon presentation by Licensee of an invoice documenting such costs and expenses. Licensee shall have no obligation to disclose to Licensor or any of its Affiliates any Licensee Development Data except as expressly set forth in this Section 8.3(b) and notwithstanding any such disclosure to Licensor, all Licensee Development Data shall be deemed the Proprietary Information of Licensee, and all rights, title and interests in and to such Licensee Development Data shall vest in Licensee, subject to Section 13.5.2.

(c) In the event that either party receives any inquiries from any Regulatory Authority that may affect the development and marketing of a Product, such party shall immediately notify the other party. Licensee shall be responsible for responding to Regulatory Authorities within the Licensee Territory and Licensor shall be responsible for responding to Regulatory Authorities within the Licensor Territory. The parties agree to exchange regulatory information and reports for compliance with local Regulatory Authorities and to provide reasonable assistance to the other in formulating a response to the aforementioned inquiries, including being available to meet with the Regulatory Authority if necessary. Licensee shall reimburse Licensor for its reasonable expenses incurred in rendering such assistance in the Licensee Territory, upon presentation by Licensor of an invoice documenting such expenses and Licensor shall reimburse Licensee for its reasonable expenses incurred in rendering such assistance in the Licensee Territory, upon presentation by Licensee of an invoice documenting such expenses.

8.4 Registrations. Subject to the terms and conditions of this Agreement, each application for Registration in the Licensee Territory shall be filed in the name of Licensee or a designated Affiliate or Sublicensee. Licensee shall own all rights, title and interests in and to all applications for Registrations and granted Registrations in the Licensee Territory. Licensee shall be responsible for all disclosures and correspondence to and with the Regulatory Authorities, and all disclosures and correspondence with any Regulatory Authority in the Licensee Territory involving Licensor shall be made through Licensee. Licensee shall keep Licensor advised of the status of all Registrations and any applications for Registration in the Licensee Territory and Licensor shall keep Licensee advised of the status of all Registrations and any applications for Registration in the Licensor Territory.

8.5 Progress Reports. Commencing upon the launch of the Product in the EU by Licensee or a Sublicensee of Licensee and continuing until the end of the Term, no later than thirty (30) days of the close of each calendar year, Licensee shall provide to Licensor a written high-level summary of Licensee's or its Sublicensee's progress and activities with respect to the commercialization of the Product in the EU ("Progress Report").

ARTICLE 9. PATENTS AND IMPROVEMENTS

9.1 Patents.

9.1.1 Patent Prosecution and Maintenance. Licensee shall use reasonable efforts in the Licensee Territory to prosecute the patent applications that are enumerated in **Exhibit 1** of this Agreement, to conduct any interference, re-examination, reissue and opposition proceedings and to maintain patents included in the Licensor Patent Rights in effect during the term of this Agreement. Licensee shall be solely responsible for all costs and expenses relating to such patent applications and patents.

9.1.2 Patent Counsel. Licensee may select patent counsel to prosecute and maintain the Licensor Patent Rights under this Agreement in the Licensee Territory, which patent counsel will be reasonably acceptable to Licensor.

9.1.3 Consultation and Decision. Licensee shall regularly consult with Licensor and shall keep Licensor advised of the status of all patent applications and patents relating to the Licensor Patent Rights by providing Licensor with copies of such patent applications and patents and copies of all patent office correspondence relating thereto including any office actions received by Licensee and responses or other papers filed by Licensee. Licensee specifically agrees to provide Licensor with copies of patent office correspondence in sufficient time for Licensor to review and comment on such correspondence and submit to Licensee any proposed response thereto. Licensee further agrees to provide Licensor with sufficient time and opportunity, but in no event less than ten (10) days, to review, comment and consult on all proposed responses to patent office correspondence relating to such patent applications and patents. Licensor agrees that all final decisions regarding the preparation and prosecution of such patent applications and patents, reissues, reexaminations, interferences and oppositions relating thereto may be made by Licensee after consultation with Licensor. Notwithstanding the foregoing, in the event of a decision regarding a Significant Event, Licensee will provide Licensor with notice of such Significant Event and Licensor shall have thirty (30) working days in which to assent or refuse to

assent to such action, with such assent not to be unreasonably withheld. For purposes of this Section 9.1.3, "Significant Event" shall mean abandonment of an application, the filing of divisional or continuation applications, the filing of any fact or expert declaration, or a significant narrowing of the scope of patent application claims. Licensee shall have the right in its sole discretion, after consultation with Licensor, to discontinue the prosecution of any such patent applications or the maintenance of any such patents, and Licensor shall have the right to assume responsibility for the prosecution of such patent applications or the maintenance of such patents at its own expense. If Licensee elects not to prosecute, and Licensor elects not to assume, any such patent applications or not to maintain any such patents in any country within the Licensee Territory, then Licensee's license rights and its obligations under this Agreement with respect to such patent applications and patents in such country shall terminate, without affecting its license rights and other obligations to pay with respect to any other patent applications or patents included in the Licensor Patent Rights.

9.1.4 Additional Patents. After the Effective Date, the parties may, by written agreement, amend **Exhibit 1** to add additional patents related to the Compound ("Additional Patents"). Upon the written amendment of **Exhibit 1**, such Additional Patents shall be prosecuted and maintained in accordance with the provisions of this Section 9.1.

9.2 Improvements.

(a) Each party shall notify the other party promptly of any sole or joint inventions directed to Improvements under such party's Control.

(b) As between the parties, Licensee shall own all rights, title and interests in and to Improvements invented solely by Licensee's employees or contractors and Licensor shall own all rights, title and interests in and to Improvements invented solely by Licensor's employees or contractors. Patent applications and patents directed to jointly invented Improvements shall be jointly assigned to and owned by Licensee and Licensor, and the rights of the parties with respect thereto shall be determined according to the laws of the countries in which such patent applications and patents are held. During the term of this Agreement, either party shall have the liberty to freely practice Improvements in its respective Territories.

(c) During the term of this Agreement, for patent applications and patents relating to Improvements invented solely by Licensor, the provisions of Section 9.1.4 shall apply.

(d) Following expiration or termination of this Agreement, Licensor shall be solely responsible, at its sole discretion and expense, for preparing, filing, prosecuting and maintaining in such countries where it deems appropriate, patent applications and patents relating to Improvements invented solely by Licensor and for conducting interference, re-examination, reissue and opposition proceedings relating to such patent applications and patents.

(e) During the term of this Agreement, Licensee shall be responsible, in its sole discretion and expense, for preparing, filing, prosecuting and maintaining in such countries where it deems appropriate, patent applications and patents relating to Improvements invented solely by Licensee or jointly by Licensee and Licensor. Notwithstanding the foregoing, if Licensee elects (after consultation with Licensor) not to prosecute, or to discontinue the prosecution of any patent applications concerning joint inventions, or to discontinue the maintenance of any patents concerning joint inventions, then (i) Licensor shall have the right to assume the full responsibility for the prosecution of such patent applications or the maintenance of such patents at its own costs expense, (ii) Licensee shall assign its interest in such patents and patent applications to Licensor and (iii) such patents and patent applications shall no longer be subject to this Agreement.

(f) Following expiration or termination of this Agreement, Licensee shall be solely responsible, in its sole discretion and expense, for preparing, filing, prosecuting and maintaining in such countries where it deems appropriate, patent applications and patents relating to Improvements invented solely by Licensee and for conducting interference, re-examination, reissue and opposition proceedings relating to such patent applications and patents.

(g) Following expiration or termination of this Agreement, the parties shall be jointly responsible for preparing, filing, prosecuting and maintaining in such countries where the parties jointly agree, patent applications and patents relating to Improvements jointly invented by the parties and for conducting interference, reexamination, reissue and opposition proceedings relating to such patent applications and patents. The parties shall jointly bear all costs relating thereto. If one party elects to discontinue the prosecution of any patent applications and patents filed pursuant to this Section 9.2(g), or not to conduct any further activities with respect to such patent applications or patents, the party electing to discontinue any such activities shall assign to the other party all right, title and interest in and to such patents or patent applications. The party electing to continue such activities shall be solely responsible for all costs relating to such activities.

ARTICLE 10. INFRINGEMENT

10.1 Infringement by a Third Party. In the event that either party becomes aware that a Compound or a Product being made, used or sold by a Third Party infringes the Licensor Patent Rights or Licensee Patent Rights licensed hereunder, such party shall promptly, and in any event not later than within three (3) days of becoming aware of such infringement, advise the other party of all known facts and circumstances relating thereto. Licensee shall have the sole right, but not the obligation, to enforce at Licensee's sole expense the Licensor Patent Rights licensed under this Agreement against infringement by Third Parties in the Licensee Territory and shall have the sole right to control the prosecution of such legal action and make all decisions with respect to such litigation, including the selection of outside counsel. Licensor shall reasonably cooperate in any such enforcement and, if necessary, join as a party therein, at the expense of Licensee. Licensee shall have the right to retain 100% of the proceeds of any such enforcement action. Subject to any protective orders and Licensee's confidentiality obligations to Third Parties, Licensee will keep Licensor timely and fully apprised of all pleadings, motions, briefs and discovery requests, as well as all claims and defenses being asserted, and all material strategic decisions in any infringement litigation for any Product. Licensor shall have the sole right, but not the obligation, to enforce at Licensor's sole expense the Licensee Patent Rights licensed under this Agreement against

infringement by Third Parties in the Licensor Territory and shall have the sole right to control the prosecution of such legal action and make all decisions with respect to such litigation, including the selection of outside counsel. Licensee shall reasonably cooperate in any such enforcement and, if necessary, join as a party therein, at the expense of Licensor. Licensor shall have the right to retain 100% of the proceeds of any such enforcement action. Subject to any protective orders and Licensor's confidentiality obligations to Third Parties, Licensor will keep Licensee timely and fully apprised of all pleadings, motions, briefs and discovery requests, as well as all claims and defenses being asserted, and all material strategic decisions in any infringement litigation for any Product.

10.2 Infringement by Licensee. In the event that it is determined by any court of competent jurisdiction that the manufacture, use or sale of any Product by Licensee or its Sublicensees in accordance with the terms and conditions of this Agreement infringes, or Licensee and Licensor reasonably determine and agree that the manufacture, use or sale of such Product is likely to infringe, an additional Third Party patent or related intellectual property right in any country in the Licensee Territory, then Licensee shall in consultation with Licensor use its reasonable best efforts to: (i) procure at Licensee's expense a license from such Third Party authorizing Licensee to continue to manufacture, use or sell such Product; or (ii) modify such Product or its manufacture so as to render it noninfringing. In the event that neither of the foregoing alternatives is reasonably available or commercially feasible, then Licensee may at its option either (a) cease the manufacture, use and sale of such Product for so long as and to the extent that such activities are infringing the relevant Third Party patents, in which case the obligation of Licensee hereunder to pay royalties shall also cease, or (b) terminate the rights and licenses granted solely with respect to a country or countries within the Licensee Territory in which the infringement of Third Party patents has occurred or is likely to occur, in which case the obligation of Licensee hereunder to pay royalties shall also terminate with respect to that country or countries within the Licensee Territory.

ARTICLE 11. INDEMNIFICATION

11.1 Indemnification by Licensee. Licensee agrees to indemnify and hold Licensor, its directors, officers, employees and agents harmless from and against any liabilities or damages or expenses in connection therewith (including reasonable attorneys' fees and costs and other expenses of litigation) resulting from (i) any willful misrepresentation of a material fact or breach of this Agreement, (ii) claims by Third Parties arising out of Licensee's or its Sublicensees' manufacture, use, sale or testing of Product; and (iii) the enforcement by Licensor of its indemnification rights against Licensee under clause (ii) of this Section 11.1.

11.2 Indemnification by Licensor. Licensor hereby agrees to indemnify and hold Licensee and its officers, directors, employees and agents harmless from and against any liabilities or damages or expenses in connection therewith (including reasonable attorneys' fees and costs and other expenses of litigation) resulting from (i) any willful misrepresentation of a material fact or breach of this Agreement, (ii) claims by Third Parties arising out of Licensor's or its Sublicensees' manufacture, use, sale or testing of Product; and (iii) the enforcement by Licensee of its indemnification rights against Licensor under clause (ii) of this Section 11.2.

11.3 Indemnification Procedures. Each indemnified party shall promptly notify the indemnifying party in writing of any action, claim or liability in respect of which the indemnified party intends to claim indemnification from the indemnifying party. The indemnified party shall permit the indemnifying party, at its discretion, to settle any such action, claim or liability, and agrees to the complete control of such defense or settlement by the indemnifying party, provided however, that such settlement does not adversely affect the rights of the indemnified party hereunder or impose any obligations on the indemnified party in addition to those set forth herein in order for it to exercise such rights. No such action, claim or liability shall be settled by the indemnified party without the prior written consent of the indemnifying party, which consent shall not be unreasonably withheld or delayed, and the indemnifying party shall not be responsible for any legal fees or other costs incurred by the indemnified party other than as provided herein. The indemnified party and its directors, officers, employees and agents shall cooperate fully with the indemnifying party and its legal representatives in the investigation and defense of any action, claim or liability covered by this indemnification, and shall have the right, but not the obligation, to be represented by counsel of their own selection and at their own expense.

11.4 Limitation of Liability. Notwithstanding anything to the contrary herein, neither party shall be liable to the other party for any indirect, incidental or consequential damages arising out of any terms or conditions in this Agreement or with respect to the performance hereof.

11.5 Survival of Representations and Warranties. The representations and warranties contained in this Agreement shall survive the expiration or termination of this Agreement and shall remain in full force and effect.

ARTICLE 12. CONFIDENTIALITY

12.1 Treatment of Proprietary Information. Except as otherwise provided in this Article 12, during the term of this Agreement and for a period of five (5) years following expiration or termination thereof, a party (the "Receiving Party") will retain in confidence and use only for purposes of this Agreement Proprietary Information supplied by or on behalf of the other party (the "Disclosing Party").

12.2 Right to Disclose. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement or any rights which survive termination or expiration hereof, a Receiving Party may disclose Proprietary Information to its Affiliates, Sublicensees, consultants, agents, outside contractors and clinical investigators (collectively the "Representatives") on condition that such Representatives agree (i) to keep the Proprietary Information confidential for a least the same time periods and to the same extent as such party is required to keep the Proprietary Information confidential and (ii) to use the Proprietary Information only for such purposes as the Receiving Party is entitled to use the Proprietary Information. Each party warrants that each of its Representatives to whom any Proprietary Information is disclosed shall previously have been informed of the confidential nature of the Proprietary Information and shall be under written obligations of confidentiality and non-use applicable to the Proprietary Information of each party that are at least as stringent as those set forth in this Article 12. The Receiving Party shall ensure that the Proprietary Information provided by the Disclosing Party shall not be used or disclosed by such Representatives except as permitted by this Agreement. The Receiving Party shall stand responsible for any breach by its Representatives of the confidentiality provisions set forth in this Agreement.

12.3 Release From Restrictions. The obligation not to disclose Proprietary Information shall not apply to any part of such Proprietary Information that:

(i) is or becomes patented, published or otherwise part of the public domain other than by the unauthorized acts of the Receiving Party or its Affiliates or Sublicensees in contravention of this Agreement; or

(ii) is disclosed to the Receiving Party by a Third Party that did not obtain such Proprietary Information directly or indirectly from the Disclosing Party; or

(iii) prior to disclosure under this Agreement, was already in the possession of the Receiving Party as evidenced by its written records, provided such Proprietary Information was not obtained, directly or indirectly, from the Disclosing Party; or

(iv) is developed by the Receiving Party independent of Proprietary Information received from the Disclosing Party as evidenced by its written records.

12.4 Public Domain. For the purpose of this Agreement, specific information disclosed as part of the Proprietary Information shall not be deemed to be in the public domain or in the prior possession of the Receiving Party merely because it is embraced by more general information in the public domain or by more general information in the prior possession of the Receiving Party.

12.5 Ownership of Proprietary Information. Except as otherwise agreed to hereunder, all Proprietary Information disclosed by the Disclosing Party shall remain the property of the Disclosing Party. Upon the written request of the Disclosing Party (i) all tangible Proprietary Information provided by the Disclosing Party (including all copies thereof and all unused samples of materials provided by the Disclosing Party) except for Proprietary Information consisting of analyses, studies and other documents prepared by or for the benefit of the Receiving Party shall be promptly returned to the Disclosing Party, and (ii) all portions of such analyses, studies and other documents not prepared by or for the benefit of the Receiving Party (including all copies thereof) which are within the definition of Proprietary Information shall be destroyed, and the Receiving Party shall certify such destruction in writing to the Disclosing Party. Notwithstanding the foregoing, the Receiving Party may retain one copy of the Proprietary Information of the Disclosing Party in its legal department for the sole purpose of determining its obligations hereunder.

12.6 Legal Disclosure. The Receiving Party may disclose the Proprietary Information of the Disclosing Party to the extent reasonably necessary in prosecuting or defending litigation, complying with applicable laws, governmental regulations or court order, or otherwise submitting required information to tax or other governmental authorities. If the Receiving Party intends to so disclose any such Proprietary Information, the Receiving Party shall provide the Disclosing Party prompt prior notice of such fact so that the Disclosing Party may seek to obtain a protective order or other appropriate remedy concerning any disclosure of such Proprietary Information. The Receiving Party will reasonably cooperate with the Disclosing Party in connection with the Disclosing Party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude the disclosure of such Proprietary Information, the Receiving Party will make such disclosure only to the extent that such disclosure is legally required and will use its reasonable efforts to have confidential treatment accorded to the disclosed Proprietary Information.

12.7 No Title. Except as otherwise expressly set forth in this Agreement, nothing herein shall be construed as giving the Receiving Party any right, title and interest in and to the Proprietary Information of the Disclosing Party.

12.8 Permitted Disclosures.

12.8.1 Disclosure by Licensee. Notwithstanding the foregoing, subject to review and comment by Licensor, Licensee may disclose Licensor Proprietary Information to the extent such disclosure is reasonably necessary for the following activities (i) the development of the Compound or the Product in the Licensee Territory, (ii) the filing of applications for Registration in the Licensee Territory, (iii) the commercialization of the Compound or the Product in the Licensee Territory or (iv) the filing or prosecution of a patent applications and patents relating to Improvements invented solely by Licensee or jointly by Licensee and Licensor.

12.8.2 Disclosure by Licensor. Notwithstanding the foregoing, subject to review and comment by Licensee, Licensor may disclose Licensee Proprietary Information to the extent such disclosure is reasonably necessary for the following activities (i) the filing or prosecution of patent applications and patents relating to Improvements invented solely by Licensor or jointly by Licensor and Licensee, and (ii) in the Licensor Territory and to the extent approved in writing by Licensee, (a) the development of the Compound or the Product, (b) the filing of applications for Registration or (c) the commercialization of the Compound or the Product.

12.9 Publications. Neither party shall submit or present any written or oral publication, any manuscript, abstract or the like which includes data or other information related to the Compound or the Products or the Proprietary Information of the other party without first obtaining the prior written consent of the other party.

ARTICLE 13. TERM AND TERMINATION

13.1 Term. Unless terminated sooner as provided herein, this Agreement shall continue in full force and effect from the Effective Date until the expiration of each of Licensee's and Licensor's obligation to pay royalties hereunder. Upon the expiration of Licensee's obligation to pay royalties hereunder, the license granted to Licensee in this Agreement will become perpetual, irrevocable and fully-paid. Likewise, upon the expiration of Licensor's obligation to pay royalties hereunder, the license granted to Licensor in this Agreement will become perpetual, irrevocable and fully-paid. Except as otherwise expressly provided in this Agreement, upon expiration or termination of this Agreement with respect to one or more countries of the Licensee Territory or Licensor Territory, as applicable, the rights and obligation of the parties with respect to each such country or countries shall cease, except as follows:

(i) upon expiration or termination by either party for any reason, the rights and obligations under Articles 7, 11, 12, 13 and 23 and the applicable provisions of Section 9.2;

(ii) expiration or termination of this Agreement shall not relieve either party of any obligations that accrued to that party prior to such expiration or termination for any reason; and

(iii) any cause of action or remedy for breach shall survive the expiration or termination of this Agreement.

13.2 Termination by Licensee.

13.2.1 Licensee may terminate this Agreement (i) in its entirety or (ii) with respect to one or more countries of the Licensee Territory without affecting the Agreement or the licenses granted hereunder in any other country of the Licensee Territory, in each case ((i) and (ii)), without cause at any time upon at least ninety (90) days prior written notice to Licensor.

13.2.2 Licensee may terminate this Agreement upon or after the material breach of this Agreement by Licensor if such breach is not cured within ninety (90) days after Licensee gives Licensor written notice thereof or upon a Payment Default.

13.2.3 Licensee may terminate this Agreement in its entirety for cause upon at least ninety (90) days prior written notice to Licensor upon or after the bankruptcy, insolvency, dissolution or winding up of Licensor other than for the purpose of reconstruction or amalgamation.

13.3 Termination by Licensor.

13.3.1 Licensor may terminate this Agreement for cause at any time upon at least ninety (90) days prior written notice to Licensee upon the occurrence of any of the following:

(a) upon or after the material breach of this Agreement by Licensee if such breach is not cured within ninety (90) days after Licensor gives Licensee written notice thereof;

(b) upon a Payment Default; or.

(c) upon or after the bankruptcy, insolvency, dissolution or winding up of Licensee other than for the purpose of reconstruction or amalgamation.

Such termination will be in its entirety, unless the termination is for a material breach that relates to one or more countries (but not all) of the Licensee Territory, in which case, Licensor may terminate this agreement only with respect to such country(ies) and such termination will not affect the Agreement or the licenses granted hereunder in any other country of the Licensee Territory.

13.4 Disputes Regarding Material Breach. Notwithstanding the foregoing, if a party gives to the other party a notice of a material breach by such other party, and such other party provides notice during the applicable cure period set forth above that such other party disputes the basis for termination pursuant to Section 13.2.2 or Section 13.3.1, then this Agreement will not terminate during the pendency of such dispute for so long as the disputing party continues to seek a resolution of such dispute in accordance with Article 24.

13.5 Rights Following Termination.

13.5.1 Subject to the provisions of Section 9.2 with respect to Improvements, in the event of termination (but not expiration) of this Agreement with respect to all countries in the Licensee Territory, to the extent in Licensee's possession, Licensee will promptly transfer and hand over to Licensor all Licensor Development Data and Licensor Know-How provided to Licensee hereunder. Each party will return to the other party all copies of the Proprietary Information supplied by one party to the other party hereunder, except that copies of such Proprietary Information may be retained by each party for archival purposes only.

13.5.2 Upon termination (but not expiration) of this Agreement or the license rights granted hereunder by either party for any reason with respect to one or all countries of the Licensee Territory (other than a termination by Licensee for an uncured breach or default by Licensor), Licensee will grant Licensor access to (and allow Licensor to obtain copies of) all Licensee Development Data and Licensee Know-How and shall promptly take all steps necessary to transfer all rights, title and interests in any Registration, marketing authorizations or other regulatory approvals to Licensor. Licensor shall have the right to disclose to a Third Party all such Licensee Development Data and Licensee Know-How in connection with Licensor's effort to license to such Third Party the right to manufacture and sell a Product in those countries where termination of Licensee's rights has occurred. Such use or disclosure shall be subject to the Licensee's rights in countries where termination has not occurred and to the right, title and interest in such Licensee Development Data and Licensee Know-How that shall remain vested in Licensee. The Third Party shall not be entitled to sublicense, assign or transfer any of the rights granted to it by Licensor except to an Affiliate of such Third Party. Licensee agrees to cooperate with and provide reasonable assistance to Licensor in its effort to license to a Third Party the use of such Licensee Development Data and Licensee Know-How. In consideration thereof, Licensor shall pay to Licensee a royalty of [**] on Net Sales of Product sold by Licensor or such Third Party for a period of [**] from the commencement of the sale of the Product by Licensor or such Third Party. Any license granted by Licensor to such Third Party that bears a royalty payable to Licensee (a "Covered License") shall be consistent with the terms and conditions of this Agreement and shall include provisions necessary to ensure that Licensor or such Third Party comply with royalty reporting and audit requirements and confidentiality. Any act or omission by such Third Party under a Covered License that would have constituted a breach of this Agreement had it been the act or omission of Licensor shall be deemed to constitute a breach of this Agreement by Licensor. Licensor shall advise Licensee in writing without delay of any breach by such Third Party and Licensor shall exercise without delay its rights with respect to such breach against such Third Party.

13.6 Disposition of Product. Upon termination (but not expiration) of this Agreement with respect to any country, Licensee shall provide Licensor a written inventory of all Product (in the form of raw material, work-in-progress and finished goods) in its and its Sublicensees' possession in such country and shall have the right to dispose of such Product within six (6) months thereafter, subject to fulfillment of the royalty obligations under this Agreement relating thereto.

13.7 Survival of Sublicenses. In the event that this Agreement is terminated by Licensor for any reason, at the request of any Sublicensee, Licensor will grant such Sublicensee a direct license to under the Licensor Know-How and Licensor Patent Rights on substantially the same terms as is set forth in the sublicense agreement between Licensee and such Sublicensee, so that the Sublicensee is put in the same position as it was prior to this Agreement being terminated; provided, however, that (i) Licensor will not have any increased obligations as a result of such direct license to the Sublicensee, (ii) as consideration for such direct license, the Sublicensee will be required to pay Licensor the same amount as Licensor would have received from Licensee (had this Agreement survived) as a result of the sublicense agreement and the Sublicensee's performance thereunder and (iii) any such direct license may be conditioned upon the Sublicensee being in good standing under the terms of the sublicense agreement.

13.8 Restrictions Following Expiration.

13.8.1 On a country-by-country basis, during the Term and continuing until the second (2nd) anniversary of the expiration of a Licensee's obligation to pay royalties to Licensor hereunder in a country in which Licensee has any Product for sale on the date of the expiration of a Licensee's obligation to pay royalties in the Licensee Territory, Licensor and its Affiliates will not, directly or indirectly, (i) sell, distribute or otherwise commercialize any Product in such country or (ii) supply or cause to supply Product to any Third Party for sale or distribution in such country.

13.8.2 Likewise, on a country-by-country basis, during the Term and continuing until the second (2nd) anniversary of the expiration of a Licensor's obligation to pay royalties to Licensee hereunder in a country in which Licensor has any Product for sale on the date of the expiration of a Licensor's obligation to pay royalties in the Licensor Territory, Licensee and its Affiliates will not, directly or indirectly, (i) sell, distribute or otherwise commercialize any Product in such country or (ii) supply or cause to supply Product to any Third Party for sale or distribution in such country.

ARTICLE 14. ASSIGNMENT

This Agreement may not be assigned or otherwise transferred by either party without the written consent of the other party except that either party without such consent may assign this Agreement (in whole or in part) (i) in connection with the transfer or sale of all or substantially all of its business assets to which this Agreement relates to a Third Party, (ii) in the event of its merger or consolidation with another company or (iii) to an Affiliate. Any purported assignment in violation of this clause shall be void. Any permitted assignee shall assume all the obligations of its assignor under this Agreement. No assignment shall relieve either party of its responsibility for the performance of any obligation that such party has accrued hereunder as of the date of assignment.

ARTICLE 15. PATENT MARKINGS

Licensee agrees to mark all Products made, used or sold in the Licensee Territory under the terms of this Agreement, or their containers, in accordance with applicable patent marking laws consistent with its patent marking practices for its other products. Licensor agrees to mark all Products made, used or sold in the Licensor Territory under the terms of this Agreement, or their containers, in accordance with applicable patent marking laws consistent with its patent marking practices for its other products.

ARTICLE 16. REGISTRATION OF LICENSES

Licensee agrees to register or give required notice concerning this Agreement, through itself or through a Sublicensee, in each country where there exists an obligation under law to so register or give notice, to pay all costs and legal fees connected therewith, and to otherwise comply with all national laws applicable to this Agreement. Upon request by Licensee, Licensor agrees to promptly execute any "short form" licenses in a form submitted to it by Licensee in order to effectuate the foregoing registration in each such country.

ARTICLE 17. PATENT TERM EXTENSION

Licensee agrees, as exclusive Licensee, to apply for and to exercise due diligence in obtaining an extension of the term of any patent included within the Licensor Patent Rights under the applicable laws of any country where such extensions are available, including, but not limited to, the Drug Price Competition and Patent Term Restoration Act of 1984 in the United States. Licensor agrees to execute such documents and take such additional actions as Licensee may reasonably request in connection therewith. Each party shall bear its own expenses in connection with the application for patent term extensions.

ARTICLE 18. FORCE MAJEURE

Neither party shall be held liable or responsible to the other party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement, other than an obligation to make a payment, when such failure or delay is caused by or results from fires, floods, embargoes, government regulations, prohibitions or interventions, wars, acts of war, terrorism, insurrections, riots, civil disobedience, strikes, lockouts, acts of God, or any other cause beyond the reasonable control of the affected party.

ARTICLE 19. NEGATION OF AGENCY.

Nothing herein contained shall be deemed to create an agency, joint venture, amalgamation, partnership, or similar relationship between Licensee and Licensor. The relationship between the parties established by this Agreement is that of independent contractors. Neither party shall have the power to bind, obligate, incur any debts or make any commitments for the other party except to the extent, if at all, specifically provided herein.

ARTICLE 20. PUBLICITY

Each party shall give notice to the other party prior to issuing any press release relating to this Agreement within due time to allow for reasonable consideration. The party issuing the press release shall give due consideration and weight to any comments or concerns raised by the other party. Notwithstanding the foregoing, neither party shall issue a press release announcing the execution of this Agreement outside of a joint press release, which will be prepared jointly by the parties.

ARTICLE 21. FILING OF THE AGREEMENT

To the extent, if any, that a party concludes in good faith that it is required to file this Agreement or a notification thereof with any governmental authority, including without limitation the U.S. Securities and Exchange Commission in accordance with applicable laws and regulations, such party may do so, subject to the confidentiality obligations set forth herein, and the other party shall cooperate in such filing or notification and shall execute all documents reasonably required in connection therewith at the, expense of the requesting party. The parties shall promptly inform each other as to the activities or inquiries of any such governmental authority relating to this Agreement, and shall cooperate, in responding to any request for further information therefrom at the expense of the requesting party.

ARTICLE 22. SEVERABILITY

Each party hereby expressly agrees and contracts that it is not the intention of either party to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. If any word, sentence, paragraph, clause or combination thereof in this Agreement is found by a court or executive body with judicial powers having jurisdiction over this Agreement or any of the parties hereto in a final unappealable order to be in violation of any such provisions in any country or community or association of countries, such word, sentence, paragraph, clause or combination thereof shall be inoperative in such country or community or association of countries, and the parties will seek in good faith to amend this Agreement in order to cure such violation; the remainder of this Agreement shall in any event remain binding upon the parties hereto.

ARTICLE 23. NOTICES

Any notices required or permitted to be given hereunder shall be in writing and shall be deemed to have been properly given if delivered in person, or if mailed by registered or certified mail (return receipt requested), postage prepaid, or by telex or facsimile or e-mail promptly confirmed by first class mail, to the addresses given below or such other addresses as may be designated in writing by the parties from time to time during the term of this Agreement. Any notice sent or by telex or facsimile or e-mail shall be effective when sent, and any notice sent by registered or certified mail shall be effective when mailed.

In the case of Licensee:

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142
Attn: 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
Attn: General Counsel
Email: [**]

and

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attn: David M. McIntosh
Email: david.mcintosh@ropesgray.com

In the case of Licensor:

Panion & BF Biotech, Inc.
16F No. 3, Yuanqu Street,
Nangang District,
Taipei, Taiwan, ROC
Attn: Michael Chiang

With a copy to (which will not constitute notice for purposes of this Agreement):

Finnegan, Henderson, Farabow, Garrett & Dunner, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
Attn: Li Feng
Email: Li.Feng@Finnegan.com

ARTICLE 24. GOVERNING LAW

This Agreement shall be governed by and construed in accordance with the laws of the State of New York, exclusive of choice-of-law rules. Any dispute between Licensor and Licensee arising from or relating to this Agreement will be determined exclusively by the United States District Court for the Southern District of New York (and the appellate courts thereof), to whose jurisdiction the parties irrevocably consent; provided, however, if for any reason that Court should lack jurisdiction over any such suit, the same shall be brought exclusively in the New York State Supreme Court, New York County, to whose jurisdiction the parties irrevocably consent. Licensor irrevocably consents that service of process may be effected in connection with any such action by certified mail addressed to its offices at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan and agrees that such service shall constitute good and sufficient service for all purposes; provided, further, that the prevailing party in any such action shall be awarded its reasonable attorneys' and expert fees and expenses incurred in connection with the action.

ARTICLE 25. AFFILIATES

Each party may perform its obligations hereunder personally or through one or more Affiliate and shall be responsible for the performance of such obligations, and any liabilities resulting from such performance. Neither party shall permit any of its Affiliates to commit any act (including any act of omission) that such party is prohibited hereunder from committing directly.

ARTICLE 26. ENTIRE AGREEMENT

This Agreement and the Exhibits hereto which are a part hereof, contain the entire understanding of the parties with respect to the subject matter hereof. All express or implied agreements and understanding, either oral or written, heretofore made are expressly merged in and made a part of this Agreement. The parties hereto may alter any of the provisions of this Agreement, but only by a written instrument duly executed by both parties hereto. This Agreement may be executed in counterparts.

ARTICLE 27. WAIVER

The failure of a party to enforce at any time for any period any of the provisions hereof shall not be construed as a waiver of such provisions or of the right of such party thereafter to enforce each such provision.

ARTICLE 28. 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 captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in location and reading the several Articles and Sections hereof.

IN WITNESS HEREOF, the parties have executed this Agreement through their duly authorized representatives to be effective as of the Second Amendment Effective Date.

AKEBIA THERAPEUTICS, INC.

By: /s/ Jason A. Amello

Name: Jason A. Amello

Title: SVP, Chief Financial Officer

PANION & BF BIOTECH INC.

By: /s/ Michael Chiang

Name: Michael Chiang

Title: Executive President

AKEBIA THERAPEUTICS, INC.

By: /s/ John Butler

Name: John Butler

Title: CEO

PANION & BF BIOTECH INC.

By: _____

Name: _____

Title: _____

Execution Version

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

AMENDED AND RESTATED LICENSE AGREEMENT

BY AND BETWEEN

AKEBIA THERAPEUTICS, INC.

AND

VIFOR (INTERNATIONAL) LTD.

Dated April 8, 2019

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AMENDED AND RESTATED LICENSE AGREEMENT

THIS AMENDED AND RESTATED **LICENSE AGREEMENT** (this "**Amended Agreement**") is made and entered into as of April 8, 2019 (the "**Amendment Execution 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 Vifor (International) Ltd., a corporation established in accordance with Swiss laws and registered in the commercial registry under CH-107.360.718, with its premises at Rechenstrasse 37, 9014 St. Gallen, Switzerland ("**Licensee**").

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, the Licensed Compound, and the Licensed Products in the Territory;

WHEREAS, as of the Amendment Execution Date, the Licensed Product is an investigational agent in Phase 3 clinical trials for the treatment of anemia secondary to chronic kidney disease for which the safety and effectiveness in the Territory has not yet been established, and, as of such date, the Licensed Product has not yet received Regulatory Approval;

WHEREAS, Licensee has commercial capabilities in the Territory, and is interested in obtaining an exclusive license to sell Licensed Products in the Field in the Territory;

WHEREAS, as of the Amendment Execution Date, Vifor Pharma Ltd. (formerly Galenica Ltd), the ultimate parent company of Licensee, and Fresenius Medical Care AG & Co KGaA ("**FMC**"), the parent company of FMCNA, are joint venture partners of Vifor Fresenius Medical Care Renal Pharma Ltd. ("**VFMCRP**"), with Vifor Pharma Ltd. owning a controlling interest of VFMCRP;

WHEREAS, Licensee and its Affiliates (including VFMCRP) are strategic partners of Fresenius Kidney Care Group LLC, a Delaware limited liability company ("**FKC**"), which is an Affiliate of FMCNA, and Licensee, indirectly through VFMCRP, has entered into a supply agreement with FKC and intends to enter into supply agreements with certain approved Third Party Dialysis Organizations;

WHEREAS, pursuant to such supply agreement with FKC, FKC will provide such Licensed Products only to Authorized Dialysis Centers (other than Formulary Clinics owned by Third Party Dialysis Organizations), and pursuant to such supply agreements with Third Party Dialysis Organizations, such Third Party Dialysis Organizations will provide such Licensed Products only to Formulary Clinics owned by such Third Party Dialysis Organizations;

WHEREAS, Akebia and Licensee are parties to that certain License Agreement dated May 12, 2017 (the "**Original Execution Date**", and such agreement, the "**Original Agreement**") pursuant to which Akebia granted Licensee an exclusive license to sell Licensed Products to FKC in the Field in the Territory;

WHEREAS, Akebia and Licensee now desire to amend and restate the Original Agreement by entering into this Amended Agreement (the Original Agreement, as amended by this Amended Agreement, the "**Agreement**"); and

WHEREAS, Licensee acknowledges that Akebia has entered into as of the Amendment Execution Date, and may during the Term enter into, other agreements with Third Parties with respect to the Licensed Products in the Territory, including granting such Third Parties rights and licenses to Promote or otherwise commercialize such Licensed Products in the Territory, and Licensee agrees that this Agreement is subject to and will be consistent with such agreements.

NOW THEREFORE, the Parties agree to amend and restate the Agreement to read in its entirety as follows:

Article 1

DEFINITIONS

1.1 "**Accounting Standards**" means (a) International Financial Reporting Standards, as adopted in Switzerland, (b) U.S. GAAP, or (c) the applicable accounting standards to which the entity making the Net Sales is subject.

1.2 "**Affiliate**" means, with respect to an entity, any corporation, or other business entity controlled by, controlling, or under common control with the first entity, with "control" meaning direct or indirect beneficial ownership of at least 50% of the voting stock of, or at least a 50% interest in the income of, the applicable entity. For clarity, as of the Amendment Execution Date, Licensee is not an Affiliate of FMC, FMCNA or any member of the FMC/TPDO Group.

1.3 "**Agreement**" has the meaning set forth in the Recitals.

1.4 "**Akebia**" has the meaning set forth in the Preamble.

1.5 "**Akebia Indemnitees**" has the meaning set forth in Section 15.2 (Indemnification by Licensee).

1.6 "**Akebia Know-How**" means all Know-How that is both (a) Controlled as of the Original Execution Date or during the Term by Akebia or any of its Affiliates, and (b) is either (i) disclosed to Licensee or any of its Affiliates pursuant to this Agreement, or (ii) reasonably necessary for the sale of a Licensed Product.

1.7 "**Akebia Patents**" means all Patents that both (a) are Controlled as of the Amendment Execution Date or during the Term by Akebia or any of its Affiliates in the Territory; and (b) [**]. All Akebia Patents as of the Amendment Execution Date are, and as of the Effective Date will be, set forth on Schedule 1.7.

1.8 "**Akebia Technology**" means Akebia Know-How and Akebia Patents.

1.9 "**Akebia Trademarks**" means one or more trademarks selected by Akebia or its Affiliates or licensees under which Akebia or its Affiliates or licensees [**], as well as the Akebia company name and logo, and all trademark registrations and applications therefor, and all goodwill associated therewith. All Akebia Trademarks as of the Amendment Execution Date are, and as of the Effective Date will be, set forth on Schedule 1.9.

1.10 "**Amended Agreement**" has the meaning set forth in the Preamble.

1.11 "**Amendment Execution Date**" has the meaning set forth in the Preamble.

1.12 "**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.

1.13 "**Applicable Law**" means any applicable law (including common law), statute, rule, regulation, order, judgment, or ordinance of any Governmental Authority (including the FDA), including those concerning environmental, health, regulatory, privacy, and safety matters.

1.14 "**Authorized Dialysis Center**" means Majority Owned Clinics and Formulary Clinics, and home dialysis programs administered through Majority Owned Clinics or Formulary Clinics.

1.15 "**Breaching Party**" has the meaning set forth in Section 16.2 (Termination for Breach).

1.16 "**Bundle Period**" means the period during which a Licensed Product is reimbursed under the ESRD PPS Bundled Payment System.

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

1.18 "**CMS**" means the Centers for Medicare & Medicaid Services.

1.19 "**Combination Product**" means any Licensed Product that is comprised of two or more APIs, at least one of which is the Licensed Compound.

1.20 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by a Party with respect to any objective under this Agreement, those efforts and resources that a company within the biopharmaceutical industry of comparable size and resources would typically devote to accomplishing such similar objective under similar circumstances, in each case, with respect to Akebia's efforts, taking into account the Relevant Factors in effect at the time such efforts are expended.

1.21 "**Comparative Sales Percentage**" means [**]%; *provided*, *however*, that if the market share of patients potentially receiving treatment [**]% or more (as compared to the percentage market share of patients potentially receiving treatment [**], then the Comparative Sales Percentage shall be equal to [**]. For example, if the market share of patients potentially receiving treatment [**] is [**]%, and subsequently [**] to [**]%, then the new Comparative Sales Percentage would be equal to: [**]%.

1.22 "**Competing Product**" means any product or product candidate that is not a Licensed Product and that (a) [**] and is approved for the DD-CKD Indication or the NDD-CKD Indication, or (b) is based on [**]. For the avoidance of doubt, the Parties acknowledge and agree that [**].

1.23 "**Confidential Information**" means 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 Original Execution Date pursuant to a Confidential Disclosure Agreement between the Parties dated [**], as amended by Amendment No. 1 dated [**]), 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, Patents, 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, 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.

1.25 "**Coordination Committee**" has the meaning set forth in Section 2.1 (Formation and Purpose of the Coordination Committee).

1.26 "**Co-Packaged Product**" means a product that contains a Licensed Product and one or more Other Components and that is either (a) packaged together for sale or shipment as a single unit or sold at a single price, or (b) marketed or sold collectively as a single product.

1.27 "**Cost of Goods Sold**" or "**COGS**" means, with respect to any Licensed Product in [**] (a) for products and services acquired from or performed by Third Parties, the [**] actual amounts [**] such Third Parties to the extent [**]; and (b) to the extent manufacturing services are performed by [**] 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 a Licensed Product [**], calculated in accordance with the Accounting Standards *provided that* for any Licensed Product manufactured by Akebia, [**] will be excluded from the calculation of COGS. In each case ((a) or (b)), COGS includes all [**], Licensed Product testing and yield loss costs, quality control, quality assurance, or other testing of Licensed Products, together with all reasonably allocated indirect costs and overhead applicable to the manufacturing of each Licensed Product, quality control, or technical operations functions, less costs of goods returned in accordance with Akebia's, or its suppliers', return policy.

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

1.29 "**DD-CKD Indication**" means the treatment of anemia in dialysis patients with chronic kidney disease.

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

1.31 "**Effective Date**" has the meaning set forth in Section 3.2.1 (Effectiveness).

1.32 "**Effective Period**" has the meaning set forth in Section 3.2.2 (Suspension).

1.33 "**ESA**" means erythropoiesis stimulating agent.

1.34 "**ESRD**" means end-stage renal disease.

1.35 "**ESRD PPS Bundled Payment System**" means Medicare's ESRD prospective payment system for a single per-treatment bundled payment that is made for the collection of renal dialysis products and services furnished to individuals for the treatment of ESRD in an ESRD facility or in a patient's home, as set forth under 42 U.S.C. § 1395rr, as in effect as of the Amendment Execution Date.

1.36 "**FDA**" means the U.S. Food and Drug Administration or any successor agency thereto.

1.37 "**Field**" means the treatment of FMCNA/TPDO Dialysis Patients solely at Authorized Dialysis Centers with a Licensed Product (a) for which Akebia receives Regulatory Approval in the DD-CKD Indication in the Territory, and (b) that is reimbursed either (i) using the TDAPA, or (ii) under the ESRD PPS Bundled Payment System.

1.38 "**Finished Form**" means a Licensed Product containing the Licensed Compound as its sole API in the [**] form in any dosage strength that receives Regulatory Approval in the Territory in the DD-CKD Indication, with all applicable packaging and labeling.

1.39 "**First Commercial Sale**" means, for each Licensed Product in the Territory, the first sale for end use or consumption to a Third Party of such Licensed Product in the Territory by Licensee or its Affiliates after the granting of Regulatory Approval in the DD-CKD Indication in the Territory for such Licensed Product by the FDA.

1.40 "**FKC**" has the meaning set forth in the Recitals.

1.41 "**Flash Reports**" has the meaning set forth in Section 11.3.1 (Flash Reports).

1.42 "**FMC**" has the meaning set forth in the Recitals.

1.43 "**FMC/TPDO Group**" means FMCNA, FMCNA's Affiliates (including FKC), Majority Owned Clinics, Third Party Dialysis Organizations, and Formulary Clinics.

1.44 "**FMCNA**" or "**Fresenius Medical Care North America**" means Fresenius Medical Care Holdings, Inc., and any successor entity of all or substantially all of Fresenius Medical Care Holdings, Inc.'s dialysis clinic business in the Territory (by operation of law or by sale, merger, restructuring, or other transfer of direct or indirect ownership of dialysis clinics).

1.45 "**FMCNA/TPDO Dialysis Patients**" means those patients who receive treatment with a Licensed Product in the DD-CKD Indication through an Authorized Dialysis Center, and for which one of the following is true: (a) the treatment is reimbursed using the TDAPA or under the ESRD PPS Bundled Payment System, (b) the treatment is reimbursed through any similar state program or commercial insurance plan, in each case, on a bundled payment basis for a defined set of services and medications, or (c) the Parties agree to include such patients as FMCNA/TPDO Dialysis Patients for purposes of this Agreement in accordance with Section 2.3.3 (Specific Responsibilities of the Coordination Committee). For clarity, FMCNA/TPDO Dialysis Patients includes TPDO Dialysis Patients.

1.46 "**Formulary Clinics**" means all dialysis clinics (including home dialysis programs) in the Territory that [**].

1.47 "**Global Phase 3 DD-CKD Program**" means the Phase 3 global clinical studies for the DD-CKD Indication, known informally as the INNO2VATE studies, consisting of a conversion study and a correction study, and known formally as the "Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Maintenance Treatment of Anemia in Subjects with Dialysis-Dependent Chronic Kidney Disease (INNO2VATE – Conversion)" (AKB-6548-CI-0017) and the "Phase 3, Randomized, Open-Label, Active-Controlled Study Evaluating the Efficacy and Safety of Oral Vadadustat for the Correction of Anemia in Subjects with Incident Dialysis-Dependent Chronic Kidney Disease (INNO2VATE – Correction)" (AKB-6548-CI-0016).

1.48 "**Governmental Authority**" means any court, agency, department, authority, or other instrumentality of any national, state, county, city, or other political subdivision.

1.49 "**HIF**" means hypoxia-inducible factor.

1.50 "**Indemnified Party**" has the meaning set forth in Section 15.3 (Indemnification Procedure).

1.51 "**Indemnifying Party**" has the meaning set forth in Section 15.3 (Indemnification Procedure).

1.52 "**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, marketing, pricing, distribution cost and sales data or descriptions.

1.53 "**Knowledge**" means the actual knowledge of each Party's [**], in each case, without any inquiry or investigation.

1.54 "**License**" has the meaning set forth in Section 3.1 (Grant of License to Licensee).

1.55 "**Licensed Compound**" means vadadustat, formerly known as AKB-6548, and any salt or crystal form thereof. Licensed Compound includes any prodrug form of vadadustat.

1.56 "**Licensed Product**" means any pharmaceutical product, drug product, preparation, formulation, or dosage form thereof that has the Licensed Compound as at least one API.

1.57 "**Licensed Product Plan**" has the meaning set forth in Section 4.7 (Licensed Product Plan).

1.58 "**Licensee**" has the meaning set forth in the Preamble.

1.59 "**Licensee Indemnitees**" has the meaning set forth in Section 15.1 (Indemnification by Akebia).

1.60 "**Licensee-FKC Supply Agreement**" has the meaning set forth in Section 5.1 (Licensee-FKC Supply Agreement).

1.61 "**Licensee-TPDO Supply Agreement**" has the meaning set forth in Section 5.3 (Licensee-TPDO Supply Agreements).

1.62 "**Losses**" has the meaning set forth in Section 15.1 (Indemnification by Akebia).

1.63 "**LSP**" has the meaning set forth in Section 5.2.1 (Terms of the Licensee-FKC Supply Agreement).

1.64 "**MACE**" means any major adverse cardiovascular event, specifically, [**].

1.65 "**MACE Endpoint**" means a [**].

1.66 "**Majority Owned Clinics**" means all dialysis clinics and home dialysis programs in the Territory that are Affiliates of FMCNA.

1.67 "**Milestone Payment**" has the meaning set forth in Section 11.2 (Milestone Payment).

1.68 "**NDA**" means a New Drug Application or its equivalent for submission to the FDA.

1.69 "**NDD-CKD Indication**" means the treatment of anemia in non-dialysis patients with chronic kidney disease.

1.70 "**Net Sales**" means the gross amounts invoiced by Licensee or its Affiliates for the sales of a Licensed Product to FKC and all Third Party Dialysis Organizations in the Territory, to the extent recognized and allowed in accordance with the Accounting Standards, as applicable and consistently applied, less the following deductions:

1.70.1 inventory management fees paid to distributors and reasonably allocated to such Licensed Product, not to exceed [**]% of aggregate Net Sales in the applicable period;

1.70.2 tariffs, duties, excises, value added tax, and other sales taxes, and other taxes imposed upon and paid with respect to the sale, transportation, delivery, use, exportation, or importation of such Licensed Product (which taxes do not include income taxes);

1.70.3 amounts actually repaid or credited upon returns, rejections, defects, recalls (due to spoilage, damage, or expiration of useful life), price adjustments, billing errors, or trial prescriptions;

1.70.4 freight, shipping, and insurance expenses specific to such Licensed Product and allocated accordingly;

1.70.5 allowances or credits actually paid or given to customers on account of price reductions affecting such Licensed Product; and

1.70.6 discounts actually paid under state-legislated or Licensee-sponsored discount prescription drug programs or reductions or coupon and voucher programs.

Net Sales will be determined from books and records of Licensee or its applicable Affiliate, maintained in accordance with the Accounting Standards, as consistently applied, with respect to sales of any Licensed Product.

The sale of Licensed Products among Licensee or Licensee's Affiliates that are [**], but in such cases Net Sales will [**] of such Licensed Products to a person or entity who is not an Affiliate.

Net Sales will not include Licensed Products transferred for use in connection with promotional use (including samples).

If Licensee or any of its Affiliates receives [**] for a Licensed Product, then the Net Sales amount for such Licensed Product will be [**].

In the event that a Licensed Product is sold as part of a Combination Product or a Co-Packaged Product, the Net Sales from the Combination Product or Co-Packaged Product, for the purposes of determining payments hereunder based on Net Sales, will be determined by multiplying the Net Sales of the Combination Product or Co-Packaged Product (as applicable), during the applicable reporting period, by the fraction, A/(A+B), where A is the average sale price of a Licensed Product when sold separately in Finished Form and B is either (a) the average sale price of the other APIs included in the Combination

Product when sold separately in finished form (in the case of a Combination Product), or (b) the average sale price of the Other Components included in the Co-Packaged Product when sold separately (in the case of a Co-Packaged Product), in each case, during the applicable reporting period or, if sales of both such Licensed Product and the other APIs did not occur in such period, then in the most recent reporting period in which sales of both occurred. In the event that such average sale price cannot be determined for both a Licensed Product and all other APIs included in such Combination Product or all Other Components included in such Co-Packaged Product (as applicable), then Net Sales for the purposes of determining payments to Akebia hereunder will be calculated by multiplying the Net Sales of the Combination Product or Co-Packaged Product (as applicable) during the applicable reporting period by the fraction of C/(C+D) where C is the fair market value of a Licensed Product and D is either (i) the fair market value of all other APIs included in the Combination Product (in the case of a Combination Product), or (ii) the average sales price of the Other Components included in such Co-Packaged Product when sold separately (in the case of a Co-Packaged Product). In such event, Licensee will in good faith make a determination of the respective fair market values of such Licensed Product and all other APIs or Other Components, as applicable, included in the Combination Product or Co-Packaged Product (as applicable).

If a Licensed Product is sold as part of a Co-Packaged Product, then Licensee or its applicable Affiliate [**].

1.71 "**Non-Breaching Party**" has the meaning set forth in Section 16.2 (Termination for Breach).

1.72 "**Original Agreement**" has the meaning set forth in the Recitals.

1.73 "**Original Execution Date**" has the meaning set forth in the Recitals.

1.74 "**Other Component**" means one or more other devices or components.

1.75 "**Party**" and collectively "**Parties**" has the meaning set forth in the Preamble.

1.76 "**Patents**" means (a) all patents and patent applications in any country or jurisdiction in the Territory, and (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates, and the like.

1.77 "**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 a Licensed Product.

1.78 "**Profit**" means, with respect to a Licensed Product in the Territory, the Net Sales or other revenue received in the Territory for such Licensed Product in a given period *minus* (a) the Supply Price paid by Licensee for such Licensed Product, *minus* (b) an amount equal to [**], and *minus* (c) [**].

1.79 "**Promote**," "**Promotion**," or "**Promoting**" means to market, detail, advertise, or otherwise promote a Licensed Product, but does not include the sale of such Licensed Product.

1.80 "**Quarterly Report**" has the meaning set forth in Section 11.3.2 (Quarterly Reports).

1.81 "**Recipient**" has the meaning set forth in Section 14.2 (Exceptions).

1.82 "**Regulatory Approval**" means any NDA approval by the FDA.

1.83 "**Regulatory Filings**" means all applications, filings, dossiers, and other documents submitted to the FDA in support of research or development of the Licensed Compound and the Licensed Products, including for the purpose of obtaining Regulatory Approval from the FDA. Regulatory Filings will include all INDs and NDAs.

1.84 "**Relevant Factors**" means the following factors that may affect the research, development, Regulatory Approval, manufacturing, or commercialization of a Licensed Product (without taking into account any other product or products that Akebia or its Affiliates may be developing, manufacturing, or commercializing): actual issues of safety, efficacy, or stability; product profile (including product modality, category and mechanism of action); stage of development or life cycle status; actual and projected research, development, Regulatory Approval, manufacturing, and commercialization costs; issues regarding the ability to manufacture or have manufactured any Licensed Product; the likelihood of obtaining Regulatory Approvals for any Licensed Product in the Territory and the timing of such Regulatory Approvals; the labeling and anticipated labeling of such Licensed Product; past performance of such Licensed Product or similar products; present and future market potential of such Licensed Product; existing or projected pricing, sales, reimbursement, and profitability of such Licensed Product; pricing or reimbursement changes in relevant countries in the Territory; and proprietary position, strength, and duration of patent protection and anticipated exclusivity of such Licensed Product; and other relevant scientific, technical, operational, and commercial factors.

1.85 "**Safety Data**" has the meaning set forth in Section 12.2 (Adverse Drug Events).

1.86 "**Sale Transaction**" has the meaning set forth in Section 18.2 (Standstill).

1.87 "**Statistically Significant**" means a p-value less than [**].

1.88 "**Supply Agreement**" has the meaning set forth in Section 10.2 (Commercial Supply Agreement).

1.89 "**Supply Price**" has the meaning set forth in Section 10.2 (Commercial Supply Agreement).

1.90 "**Suspension Period**" has the meaning set forth in Section 3.2.2 (Suspension).

1.91 "**TDAPA**" means Medicare's transitional drug add-on payment adjustment as defined under 42 CFR § 413.234(c) and as amended in the Federal Register / Vol. 83, No. 220 / November 14, 2018 and in effect as of the Amendment Execution Date.

1.92 "**TDAPA Period**" means the period of time during which a Licensed Product is reimbursed using the TDAPA.

1.93 "**Term**" has the meaning set forth in Section 16.1 (Term).

1.94 "**Territory**" means the United States of America and its possessions, including Puerto Rico.

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

1.96 "**Third Party Dialysis Organization**" (or "**TPDO**") means a Third Party identified on Schedule 5.5 that owns Formulary Clinics, has been approved by Akebia in accordance with Section 5.5.1 (FMC/TPDO Group; Addition of Third Party Dialysis Organizations), and has entered into a Licensee-TPDO Supply Agreement meeting the requirements set forth in Section 5.3 (Licensee-TPDO Supply Agreements).

1.97 "**TPDO Dialysis Patient**" means those FMCNA/TPDO Dialysis Patients who receive treatment through a Formulary Clinic owned by a Third Party Dialysis Organization.

1.98 "**U.S.**" means the United States of America and its territories and possessions, including Puerto Rico.

1.99 "**Valid Claim**" means (a) a claim in any issued and unexpired Akebia Patent in the Territory, which claim has not been held invalid or unenforceable by a non-appealed or un-appealable decision of a court or Governmental Authority or other appropriate body of competent jurisdiction and has not been admitted invalid or unenforceable through reissue, reexamination, or disclaimer, or has not been made unenforceable due to failure to pay maintenance fees; or (b) a claim in any pending Akebia Patent in the Territory that has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application; *provided that* such claim has not been pending more than seven years from the priority date of such application (but if such pending claim with a pendency of seven years or longer subsequently issues it will be considered a Valid Claim upon issuance). "Valid Claim" does not include any claim in any issued and unexpired Akebia Patent in the Territory Covering an alternative manufacturing process to produce the Licensed Compound or a Licensed Product, including its components (*i.e.*, a manufacturing process other than the manufacturing process used to produce the Licensed Compound or a Licensed Product as of the Effective Date).

1.100 "**VFMCRP**" has the meaning set forth in the Recitals.

Article 2

GOVERNANCE

2.1. **Formation and Purpose of Coordination Committee**. Licensee and Akebia will establish the coordination committee ("**Coordination Committee**"), which committee will coordinate and oversee the Parties' activities hereunder and have the additional responsibilities provided for herein. The Coordination Committee will dissolve upon the expiration of the Term. Each Party will designate up to three representatives with appropriate knowledge and expertise to serve as members of the Coordination Committee. Each Party may replace its Coordination Committee representatives at any time upon written notice to the other Party.

2.2. **Meetings**. The Coordination Committee will hold meetings at such times as it elects to do so, but in no event will such meetings be held less frequently than [**] per calendar year, and such meetings may be held by audio or video teleconference. Other employees of each Party involved in activities under this Agreement may attend meetings of the Coordination Committee as participants, and, with the consent of each Party, consultants, representatives, or advisors involved in the same activities may attend meetings of the Coordination Committee as observers; *provided*, *however*, that such Third Party participants and observers are under legally binding obligations of confidentiality and non-use applicable to the Confidential Information of each Party that are at least as stringent as those set forth in Article 14 (Confidentiality).

2.3. **Specific Responsibilities of the Coordination Committee**. The Coordination Committee will:

2.3.1 coordinate the activities of the Parties hereunder;

2.3.2 [**] a Party's indication of interest in having [**], as described in [**];

2.3.3 [**] whether to add or remove any patient populations from the definition of FMCNA/TPDO Dialysis Patients, as described in Section 4.5 (FMCNA/TPDO Dialysis Patients);

2.3.4 [**] whether to add or remove any Authorized Dialysis Centers from Schedule 5.5;

2.3.5 [**] any required revisions to this Agreement in response to any reimbursement system change, as described under Section 4.6 (Reimbursement System Changes);

2.3.6 [**] Akebia's initial Licensed Product Plan or any amendment or update thereto, or any matter related to the Licensed Product Plan referred to the Coordination Committee by either Party, as described under Section 4.7 (Licensed Product Plan);

2.3.7 [**] supply of the Licensed Products in the Territory;

2.3.8 perform such other functions as appropriate to further the purposes of this Agreement as determined by the Parties;

2.3.9 receive at least on a [**] basis updates regarding Akebia's [**] of all Licensed Products for the DD-CKD Indication that are [**] as defined in this Agreement [**] in the Territory; and

2.3.10 [**] any adjustment to the Comparative Sales Percentage following a [**] in the market share of patients potentially receiving treatment [**].

Article 3

LICENSE GRANT

3.1. **Grant of License to Licensee**. Subject to the terms and conditions of this Agreement (including Section 3.2 (Effectiveness and Suspension), Section 3.3 (No Implied Rights), and Section 7.1 (Akebia Restrictions)), Akebia hereby grants to Licensee an exclusive (even as to Akebia), non-sublicensable, non-transferrable, license under the Akebia Technology to sell the Licensed Products solely to FKC and Third Party Dialysis Organizations in the Territory in the Field during the Term, subject to the limitations set forth in Section 3.2 (Effectiveness and Suspension) (the "**License**").

3.2. **Effectiveness and Suspension**.

3.2.1 **Effectiveness**. The License granted in Section 3.1 (Grant of License to Licensee) will only become effective and exercisable by Licensee if and when (a) the FDA has granted Regulatory Approval for a Licensed Product in the DD-CKD Indication in the Territory, (b) upon the earlier of a determination by CMS that such Licensed Product is either (i) to be reimbursed using the TDAPA or (ii) included as part of the ESRD PPS Bundled Payment System, and (c) Licensee has paid to Akebia the Milestone Payment in accordance with Section 11.2 (Milestone Payment) (the date on which (a), (b), and (c) have occurred, the "**Effective Date**"). Furthermore, such License will become effective with respect to each particular Third Party Dialysis Organization if, as of the Effective Date, Licensee has entered into, or thereafter upon Licensee entering into, a Licensee-TPDO Supply Agreement with such Third Party Dialysis Organization in accordance with Section 5.5.1 (FMC/TPDO Group; Addition of Third Party Dialysis Organizations).

3.2.2 **Suspension**. Following the Effective Date, the License granted in Section 3.1 (Grant of License to Licensee), will remain in effect and exercisable by Licensee (a) during the TDAPA Period and (b) during the Bundle Period, in each case ((a) and (b)), except during any period during which the License is suspended pursuant to Section 4.6 (Reimbursement System Changes), Section 4.7 (Licensed Product Plan), Section 16.7 (Termination or Suspension for Impacts on Pricing), or Section 16.8.3 (Suspension Based on Comparative Sales Levels) (the "**Effective Period**"). During any period after the Effective Date during the Term that is not an Effective Period (a "**Suspension Period**"), the provisions set forth in Section 16.14 (Suspension of Licensed Rights) shall apply.

3.3. **No Implied Rights**. Licensee will not practice the Akebia Technology or exploit the Licensed Compound or any Licensed Product other than as expressly licensed and permitted under this Agreement. Nothing in this Agreement will be interpreted to grant Licensee or any of its Affiliates any rights under any intellectual property rights owned or Controlled by Akebia or its Affiliates (including Akebia Technology) that are not expressly granted herein, whether by implication, estoppel, or otherwise. Any rights not expressly granted to Licensee by Akebia under this Agreement are hereby retained by Akebia. Without limiting the generality of the foregoing, Akebia retains the exclusive right to sell Licensed Products to any Third Party outside of the Field.

Article 4

SALES OF LICENSED PRODUCTS

4.1. **No Unauthorized Sales**. Licensee will not import, offer for sale, sell, or distribute the Licensed Compound or any Licensed Product (a) other than as expressly set forth in this Agreement in the Field in the Territory, (b) outside of the Territory, or (c) to any person or entity who uses or who Licensee reasonably expects will use such Licensed Product outside of the Field in the Territory. Licensee will promptly report to Akebia any unauthorized use, distribution, or transfer of the Licensed Compound or any Licensed Product in the Territory by or on behalf of Licensee or its Affiliates, FKC, the LSP, the Third Party Dialysis Organizations or any Authorized Dialysis Center. Licensee will use Commercially Reasonable Efforts to stop any such unauthorized use, distribution, or transfer of such Licensed Compound or Licensed Product. In addition, if there is any unauthorized use, distribution, or transfer of any Licensed Product by FKC, the LSP, the Third Party Dialysis Organizations or any Authorized Dialysis Center or any of their Affiliates to or by a Third Party that is not an FMCNA/TPDO Dialysis Patient or Authorized Dialysis Center, then, if Licensee does not cause such unauthorized use, distribution, or transfer to cease or terminate the rights of FKC or the offending LSP, Third Party Dialysis Organization, Authorized Dialysis Center or any of their Affiliates, in each case, within [**] of the date on which Licensee knows or should have known about such unauthorized use, distribution, or transfer, then the Parties will discuss in good faith an agreeable resolution for a period of [**]. If the Parties do not reach such a resolution during such [**] period, then Akebia may terminate this Agreement pursuant to Section 16.4 (Termination by Akebia for Unauthorized Sales).

4.2. **Codes, Marks, and Packaging**. Unless otherwise agreed by the Parties, the Licensed Products sold by Licensee to FKC and Third Party Dialysis Organizations under this Agreement will not be resold or distributed under a different labeler code, product code, trade name, trademark, or packaging than units sold by Akebia outside of this Agreement or supplied by Akebia under this Agreement. Licensee will not change any such code, trade name, trademark, or packaging of any Licensed Product supplied to it under the Supply Agreement and will not affix any label or sticker on any Licensed Product without Akebia's prior written consent.

4.3. **Promotion and Detailing**. Akebia retains for itself and on behalf of its Affiliates and licensees (other than Licensee) the sole right to Promote the Licensed Products, and Licensee and its Affiliates will not, and Licensee will ensure that the entities in the FMC/TPDO Group do not, Promote any Licensed Product. If either Party desires [**], then such Party will provide such [**] to the other Party in writing as soon as possible after [**] for a Licensed Product in the DD-CKD Indication in the Territory, and the Parties will [**] such [**] in the Territory through the Coordination Committee pursuant to Section 2.3.2 (Specific Responsibilities of the Coordination Committee). In any event, Licensee will provide written notification to Akebia of [**] no later than [**] after (a) the [**] in the DD-CKD Indication in the Territory, and (b) [**] (i) [**] the TDAPA or (ii) [**] the ESRD PPS Bundled Payment System, and following such notice the Parties will [**]. Nothing in this Agreement will prohibit FKC or any entity in the FMC/TPDO Group from including references to any Licensed Product or otherwise engaging in customary and routine clinical communications with their respective patient care staff regarding any Licensed Product or dosing regimens that include any Licensed Product. Licensee and its Affiliates will only use Product Materials that are prepared by Akebia, or otherwise approved in advance in writing by Akebia, in each case, in connection with its sale of such Licensed Products under this Agreement or any [**] that may be [**] in accordance with this Section 4.3 (Promotion and Detailing). In addition, Licensee will ensure that the entities in the FMC/TPDO Group only use Product Materials that are consistent with those Product Materials prepared and provided by Akebia. For the avoidance of doubt, unless otherwise agreed in writing by the Parties pursuant to this Section 4.3 (Promotion and Detailing), nothing in this Agreement will prevent Akebia or its Affiliates or licensees (other than Licensee) from Promoting any Licensed Product at any Authorized Dialysis Center.

4.4. **Use by the FMC/TPDO Group**.

4.4.1 **Medicaid or 340B Programs**. Licensee will, will cause its Affiliates to, and will require the FMC/TPDO Group to, use and sell (as applicable) each Licensed Product solely in the Field in the Territory. To the fullest extent permitted by Applicable Law, Licensee will not, and will not knowingly permit its Affiliates, or the FMC/TPDO Group to, use or sell (as applicable) any Licensed Product in any manner that [**]. In addition, to the fullest extent permitted by Applicable Law, in a written agreement with each of its Affiliates, or the FMC/TPDO Group, Licensee will cause and require such Affiliates, or members of the FMC/TPDO Group not to use or sell (as applicable) any Licensed Product in any manner that [**]. Licensee will provide prompt written notice to Akebia if Licensee or any of its Affiliates, or member of the FMC/TPDO Group uses or sells, or plans to use or sell, in each case, any Licensed Product in any manner that [**].

4.4.2 **Licensed Product Prices**. To the fullest extent permitted by Applicable Law, Licensee will not, and will not knowingly permit its Affiliates, or the FMC/TPDO Group to, use or sell (as applicable) any Licensed Product in any manner that would result in [**]. In addition, to the fullest extent permitted by Applicable Law, in a written agreement with each of its Affiliates, or any member of the FMC/TPDO Group that receives any Licensed Product, Licensee will cause and require such Affiliates, or member of the FMC/TPDO Group not to use or sell (as applicable) such Licensed Product in any manner that would result in [**].

4.5. **FMCNA/TPDO Dialysis Patients**. Without limiting the generality of Section 6.2 (Intention Regarding Impacts on Pricing), it is the intention of the Parties that no patient will receive any Licensed Product supplied under this Agreement if the supply of such Licensed Product to such patient [**]. The Coordination Committee will [**] of any patient populations from the definition of FMCNA/TPDO Dialysis Patients, and following such recommendation by the Coordination Committee the Parties may agree in writing whether to [**] (as applicable) such patient populations in or from the definition of FMCNA/TPDO Dialysis Patients; *provided that* no patient will be included in the definition of FMCNA/TPDO Dialysis Patient if the supply of such Licensed Product to such patient would violate the intention statement set forth in the first sentence of Section 4.5 (FMCNA/TPDO Dialysis Patients), and any such patient will be removed from such definition.

4.6. **Reimbursement System Changes**. In the event of a proposed rule change to the TDAPA or the ESRD PPS Bundled Payment System, the Coordination Committee will [**] revisions to this Agreement, if any, in response to such proposed rule change. Following such [**] by the Coordination Committee, the Parties may [**] for the purpose of entering into a written amendment to this Agreement or such other changes to this Agreement as the Parties may agree. If such proposed rule change is not [**] to the TDAPA or the ESRD PPS Bundled Payment System and the Parties fail to enter into such a written amendment within [**] of issuance of the proposed rule change (unless the Parties agree in writing that no amendment is necessary), (a) if the License is not then in effect, then the License will not go into effect under Section 3.2.1 (Effectiveness) (and the Effective Date will not occur) until the Parties enter into such an amendment, or (b) if the License is then in effect, then Akebia may elect to suspend the License and commence a Suspension Period under Section 3.2.2 (Suspension), which Suspension Period will continue until the Parties enter into such an amendment.

4.7. **Licensed Product Plan**. [**], Akebia will prepare and submit to the Coordination Committee for its [**], pursuant to Section 2.3.6 (Specific Responsibilities of the Coordination Committee), a plan setting forth [**] (the "**Licensed Product Plan**"). The Licensed Product Plan may include information relating to [**]. In any event, the Licensed Product Plan must be [**]. Prior to the Effective Date, the Parties, working through the Coordination Committee, will [**] the Licensed Product Plan, and Akebia will [**] into a revised Licensed Product Plan. [**]. After the Effective Date, Akebia may prepare and submit to the Coordination Committee for its [**] amendments to the Licensed Product Plan on an as-needed basis, for example [**]. The Parties, working through the Coordination Committee, will [**] such amendments, and Akebia will give due consideration to and use good faith efforts to incorporate any reasonable recommendations of Licensee into such amendments. After the Effective Date, if Licensee does not implement the Licensed Product Plan meeting the requirements of this Section 4.7 (Licensed Product Plan), and any amendments thereto, then Akebia may elect to suspend the License and commence a Suspension Period under Section 3.2.2 (Suspension).

Article 5

SUPPLY AGREEMENTS

5.1. **Licensee-FKC Supply Agreement**. Licensee has entered into a supply agreement with its Affiliate VFMCRP dated as of December 18, 2018, and in turn VFMCRP has entered into an identical supply agreement with FKC with an effective date of December 18, 2018, pursuant to which, after the Effective Date, Licensed Products will be sold by Licensee to VFMCRP and from VFMCRP to FKC in an arms-length transaction for use in Authorized Dialysis Centers, other than those Formulary Clinics owned by Third Party Dialysis Organizations (together, the "**Licensee-FKC Supply Agreement**"), and only pursuant to such agreements.

5.1.1 **Initial Supply Agreements**. Licensee represents and warrants that the Licensee-FKC Supply Agreement satisfies the requirements of Section 5.2 (Terms of the Licensee-FKC Supply Agreement), and does not include any terms related to [**] of any Licensed Product. If the Licensee-FKC Supply Agreement is terminated or expires, then Akebia may terminate this Agreement pursuant to Section 16.6 (Termination by Akebia for Failure to Amend the Licensee-FKC Supply Agreement).

5.1.2 **Amendment to Supply Agreement**. No later than [**] after (a) the FDA has granted Regulatory Approval for a Licensed Product in the DD-CKD Indication in the Territory, and (b) the earlier of a determination by CMS that such Licensed Product (i) is to be reimbursed using the TDAPA or (ii) is included as part of the ESRD PPS Bundled Payment System, Licensee and FKC will amend the Licensee-FKC Supply Agreement to finalize such agreement in order to satisfy all requirements of Section 5.2 (Terms of the Licensee-FKC Supply Agreement). If Licensee and FKC do not enter into an amendment of such Licensee-FKC Supply Agreement during such [**] period, then Akebia may terminate this Agreement pursuant to Section 16.6 (Termination by Akebia for Failure to Amend the Licensee-FKC Supply Agreement**)**. Licensee will provide notice to Akebia that the amendments described herein have been executed and delivered by the parties thereto no later than [**] after entering into such amendments.

5.2. **Terms of the Licensee-FKC Supply Agreement**. Licensee will ensure that the Licensee-FKC Supply Agreement:

5.2.1 requires that FKC either (a) use [**] logistic service providers (each, an "**LSP**") to provide the Licensed Products solely to the Authorized Dialysis Centers (other than those Formulary Clinics owned by Third Party Dialysis Organizations), in which arrangement LSP will not own or take title to any Licensed Product, or (b) itself directly provide such Licensed Products solely to Authorized Dialysis Centers other than those Formulary Clinics owned by Third Party Dialysis Organizations;

5.2.2 prohibits FKC from distributing or transferring Licensed Products to any person or entity other than (a) the LSPs or (b) Authorized Dialysis Centers that are not Formulary Clinics owned by Third Party Dialysis Organizations;

5.2.3 requires that FKC report any unauthorized use, distribution, or transfer of any Licensed Product promptly to Licensee;

5.2.4 names Akebia as an intended third party beneficiary of such Licensee-FKC Supply Agreement with respect to relevant and appropriate provisions of such agreement;

5.2.5 (a) prohibits FKC and FMCNA, FMCNA's Affiliates (including FKC), or Majority Owned Clinics from [**], except as required by Applicable Law), and (b) [**];

5.2.6 requires FKC to cause each Authorized Dialysis Center to (a) not distribute or transfer any Licensed Product to any person or entity other than an FMCNA/TPDO Dialysis Patient or another Authorized Dialysis Center, (b) use each Licensed Product, and implement reasonable measures to ensure that each Licensed Product is used, only for (i) the treatment of FMCNA/TPDO Dialysis Patients in the DD-CKD Indication, and (ii) delivering clinical treatment consistent with the requirements of Section 4.4 (Use by the FMC/TPDO Group) and to FMCNA/TPDO Dialysis Patients; (c) report any unauthorized use, distribution, or transfer of any Licensed Product promptly to Licensee; and (d) [**], except as required by Applicable Law and to promptly inform Licensee, FKC, and Akebia if the Authorized Dialysis Center believes that it is required by Applicable Law [**]; and

5.2.7 contains such additional provisions as may be necessary to ensure Licensee's compliance with the terms set forth in this Agreement.

5.3. **Licensee-TPDO Supply Agreements**. Licensee will enter into supply agreements with each Third Party Dialysis Organization pursuant to which, after the Effective Date, Licensee will sell Licensed Products to such Third Party Dialysis Organizations in arms-length transactions for use in Formulary Clinics owned by such Third Party Dialysis Organizations (each such supply agreement, a "**Licensee-TPDO Supply Agreement**"), and only pursuant to such agreement. Licensee will ensure that each Licensee-TPDO Supply Agreement with each Third Party Dialysis Organization:

5.3.1 requires that the Third Party Dialysis Organization itself directly provide Licensed Products solely to Formulary Clinics owned by such Third Party Dialysis Organization that have been approved by Akebia as provided in Section 5.5 (FMC/TPDO Group);

5.3.2 prohibits the Third Party Dialysis Organization from distributing or transferring Licensed Products to any person or entity other than Formulary Clinics owned by such Third Party Dialysis Organization and approved by Akebia as provided in Section 5.5 (FMC/TPDO Group);

5.3.3 requires that the Third Party Dialysis Organization report any unauthorized use, distribution, or transfer of any Licensed Product promptly to Licensee;

5.3.4 names Akebia as an intended third party beneficiary of such Licensee-TPDO Supply Agreement with respect to relevant and appropriate provisions of such agreement;

5.3.5 (a) prohibits the Third Party Dialysis Organization and its Formulary Clinics from [**], except as required by Applicable Law, and (b) [**];

5.3.6 requires the Third Party Dialysis Organization to (a) not distribute or transfer any Licensed Product to any person or entity other than a TPDO Dialysis Patient or a Formulary Clinic owned by such Third Party Dialysis Organization, (b) use each Licensed Product, and implement reasonable measures to ensure that each Licensed Product is used, only for (i) the treatment of TPDO Dialysis Patients in the DD-CKD Indication, and (ii) delivering clinical treatment consistent with the requirements of Section 4.4 (Use by the FMC/TPDO Group); (c) report any unauthorized use, distribution, or transfer of any Licensed Product promptly to Licensee; and (d) [**], except as required by Applicable Law and to promptly inform Licensee, the Third Party Dialysis Organization, and Akebia if such Third Party Dialysis Organization or any of its Formulary Clinics believes that it is required by Applicable Law [**];

5.3.7 permits Licensee to terminate such Licensee-TPDO Supply Agreement as contemplated by Section 16.8.2 (Termination of Third Party Dialysis Organizations);

5.3.8 permits Akebia to take assignment of such Licensee-TPDO Supply Agreement in the event this Agreement is terminated pursuant to Section 16.8.1 (Termination Based on Aggregate Sales Levels) or Section 16.8.4 (Termination Based on Comparative Sales Levels); and

5.3.9 contains such additional provisions as may be necessary to ensure Licensee's compliance with the terms set forth in this Agreement.

5.4. **Akebia's Right to Review Agreements**. Upon request, Licensee further agrees to permit an independent auditor or law firm selected by Akebia and approved by Licensee, which approval will not be unreasonably withheld or delayed, to examine the Licensee-FKC Supply Agreement and each Licensee-TPDO Supply Agreement, or other agreements between Licensee and FKC, or any member of the FMC/TPDO Group, regarding a Licensed Product, in each case, solely to ensure that such agreements are consistent with the terms set forth in this Agreement. Such auditor or law firm will be bound by a legal agreement obligating it to maintain the confidentiality of such information and not to share such information with Akebia or any other person. Such auditor or law firm will summarize its findings solely by stating whether or not such agreements are consistent with Licensee's obligations hereunder, and if such agreements are inconsistent with Licensee's obligations, identify such inconsistencies to Akebia. Such examination will not be performed more than once per calendar year. Akebia will be responsible for the expenses incurred in connection with such examination, except in the event that the results of any examination reveal that such agreements are materially inconsistent with the terms set forth in this Agreement, in which case reasonable fees for such examination will be paid by Licensee.

5.5. **FMC/TPDO Group**.

5.5.1 **FMC/TPDO Group; Addition of Third Party Dialysis Organizations**. As of the Amendment Execution Date, listed on Schedule 5.5 are all of the Authorized Dialysis Centers (including each Formulary Clinic and Majority Owned Clinic, which are each separately identified on Schedule 5.5) and each Third Party Dialysis Organization and each Formulary Clinic owned by each such Third Party Dialysis Organization. Licensee will provide to the Coordination Committee an updated Schedule 5.5 [**], and on the Effective Date; *provided that*, [**], Licensee will promptly provide to the Coordination Committee an updated Schedule 5.5 that includes, under the heading 'Formulary Clinics,' each Third Party Dialysis Organization [**] and such Third Party Dialysis Organization's Formulary Clinics; and *provided further* that the License granted in Section 3.1 (Grant of License to Licensee) will only become effective and exercisable by Licensee with respect to a Third Party Dialysis Organization and its Formulary Clinics, and such Third Party Dialysis Organization and its Formulary Clinics will only be considered Authorized Dialysis Centers for the purposes of this Agreement when Licensee has entered into a supply agreement with such Third Party Dialysis Organization that contains the supply agreement terms set forth in Section 5.3 (Licensee-TPDO Supply Agreements) and only for so long as such Licensee-TPDO Supply Agreement remains in effect. Licensee will cause each Third Party Dialysis Organization to adhere to the obligations set forth in Article 4 (Sales of Licensed Products).

5.5.2 **Schedule 5.5**. [**] the Third Party Dialysis Organizations and their Formulary Clinics set forth on Schedule 5.5 hereto as of the Amendment Execution Date. Licensee represents and warrants that attached hereto as Schedule 5.5 is an updated version of Schedule 5.5 that is accurate and complete as of the Amendment Execution Date.

Article 6

PRICING AND PRICE REPORTING

6.1. **Pricing**. Other than with respect to the FMC/TPDO Group's customary dialysis clinic cost reporting to CMS and any other Governmental Authority, Licensee will not, will cause its Affiliates not to, and will require the FMC/TPDO Group not to, disclose [**], and in each case, such information will be Confidential Information subject to the terms of Article 14 (Confidentiality).

6.2. **Intention Regarding Impacts on Pricing**. Akebia intends, and enters into this Agreement in reliance upon, the Agreement and the supply of Licensed Product by Akebia to Licensee under the Supply Agreement not giving rise to, or otherwise affecting, [**].

6.3. **Impacts on Pricing**. If, at any time, (a) there has been a breach of Section 6.1 (Pricing), (b) through the actions by or on behalf of Licensee or any of its Affiliates, or members of the FMC/TPDO Group [**], and even if such actions do not constitute a breach by Licensee under Section 4.4.2 (Licensed Product Prices)), [**], or (c) [**], then, in each case, without limiting Akebia's other rights and remedies under this Agreement, the Parties will [**] an agreeable resolution for a period of [**]. If the Parties do not reach such a resolution during such [**] period, then Akebia may suspend the License or terminate this Agreement pursuant to Section 16.7 (Termination or Suspension by Akebia for Impacts on Pricing).

Article 7

EXCLUSIVITY

7.1. **Akebia Restrictions**. During the Effective Period, Akebia will not, and will cause its Affiliates and licensees to not, sell any Licensed Product directly to any member of the FMC/TPDO Group for any use in the Field in the Territory; *provided*, *however*, that Akebia will not be required to prohibit any Third Party wholesaler or distributor from selling any Licensed Product to the FMC/TPDO Group.

7.2. **Licensee Restrictions**. Without the prior written consent of Akebia, neither Licensee nor any of its Affiliates will directly or indirectly Promote, sell, or have sold, or enter into any agreement to Promote, sell, or have sold, any Competing Product in the Territory to FKC, any entity in or member of the FMC/TPDO Group, or any Authorized Dialysis Center. Notwithstanding the foregoing, if [**].

Article 8

REGULATORY

Akebia will use Commercially Reasonable Efforts to (a) prepare the NDA in the Territory for each Licensed Product based on its global development plan for such Licensed Product, and (b) obtain and maintain Regulatory Approval in the DD-CKD Indication in the Territory for each Licensed Product. Akebia will be responsible for preparing, filing, and submitting, directly or through its Affiliates or licensees, all Regulatory Filings and correspondence with the applicable regulatory authorities for each Licensed Product at its sole cost and expense.

Article 9

TRADEMARKS; NAMES

9.1. **Trademark Responsibility**. Akebia will be responsible for (a) registering, prosecuting, maintaining, and enforcing the Akebia Trademarks in the Territory, (b) preparing any guidelines applicable to the use of the Akebia Trademarks, and (c) investigating and defending any infringement or threatened infringement relating to any of the foregoing, in each case, at its sole cost and expense. Licensee will cooperate and assist Akebia with any of the foregoing activities with respect to all Akebia Trademarks, including, if requested by Akebia, providing any specifications, affidavits, declarations, or other documents necessary for Akebia to submit to appropriate Governmental Authorities in order to register and prosecute the Akebia Trademarks. Akebia will own and be responsible for securing any domain names associated with the Akebia Trademarks, and will be responsible for the costs associated with protecting such domain names. Neither Licensee nor any of its Affiliates will obtain or hold any such domain name in its own name.

9.2. **Trademark License**. Subject to the terms and conditions of this Agreement, effective as of the Effective Date, Akebia hereby grants and will grant to Licensee and its Affiliates a non-exclusive non-sublicensable, non-transferrable, royalty-free license to use the Akebia Trademarks solely in connection with the sale, and, [**], of the Licensed Products in the Field in the Territory in accordance with this Agreement. Licensee will maintain the quality of the Licensed Products in accordance with this Agreement and the Supply Agreement. Licensee additionally will assure at all times that the Licensed Products are sold in accordance with Applicable Law.

9.3. **Trademark Ownership and Cooperation**. Each Party acknowledges that Akebia has sole and exclusive ownership of all rights, title, and interests in and to the Akebia Trademarks. Licensee will not, and will cause its Affiliates and the entities in the FMC/TPDO Group not to, register in their own name any trademark, corporate name, domain name, social media account, or other source identifier containing any trademark owned by Akebia or any word or mark that is confusingly similar to any such trademark. All use of any Akebia Trademark and all goodwill and benefit arising from such use will inure to the sole and exclusive benefit of Akebia. Licensee will place and display the Akebia Trademarks on and in connection with the Licensed Products only in such form and manner as specified in the guidelines adopted from time-to-time by Akebia and provided to Licensee. Except as otherwise expressly provided in this Agreement, Licensee is not granted any license under, and will not use, any trademarks of Akebia in connection with any Licensed Product.

9.4. **Defense of Third Party Infringement Claims**.

9.4.1 **Notice; Akebia Initiation**. Licensee will immediately provide written notice to Akebia if a Third Party asserts that a Patent or other right controlled by such Third Party is or will be infringed by Licensee's activities under this Agreement or Licensee becomes aware of a Patent or other right that might form the basis for such a claim, which notice will include all facts related to such claim in reasonable detail. [**].

9.4.2 **Right to Defend**. If, during the Term of the Agreement, a Third Party asserts that a Patent or other right controlled by such Third Party is infringed or will be infringed in the Territory by Licensee's exercise of the rights granted to it under this Agreement, then:

(a) *[**]* in the Territory, [**] will defend [**] against any such claim at its own expense using the counsel of its own choosing, so long as [**] is in breach of any of its obligations under this Agreement. [**] will be responsible for [**]% of the amounts owed to any Third Party directly related to such claim, whether by settlement or judgment; and

(b) *[**]* in the Territory, [**] will have the right, but not the obligation, to defend any such claim at its own expense using the counsel of its own choosing. If [**] exercises such right to defend, then it will be responsible for [**]% of the amounts owed to any Third Party directly related to such claim, whether by settlement or judgment.

In addition, with respect to any such claim by a Third Party that a Patent or other right controlled by such Third Party is infringed or will be infringed as a result of Licensee's activities under this Agreement in the Territory (whether or not [**]), the Parties will reasonably assist each other and cooperate and share information related to any such claim.

9.4.3 **Responsibility for Third Party Licenses**. If at any time during the Term, Akebia believes that it is necessary or advisable to seek to acquire or obtain a license from any Third Party in order to avoid infringement of Patents owned or controlled by such Third Party as a result of Licensee's activities under this Agreement, whether or not such Third Party has instituted an infringement claim, then Akebia will have the sole right, but not the obligation, [**] under such Patents from such Third Party. [**]. This Section 9.4.3 (Responsibility for Third Party Licenses) will not be interpreted as placing on either Party a duty of inquiry regarding Third Party intellectual property rights.

Article 10

MANUFACTURING AND SUPPLY

10.1. **Commercial Supply**. Subject to the terms and conditions of this Agreement and the Supply Agreement, Licensee will purchase from Akebia all of Licensee's requirements of the Licensed Products in Finished Form for sale in the Territory.

10.2. **Commercial Supply Agreement**. During the [**] period after the [**], the Parties will discuss and use good faith efforts to agree on the material terms to be included in the Supply Agreement. No later than [**] after the filing of the NDA, the Parties will enter into a supply agreement for the commercial supply to Licensee of the Licensed Products in Finished Form that contains standard and customary terms for commercial supply arrangements (the "**Supply Agreement**"), which Supply Agreement will include those material terms on which the Parties have agreed pursuant to this Article 10 (Manufacturing and Supply). The supply price for the Licensed Products supplied by Akebia to Licensee pursuant to the Supply Agreement will be equal to [**] *plus* [**] (the "**Supply Price**") and the term and effective period of the Supply Agreement will be conterminous with the Term and Effective Period of this Agreement.

Article 11

PAYMENTS

11.1. **Profit Share**. Subject to the provisions of this Agreement, as partial consideration for the License, Licensee will pay to Akebia [**]% of the Profit accrued by Licensee or its Affiliates with respect to the sale of Licensed Products in each [**]; *provided that* if [**] then, in lieu of the foregoing [**]% profit share, Licensee will pay to Akebia [**]% of the Profit accrued by Licensee or its Affiliates with respect to the sale of Licensed Products in each [**]. Licensee will make each such payment to Akebia [**].

11.2. **Milestone Payment**. Subject to the provisions of this Agreement, including Section 4.6 (Reimbursement System Changes), as further consideration for the License, Licensee will pay to Akebia a non-creditable, nonrefundable payment of $25,000,000 (the "**Milestone Payment**") no later than [**] following the date on which the following conditions are satisfied: (a) the FDA has granted Regulatory Approval for a Licensed Product in the DD-CKD Indication in the Territory, and (b) either upon the earlier of a determination by CMS that such Licensed Product (i) is to be reimbursed using the TDAPA or (ii) is included as part of the ESRD PPS Bundled Payment System. For clarity, if there has been a reimbursement system change under Section 4.6 (Reimbursement System Changes), the Milestone Payment shall not be due unless the Parties have either (A) entered into an amendment to this Agreement with respect to such change or (B) agreed in writing that no such amendment is necessary.

11.3. **Sales Reports**.

11.3.1 **Flash Reports**. Within [**] after the end of each calendar quarter in which Licensee or its Affiliates sell a Licensed Product, Licensee will provide to Akebia a "flash" report. Each such flash report will set forth (a) for the first and second month of such calendar quarter: (i) the actual gross sales of all Licensed Products sold by Licensee or its Affiliates in the Territory in such months; and (ii) the actual total aggregate Net Sales of the Licensed Products sold by Licensee or its Affiliates in the Territory in such months, and (b) for the third month of such calendar quarter, Licensee's good faith estimate of the amounts set forth in the foregoing clauses (a)(i) and (a)(ii) of this Section 11.3.1 (Flash Reports). All amounts for the third month of each calendar quarter included in each Flash Report will be prepared as good faith estimates and will be updated with definitive numbers in the applicable Quarterly Report.

11.3.2 **Quarterly Reports**. In addition to the flash reports to be provided in accordance with Section 11.3.1 (Flash Reports), within [**] after the end of each calendar quarter in which Licensee or its Affiliate sells any Licensed Product, Licensee will provide to Akebia a detailed written sales report (each, a "**Quarterly Report**") that sets forth (a) the units of each Licensed Product purchased by FKC and each Third Party Dialysis Organization, (b) the number of units of each Licensed Product held in inventory at all centralized warehouses of FKC and each Third Party Dialysis Organization, (c) the number of units of Licensed Products dispensed to FMCNA/TPDO Dialysis Patients (including a breakdown of units dispensed to TPDO Dialysis Patients), (d) Net Sales of Licensed Products sold to FKC and each Third Party Dialysis Organization during such calendar quarter and the Profit in such calendar quarter from such sales, together with all calculations used to determine such Net Sales and Profit, and (e) a certification of an executive officer of FKC and each Third Party Dialysis Organization stating whether or not the [**]% threshold set forth in Section 16.8.1 (Termination Based on Aggregate Sales Levels) or Section 16.8.2

(Termination of Third Party Dialysis Organizations), respectively, has been achieved for the previous calendar quarter, which, in the case of ((a) through (d)), will be broken down on a monthly and quarterly basis. In addition, on an annual basis, Licensee will provide to Akebia the annual Net Sales and Profit forecasts for each Licensed Product to be sold by Licensee under the License in the upcoming calendar year. The Parties will seek to resolve any questions or issues related to a Quarterly Report within [**] following receipt by Akebia of such Quarterly Report.

11.4. **Accounting**. Licensee agrees to keep full, clear, and accurate records in accordance with the Accounting Standards consistently applied for a period of at least three years after the relevant payment is owed pursuant to this Agreement in sufficient detail to enable compensation payable to Akebia hereunder to be determined. Licensee further agrees to permit its books and records to be examined by an independent accounting firm selected by Akebia and approved by Licensee, which approval will not be unreasonably withheld or delayed, to verify the reports provided in Section 11.3 (Sales Reports), including the FMC/TPDO Group's [**] during the applicable period. Such auditor will be bound by a legal agreement obligating it to maintain the confidentiality of such information and to not share it with Akebia. The auditor's report will be provided simultaneously to both Licensee and Akebia, will be limited to a disclosure of the extent of any underpayment or overpayment by Licensee in sufficient detail to allow Akebia and Licensee to understand the source of any error. Such audit will not be performed more frequently than once per calendar year. Such examination is to be made at the expense of Akebia, except in the event that the results of the audit reveal an underpayment by Licensee of [**]% or more during the period being audited, in which case reasonable audit fees for such examination will be paid by Licensee.

11.5. **Methods of Payment**. All payments due to Akebia under this Agreement will be made in U.S. Dollars by wire transfer to a bank account of Akebia designated from time-to-time in writing by Akebia.

11.6. **Late Payments**. Any amount owed by Licensee to Akebia under this Agreement that is not paid within the applicable time period set forth herein will accrue interest at the lesser of (a) the London Interbank Offered Rate *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 17 (Dispute Resolution; Governing Law).

Article 12

INFORMATION AND ADVERSE DRUG EVENTS AND REPORTS

12.1. **Data Security**. During the Term of this Agreement, Licensee will maintain and, as applicable, cause its Affiliates to maintain, environmental, safety, and facility procedures, data security procedures and other safeguards against the disclosure, destruction, loss, or alteration of any clinical data, post-marketing data, commercialization information, or any other information concerning the Licensed Compound or the Licensed Products known by Licensee or any of its Affiliates at any time during the Term that are no less rigorous than those maintained by Licensee (or any of its Affiliates) for its own information of a similar nature.

12.2. **Adverse Drug Events**. Licensee will provide to Akebia any information that it becomes aware of in the Territory concerning any adverse event relating to the Licensed Compound or any Licensed Product, whether or not determined to be attributable to the Licensed Compound or any 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**") no later than [**] after becoming aware of any such Safety Data. Akebia will own all of the Safety Data, and the global safety database associated with the Licensed Products will be owned and maintained by Akebia. [**] will have the sole right and responsibility to administer and otherwise make decisions with respect to recalls and withdrawals of a Licensed Product, and [**] will, [**], provide assistance and cooperation reasonably requested by [**] in connection with any such recall or withdrawal.

Article 13

REPRESENTATIONS, WARRANTIES, AND COVENANTS

13.1. **Mutual Representations and Warranties**. Each of Licensee and Akebia hereby represents and warrants to the other Party as of the Amendment Execution Date that:

13.1.1 (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.

13.1.2 The execution, delivery and performance of this Agreement by it has been duly authorized by all requisite corporate action.

13.1.3 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 such Party 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.

13.1.4 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.

13.1.5 It has obtained all necessary consents, approvals, and authorizations of all Governmental Authorities and other Third Parties required to be obtained in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder.

13.1.6 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, 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.

13.1.7 It has the right to grant the rights and licenses described in this Agreement.

13.2. **Additional Mutual Representations and Warranties**. Each of Licensee and Akebia represents and warrants as of the Amendment Execution Date that it has not been debarred by the FDA, is not the subject of a conviction described in Section 306 of the FD&C Act, and is not subject to any similar sanction of other Governmental Authorities outside of the Territory, and neither it nor any of its Affiliates has used, in any capacity, any person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act, or is subject to any such similar sanction.

13.3. **Additional Akebia Representations and Warranties**. Akebia hereby represents and warrants as of the Amendment Execution Date that:

13.3.1 The Akebia Patents and the Akebia Trademarks have been duly filed in the Territory.

13.3.2 All applicable filing, maintenance, and other fees have been timely paid for all of the Akebia Patents set forth on Schedule 1.7 and the Akebia Trademarks set forth on Schedule 1.9, and, to Akebia's Knowledge, all of the Akebia Patents set forth on Schedule 1.7 that are issued patents and the Akebia Trademarks set forth on Schedule 1.9 that are registered trademarks, in each case, are in full force and effect.

13.3.3 There is no pending or, to Akebia's Knowledge, threatened (in writing) re-examination, opposition, interference, *inter partes* review, or claim challenging the inventorship, ownership, validity, enforceability, or patentability of the Akebia Patents or other litigation or proceeding in the Territory relating to any of the Akebia Patents.

13.3.4 The sale of the Licensed Products does not and will not infringe any valid Patent or other intellectual property rights of any Third Party in the Territory.

13.3.5 Akebia has received no written notice of any claim that a patent or trade secret owned or controlled by a Third Party is or would be infringed or misappropriated by the sale of the Licensed Products in the Territory.

13.3.6 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.

13.3.7 There are no investigations, inquiries, actions, or other proceedings pending before or to Akebia's Knowledge threatened by the FDA or other Governmental Authority in the Territory with respect to the Licensed Products arising from any default by Akebia or a Third Party acting on behalf Akebia in the research or development of the Licensed Compound, and Akebia has not received written notice threatening any such investigation, inquiry, action or other proceeding.

13.3.8 Akebia owns or has licensed the rights, title, and interests in and to the Akebia Technology granted to Licensee pursuant the License.

13.3.9 The research, development, and manufacture of the Licensed Products conducted by Akebia or its Affiliates has been conducted in compliance with Applicable Law and, to Akebia's Knowledge, the research, development, and manufacture of the Licensed Products conducted by Akebia's Third Party contractors has been conducted in compliance with Applicable Law.

13.4. Additional Licensee Representations and Warranties. Licensee hereby represents and warrants as of the Amendment Execution Date that:

13.4.1 Vifor Pharma Ltd. and Fresenius Medical Care AG & Co KGaA are the joint venture partners of VFMCRP, with Vifor Pharma Ltd. owning a controlling interest of VFMCRP and Fresenius Medical Care AG & Co KGaA owning the remaining interest.

13.4.2 FKC is an Affiliate of FMCNA and a strategic partner of Licensee.

13.4.3 Licensee is not an Affiliate of FMC, FMCNA or any member of the FMC/TPDO Group.

13.4.4 Licensee is a drug manufacturer that is not engaged in the wholesale distribution of prescription drugs to "retail community pharmacies" (as that term is defined in 42 U.S.C. § 1396r-8(k)(10)).

13.4.5 The transmission of all information required to be included in each Quarterly Report pursuant to this Agreement is consistent with Applicable Law and Licensee's contractual obligations with Third Parties.

13.5. Additional Covenants.

13.5.1 Each Party covenants that it will not engage, in any capacity in connection with this Agreement or any ancillary agreements, any person who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act, or is subject to any such similar sanction. Each Party will inform the other Party in writing promptly if it or any person engaged by it or any of its Affiliates who is performing services under this Agreement, or any ancillary agreements, is debarred or is the subject of a conviction described in Section 306 of the FD&C Act, or if any action, suit, claim, investigation, or legal or administrative proceeding is pending or, to each Party's knowledge, is threatened, relating to the debarment or conviction of a Party, any of its Affiliates, or any such person performing services hereunder or thereunder.

13.5.2 Each Party covenants that it will comply with all Applicable Laws in performing its activities hereunder.

13.5.3 If either Party determines, based on reasonable advice of counsel, that its compliance with this Agreement will violate Applicable Law, then the Parties will negotiate to amend this Agreement as necessary to ensure that the terms hereof to permit such Party to comply with Applicable Law and this Agreement during the Term.

13.5.4 Licensee covenants that throughout the Term it will not, and will cause each of its Affiliates that are involved in the supply or distribution of any Licensed Product to not, engage in the wholesale distribution of prescription drugs to "retail community pharmacies" (as that term is defined in 42 U.S.C. § 1396r-8(k)(10)) in the Territory.

13.5.5 Licensee covenants that throughout the Term it will provide prompt written notice to Akebia in the event that any of its Affiliates intends to engage, or has engaged, in the wholesale distribution of prescription drugs to "retail community pharmacies" (as that term is defined in 42 U.S.C. § 1396r-8(k)(10)) in the Territory.

13.5.6 On the Effective Date, Akebia will provide to Licensee an updated Schedule 1.7 that includes all Akebia Patents as of the Effective Date, and an updated Schedule 1.9 that includes all Akebia Trademarks as of the Effective Date.

13.6. **Disclaimer**. EXCEPT AS EXPRESSLY SET FORTH HEREIN, INCLUDING THE WARRANTIES SET FORTH IN SECTION 13.3 (ADDITIONAL AKEBIA REPRESENTATIONS AND WARRANTIES), THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY AKEBIA ARE PROVIDED "AS IS" AND WITHOUT WARRANTY. EXCEPT AS EXPRESSLY SET FORTH HEREIN, INCLUDING THE WARRANTIES SET FORTH IN SECTION 13.3 (ADDITIONAL AKEBIA REPRESENTATIONS AND WARRANTIES), AKEBIA EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR ENFORCEABILITY OF ITS 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.

13.7. **Limitation of Liability**. NEITHER OF THE PARTIES WILL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, INDIRECT, CONSEQUENTIAL, OR PUNITIVE DAMAGES OR DAMAGES FOR LOSS OF PROFIT OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT, ITS PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER, EXCEPT TO THE EXTENT THE DAMAGES RESULT FROM A PARTY'S WILLFUL MISCONDUCT, OR INTENTIONAL BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT, A BREACH OF THE OBLIGATIONS OF A PARTY UNDER [**], A VIOLATION BY A PARTY OR ITS AFFILIATES OF [**].

Article 14

CONFIDENTIALITY

14.1. **Generally**. During the Term and for a period of seven years following the early termination of this Agreement, each Party (a) will maintain in confidence all Confidential Information of the other Party; (b) will not use such Confidential Information for any purpose except in connection with the activities contemplated by this Agreement or in order to further the purpose of this Agreement; and (c) will not disclose such Confidential Information, except that each Party may disclose such Confidential Information to its Affiliates, investors, prospective investors, lenders, prospective lenders, financing sources, prospective financing sources (including, in each case, in connection with any royalty factoring or similar transaction), prospective acquirers, licensees, sublicensees, prospective sublicensees, employees, consultants, financial or legal advisors, agents, or subcontractors who are bound by obligations of nondisclosure and non-use no less stringent than those set forth in this Article 14 (Confidentiality) and to whom such disclosure is reasonably necessary or advisable in connection with such Party's activities as contemplated in this Agreement or in connection with financing or acquisition activities (including its right to assign its rights hereunder pursuant to Section 18.1 (Assignment) as part of a royalty factoring or other similar transaction). Each Party will ensure that its Affiliates, investors, prospective investors, lenders, prospective lenders, acquirors, licensees, sublicensees, prospective acquirors, licensees, sublicensees, prospective sublicensees, employees, consultants, agents, consultants, and subcontractors comply with these obligations. Each Party will notify the other Party promptly on discovery of any unauthorized use or disclosure of the other Party's Confidential Information, including the other Party's trade secrets or proprietary information. Licensee acknowledges that all (i) Safety Data, (ii) Akebia Know-How, and (iii) other information related to Akebia's and its Affiliates', licensees', and sublicensees' development and commercialization of the Licensed Compound and the Licensed Products constitutes Confidential Information of Akebia. The terms of this Agreement will be the Confidential Information of each Party.

14.2. **Exceptions**. The obligations of confidentiality, non-disclosure, and non-use set forth in Section 14.1 (Generally) will not apply to the extent the receiving Party (the "**Recipient**") can demonstrate that the disclosed information (a) was in the public domain at the time of disclosure to the Recipient by the other Party, or thereafter entered the public domain, in each case, other than as a result of actions of the Recipient, its Affiliates, employees, licensees, agents, or subcontractors, in breach of this Agreement; (b) was rightfully known by the Recipient or its Affiliates (as shown by its written records) prior to the date of disclosure to the Recipient by the other Party; (c) was received by the Recipient or its Affiliates on an unrestricted basis from a Third Party rightfully in possession of such information and not under a duty of confidentiality to the other Party; or (d) was independently developed by or for the Recipient or its Affiliates without reference to or reliance on the Confidential Information of the other Party (as demonstrated by written records). Notwithstanding any other provision of this Agreement, the Recipient's disclosure of Confidential Information will not be prohibited if such disclosure: (i) is in response to a valid order of a court or other Governmental Authority; or (ii) is otherwise required by Applicable Law or regulation or rules of a nationally recognized securities exchange. Further notwithstanding any other provision of this Agreement, Akebia may disclose Licensee's Confidential Information to the extent disclosure is required in connection with the filing or prosecuting patent applications, prosecuting, or defending litigation, responding to an investigation by a Governmental Authority, or otherwise establishing rights or enforcing obligations under this Agreement, making Regulatory Filings with respect to the Licensed Products, or conducting research, development, or clinical studies with respect to the Licensed Products. If a Recipient is required to disclose Confidential Information pursuant to this Section 14.2 (Exceptions), then prior to any disclosure the Recipient will provide the other Party with prior written notice of such disclosure in order to permit the other Party to seek a protective order or other confidential treatment of such Confidential Information.

14.3. **Publicity**. The Parties recognize that each Party may from time-to-time desire to issue press releases and make other public statements or disclosures regarding the terms of this Agreement. In such event, the Party desiring to issue a press release or make a public statement or disclosure will provide the other Party with a copy of the proposed press release, statement, or disclosure for review and approval as soon as practicable prior to publication, which advance approval will not be unreasonably withheld or delayed. No other public statement or disclosure of, or concerning, the terms of this Agreement will be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party. Once any public statement or disclosure has been approved in accordance with this Section 14.3 (Publicity), then either Party may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding the foregoing provisions of this Article 14 (Confidentiality), a Party may disclose the terms of this Agreement where required, as reasonably determined by the disclosing Party, by Applicable Law, regulation or legal process, or by applicable stock exchange rule (with prompt notice of any such legally required disclosure to the other Party and, to the extent practicable, sufficient opportunity for the other Party to review and comment on such required disclosure and request confidential treatment thereof or a protective order therefor).

14.4. **Publications**. If, [**], Licensee, its Affiliates, FMCNA, the FMC/TPDO Group, or any healthcare professional having an investigator initiated trial agreement in place with any of the previously listed entities desires to publish any clinical data or other clinic results from the administration of the Licensed Compound or any Licensed Product, then Licensee will, will cause its Affiliates to, and will cause FMCNA, the FMC/TPDO Group, and such healthcare professionals to, in each case, [**]. If Akebia determines that any such proposed publication contains patentable subject matter requiring protection, then Akebia may require the delay of such publication for a period of time not to exceed an additional [**] to pursue such protection or negotiate with such healthcare professional. If Akebia determines that the proposed publication contains Confidential Information,

then Akebia may require such Confidential Information to be deleted from such publication. If, [**], Licensee, its Affiliates, FMCNA, or the FMC/TPDO Group desires to publish any preclinical or non-clinical results from the research and development of the Licensed Compound or any Licensed Product, then Licensee will, will cause its Affiliates to, and will cause FMCNA and the FMC/TPDO Group to, in each case, [**].

Article 15

INDEMNIFICATION

15.1. **Indemnification by Akebia**. Unless otherwise provided herein, 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) a breach of this Agreement by Akebia, (b) [**] of a Licensed Product by or on behalf of Akebia or its Affiliates or licensees (other than Licensee, the LSP, or a member of the FMC/TPDO Group), or (c) the negligence or willful misconduct of any Akebia Indemnitee (as defined in Section 15.2 (Indemnification by Licensee)). 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.

15.2. **Indemnification by Licensee**. Unless otherwise provided herein, 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) a breach of this Agreement by Licensee, (b) [**], in each case, of a Licensed Product by or on behalf of Licensee, the LSP, or the FMC/TPDO Group (including any communications regarding such Licensed Product by Licensee, the LSP, or the FMC/TPDO Group), or (c) the negligence or willful misconduct of any Licensee Indemnitee. Notwithstanding the foregoing, Licensee will not have any obligation to indemnify the Akebia Indemnitees (i) 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, or (ii) for any [**] of any Licensed Product, other than any [**] of any Licensed Product by or on behalf of Licensee, the LSP, or the FMC/TPDO Group.

15.3. **Indemnification Procedure**. Each Party, if seeking indemnification under this Article 15 (Indemnification) (the "**Indemnified Party**"), will give [**] written notice of the claim to the other Party (the "**Indemnifying Party**"); *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, exercisable by written notice to the Indemnified Party, 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, at its own expense, except that the fees and expenses of the Indemnified Party's counsel will 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 15.3 (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 that would have an adverse effect on the Indemnified Party's interests (including any rights under this Agreement or the scope or enforceability of any Patents, 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 or delayed. 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 14 (Confidentiality). The Indemnifying Party will provide periodic updates to the Indemnified Party (and its counsel, if applicable) regarding its defense of the action with immediate notice regarding any material developments. 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 15.3 (Indemnification Procedure).

15.4. **Insurance**. Akebia and Licensee will each, at their own expense, obtain and maintain insurance with respect to the use and sale of the Licensed Products under this Agreement in such amount and subject to such deductibles and other limitations as biopharmaceutical companies in the Territory customarily maintain with respect to the use and sale of similar products. Each Party will provide a copy of such insurance policy to the other Party upon request.

Article 16

TERM AND TERMINATION

16.1. **Term**. The term of this Agreement will begin on the Original Execution Date and, unless earlier terminated in accordance with the terms of this Article 16 (Term and Termination), will extend until the later of (a) expiration of the last-to-expire Valid Claim [**] that would, but for the licenses granted hereunder, be infringed by the making, using, selling, or importing of such Licensed Product in the Territory, or (b) expiration of marketing or regulatory exclusivity in the Territory (the "**Term**").

16.2. **Termination for Breach**. Subject to the terms and conditions of this Section 16.2 (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 the Non-Breaching Party provides written notice to cure such breach. Notwithstanding the foregoing, if a Non-Breaching Party provides notice to the Breaching Party pursuant to this Section 16.2 (Termination for Breach) of an alleged material breach by such Breaching Party, and such Non-Breaching Party provides notice during the applicable cure period set forth above that such Non-Breaching Party disputes the basis for termination pursuant to this Section 16.2 (Termination for Breach) and initiates the dispute resolution procedure set forth in Article 17 (Dispute Resolution; Governing Law) during the applicable cure period, then the cure periods set forth in this Section 16.2 (Termination for Breach) for the alleged material breach will run from the date

that such written notice is first provided to the Breaching Party through the resolution of such dispute pursuant to Article 17 (Dispute Resolution; Governing Law) and it is understood and acknowledged that, during the pendency of a dispute pursuant this Section 16.2 (Termination for Breach), all of the terms and conditions of this Agreement will remain in effect, and the Parties will continue to perform all of their respective obligations under this Agreement. 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.

16.3. **Termination for Bankruptcy**. Subject to the terms and conditions of this Agreement, either Party may terminate this Agreement upon notice to the other Party should the other Party: (a) consent to the appointment of a receiver or a general assignment for the benefit of creditors of the other Party that is not discharged within [**], or (b) file a petition under any bankruptcy or insolvency law or have any such petition filed against it that has not been stayed within [**] of such filing.

16.4. **Termination by Akebia for Unauthorized Sales**. If the Parties do not reach a resolution of the applicable matter during the [**] period as set forth under Section 4.1 (No Unauthorized Sales), or Licensee does not (a) [**] any unauthorized use, distribution, or transfer of the Licensed Compound or any Licensed Product by Licensee, FKC, its LSP, any Third Party Dialysis Organization, or any Authorized Dialysis Center to or by a Third Party that is not an FMCNA/TPDO Dialysis Patient or Authorized Dialysis Center, or (b) [**] of FKC or any LSP, Third Party Dialysis Organization or Authorized Dialysis Center that is using, distributing, or transferring the Licensed Compound or any Licensed Product other than as expressly permitted under this Agreement, in each case ((a) and (b)), then Akebia may terminate this Agreement with immediate effect upon written notice to Licensee.

16.5. **Termination by Akebia Upon Occurrence of Certain Events**. If any of the following events occur, then, Akebia may terminate this Agreement with immediate effect upon written notice to Licensee:

16.5.1 Licensee or its Affiliate involved in the supply or distribution of any Licensed Product becomes an Affiliate of FMC, FMCNA or any member of the FMC/TPDO Group; or

16.5.2 There is no affiliation or other strategic relationship between Licensee or its Affiliate involved in the supply or distribution of any Licensed Product and FMC or FMCNA.

16.6. **Termination by Akebia for Failure to Amend the Licensee-FKC Supply Agreement**. Akebia may terminate this Agreement with immediate effect upon written notice to Licensee if (a) Licensee does not enter into an amendment of the Licensee-FKC Supply Agreement in accordance with Section 5.1.2 (Amendment to Supply Agreement) within [**] after (i) the FDA has granted Regulatory Approval for a Licensed Product in the DD-CKD Indication in the Territory, and (ii) the earlier of a determination by CMS that a Licensed Product (A) is to be reimbursed using the TDAPA or (B) is included as part of the ESRD PPS Bundled Payment System, or (b) the Licensee-FKC Supply Agreement is terminated or expires.

16.7. **Termination or Suspension by Akebia for Impacts on Pricing**. If (a) there has been a breach of Section 6.1 (Pricing), (b) through the actions by or on behalf of Licensee, any of its Affiliates or any member of the FMC/TPDO Group (even if pursuant to FMC/TPDO Group's customary dialysis clinic cost reporting to CMS or any other Governmental Authority, and even if such actions do not constitute a breach by Licensee under Section 4.4.2 (Licensed Product Prices)), any Third Party purchaser or potential purchaser (other than either Party's Affiliates or FMCNA, FMCNA's Affiliates (including FKC), or Majority Owned Clinics) becomes aware of the price at which

Licensee, any of its Affiliates or any member of the FMC/TPDO Group acquired any Licensed Product, or the price at which such entity sells any Licensed Product to any purchaser (even if pursuant to FMC/TPDO Group's customary dialysis clinic cost reporting to CMS or any other Governmental Authority), (c) [**], or (d) Licensee, any of its Affiliates or any member of the FMC/TPDO Group sells, or plans to sell, in each case, any Licensed Product in any manner that [**], and, in each case ((a) through (d)), the Parties do not reach an agreeable resolution within [**] after Akebia notifies Licensee of its intent to terminate based on such condition, then, in either case, Akebia may elect to either (i) terminate this Agreement or (ii) suspend the License and commence a Suspension Period under Section 3.2.2 (Suspension), in each case ((i) and (ii)), with immediate effect upon written notice to Licensee. If Akebia elects to suspend the License, Akebia may reinstate the License (such reinstatement resuming the Effective Period) at any time during the Term upon written notice to Licensee.

16.8. Termination or Suspension by Akebia for Net Sales Levels.

16.8.1 Termination Based on Aggregate Sales Levels. Commencing on the [**] of First Commercial Sale of a Licensed Product in the Territory, Akebia may terminate this Agreement with immediate effect upon written notice to Licensee within the time period stated herein if the aggregate Net Sales of all Licensed Products during any [**] period is less than or equal to [**]% of the FMC/TPDO Group's [**] during the preceding [**] period. To exercise the foregoing termination right, Akebia must provide such notice of termination to Licensee no later than [**] after Akebia's receipt of the Quarterly Report that documents that the aggregate Net Sales of all Licensed Products in the preceding [**] is less than or equal to [**]% of the FMC/TPDO Group's total spending (amounts paid to manufacturers or wholesalers) for all [**] during such [**] period and, absent such timely notice, [**].

16.8.2 Termination of Third Party Dialysis Organizations. Commencing on the [**] of the First Commercial Sale of a Licensed Product in the Territory, Akebia may require Licensee to terminate a Licensee-TPDO Supply Agreement by providing a written request to Licensee no later than [**] after Akebia's receipt of a Quarterly Report that documents that the aggregate Net Sales of all Licensed Products under such Licensee-TPDO Supply Agreement in the preceding [**] is less than or equal to [**]% of the applicable Third Party Dialysis Organization's [**] during such [**] period. Upon receiving such request, Licensee will terminate the Licensee-TPDO Supply Agreement with such Third Party Dialysis Organization. Upon such termination, [**] for the purposes of this Agreement, and [**].

16.8.3 Suspension Based on Comparative Sales Levels. Commencing with the [**] the First Commercial Sale and [**], if the [**] of all Licensed Products under this Agreement during [**] the Comparative Sales Percentage [**] period, then Akebia may suspend the License in accordance with Section 16.14 (Suspension of Licensed Rights) with effect [**] after written notice to Licensee. To exercise the foregoing suspension right, Akebia must provide such notice of suspension to Licensee no later than [**] after Akebia's receipt of the Quarterly Report that documents Licensee's aggregate Net Sales of all Licensed Products for the [**] of [**]. Notwithstanding the foregoing, Akebia will not have the right to suspend the License pursuant to this Section 16.8.3 (Suspension Based on Comparative Sales Levels) [**] by Licensee in accordance with the Supply Agreement.

16.8.4 **Termination Based on Comparative Sales Levels**. [**], if the [**] of all Licensed Products under this Agreement during any preceding [**] period are [**] the Comparative Sales Percentage [**] during such [**] period, then Akebia may terminate this Agreement by providing written notice of such termination to Licensee*; provided, however,* that such termination will *not* become effective if during the [**] following the conclusion of such [**] period there are [**] the Comparative Sales Percentage [**], in which case, this Agreement shall not terminate at the end of such [**] period. To exercise the foregoing termination right, Akebia must provide its written notice of termination to Licensee no later than [**] after Akebia's receipt of the Quarterly Report that documents Licensee's [**] period. Such termination will become effective upon the date that Akebia receives the Quarterly Report that documents that there have not been [**] period [**] as defined in this Agreement; *provided, however,* that if Licensee does not provide such Quarterly Report within the [**] period required by Section 11.3.2 (Quarterly Reports), then such termination will become effective upon the expiration of such [**] period. Notwithstanding the foregoing, Akebia will not have the right to terminate this Agreement pursuant to this Section 16.8.4 (Termination Based on Comparative Sales Levels) [**] Licensee in accordance with the Supply Agreement.

16.9. **Termination by Akebia for Patent Challenge**. Akebia may terminate this Agreement with immediate effect upon written notice to Licensee if Licensee or any of its Affiliates contests the validity or enforceability of any Patent Controlled by Akebia or any of its Affiliates that Covers a Licensed Product or its manufacture, use, sale, or importation, in any court, arbitration proceeding, or other tribunal, including the United States Patent and Trademark Office and the United States International Trade Commission. As used in this definition, the term "contest" includes (a) filing an action under 28 U.S.C. §§ 2201-2202 seeking a declaration of invalidity or unenforceability of any such Patent; (b) filing, or joining in, a petition under 35 U.S.C. § 311 to institute *inter partes* review of any such Patent; (c) filing, or joining in, a petition under 35 U.S.C. § 321 to institute post-grant review of any such Patent or any portion thereof; (d) filing or commencing any opposition, nullity, or similar proceedings challenging the validity of any such Patent in any country, or (e) any foreign equivalent of clauses (a), (b), (c), or (d).

16.10. **Termination by Licensee for Convenience**. At any time after release of the topline data from the Global Phase 3 DD-CKD Program, 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 written agreement of both Akebia and Licensee.

16.11. **Termination Based on Written Agreement of the Parties**. This Agreement may be terminated in its entirety upon the written agreement of both Akebia and Licensee.

16.12. **Effects of Termination**. In the event of any expiration or termination of this Agreement, the following will apply:

16.12.1 **Termination of Licenses**. Except as expressly set forth in this Section 16.12 (Effects of Termination), and subject to Section 16.15 (Survival; Accrued Rights), all rights and licenses granted to Licensee under this Agreement will automatically terminate.

16.12.2 Return of Confidential Information. Licensee will cease using the Akebia Technology and will return to Akebia 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 Recipient will provide a written confirmation of such destruction within [**] of such request; *provided*, *however*, that the foregoing will not apply to any 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, *provided*, *further*, that [**].

16.12.3 Cessation of Sales. Except for sales made in accordance with Section 16.12.4(a)(i) (Termination Other than for Cause by Akebia), Licensee will cease all sales of Licensed Product in the Territory.

16.12.4 Sell-Off or Buy-Back.

(a) Termination Other than for Cause by Akebia. If this Agreement is terminated by Licensee pursuant to Section 16.3 (Termination for Bankruptcy), then, after the effective date of such termination: (i) Licensee may continue to sell the Licensed Products for a period of [**] after the effective date of such termination in order to fill existing binding orders and commitments, and (ii) following such [**] period, at Akebia's option and in its sole discretion, [**] for such Licensed Products by Licensee or its Affiliates. Licensee will destroy, or cause to be destroyed, all Licensed Products remaining in inventory that [**] following such [**] period, at Licensee's cost and expense.

(b) Termination for Cause by Akebia. If this Agreement is terminated by Akebia pursuant to Section 16.2 (Termination for Breach), Section 16.4 (Termination by Akebia for Unauthorized Sales), Section 16.5 (Termination by Akebia Upon Occurrence of Certain Events), Section 16.6 (Termination by Akebia for Failure to Amend the Licensee-FKC Supply Agreement), Section 16.7 (Termination or Suspension by Akebia for Impacts on Pricing), 16.8.1 (Termination Based on Aggregate Sales Levels), Section 16.8.4 (Termination Based on Comparative Sales Levels), Section 16.9 (Termination by Akebia for Patent Challenge), or Section 16.10 (Termination by Licensee for Convenience), then, after the effective date of such termination, at Akebia's option in its sole discretion, [**] for such Licensed Products by Licensee or its Affiliates. Licensee will destroy, or cause to be destroyed, all Licensed Products remaining in inventory as of the effective date of termination that [**], at Licensee's cost and expense.

16.13. Additional Effect of Termination for Net Sales Levels. If Akebia terminates this Agreement pursuant to 16.8.1 (Termination Based on Aggregate Sales Levels) or Section 16.8.4 (Termination Based on Comparative Sales Levels), then, in addition to the effects of termination set forth in Section 16.12 (Effects of Termination), upon Akebia's request (in its sole discretion) Akebia [**] effective upon the date of such termination.

16.14. Suspension of Licensed Rights. Promptly following the commencement of any Suspension Period (as set forth under Section 3.2.2 (Suspension)), Licensee will [**]. During any Suspension Period the Articles and Sections set forth in Section 16.15 (Survival; Accrued Rights) will survive. Upon the commencement of any Suspension Period, if and only if sales of Licensed Products have commenced, Akebia will [**] at a [**] of [**]% of [**]. Except as provided in this Section 16.14 (Suspension of Licensed Rights) and Section 16.15 (Survival; Accrued Rights), during the Suspension Period, all other rights and obligations of the Parties pursuant to the License will be suspended and be of no force and effect.

16.15. **Survival; Accrued Rights**. The following Articles and Sections of this Agreement will survive suspension of the License or expiration or early termination of the Agreement for any reason: Section 9.1 (Trademark Responsibility), Section 9.3 (Trademark Ownership and Cooperation), Section 11.3 (Sales Reports), but only with respect to Net Sales made during the Term, Section 11.4 (Accounting), Section 11.5 (Methods of Payment), Section 11.6 (Late Payments), Section 13.7 (Limitation of Liability), Article 14 (Confidentiality), Article 15 (Indemnification), other than Section 15.4 (Insurance), Section 16.12 (Effects of Termination), Section 16.13 (Additional Effects of Termination for Net Sales Levels), this Section 16.15 (Survival; Accrued Rights), Article 17 (Dispute Resolution; Governing Law), and Article 18 (Miscellaneous). In any event, suspension of the License or expiration or termination of this Agreement will not relieve the Parties of any liability that accrued hereunder prior to the effective date of such suspension, expiration or termination (including Licensee's obligation to pay Akebia pursuant to Article 11 (Payments) with respect to sales made prior to such suspension, 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.

Article 17

DISPUTE RESOLUTION; GOVERNING LAW

17.1. **Executive Officers**. Unless otherwise set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties, the Parties will refer such dispute to their respective chief executive officers, and such chief executive officers will attempt in good faith to resolve such dispute.

17.2. **Litigation**. Any unresolved dispute which was subject to Section 17.1 (Executive Officers) must be brought exclusively in a court of competent jurisdiction, federal or state, located in the State of New York, and in no other jurisdiction. Each Party hereby consents to personal jurisdiction and venue in, and agrees to service of process issued or authorized by, such court.

17.3. **Jurisdiction**. Each Party to this Agreement, by its execution hereof, (a) hereby irrevocably submits to the exclusive jurisdiction of the United States District Court for the Southern District of New York and state courts located in New York, New York for the purpose of any and all unresolved disputes which were subject to Section 17.1 (Executive Officers), (b) hereby waives to the extent not prohibited by Applicable Law, and agrees not to assert, by way of motion, as a defense or otherwise, in any such action, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that any such action brought in one of the above-named courts in such jurisdiction should be dismissed on grounds of *forum non conveniens*, should be transferred to any court other than one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such court, and (c) hereby agrees not to commence any such action other than before one of the above-named courts nor to make any motion or take any other action seeking or intending to cause the transfer or removal of any such action to any court other than one of the above-named courts whether on the grounds of inconvenient forum or otherwise. Notwithstanding the foregoing, application may be made to any court of competent jurisdiction with respect to the enforcement of any judgment or award.

17.4. **Governing Law**. This Agreement will be governed by and construed in accordance with the laws of the State of New York, without reference to conflict of law principles.

17.5. **Injunctive Relief**. Notwithstanding the foregoing, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance, or other injunctive relief) in any court or other forum, without first submitting to the dispute resolution procedures set forth in Section 17.1 (Executive Officers).

Article 18

MISCELLANEOUS

18.1. **Assignment**. Neither Party may assign this Agreement and the licenses herein granted without the other Party's prior written consent, except that either Party may assign this Agreement in its entirety in writing to 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 prior written notice to the other Party and need not obtain the other Party's consent; *provided that* the permitted assignee must assume all obligations of the assigning Party under the Agreement in writing and the assigning Party will remain fully liable for the performance of its obligations hereunder by such permitted assignee. In addition, and notwithstanding the foregoing, Akebia may assign its right to receive payments under this Agreement as part of a royalty factoring or other similar 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 18.1 (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.

18.2. **Standstill**. Except in connection with the acquisition of shares by Licensee pursuant to the terms of the Investment Agreement dated as of the Original Execution Date by and between the Parties, Licensee will not, without the written consent of Akebia, acquire directly or indirectly, in a public or private transaction, including by purchase in the open market, any common stock of Akebia if the Licensee's beneficial ownership of the common stock of Akebia would thereafter exceed [**]%. In addition, unless approved in advance in writing by Akebia, Licensee will not, directly or indirectly:

(a) Make any statement or proposal to Akebia, other than a non-public statement or proposal delivered directly to the chief executive officer or chairman of the board of directors, or to any of Akebia's stockholders regarding, or make any public announcement, proposal, or offer (including a "solicitation" of "proxies" as such terms are defined or used in Regulation 14A of the Exchange Act) with respect to, or otherwise solicit, seek, or offer to effect (including, for the avoidance of doubt, indirectly by means of communication with the press or media) (i) any business combination, merger, tender offer, exchange offer, or similar transaction involving Akebia, (ii) any restructuring, recapitalization, liquidation, or similar transaction involving Akebia, (iii) any acquisition of any of Akebia's equity securities or assets or rights or options to acquire equity securities or assets, (iv) any proposal to seek representation on the board of directors of Akebia or otherwise seek to control or influence the management, board of directors, or policies of Akebia, or (v) any proposal, arrangement, or other statement that is inconsistent with this Section 18.2 (Standstill);

(b) Instigate, encourage, or assist any Third Party (including forming a "group" with any such Third Party) to do, or enter into any discussions or agreements with any Third Party with respect to, any of the actions set forth in Section 18.2 (Standstill); or

(c) Take any action that would reasonably be expected to require Akebia or any of its Affiliates to make a public announcement regarding any of the actions set forth in Section 18.2 (Standstill).

Notwithstanding the foregoing provisions, the restrictions set forth in this Section 18.2 (Standstill) will terminate and be of no further force and effect (a) [**], *provided that* the provisions of this Section 18.2 (Standstill) will be revived if such [**]; or (b) upon the expiration or termination of this Agreement. For the avoidance of doubt, nothing in this Section 18.2 (Standstill) will prohibit Licensee from acquiring beneficial ownership of the common stock of Akebia to the extent such ownership remains less than [**]% of Akebia's total outstanding common stock. For purposes of this Section 18.2 (Standstill), "**Sale Transaction**" means a transaction between Akebia and a Third Party (i) involving the direct or indirect acquisition by such Third Party of [**]% or more of Akebia's outstanding shares of common stock or consolidated assets (including assets held by subsidiaries), *excluding* a transaction in which (A) [**], or (B) [**], or (ii) involving the sale of substantially all of Akebia's rights with respect to the Licensed Products.

18.3. **Force Majeure**. If either Party will be delayed, interrupted in, or prevented from the performance of any obligation hereunder by reason of any cause beyond its reasonable control, including an act of God, fire, flood, earthquake, war (declared or undeclared), public disaster, act of terrorism, or strikes (other than strikes of a Party's own employees), then such Party will not be liable to the other therefor; and the time for performance of such obligation will be extended for a period equal to the duration of the force majeure that occasioned the delay, interruption, or prevention. The Party invoking such force majeure rights of this Section 18.3 (Force Majeure) must notify the other Party by courier or overnight dispatch (*e.g.*, Federal Express) no later than 30 days after each of the first and last day of the force majeure unless the force majeure renders such notification impossible, in which case notification will be made as soon as possible. If the delay resulting from the force majeure exceeds three months, then the Party not affected by the force majeure will have the right to terminate this Agreement forthwith pursuant to Section 16.2 (Termination for Breach) with the consequences set out in Section 16.12 (Effects of Termination), as if the Party affected by the force majeure were in material breach of this Agreement.

18.4. **Entire Agreement**. This Agreement, together with exhibits and schedules attached hereto, (a) constitutes the entire agreement between the Parties with respect to the subject matter hereof, (b) amends and restates the Original Agreement in its entirety, and (c) supersedes all prior understandings of the Parties with respect thereto (including the Original Agreement and that certain Confidential Disclosure Agreement between the Parties dated [**], as amended by Amendment No. 1 dated [**]) and will not be modified, amended, or terminated, except as herein provided or except by another agreement in writing executed by the Parties.

18.5. **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; *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 to agree to such amendment, then either Party may submit the matter for resolution pursuant to Article 17 (Dispute Resolution; Governing Law).

18.6. **Notices**. Any notice or report required or permitted to be given under this Agreement will be in writing and will be mailed by internationally recognized express delivery service, or sent by email or facsimile and confirmed by mailing, as follows:

If to Akebia:

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142
Attention: Chief Executive Officer
Facsimile: [**]
Email: [**]

With copies to (which will not constitute notice for purposes of this Agreement):

Akebia Therapeutics, Inc.
245 First Street
Cambridge, MA 02142
Attention: Senior Vice President, Chief Legal Officer and Secretary
Facsimile: [**]
Email: [**]

and

Ropes & Gray LLP
Prudential Tower, 800 Boylston Street
Boston, MA 02199-3600
Attention: [**]
Facsimile: [**]
Email: [**]

If to Licensee:

Vifor Pharma Management Ltd.
Flughofstrasse 61, 8152 Glattbrugg, Switzerland
Attention: [**]
Facsimile: [**]
Email: [**]

With a copy to (which will not constitute notice for purposes of this Agreement):

Vifor Pharma Management Ltd
Flughofstrasse 61, 8152 Glattbrugg, Switzerland
Facsimile: [**]
Attention: [**]
Email: [**]

18.7. **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.

18.8. **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 authorization from the other Party.

18.9. **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.

18.10. **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.

18.11. **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.

18.12. **Counterparts**. This Agreement may be executed in counterparts, all of which taken together will be regarded as one and the same instrument. This Agreement may be executed by facsimile, .pdf, or other electronically transmitted signatures and such signatures will be deemed to bind each Party hereto as if they were the original signatures.

[Remainder of page intentionally left blank; signature page follows.]

IN WITNESS WHEREOF, the Parties have executed this Amended Agreement through their duly authorized representatives to be effective as of the Amendment Execution Date.

AKEBIA THERAPEUTICS, INC.		VIFOR (INTERNATIONAL) LTD.	
By:	/s/ Jason A. Amello	By:	/s/ Dr. Christoph Springer
Name:	Jason A. Amello	Name:	Dr. Christoph Springer
Title:	SVP, CFO	Title:	Chief Strategy Officer

AKEBIA THERAPEUTICS, INC.		VIFOR (INTERNATIONAL) LTD.	
By:	/s/ John P. Butler	By:	/s/ Dr. Oliver P. Kronenberg
Name:	John P. Butler	Name:	Dr. Oliver P. Kronenberg
Title:	CEO	Title:	Group General Counsel

Exhibit 10.3

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (together with together with all Appendices, Exhibits and Schedules attached hereto, entered into by the Parties, the "Agreement") is made and entered into on the date of last signature (the "Effective Date") by and between **AKEBIA THERAPEUTICS, INC.**, a Delaware corporation with an office at 245 First Street, Suite 1100, Cambridge, MA 02142 ("**Akebia**") and **ESTEVE QUÍMICA, S.A.**, a corporation organized under the laws of Spain, with an office at Torre ESTEVE – Pg. Zona Franca, 109, 08038 Barcelona, SPAIN, ("**EQ**").

WHEREAS, pursuant to this Agreement, and subject to the terms and conditions and for the consideration described herein, EQ shall manufacture and supply Product for Akebia's commercial purposes (that is to say, for the purposes of commercial manufacturing of drug product) and Akebia shall pay EQ for such Product as described herein.

NOW THEREFORE, the Parties hereby agree:

1. Agreement Definitions. When used in this Agreement the following terms and expressions will have the following meaning:

Affiliate means, with respect to either Akebia or EQ, any corporation, company, partnership, joint venture and/or firm which controls, is controlled by or is under common control with Akebia or EQ, as applicable. As used in this definition, "control" means (i) in the case of corporate entities, direct or indirect ownership of more than fifty percent (50%) of the stock or shares having the right to vote for the election of directors (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction); and (ii) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect more than fifty percent (50%) of the members of the governing body of such non-corporate entity.

Agreement means this Supply Agreement, together with all Appendixes and Schedules attached hereto, as amended from time to time by the Parties.

Akebia Equipment means any Equipment that, to the extent agreed by the Parties, is provided by Akebia or its designees for the purposes of the Manufacture of Product.

Akebia Improvements means any Technology and discoveries, inventions, developments, modifications, innovations, updates, enhancements, improvements, writings or rights (whether or not protectable under patent, trademark, copyright or similar laws) that are conceived, discovered, invented, developed, created, made or reduced to practice during the provision of the Services, (i) by Akebia; or (ii) by EQ or both Parties jointly, solely to the extent specific to any Akebia Materials, Manufacture Materials or Product.

Akebia Materials means any materials provided by Akebia or its designees to EQ, for the purposes of providing the Services. Akebia Materials shall be provided free of cost or charge to EQ.

Akebia Technology means any Technology of Akebia (i) existing prior to the Effective Date, or (ii) developed or obtained by or on behalf of Akebia independent of this Agreement and without reliance upon the Confidential Information of EQ. For clarification, Akebia Technology includes the Technology developed by EQ for or on behalf of Akebia pursuant to the Master Services Agreement by and between the Parties dated as of July 15, 2015 (hereinafter "**Master Services Agreement**") or any Statement of Work (as such term in defined in the referred Master Services Agreement) entered into by the Parties thereunder.

Applicable Law means any laws, rules, regulations, guidelines, or requirements of any Authorities that may be in effect from time to time and that may be applicable to any of the activities performed by any of the Parties pursuant to this Agreement (for clarification, when the term Applicable Law is used to define the legal framework applicable to a Party's activities under this Agreement such term shall mean any laws, rules, regulations, guidelines, or requirements applicable in the country where such Party's activities are performed). Notwithstanding the foregoing, international laws and regulations that apply respectively to each other's activities shall be observed under this Agreement.

Authority means any supra-national, federal, national, regional, state, provincial, or local authority responsible for granting approvals relating to the performance of Services under this Agreement or for issuing any Applicable Law or for exercising authority with respect to the Manufacture of any Product in the country where such Manufacture is performed.

Batch means a specific quantity of Product that is intended to be of uniform character and quality, within specified limits, in compliance with the Specifications, and produced during the same cycle of Manufacture as defined by the applicable Batch Record.

Batch Documentation means, for each Batch, the Certificate of Compliance and the Certificate of Analysis.

Batch Records means the set of detailed processing instructions which EQ follows or has followed to Manufacture each Batch of Product.

Business Day means any calendar day in which the banks in both Cambridge, Massachusetts (USA) and Barcelona, Spain are open for business.

Business Records means all records, including reports, accounts, costs of procuring raw materials, notes and data of all information and results obtained from performance of Services.

Certificate of Analysis means a document signed by an authorized representative of EQ, describing testing methods applied to Product and the results of testing.

Certificate of Compliance means a document signed by an authorized representative of EQ, certifying that a particular Batch was Manufactured in accordance with cGMP, Applicable Laws and the Specifications.

Certificate of Lot Disposition a document approved by Akebia's quality assurance department, that assigns disposition status to each Batch of Product.

cGMP means current good manufacturing practices and regulations applicable to the Manufacture of Product that are promulgated by any Authority and which may be in effect from time to time and applicable to the Services.

EQ Improvements means any Technology and discoveries, inventions, developments, modifications, innovations, updates, enhancements, improvements, writings or rights (whether or not protectable under patent, trademark, copyright or similar laws) that are conceived, discovered, invented, developed, created, made or reduced to practice, by or on behalf of EQ, in connection with the performance of Services under this Agreement, that have general applications and are not specific to any Akebia Materials, Manufacture Materials or Product, or are otherwise distinct from Akebia Improvements and Akebia Technology.

EQ Technology means any Technology of EQ (a) existing prior to the Effective Date; or (b) developed or obtained by or on behalf of EQ independent of this Agreement and without reliance upon the Confidential Information of Akebia.

Equipment means any equipment or machinery, including Akebia Equipment, used by EQ at the Facilities in the Manufacturing of Product for Akebia.

Facility means the premise or premises of the manufacturing plant in [**], owned and used by EQ, where EQ carries out the Manufacturing of the Product for Akebia and the premise or premises of the manufacturing plant of [**] where such Affiliate of EQ shall manufacture certain [**] to be used by EQ in the Manufacture of the Product.

Force Majeure means an event caused by facts or circumstances which a Party could not foresee or which, if foreseeable, they could not avoid using commercially reasonable efforts.

Gross Negligence means a conscious, voluntary act or omission in reckless disregard of a legal duty and of the consequences to another party.

Manufacture and **Manufacturing** means any steps, processes and activities necessary to produce Product including the manufacturing, processing, packaging, labeling, quality control testing, storage and release of Product for Akebia up until the time that a Certificate of Compliance is signed.

Manufacture Materials means the substances detailed in Appendix A and other materials that are necessary for production of the Product at EQ facilities and are required to be procured by EQ for the Manufacture of Product.

Manufacturing Process means the processes and activities (or any step in any such processes or activities) to be carried out by EQ to Manufacture the Product for Akebia, as contemplated in the Master Batch Record.

Master Batch Record means the set of detailed processing instructions which EQ must follow to Manufacture each Batch of Product for Akebia in accordance with the Specifications and Applicable Law.

Non-Conforming Product means a Batch of Product delivered by or on behalf of EQ to Akebia, or to a Third Party contractor of Akebia, which, as determined either between the Parties or by an independent testing laboratory, fails to conform to the Specifications and such failure existed when the Batch of Product was delivered by or on behalf of EQ.

Non-Conformity means a non-conformity with the Specifications.

Party or **Parties** means EQ and/or Akebia, referred to individually or collectively, as required by the context.

Product means the active pharmaceutical ingredient in vadadustat with the final Specifications agreed by the Parties as indicated in Section 2.2.1.

Services means the Manufacturing and supply of Products by EQ to Akebia as set forth in this Agreement.

Specifications means the technical and quality assurance specifications for the Product agreed by the Parties as indicated in Section 2.2.1, as they may be amended by written agreement of EQ and Akebia from time to time.

Technology means any methods, techniques, trade secrets, copyrights, know-how, data, documentation, regulatory submissions, specifications and other intellectual property of any kind (whether or not protectable under patent, trademark, copyright or similar laws).

Term means the period of time during which this Agreement is in effect as set forth in Section 10.1 herein.

Third Party means any person or entity other than EQ, Akebia and their respective Affiliates.

2. About Services.

2.1. Provision of Services and Product.

2.1.1. General. EQ will use all such commercially reasonable efforts to perform the Services and deliver Product as directed by the Binding Forecast (as defined below) and the subsequent Purchase Orders issued by Akebia and accepted by EQ, in accordance with the terms and conditions of this Agreement, and exercising the industry standard of skill, care and diligence.

2.1.2. Minimum Purchase Obligation. Unless otherwise agreed to in writing between the Parties, Akebia shall, upon regulatory approval to market a drug product containing the Product in the United States or Europe, by the Food and Drug Administration or the European Medicines Agency respectively ("**US/EU Approval**") and each year during the Term (for this purpose, the first year starting on the date the referred US/EU Approval is granted and ending on the following 31st of December and the last year ending on the date this Agreement expires or is terminated), purchase from EQ, per the terms of this Agreement, the greater of:

(a) at least [**]% of Akebia's, and its Affiliates and licensee's, global needs for Product for commercial purposes (the "**Global Demand**"); or

(b) at least [**] of Product in a calendar year.

The foregoing shall be considered Akebia's minimum purchase obligation under this agreement ("Minimum Purchase Obligation"). Notwithstanding the foregoing, it is understood between the Parties that, except for the last year of the Term, failure by Akebia to achieve the Minimum Purchase Obligation for a year shall not be considered a material breach of this Agreement, *provided* that: (i) Akebia has purchased during such year from EQ at least [**]% of its global needs of Product, (ii) the shortfall to achieve the Minimum Purchase Obligation is added to the Minimum Purchase Obligation applicable for the following year; and (iii) such Minimum Purchase Obligation applicable for the following year (with the addition of the shortfall to achieve the Minimum Purchase Obligation of the prior year) is achieved by Akebia at the end of such following year. The foregoing is further *provided* that if the Minimum Purchase Obligation applicable for the last year in which this Agreement is in effect is not achieved by Akebia, Akebia shall pay EQ the Supply Price for [**]% of the difference between Akebia's actual purchase amount for the applicable year, and the Minimum Purchase Obligation for that year.

2.1.3. Applicable Law, Approvals. EQ will be responsible for obtaining from any Authority, at its expense, such approvals as may be necessary for EQ under Applicable Law for the performance of Services by EQ. At Akebia's request, EQ will provide Akebia with copies of all such approvals. EQ will perform the Services in compliance with Applicable Laws and will also comply with the provisions of the Foreign Corrupt Practices Act of 1977, the UK Bribery Act, the 1997 OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, and, if applicable to EQ's activities, other local and international anti-corruption and anti-bribery laws. In the event that Akebia requires EQ to comply with any requirements in addition to what is set forth in Applicable Laws, Akebia shall inform EQ of such additional requirements and the Parties shall discuss in good faith how to proceed. EQ shall make commercially reasonable efforts to accept and implement the additional requirements as requested by Akebia. Should the Parties fail to agree on how to proceed, the matter will be resolved as detailed in Section 11.10. EQ shall not be required to accept any Purchase Order with such additional requirements until an agreement is reached.

2.1.4. **Facilities and Staff.** EQ will perform all Services at the Facilities, providing all staff necessary to perform the Services in accordance with the terms of this Agreement, and shall hold as appropriate at either the Facilities all Equipment, Akebia Equipment, Akebia Materials and other items used in the Services. EQ will not change the location of such Facilities or use any additional facility for the performance of Services under this Agreement without the prior written consent from Akebia, which will not be unreasonably denied, withheld or conditioned.

2.1.5. **Facilities Validation.** EQ will be responsible for performing all validation of the Facilities and Equipment and cleaning and maintenance processes employed in the Manufacturing Process in accordance with cGMP, EQ's standard operating procedures, the applicable Quality Agreement, Applicable Laws, and in accordance with any other validation procedures requested by Akebia and approved to in writing to EQ.

2.1.6. **Process Validation.** EQ has, as of the Effective Date of this Agreement, commenced [**] activities for [**] of Product manufacturing at EQ Facilities. Such activities are, and will continue to be, conducted in accordance with the Master Services Agreement. The corresponding work orders under such Master Services Agreement issued by Akebia and accepted by EQ shall be governed by the Master Services Agreement, and any other agreements reached by the Parties with respect such process validation activities, until such activities conclude.

2.1.7. **Audits.** With reasonable notice by Akebia to EQ and during normal business hours, EQ will allow Akebia employees to, at Akebia's cost, observe the Manufacturing of the Product by EQ at the Facility, review Records pertaining to Services and inspect the Facilities used by EQ to render Services. Except with the prior consent of EQ, which shall not be unreasonably denied, withheld or conditioned, or as required by Authorities, such audits shall not take place more than [**].

2.1.8. **Inspections.** EQ will permit Akebia to be present and participate in any visit to or inspection by any Authority (if and to the extent it relates in any way to any Product, or the Manufacturing Process). EQ will give as much advance notice as possible to Akebia of any such visit or inspection. Unless prohibited by Applicable Law, EQ will provide Akebia with a copy of any report or other written communication received from such Authority in connection with such visit or inspection, and any written communication received from any Authority relating to the Product, the Facility (if it relates to or affects the Manufacture of Product) or the Manufacturing Process, and, unless prohibited by Applicable Law, will consult with Akebia before responding to each such communication. EQ will comply with all reasonable requests and comments by Akebia with respect to all contacts and communications with any regulatory authority relating to the Services.

2.1.9. **Batch Records Retention.** EQ will maintain all Batch Records in a secure area reasonably protected from fire, theft and destruction. All Batch Records will be the property of Akebia. EQ will not transfer, deliver or otherwise provide any Batch Records to any third party without the prior written approval of Akebia. Batch Records will be retained by EQ for a minimum period of [**] following completion of the Manufacture of such Batch, or longer if required by Applicable Law (therefore, once such period has expired, EQ shall not have an obligation under this Agreement to further retain the Records for the Batch of Product). EQ will, solely at the direction and written request of Akebia, and at Akebia's cost and expense, promptly deliver Batch Records to Akebia or its designee, unless the Batch Records are required to be retained by EQ by Applicable Law or regulation or for insurance purposes; in which case, EQ shall deliver copies of such Batch Records to Akebia, and retain copies to satisfy such Applicable Law or regulation.

2.1.10. **Business Records Retention.** EQ will maintain all Business Records in a secure area reasonably protected from fire, theft and destruction. Business Records will be retained by EQ for at least the minimum period required by Applicable Law. EQ will, and at Akebia's cost and expense, allow Akebia or its designee to access (at reasonable and agreed upon times, or by sending copies to Akebia either physically or electronically, as agreed between the Parties and no more than once every calendar year) any and all Business Records that, for the reasons and purposes and within the scope indicated in this Section 2.1.10, Akebia requests to review. The reasons, scope and purpose for Akebia's review of Business Records shall be regarding matters related with this Agreement only (not with any other matters), which may include, but shall not be limited to, verification of the price of Manufacture Materials. Review of Business Records by Akebia shall be conducted under confidential conditions and Akebia shall treat Business Records as Confidential Information as defined under this Agreement.

2.1.11. **Sample Retention.** EQ will take samples of Product Manufactured under this Agreement and shall retain them for such period and in such quantities as may be required by cGMP or any Applicable Law. Upon Akebia's request and at Akebia's cost and expense, EQ will promptly destroy such samples if EQ has them in excess of those that EQ is required to retain according to Applicable Law.

2.1.12. **Safety Procedures.** EQ will be solely responsible for implementing and maintaining health and safety procedures for the performance of Services and for the handling of any materials or hazardous waste used in or generated by the Services in accordance with Applicable Law. EQ will develop safety and handling procedures for Product and for its Manufacture Materials.

2.1.13. **Testing.** The Product Manufactured under this Agreement will be Manufactured in accordance with the agreed Manufacturing Process, the Specifications and cGMP. Each Batch of Product will be sampled and tested by EQ against and in accordance with the Specifications, and the quality assurance department of EQ will review the documentation relating to the Manufacture of the Batch and will assess if the Manufacture has taken place in compliance with cGMP and the Manufacturing Process.

2.2. Manufacturing Process, Specifications and Akebia Technology Transfer.

2.2.1. **Technology Transfer.** As soon as possible after the execution of this Agreement, following the Process Validation, the Parties will agree on the Manufacturing Process and the Specifications, and, unless agreed by the Parties in writing to the contrary, Akebia will transfer to EQ all Akebia Technology required for the Manufacture of the Product which is not already in the possession of EQ. Any Akebia Technology transferred to EQ for the development and/or Manufacturing of the Product has been and shall be generated in compliance with any Applicable Law, and shall be true, complete and correct in all material respects, to the best of Akebia's knowledge.

2.2.2. **Changes to Manufacturing Process or Specifications.** Any change to the Manufacturing Process or Specifications must be approved in advance by EQ and Akebia, irrespective of whether the change is proposed by either Party or becomes mandatory under any Applicable Law. Before approving and implementing any such change, the Parties will negotiate in good faith and agree upon the allocation of any resulting cost savings or incremental additional costs to be incurred by EQ as a result of such change. However, in case of changes that become mandatory under any Applicable Law, unless otherwise agreed to between the Parties, Akebia shall bear all resulting additional costs, except if such changes are also legally required for products manufactured by EQ for other customers, in which case the resulting additional costs will be proportionally distributed among all such customers and Akebia.

Supply Price shall be adjusted each year, as required, to fully absorb the yearly amortization of such additional costs resulting from such mandatory changes. For clarification, reductions or savings in EQ's Manufacturing costs that result from the implementation by EQ of improvements, changes or efficiencies developed solely by EQ in the Manufacturing Process or, in general, the Manufacturing activities of EQ, shall not result in a reduction of the supply Price unless otherwise specifically agreed by the Parties.

2.3. Planning, Forecasts.

2.3.1. On the [**] of each calendar quarter, Akebia will provide EQ a rolling forecast for Akebia's anticipated need for Product supplied by EQ each calendar quarter in the following [**] months, or shorter period as may remain under the Term ("**Proposed Forecast**"). The first [**] months of each Proposed Forecast shall be binding on the Parties, once accepted by EQ ("**Binding Forecast"**). The remaining [**] months will be projected in good faith, but will remain non-binding ("**Non-Binding Forecast**").

The first Proposed Forecast under this Agreement is the fully executed version of the forecast that was received by email by EQ from Akebia on [**] ("**First Forecast**"). Upon execution of this Agreement, the First Forecast shall be considered accepted by EQ, and, therefore, the initial [**] months of the First Forecast shall be binding on the Parties and become the first Binding Forecast.

For future forecasts, EQ must communicate its written acceptance or rejection of the Proposed Forecast to Akebia within [**] of its receipt by EQ. Failure by EQ to accept or reject the Proposed Forecast within [**] of its receipt will result in the first [**] months of Proposed Forecast becoming a Binding Forecast and, therefore, become binding upon both Parties. For clarification, upon acceptance of a Proposed Forecast by EQ, only the first [**] months of Proposed Forecast become a Binding Forecast and, therefore, the rest of the months in the Proposed Forecast remain a Non-Binding Forecast.

2.3.2. Except with EQ's specific written acceptance, which shall not be unreasonably denied, withheld or conditioned, the volumes for a new quarter in the Binding Forecast shall not be below [**] percent ([**]%), nor shall it be above [**] percent ([**]%) of the volumes forecasted for such quarter in the previous Non-Binding Forecast. Except with EQ's specific written acceptance, which shall not be unreasonably denied, withheld or conditioned, a newly provided forecast shall not amend a previous Binding Forecast.

Unless otherwise agreed in good faith between the Parties, the maximum aggregate volume of Product that EQ anticipates being able to Manufacture and supply during each period of [**] months while this Agreement is in effect is [**] of total Product ("**Maximum Volume**") and, therefore, except with the specific written acceptance of EQ, the Forecasts provided by Akebia shall not exceed the Maximum Volume during any [**] months period during the Term.

2.3.3. Events of a regulatory nature that prevent Akebia from launching its product, vadadustat, (e.g. delay in market approvals from regulatory agencies, etc.) which then prevents or delays Akebia from purchasing an amount of Product within a Binding Forecast period, shall not constitute a material breach of this Agreement on the part of Akebia, and any such shortfall or gap due to delays of a regulatory nature will be resolved in good faith between the Parties. The foregoing is provided, *however*, that Akebia shall pay to EQ:

(a) the Supply Price corresponding to the amount of Product already Manufactured and Product in-process ("**Undelivered Product**"). Fully Manufactured Undelivered Product which Supply Price is paid by Akebia to EQ as contemplated in this Section will be made available by EQ to Akebia promptly upon completion of the Manufacturing process at the time of their completion in accordance with the delivery terms set forth in this Agreement. Notwithstanding the foregoing, the Parties may use reasonable factors, including the shelf-life of the completed Undelivered Product, to together decide whether Undelivered Product may be used to fulfill future Purchase Order(s) as part of future Binding Forecasts rather than delivering the Undelivered Product promptly as set forth above. In that case, each unit of Undelivered Product that the Parties agree may be used to fulfill future Purchase Order(s) will be kept by EQ, and made part of future Purchase Order(s) as agreed by the Parties. Akebia shall not be obligated to pay the Supply Price for such Undelivered Product until it is invoiced by EQ in accordance with sections 2.4 and 2.7 below; and

(b) the costs and expenses associated with procuring the Manufacturing Materials or any other non-cancellable obligations that EQ has reasonably incurred in order to supply Product under the Binding Forecast(s). Upon receipt of payment by Akebia for the Manufacturing Materials the Manufacture Materials shall become Akebia property, and delivered to Akebia at Akebia's cost, or otherwise disposed of as agreed between the Parties. Notwithstanding the foregoing, the Parties may use reasonable factors, including the shelf-life of any such Manufacture Materials, to together decide whether such Manufacture Materials may be used to Manufacture future Products as part of future Binding Forecasts. In that case, those Manufacturing Materials that the Parties agree that may be used to Manufacture Products as part of future Binding Forecasts shall not be paid by Akebia as contemplated in this Section 2.3.3 (b) but shall be kept by EQ for its use in the Manufacture of such future Products.

If Akebia finally and definitely ceases or decides not to pursue the regulatory approval of any product containing the Product, Akebia shall be entitled to terminate this Agreement with immediate effect; provided, however, that the provisions of Section 10.5 shall also apply in the event of such termination.

2.4. Purchase Orders.

2.4.1. Throughout the Term, Akebia shall submit to EQ a binding Purchase Order for the volume of Product requested for the upcoming Binding Forecast period ("**Purchase Order**") in Akebia's standard format to facilitate payment to EQ. Except in the event that it is otherwise specifically agreed by the Parties for an specific Purchase Order, the terms of a Purchase Order shall not change or add to the terms of this Agreement. The terms of Purchase Orders submitted by Akebia may only be changed with the specific written agreement of both Parties. The first Purchase Order after the Effective Date of this Agreement shall be submitted by Akebia to EQ no later than [**] after the Effective Date, and shall represent a Purchase Order for the first [**] months of the First Forecast.

2.4.2. EQ shall provide, no later than [**] after receipt of each Forecast from Akebia, an updated production forecast for the following [**] months in order for Akebia to plan for Batch Documentation review.

2.4.3. EQ shall deliver the Product on the date agreed by the Parties in the corresponding Purchase Order (provided that deliveries in +/- [**] from the delivery date agreed in the Purchase Order and shortfalls in Product delivery of less than [**] percent ([**]%) of the agreed volume of Product in a Purchase Order shall be accepted), which shall be no less than [**] from the date of receipt of the Purchase Order by EQ.

Shortfalls in Product delivery of less than [**] percent ([**]%) shall be resolved in good faith between the Parties aiming to achieve delivery of one hundred percent (100%) of the Product in the Purchase Order affected by the shortfall as soon as reasonably practical for EQ.

If EQ is unable to deliver the Product within [**] from the agreed date or in at least [**]% of the agreed volume of Product, the Parties will discuss appropriate steps to alleviate such a shortfall but Akebia will have the right, in its discretion, to (i) require EQ to use commercially reasonable efforts to make up the shortfall as promptly as reasonably practical or (ii) have the quantity of the shortfall of Product be manufactured and supplied by a Third Party. If Akebia elects to secure from a Third Party any quantity of Product to make up the shortfall, EQ shall (a) refund to Akebia the Price paid to EQ for the Product in the shortfall (provided that if the Price for the Product in the shortfall has not been yet paid by Akebia, such Price shall not have to be paid by Akebia), and (b) pay to Akebia the Price paid to the Third Party manufacturer beyond the Price that Akebia would have had to pay to EQ for the shortfall quantity of Product under this Agreement.

2.4.4. EQ shall not be liable for any delay in supplying Product when such delay is due to: (a) reasonably unforeseeable and significant Manufacture Material(s) supply chain issues that could not have been prevented or avoided through reasonable means by EQ; or (b) EQ not being provided, or being provided with defective Akebia Materials, Akebia Equipment or Akebia Technology for EQ to Manufacture the Product, or (c) any fact, circumstance or reason attributable to Akebia or its designees. Notwithstanding the foregoing, the Parties expect EQ to maintain a comprehensive, reasonable (as per industry standards) supply chain strategy with respect to Manufacture Materials, and EQ shall be liable under the terms of Section 2.4.3 for any delay to Product delivery caused by a failure of EQ to maintain a reasonable risk mitigation strategy reasonably capable of mitigating any possible issues of sourcing Manufacture Materials.

2.5. <u>Supply of Materials</u>.

2.5.1. Except for the Akebia Materials that the Parties agree shall be supplied by Akebia to EQ, EQ shall be responsible for producing or procuring through the appropriate Third Party suppliers, all the Manufacture Materials required by EQ for the Manufacture of the Products. EQ shall be responsible for ensuring that such Manufacture Materials comply with the Specifications and for adequately reviewing, testing and storing such Manufacture Materials.

2.5.2. EQ agrees (a) to store all Akebia Materials according to the terms and conditions set forth in this Agreement and directions provided by Akebia; (b) not to provide Akebia Materials to any Third Party without the express prior written consent of Akebia; (c) not to use Akebia Materials for any purpose other than conducting the Services; and (d) to destroy or return to Akebia, in Akebia's discretion and at Akebia's cost and expense, all unused quantities of Akebia Materials according to Akebia's written directions.

2.5.3. Akebia shall be responsible for delivery of the Akebia Materials [**] to a Facility. If applicable, EQ shall provide Akebia with reasonable assistance to obtain and maintain any necessary import approvals, licenses, customs clearance applications, forms and other correspondence in connection with the delivery of the Akebia Materials.

2.5.4. Akebia will ensure that Akebia Materials are delivered timely and that such Akebia Materials comply with their respective specifications, if applicable. Prior to using any Akebia Materials, EQ will review and test them against such Specifications, if applicable. In the event of any disagreement between the Parties regarding whether any Akebia Materials meet the agreed specifications or not, the provisions of Section 2.7 hereof shall apply.

2.5.5. Akebia will at all times retain title to and ownership of the Akebia Materials. EQ will provide within a Facility an area or areas where the Akebia Materials, the Product, and any Manufacture Materials, are segregated and stored in accordance with any applicable specifications and cGMP, and in such a way as to be able at all times to clearly distinguish such Akebia Materials, Product, intermediates and components from other products and materials belonging to EQ, or held by it for a Third Party. EQ will ensure that Akebia Materials, the Product, and any Manufacture Materials, are free and clear of any liens or encumbrances attributable to or related to EQ or its Affiliates. EQ will at all times take such measures as are reasonably customary to protect the Akebia Materials, the Product, and any intermediates and components of Akebia Materials or Product, from loss, damage and theft at all stages of the Manufacturing Process. EQ will immediately notify Akebia if at any time it believes any Akebia Materials, the Product, or any Manufacture Materials, have been damaged, lost or stolen.

2.6. Supply of Equipment.

2.6.1. Prior to accepting any Binding Forecast, EQ will verify that it has all Equipment necessary to perform the Services. In case EQ does not have certain Equipment necessary to perform the Services, the Parties shall discuss how to proceed before any Purchase Order relating to such Binding Forecast is accepted.

2.6.2. To the extent agreed by the Parties, Akebia will timely deliver the Akebia Equipment to EQ. EQ will not use the Akebia Equipment except in performance of services under this Agreement and shall follow the instructions and comply with the specifications of the Akebia Equipment. Title to any Equipment other than the Akebia Equipment will remain with EQ. Title to the Akebia Equipment will remain with Akebia and EQ will ensure that the Akebia Equipment is properly labeled as Akebia property and remains free and clear of any liens or encumbrances attributable to or related to EQ or its Affiliates. At Akebia's written request and cost the Akebia Equipment will be returned to Akebia, or to Akebia's designee. Within [**] after any termination or expiration of this Agreement, EQ shall notify Akebia in writing if any Akebia Equipment remains at an EQ Facility. If, after [**] from the day in which Akebia receives the referred written notice from EQ, EQ has not received a written notice from Akebia requesting EQ to return the Akebia Equipment to Akebia or if in such notice Akebia only requests that some of the Akebia Materials are returned, EQ shall have the right to either (a) dispose of any remaining Akebia Equipment at Akebia's cost; or (b) purchase from Akebia remaining Akebia Equipment at the current market value of such Akebia Equipment, without markup. EQ will be responsible, at its own cost, for ordinary maintenance of the Akebia Equipment while in EQ's possession as per reasonable instructions provided by Akebia. Repairs of any Akebia Equipment shall be at Akebia's cost and expense, unless repair is needed due to EQ's negligence or wrongful acts. EQ will immediately notify Akebia if at any time it believes any Akebia Equipment has been damaged, lost or stolen.

2.7. Delivery and Acceptance Process.

2.7.1. Release of Product and Invoicing. If, based upon the review performed by EQ, a Batch of Product conforms to the Specifications and was Manufactured according to cGMP and the Manufacturing Process, then a Certificate of Compliance shall be completed by EQ, [**]. At the time of invoice, EQ will deliver the Batch Documentation to Akebia. It is understood that EQ agrees to provide Akebia supporting Batch Documentation as it is completed throughout a Manufacturing campaign. Upon Akebia's request, EQ shall also deliver to Akebia all raw data and other Batch Records in the possession or under the control of EQ relating to the Manufacture of each Batch of Product.

No delivery of Product by EQ will occur without prior release for delivery by Akebia's quality assurance department. Akebia's Certificate of Lot Disposition must be received by EQ prior to delivery of Product. For such purpose, Akebia's quality department will review the documentation provided by EQ for the Batch of Product and, within [**] of receipt of such documentation, will provide EQ with the Certificate of Lot Disposition or, otherwise, with its justified objections to issuing the Certificate of Lot Disposition. Akebia's quality assurance department will not refuse to issue the Certificate of Lot Disposition for any reasons other than objections relating to the quality of the Product for which such certificate should be issued.

2.7.2. Delivery of Product. If Akebia's quality assurance department issues a Certificate of Lot Disposition, EQ shall deliver Product in accordance with the agreed instructions for shipping and packaging agreed to by the Parties in writing. Delivery will be [**] and Akebia shall be responsible for Product after title and risk of loss vests with Akebia in accordance with [**]. Akebia shall collect the Products as soon as reasonably practicable after the date in which EQ has received the above-mentioned Certificate of Lot Disposition from Akebia´s quality assurance department, but, except as otherwise specifically agreed by the Parties, within [**] from the date of the invoice by EQ.

If Akebia does not collect the Products within the referred [**] period referenced above, and unless otherwise specifically agreed by the Parties, either;

(a) If such delay in collection of the Product is caused by Akebia, EQ shall be entitled to charge a reasonable storage fee to Akebia until the date that Akebia actually collects the Products and, in case the Product is to be shipped outside the European Union, EQ shall invoice Akebia the corresponding Value Added Tax ("VAT"). EQ shall provide Akebia with reasonable assistance to obtain and maintain any necessary export approvals, licenses and customs clearance applications, forms and other correspondence in connection with the Product.

(b) If such delay in collection of the Product is caused, in whole or in part, by EQ, it is agreed that EQ, rather than Akebia, shall appear as exporter of record in the corresponding export documentation (DUA). Any such change in exporter of record shall not change the commercial conditions that have been agreed by the Parties under this Agreement (for example, risk of loss and INCOTERMS™ 2010).

2.7.3. Inspection and Acceptance of Product. Any claim of Akebia or its designees concerning Non-Conforming Products shall be communicated by Akebia to EQ in writing as soon as possible but in no event later than [**] from its discovery by Akebia or its designees. Any such Non-Conformity claim will need to be accompanied by a sample of the Product analyzed by Akebia and with all relevant documentation regarding such analysis, including but not limited to the Certificate of Analysis and a report indicating the methods used by Akebia. For clarification, after the end of the above-mentioned period to claim a Non-Conformity of Products, Akebia and its designees shall not be entitled to claim that the Products delivered by EQ were Non-Conforming Products. Also, Akebia and its designees shall not be entitled to claim that the Products delivered by EQ were Non-Conforming Products if Akebia, or as appropriate, its designees, fail to perform the tests, analysis, inspections and/or reviews of the Product appropriately and in a timely manner, and/or complete its related documentation required under Applicable Laws, the Quality Agreement, and/or cGMP.

2.7.4. Product Quality Disputes. In case of any disagreement between the Parties regarding as to whether any a Product is Non-Conforming Product, the quality assurance representatives of the Parties will attempt to resolve any such disagreement in good faith. If the disagreement is not resolved in a reasonable time (which will not exceed [**]), a representative sample of the Product and/or relevant documentation will be submitted to an independent testing laboratory of recognized standing in the industry and agreed upon by the Parties for tests and final determination of whether or not such Product is a Non-Conforming Product. Such laboratory will use the test methods contained in the applicable Specifications. The determination of conformance by such laboratory will be final and binding on the Parties. The fees and expenses of the laboratory will be paid by the Party against whom the determination is made.

2.7.5. Product Non-Conformance and Remedies. If any Product is agreed by the Parties, or is determined in accordance with Section 2.7.4., to be a Non-Conforming Product, EQ shall be liable to Akebia for such Non-Conforming Product; provided that (except in respect to Third Party claims, which shall be subject to the provisions of Section 9 below) EQ's liability shall be limited to, at Akebia's option, (i) refunding in full the Price paid by Akebia for the Non-Conforming Product, including the cost of Akebia Materials used in the Manufacture of such Non-Conforming Product; or (ii) at EQ's cost and expense, supply to Akebia Product that is not Non-Conforming Product (in the same quantity as the Product that has been agreed by the Parties to be Non-Conforming Product) as soon as reasonably possible; or (iii) if possible according to Applicable Law and cGMP, reworking or reprocessing the Non-Conforming Product, at EQ's cost and expense, so that the Non-Conforming Product conforms to Specifications.

Notwithstanding the foregoing, should EQ provide Non-Conforming Product that, after a diligent quality investigation performed in accordance with cGMP, the Quality Agreement, and industry good practices, are attributable, in whole or in part, to EQ's failure to comply with cGMP, the Quality Agreement, or their obligations under this Agreement, EQ shall be responsible, up to the amounts indicated in Section 9.5 hereof, for the resulting costs and expenses to Akebia, including, without limitation, the costs of any resulting recall, expenses related to communications and meetings with all required regulatory agencies, expenses of replacement stock of Product, the cost of notifying customers, the costs associated with shipment and destruction of recalled drug product containing the Product from customers, and replacement Product equal to the amount of Product found to contain the Non-Conformity.

EQ shall not be responsible for the costs associated with any Non-Conforming Product that has been detected by Akebia and Akebia fails to communicate it to EQ within [**], or if Akebia (or the Third Party that receives the Product supplied by EQ on behalf of Akebia) fails to appropriately and timely perform the tests, analysis, inspections and/or reviews of the Product, and/or complete its related documentation required under Applicable Laws, the Quality Agreement, and/or industry good practices.

2.7.6. Disposition of Non-Conforming Product. The ultimate disposition of Non-Conforming Product, which shall be carried out in accordance with Applicable Law, will be the responsibility of Akebia's quality assurance department. The costs associated with the disposal of any Non-Conforming Product shall be borne by EQ.

2.8. Subcontracting. With Akebia's prior written consent, EQ may subcontract the performance of specific obligations of EQ to an Affiliate of EQ or to a qualified Third Party; provided, that (a) such Affiliate or Third Party performs those Services in a manner consistent with the terms and conditions of this Agreement; and (b) EQ remains liable for the performance of such Affiliate or Third Party.

2.9. Quality Agreement. In accordance with Applicable Law, the Parties shall agree upon a quality agreement describing, in accordance with this Agreement, the quality assurance responsibilities and obligations of the Parties for the Manufacture of Product ("**Quality Agreement**").

3. Price and Payments.

3.1. Price. Price for the Product supplied by EQ to Akebia during the Term of this Agreement shall be determined as set forth in Appendix B ("**Price or Supply Price**"). Each invoice from EQ will include such Price and the quantities of Product per the applicable Purchase Order.

3.2. Modifications in Price. Notwithstanding the foregoing, the Parties agree that any change in the EQ cost of Manufacture Materials necessary to manufacture Product shall be [**]. EQ shall diligently monitor any such change in cost at least on a [**] basis, and shall [**] the Price for the Product in any subsequent delivery of Product where Manufacture Materials with such change in costs are used. Accuracy as to the monitoring and representation of changes in Manufacture Material costs shall be verifiable by Akebia in any audit of EQ by Akebia.

3.3. Invoice. EQ will invoice Akebia referencing in each such invoice the Purchase Order(s) to which the invoice relates. EQ will invoice on the date in which, as contemplated in Section 2.7.1 hereof, [**].

3.4. Payments. Payment will be due [**] after the date of the invoice. Akebia will make all payments pursuant to this Agreement by wire transfer to a bank account designated by EQ, without deduction of any transfer charges or banking commissions. Payments must be made in all cases under these conditions even if, for whatever reason, Akebia does not take delivery of the Products after EQ has communicated that they have been cleared for delivery The foregoing is except and provided that Akebia will be entitled to withhold payment of the part of EQ's invoices that refer to Products that Akebia claims to be Non-Conforming in accordance with Section 2.7.5. hereof. If the Parties agree or it is ultimately determined, as indicated in Section 2.7.5, that (i) the Products were Non-Conforming Products, the remedies also indicated in Section 2.7.5 shall apply, or that (ii) the Products were conforming to the Specifications, Akebia will immediately pay to EQ the withheld part of EQ's invoice, together with the interest indicated in Section 3.5.

3.5. Interest on Late Payments. Any amounts not paid on the date due under this Agreement shall be subject to interest from the date payment was due through and including the date upon which payment is received. Interest shall accrue on a daily basis and be calculated on the assumption of a 360 day year and using an annual rate equal to the official published one year EURIBOR ("***Euro Interbank Offered Rate***"), as may vary during the Term, plus [**] basis points. Interest shall be payable on demand. Interest shall not be compounded.

3.6. Taxes. The Prices specified in this Agreement are exclusive of any sales, use, excise, VAT or similar taxes, and of any export and import duties which may be levied as a result of the shipment of the Product. It shall be EQ's sole obligation to report all compensation received by EQ hereunder for Services as may be required by Applicable Law. Akebia shall pay all applicable sales and use taxes, including all applicable goods and services tax, value added tax, local taxes, applicable duties, electronic delivery taxes, sales, use and excise taxes, levies and import and export fees (collectively, "Taxes") that are required by law in connection with the provision of Services and that are not recoverable by EQ. EQ shall reasonably cooperate and assist Akebia in recovering any non-applicable taxes due to Akebia. Where any Taxes are paid directly to a tax authority or government by Akebia, Akebia shall not deduct this amount from any amount due to EQ.

4. Representations and Warranties of EQ. EQ represents and warrants as follows:

4.1. Organization of EQ. EQ is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.

4.2. Enforceability of this Agreement. The execution and delivery of this Agreement by EQ has been authorized by all requisite corporate or company action. This Agreement is and will remain a valid and binding obligation of EQ, enforceable in accordance with its terms, subject to Applicable Laws.

4.3. Absence of Other Contractual Restrictions. EQ is under no contractual or other obligation or restriction that is inconsistent with EQ's execution or performance of this Agreement. EQ will not enter into any agreement, either written or oral, that would conflict with EQ's responsibilities under this Agreement.

4.4. Qualifications of EQ Personnel**.** EQ has engaged, will engage and will cause its Affiliates involved in rendering Services to engage, employees and permitted subcontractors including consultants (collectively, "EQ Personnel") with the proper skill, training and experience to provide services detailed in this Agreement. The foregoing is provided that the involvement of Affiliates of EQ in providing the Services shall require Akebia's prior approval (which is hereby granted by Akebia for the manufacturing of certain intermediates of the Product by and at the Facilities. Before providing Services, all EQ Personnel must be subject to binding commitments with EQ under which they have confidentiality obligations with regard to Akebia's Confidential Information (as defined below) that are consistent with the terms of this Agreement.

4.5. Compliance. EQ will perform all Services with requisite care, skill and diligence, in accordance with Applicable Law, cGMPs and industry standards and that at the time of delivery to Akebia, the Product Manufactured by EQ shall conform to the Specifications and will not be will not be adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335(a).

4.6. Conflicts with Rights of Third Parties. To EQ's knowledge, having made reasonable investigations in the ordinary course of business, the use of EQ Technology by EQ for the Manufacture of the Products for Akebia as contemplated in this Agreement will not violate any patent, trade secret or other proprietary or intellectual property rights of any Third Party.

4.7. Absence of Debarment. EQ, its Affiliates, EQ Personnel and each of their respective officers and directors, as applicable: (a) have not been debarred and are not subject to a pending debarment, and will not use in any capacity in connection with Services any person who has been debarred or is subject to a pending debarment, pursuant to section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 335a; (b) are not ineligible to participate in any federal and/or state healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)); (c) are not disqualified by any government or regulatory authorities from performing specific services, and are not subject to a pending disqualification proceeding; and (d) have not been convicted of a criminal offense related to the provision of healthcare items or services and are not subject to any such pending action. EQ will notify Akebia immediately if EQ, its Affiliates, any EQ Personnel, or any of their respective officers or directors, as applicable, is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of EQ's knowledge, is threatened.

5. Representations and Warranties of Akebia. Akebia represents and warrants as follows:

5.1. Organization of Akebia**.** Akebia is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.

5.2. Enforceability of this Agreement. The execution and delivery of this Agreement by Akebia has been authorized by all requisite corporate or company action. This Agreement is and will remain a valid and binding obligation of Akebia, enforceable in accordance with its terms, subject to Applicable Laws.

5.3. Absence of Other Contractual Restrictions. Akebia is under no contractual or other obligation or restriction that is inconsistent with Akebia's execution or performance of this Agreement. Akebia will not enter into any agreement, either written or oral, that would conflict with Akebia's responsibilities under this Agreement.

5.4. Akebia Technology Transfer. To the best of Akebia's knowledge, any Akebia Technology transferred to EQ for the development and/or Manufacturing of the Product has been and shall be generated in compliance with any Applicable Law and shall be true, complete and correct in all material respects and sufficient for its intended purpose and use.

5.5. Conflicts with Rights of Third Parties**.** To its knowledge, having made reasonable investigations in the ordinary course of business, the use by EQ of Akebia Materials and Akebia Technology as provided to EQ for the provision of the Services will not violate any patent, trade secret or other proprietary or intellectual property rights of any Third Party.

5.6. Compliance with Applicable Law. Any activities carried out by Akebia, its Affiliates, officers, directors and employees in connection with this Agreement shall comply with any Applicable Law. When inspecting the Product supplied by EQ and testing it for compliance with the Specifications, Akebia shall comply with any Applicable Law and shall do so with appropriate care, skill and diligence.

6. Disclaimer of Other Representations and Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY SPECIFICALLY DISCLAIMS, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE.

7. Proprietary Rights.

7.1. Akebia Technology. All rights to and interests in Akebia Technology will remain solely in Akebia and, other than as set forth herein, no right or interest therein is transferred or granted to EQ under this Agreement. EQ acknowledges and agrees that it does not acquire a license or any other right to Akebia Technology except for the limited purpose of carrying out its duties and obligations under this Agreement and that such license will expire upon the expiration or termination of this Agreement.

7.2. Akebia Improvements. EQ shall communicate to Akebia any Akebia Improvements made by EQ in the performance of the Services. All rights to and interest in Akebia Improvements (patentable or not) will remain solely in Akebia and, other than as set forth herein, no right or interest therein is transferred or granted to EQ under this Agreement.

7.3. EQ Technology. All rights to and interests in EQ Technology will remain solely in EQ and, except as otherwise set forth in this Agreement, no right or interest therein is transferred or granted to Akebia under this Agreement. EQ hereby grants to Akebia a [**] license in the EQ Technology to Akebia solely to use Product delivered by EQ to Akebia under this Agreement for (i) the development, manufacture and/or commercialization (directly by Akebia, through Akebia's designees or by Akebia's sub-licensees) of drug products, or (ii) any other legally permitted use of such Product delivered by EQ (for clarification, the license contemplated in this paragraph shall not allow Akebia, its designees or its sub-licensees to use EQ Technology for the manufacture, directly or through its designees, of drug products that do not contain Product delivered by EQ to Akebia under this Agreement).

7.4. EQ Improvements. EQ shall communicate to Akebia any EQ Improvements made by EQ in the performance of the Services. Any and all rights and title to EQ Improvements made by EQ in the performance of the Services (patentable or not) will be the sole and exclusive property of EQ.

8. Confidential Information.

8.1. Definition. "Confidential Information" means any and all non-public scientific, technical, financial or business information, or data or trade secrets in whatever form (written, oral or visual) that is furnished or otherwise made known directly or indirectly by one Party (the "Discloser") to the other (the "Recipient") pursuant to the terms of this Agreement or otherwise in connection with this Agreement, whether marked confidential or not, and irrespective of whether such information was furnished or otherwise made known prior to or after the Effective Date. Prior to the Effective Date, the Master Services Agreement between the Parties shall govern.

8.2. Obligations. During the term of this Agreement and for a period of [**] thereafter (and in the case of trade secrets, until such time as Discloser no longer treats such information as a trade secret), Recipient agrees to (a) hold in confidence all Discloser's Confidential Information, and not disclose Discloser's Confidential Information except as expressly provided in Section 8.3, without the prior written consent of Discloser; (b) use Discloser's Confidential Information solely to carry out Recipient's rights or obligations under this Agreement; (c) treat Discloser's Confidential Information with the same degree of care Recipient uses to protect Recipient's own confidential information but in no event with less than a reasonable degree of care; and (d) reproduce Discloser's Confidential Information solely to the extent necessary to carry out Recipient's rights or obligations under this Agreement, with all such reproductions being considered Discloser's Confidential Information.

8.3. Permitted Disclosures. Recipient may provide Discloser's Confidential Information solely to its employees or contractors (but if Recipient is EQ, then solely to EQ Personnel who are in compliance with Section 4.4 hereof) on a need-to-know basis and solely as necessary to carry out Recipient's rights or obligations under this Agreement; provided, that Recipient remains liable for the compliance of such employees or contractors (or if EQ is Recipient, the compliance of such EQ Personnel) with the terms of this Agreement. If Recipient is required by a governmental authority or by order of a court of competent jurisdiction to disclose any of Discloser's Confidential Information, Recipient will give Discloser prompt written notice of such requirement or order and Recipient will take all reasonable and lawful actions to avoid or minimize the degree of such disclosure. Recipient will cooperate reasonably with Discloser in any efforts to seek a protective order.

8.4. Exceptions. Recipient's obligations of non-disclosure and non-use under this Agreement will not apply to any portion of Discloser's Confidential Information that Recipient can demonstrate, by competent proof:

(a) is generally known to the public at the time of disclosure or becomes generally known through no wrongful act on the part of Recipient;

(b) is in Recipient's possession at the time of disclosure other than as a result of Recipient's breach of any legal obligation;

(c) becomes known to Recipient on a non-confidential basis through disclosure by sources other than Discloser having the legal right to disclose such Confidential Information; or

(d) is independently developed by Recipient without reference to or reliance upon Discloser's Confidential Information.

8.5. Public Announcements. Neither Party shall issue any public announcement, press release, or other public disclosure regarding this Agreement or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules or common practices of a stock exchange on which the securities of the disclosing Party are listed. Both Parties agree that each of them may disclose that Akebia has engaged EQ as a manufacturer for the Product.

9. Indemnification and Insurance.

9.1. Indemnification by EQ. EQ will indemnify, defend and hold harmless Akebia, its Affiliates, and its and their respective officers, directors, employees and agents (collectively, the "Akebia Indemnitees") against any and all losses, damages, liabilities or expenses (including reasonable attorney's fees and other costs of defense) (collectively, "Losses") that any of them may suffer in connection with any and all suits, investigations, claims, or demands of Third Parties (collectively, "Third Party Claims") arising from, relating to or occurring as a result of (a) any EQ Indemnitee's negligence or willful misconduct in performing its obligations under this Agreement; (b) the use of EQ Technology by EQ for the Manufacture of the Products for Akebia violating any patent, trade secret or other proprietary or intellectual property rights of any Third Party; or (c) EQ's breach of this Agreement; *except to* the extent that such Third Party Claims are due to any breach by Akebia of its obligations under this Agreement or the negligence or willful misconduct of Akebia. For clarity, for product liability claims, EQ shall not indemnify Akebia if the relevant Product conformed to the Specifications at the time of delivery by EQ, or if the failure of the Product to conform should have been reasonably detected by Akebia via a visual inspection or via testing, inspection, analysis or review of the Product or is related documentation as required under Applicable Law, the Quality Agreement and/or cGMP.

9.2. Indemnification by Akebia. Akebia will indemnify, defend and hold harmless EQ, its Affiliates, and its and their respective officers, directors, employees and agents (collectively, the "EQ Indemnitees") against any Losses that any of them may suffer in connection with any Third Party Claims arising from, relating to or occurring as a result of (a) the development, further manufacture, commercialization or use of any product containing the Product (including, but not limited to, product liability claims and claims that such product infringes any Third Party rights and claims for personal damages or injuries); (b) Akebia Technology transferred to EQ for the Development and/or Manufacturing of the Product not having been generated in compliance with Applicable Laws, or not being true, complete and correct in all material respects, or being insufficient for its intended purpose and use or violating any patent, trade secret or other proprietary or intellectual property rights of any Third Party; (c) any Akebia Indemnitee's negligence or willful misconduct in performing obligations under this Agreement; or (d) Akebia's breach of this Agreement; *except to* the extent that such Third Party Claims are due to any breach by EQ of its obligations under this Agreement, any Non-Conforming Product supplied by EQ (except if the Product's Non-Conformity should have been reasonably detected by Akebia via a visual inspection or via testing, inspection, analysis or review of the Product or is related documentation as required under Applicable Law, the Quality Agreement and/or cGMP), or negligence or willful misconduct of EQ.

9.3. Indemnification Procedures. Each Party must promptly notify the other Party after receipt of any Third Party Claims for which the other Party might be liable under Section 9.1 or 9.2 hereof, as applicable. The indemnifying Party will have the sole right to defend, negotiate, and settle such claims. The indemnified Party will be entitled to participate in the defense of such matter and to employ counsel at its expense to assist in such defense; provided, however, that the indemnifying Party will have final decision-making authority regarding all aspects of the defense of the claim. The indemnified Party will provide the indemnifying Party with such information and assistance as the indemnifying Party may reasonably request, at the expense of the indemnifying Party. Neither Party will be responsible or bound by any settlement of any claim or suit made without its prior written consent; provided, however, that the indemnified Party will not unreasonably withhold or delay such consent.

9.4. Exclusion of Indirect and Consequential Damages. EXCEPT IN THE EVENT OF WILFUL MISCONDUCT OR GROSS NEGLIGENCE, OR BREACH OF THE PARTIES' OBLIGATIONS OF CONFIDENTIALITY UNDER THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL (INCLUDING LOST PROFITS, BUSINESS OR GOODWILL), PUNITIVE OR INDIRECT DAMAGES SUFFERED OR INCURRED BY THE OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT, HOWEVER CAUSED, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

9.5. Liability Limitation. EXCEPTING ANY BREACH OF THEIR OBLIGATIONS OF CONFIDENTIALITY IN SECTION 8, THEIR OBLIGATIONS IN SECTION 11.1, EACH PARTY'S LIABILITY UNDER SECTION 9.1 AND 9.2, AND NOTWITHSTANDING THEIR OBLIGATIONS UNDER SECTION 9 HEREIN, THE PARTIES' MAXIMUM AGGREGATE TOTAL LIABILITY TO EACH OTHER UNDER THIS AGREEMENT WILL NOT EXCEED DURING EACH CALENDAR YEAR THE HIGHER OF (I) [**]; AND (II) [**]; PROVIDED, THAT, NOTHING IN THIS AGREEMENT EXCLUDES OR LIMITS A PARTY'S LIABILITY FOR DAMAGES RESULTING FROM [**] OF ITS OBLIGATIONS IMPOSED UNDER THIS AGREEMENT IF SUCH [**] ARE THE RESULT OF SUCH PARTY'S [**] OR [**].

9.6. Insurance. EQ will carry, with financially sound and reputable insurers, insurance coverage (including worker's compensation at or above the applicable statutory limits, comprehensive liability coverage with contractual liability, and professional liability/errors and omissions coverage) with respect to the conduct of its business against loss from such risks and in such amounts as is customary for well-insured companies engaged in similar businesses and sufficient to support its obligations under this Agreement. Upon the request of Akebia, EQ will provide Akebia with a Certificate of Insurance evidencing such coverage, and providing that [**] advance written notice will be given to Akebia of any material change or cancellation in coverage or limits. EQ may use self-insurance, and the use of primary and excess limits to achieve the total required limits is acceptable.

10. Term and Termination.

10.1. Term. This Agreement is effective on the Effective Date and will expire on the 4th anniversary of the Effective Date. Not later than the [**], the Parties shall conclude good faith negotiations on [**], as well as [**] applicable for the [**] that may be agreed by the Parties.

10.2. Akebia Termination at Will. Akebia will have the right, in its sole discretion, to terminate this Agreement for any reason upon one hundred and eighty (180) days prior written notice to EQ.

10.3. Akebia Termination for Cause. Akebia may terminate this Agreement or any Purchase Orders if EQ fails to cure a material breach of this Agreement by EQ within [**] after receiving written notice from Akebia of such breach. Further, Akebia may terminate this Agreement or any Purchase Orders with immediate effect at any time upon written notice to EQ in the event of a material breach of this Agreement by EQ which cannot be cured (*e.g.*, breach of confidentiality obligations under Section 8).

10.4. Termination by EQ for Cause. EQ may terminate this Agreement or any Purchase Orders if Akebia fails to cure its material breach of this Agreement within [**] after receiving written notice from EQ of such breach. Further, EQ may terminate this Agreement or any Purchase Orders with immediate effect at any time upon written notice to Akebia in the event of a material breach of this Agreement by Akebia which cannot be cured.

10.5. Effect of Termination or Expiration. Upon termination or expiration of this Agreement, neither EQ nor Akebia will have any further obligations under this Agreement provided, that, such termination or expiration shall be without prejudice to any rights that have accrued to the benefit of a Party prior to such expiration or termination and, further provided, that:

(a) Except in the event of termination of the Agreement by Akebia in accordance with Section 10.3. hereof, Akebia will promptly pay to EQ: (i) the Price of any existing inventories of Product or Product in-process held by EQ that are subject to a Binding Forecast in effect at the time of such expiration or termination; (ii) the cost of any unused Manufacture Materials at the time of such termination; (iii) the cost of any unused Manufacture Materials which EQ has purchased for Manufacture of Product, acting diligently in the ordinary course of business in order to perform the Services in accordance with the current

Binding Forecast provided by Akebia, and have not yet begun such Manufacture at the time of such expiration or termination; (iv) the unamortized cost of any Equipment purchased by EQ after the Effective Date or of any other special investment made by EQ after the Effective Date, in both cases, if these have been made in connection with an accepted Purchase Order and have been agreed with Akebia in writing prior to EQ accepting such Purchase Order; (v) the costs and expenses in relation to the termination of irrevocable commitments made in connection with any Binding Forecast prior to termination; and/or (vi) the costs of terminating on-going work under any accepted Purchase Orders. At Akebia's election in writing EQ will deliver or destroy all Product and Materials as directed by Akebia. Delivery shall be [**] and at no additional cost for Akebia, and destruction shall be at Akebia's cost.

(b) each Recipient will promptly return to the Discloser all of Discloser's Confidential Information (including all copies) provided to Recipient under this Agreement, except for one (1) copy which Recipient may retain solely to monitor Recipient's surviving obligations of confidentiality and non-use and, to exercise all surviving rights under this Agreement; and

(c) the terms and conditions under Articles 6, 7, 8 and 9 and under Sections 10.5, 11.1(e), 11.3, 11.5, 11.8, 11.9, 11.10, 11.11 and 11.12 will survive any such termination or expiration.

11. Miscellaneous.

11.1. Exclusivity and Patent Challenges. The Parties acknowledge that Akebia and/or its Affiliates shall supply secret and substantial know-how to EQ for the purposes of this Agreement. In order to protect that know-how and without prejudice to EQ's obligations under this Agreement, EQ agrees that:

(a) during the Term of this Agreement, neither EQ nor any of its Affiliates shall use Akebia Technology, Akebia Improvements, or any other know-how of Akebia to [**];

(b) during the Term of this Agreement, in any country, neither EQ, nor any of its Affiliates shall [**];

(c) during the Term of this Agreement and for two (2) years thereafter, neither EQ nor any of its Affiliates shall (i) commence or participate in [**], or otherwise assert in writing [**]; or (ii) [**];

(d) after the Term of this Agreement and for so long as Akebia owns or controls patented rights covering the manufacture, use or sale of vadadustat or intermediates thereof in any country in the world (collectively, the "Akebia Patent Rights"), neither EQ nor any of its Affiliates shall [**]; and

(e) after the termination of this Agreement, EQ shall never use or exploit any Akebia Patent Rights while they remain patented, or Akebia Technology, Akebia Improvements, or other substantial know-how received from or on behalf of Akebia in connection with the activities performed hereunder, unless the content of such technology or improvement is publicly available, is independently developed by EQ (without using any Akebia Technology, Akebia Improvements, or other substantial know-how received from or on behalf of Akebia in connection with the activities performed hereunder) or obtained by EQ from a Third Party that has developed it independently from EQ or Akebia.

11.2. Force Majeure. Except as otherwise expressly set forth in this Agreement, neither Party will be deemed to have breached this Agreement for failure or delay in fulfilling or performing any obligation under this Agreement when such failure or delay is caused by or results from Force Majeure. The Party affected by any Force Majeure will promptly notify the other Party, explaining the nature, details and expected duration thereof. Such Party will also notify the other Party from time to time as to when the affected Party reasonably expects to resume performance in whole or in part of its obligations under this Agreement, and notify the other Party of the cessation of any such event. A Party affected by Force Majeure will use commercially reasonable efforts to remedy, remove or mitigate such event and the effects thereof with all reasonable dispatch. Upon termination of the Force Majeure, the performance of any suspended obligation or duty will promptly recommence. In the event that the affected Party's failure or delay remains uncured for a period of [**], the other Party may thereafter terminate this Agreement immediately upon written notice.

11.3. Independent Contractor. EQ is an independent contractor and not an agent or employee of Akebia. EQ will not in any way represent itself to be an agent, employee, partner or joint venturer of or with Akebia, and EQ has no authority to obligate or bind Akebia by contract or otherwise. EQ has full power and authority to determine the means, manner and method of performance of Services. EQ is responsible for, and will withhold and/or pay, any and all applicable federal, state or local taxes, payroll taxes, workers' compensation contributions, unemployment insurance contributions, or other payroll deductions from the compensation of EQ's employees and other EQ Personnel and no such employees or other EQ Personnel will be entitled to any benefits applicable to or available to employees of Akebia. EQ understands and agrees that it is solely responsible for such matters and that it will indemnify Akebia and hold Akebia harmless from all claims and demands in connection with such matters.

11.4. Notices. All notices must be in writing and sent to the address for the recipient set forth below or at such other address as the recipient may specify in writing under this procedure. All notices must be given (a) by personal delivery, with receipt acknowledged; or (b) by prepaid certified or registered mail, return receipt requested; or (c) by prepaid recognized express delivery service. This clause is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement. Notices will be effective upon receipt or at a later date stated in the notice.

To Akebia:

AKEBIA THERAPEUTICS, INC.
245 First Street
Cambridge, MA 02142
Attention: Vice President, Manufacturing
cc: General Counsel
[**]

To EQ: **ESTEVE QUÍMICA, S.A.**
Torre ESTEVE – Pg. Zona Franca, 109
Barcelona, SPAIN, 08038
Attention: Pere Mañé, Managing Director
[**]

11.5. Assignment. Neither Party shall have the right to assign any or all of its rights or obligations under this Agreement without the other Party's prior written consent, which consent shall not unreasonably be withheld, delayed or conditioned.

Notwithstanding the foregoing, prior written consent shall not be required in connection with a merger, reorganization, consolidation, or a sale of all or substantially all of a Party's assets or relevant business to which this Agreement relates and, the assigning Party shall cause the Third Party to assume the assigning Party's rights and obligations hereunder. For clarity, Akebia agrees that it shall not, directly or indirectly, assign or transfer its rights to commercialize vadadustat without also assigning (to the same assignee or transferee for vadadustat) this Agreement.

The Parties agree to notify the other as soon as commercially reasonable, should any such assignment to a Third Party occur, or could potentially occur. This Agreement is binding upon, and will inure to the benefit of, the Parties and their respective successors and permitted assigns.

11.6. No Benefit to Third Parties. The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other persons.

11.7. Entire Agreement. Except as set forth in Section 2.1.7., this Agreement, together with the attached Exhibits and any Purchase Orders accepted by the Parties as set forth in this Agreement, each of which shall be deemed incorporated into this Agreement, constitute the entire agreement between the Parties with respect to the specific subject matter of this Agreement and all prior agreements, oral or written, with respect to such subject matter are superseded, provided, however, that the provisions of such agreements intended to survive following expiration or termination shall survive in accordance with their terms. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. If there is any conflict, discrepancy or inconsistency between the terms of this Agreement and any Purchase Order the terms of this Agreement will control unless specifically stated and agreed by the Parties in the Purchase Order.

11.8. No Modification. This Agreement may be changed only by a writing signed by authorized representatives of each Party.

11.9. Severability; Reformation. Each provision in this Agreement is independent and severable from the others, and no provision will be rendered unenforceable because any other provision is found by a proper authority to be invalid or unenforceable in whole or in part. If any provision of this Agreement is found by such an authority to be invalid or unenforceable in whole or in part, such provision will be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision and the intent of the Parties, in accordance with Applicable Law.

11.10. Dispute Resolution. If a dispute arises between the Parties relating to this Agreement, the Parties shall meet in good faith to discuss and resolve the dispute. If the Parties cannot resolve the dispute within [**], senior management representatives of each Party will meet in good faith to resolve the dispute. If the dispute remains unresolved after attempted resolution by senior management representatives of the Parties as described above, then each Party will be free to pursue any available remedy at law or in equity. Each Party will bear its own legal fees and any costs incurred under this Section 11.10. Nothing in this Section 11.10 shall be interpreted to (i) modify either Party's termination rights in Section 10; or (ii) prohibit the Chief Executive Officer ("CEO") of either Party from reaching out to the CEO of the other Party at any time to attempt to resolve the dispute.

11.11. Governing Law. This Agreement and any disputes arising out of or relating to this Agreement will be governed by, construed and interpreted in accordance with the laws of [**] without regard to any choice of law principle that would require the application of the law of another jurisdiction. The Parties expressly reject any application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

11.12. Jurisdiction; Venue. For any legal action or proceeding concerning the validity, interpretation or enforcement of this Agreement, or otherwise concerning matters arising out of or related to this Agreement including its performance or breach, the Parties hereby irrevocably submit to the exclusive jurisdiction of the courts and tribunals of the of [**]. Nothing in this clause shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief, if such Party thinks this is necessary to protect its interests.

11.13. Waivers. Any delay in enforcing a Party's rights under this Agreement, or any waiver as to a particular default or other matter, will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written waiver relating to a particular matter for a particular period of time signed by an authorized representative of the waiving Party, as applicable.

11.14. No Strict Construction; Headings; Interpretation. This Agreement has been prepared jointly and will not be strictly construed against either Party. The section headings are included solely for convenience of reference and will not control or affect the meaning or interpretation of any of the provisions of this Agreement. The words "include," "includes" and "including" when used in this Agreement are deemed to be followed by the phrase "but not limited to".

11.15. Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed to be an original and all of which together will constitute one and the same instrument. A facsimile or portable document format ("**.pdf**") copy of this Agreement, including the signature pages, will be deemed an original.

[Signature page follows]

IN WITNESS WHEREOF, each Party has caused this Agreement to be executed by its duly authorized representative as of the Effective Date.

AKEBIA THERAPEUTICS, INC.		**ESTEVE QUÍMICA, S.A**	
By:	/s/ Jason A. Amello	By:	/s/ Pere Mañé
Print Name:	Jason A. Amello	Print Name:	Pere Mañé
Title:	SVP, Chief Financial Officer	Title:	Managing Director
Date:	9-April 2019	Date:	March 12, 2019

AKEBIA THERAPEUTICS, INC.		**ESTEVE QUÍMICA, S.A**	
By:	/s/ John Butler	By:	/s/ Manuel Lourenço
Print Name:	John Butler	Print Name:	Manuel Lourenço
Title:	CEO	Title:	Global API Business Director
Date:	9-April 2019	Date:	March 15, 2019

Exhibit 10.4

MASTER CONSULTING SERVICES AGREEMENT

This Master Consulting Services Agreement, **including Exhibits A-D** (the "Agreement") is entered into as of **June 10, 2019** (the "Effective Date") by and between **Scott A. Canute** with an address of _____ ("Consultant") and **Akebia Therapeutics, Inc**. ("Akebia" or the "Company"), a Delaware corporation having an address at 245 First Street, Cambridge, MA 02142. Consultant and Akebia are each referenced individually herein as a "Party" and together as the "Parties."

WHEREAS, Akebia wishes to engage Consultant to provide certain consulting and other services to Akebia, and Consultant is willing to provide such services to Akebia, in each case on the terms and conditions set forth in this Agreement and all applicable Statements of Work as defined below.

NOW, THEREFORE, in consideration of the foregoing, and of the mutual covenants set forth in this Agreement and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. Consulting Services.

(a) From time to time, Akebia may request that Consultant provide certain consulting and other services (the "Services") described in one or more statements of work executed by both Parties and referencing this Agreement ("Statement of Work") numbered sequentially. However, neither Akebia nor Consultant is obligated to execute any Statement of Work. Each such Statement of Work shall contain material terms for Services specifically requested by Akebia and agreed upon by Consultant, such as project objectives, fees, deliverables, specifications and other requirements, and the project schedule. In the event of any conflict between this Agreement and any Statement of Work, this Agreement shall prevail, except to the extent that the Statement of Work expressly specifies that a particular provision in the Statement of Work will supersede this Agreement. The initial Statement of Work is attached to this Agreement as **Exhibit A**.

(b) Once executed, any changes in or additions to a Statement of Work, including but not limited to, changes to scope, fees, and timing, will be made only by a mutual written agreement in the form of a change order ("Change Order").

(c) Consultant will render the Services at such times and locations as reasonably requested by Akebia and will provide Akebia with written project or status reports as specified by Akebia. The Consultant will allow Akebia representatives to review and audit the content, quality, and results of these reports and the Services. The Consultant will also provide Akebia with such writings, specifications, drawings, models, and the like, as are appropriate to the nature of the Services.

(d) Consultant agrees to: (i) use reasonable efforts to make himself available to provide the Services during the Term of this Agreement as requested by Akebia; (ii) provide all Services within the time specified in the applicable Statement of Work, and (iii) perform the Services in accordance with the highest prevailing industry standards and practices for the performance of similar services.

(e) Akebia and Consultant acknowledge that Consultant's Services under the Agreement constitute "Employment" pursuant to the terms of Akebia's 2014 Incentive Plan, as amended (the "Plan") and equity award agreements thereunder (the "Equity Award Agreements"), and, as such, Consultant's outstanding option and restricted stock unit awards, as applicable, shall (i) continue to vest and (ii) in the case of the options, remain exercisable, in the case of each of (i) and (ii), for the Term and pursuant to the terms of the Plan and the applicable Equity Award Agreements.

2. Consulting Fees.

(a) As full consideration for Services, Akebia will pay Consultant the amount set forth in each applicable Statement of Work in accordance with Section 2(c) through 2(e) below and the payment schedule set forth in each Statement of Work ("Compensation"). Consultant will invoice Akebia for all amounts due in United States Dollars, unless otherwise indicated in a Statement of Work.

(b) Subject to compliance with the attached Travel and Expense Reimbursement Policy attached hereto as **Exhibit B**, Akebia shall pay for Consultant's documented reasonable, out-of-pocket expenses, including reasonable travel, lodging and meal expenses, relating directly to the provision of the Services as contemplated in the applicable Statement of Work. Akebia shall not pay for expenses for spouses or guests of Consultant. If required by Akebia, travel and accommodations shall be booked through Akebia or Akebia's travel vendor. Individual expenses greater than $500 require Akebia's prior written approval.

(c) Payments to Consultant may be subject to U.S. tax withholding. The withholding amount may be reduced or eliminated depending on provisions of an applicable Income Tax Treaty, and whether certain documents are provided to Akebia by the Consultant. Therefore, as a condition to payment under this Agreement, the Consultant shall provide a U.S. taxpayer identification number ("TIN") and complete the appropriate tax form designated by Akebia to confirm Consultant's tax status (e.g., an IRS Form W-9 or W-8BEN). If Consultant does not timely provide the TIN or an accurate completed tax form to Akebia, then Akebia will withhold income tax. Irrespective of whether income tax withholding applies, Akebia may be required to file reports with tax authorities in connection with payments made to Consultant under this Agreement.

(d) All invoices are due on or before the fifth (5th) business day of each month for Services rendered in the prior month or as otherwise specified in the applicable Statement of Work, providing such detail as Akebia reasonably requires. Invoices are to be sent to Akebia Therapeutics, Inc., to the attention of Accounts Payable, 245 First Street, Cambridge, MA, 02142 or via email to apinvoices@akebia.com. Akebia will pay undisputed invoices within forty-five (45) days of Akebia's receipt of such invoice.

(e) **All invoices must refer to the purchase order number.** A sample invoice is attached as **Exhibit C** to this Agreement. Consultant will retain complete and accurate financial records related to all expenses and Services performed for Akebia, including, but not limited to, records related to invoice calculations, and such records will be subject to audit by Akebia.

3. Developments.

(a) Akebia may use any results or products of the Services without further payment or obligation. However, Akebia understands and agrees that in connection with Services contemplated by this Agreement Consultant may utilize and deliver materials, data, results, documents, information, ideas, improvements, inventions, tools, templates, knowledge, and techniques that were owned or licensed by Consultant prior to performing the Services (the "Consultant Pre-Existing IP"). All Consultant Pre-Existing IP shall be and remain the exclusive property of Consultant, and no right, title or interest in any Consultant Pre-Existing IP is conveyed by this Agreement to Akebia other than the limited license granted below in Section 3(b).

(b) Consultant hereby grants to Akebia, and Akebia hereby accepts, a fully paid-up, worldwide, perpetual, royalty-free, non-exclusive, non-sublicenseable, non-transferable license to use, execute, reproduce, translate, and modify any Consultant Pre-Existing IP delivered in connection with the Services for the limited purposes of Akebia's use and enjoyment of the Services.

(c) Subject to the provisions of Section 3(a) and 3(b) above, any inventions, improvements, or ideas made or conceived by the Consultant in connection with or during the performance of the Services shall be delivered to and be the property of Akebia. The Consultant, without charge to Akebia (other than reasonable payment for time involved if this Agreement shall have terminated), shall execute, acknowledge, and deliver to Akebia all papers, including applications for patents, as are necessary for Akebia to publish or protect said inventions, improvements, and ideas by patent or otherwise in any and all countries, and to vest title to said patents, inventions, improvements, and ideas in Akebia or its nominees, their successors or assigns. The Consultant will assist Akebia, as needed and at Akebia's expense, in any Patent Office proceeding or litigation involving said inventions, improvements, or ideas. The Consultant will keep contemporaneous written records of work done under this Agreement, and will submit such records to Akebia when requested or at the termination of this Agreement. Consultant hereby assigns to the Akebia all inventions and any and all related patents, copyrights, trademarks, trade names, trade secrets and other industrial and intellectual property rights and applications therefore, in the United States and elsewhere, and appoints any officer of Akebia as his duly authorized attorney to execute, file, prosecute and protect the same before any government agency, court, or authority.

(d) Akebia shall retain ownership of all right, title, and interest in and to any of its materials, data, results, documents, information, ideas, improvements inventions, tools templates, knowledge, and techniques that are owned or licensed by Akebia and provided to Consultant in connection with the Services ("Akebia Pre-Existing IP"). Akebia hereby grants to Consultant and Consultant hereby accepts, a fully paid-up, worldwide, royalty-free, non-exclusive, non-sublicenseable, non-transferable license to use execute, reproduce, translate, and modify any Akebia Pre-Existing IP to the extent necessary for Consultant to perform the Services.

(e) Any copyrightable work created by Consultant in connection with and arising from the performance of the Services shall be considered a work made for hire within the meaning of the Copyright Act of 1976, whether published or not. All rights in this work shall be the property of Akebia as author and owner of the copyright.

(f) Consultant warrants that he has the right to make the assignments made by him hereunder, and further warrants that no intellectual property incorporated into any Services provided to Akebia will infringe any patent, copyright, trademark, trade secret or other proprietary right of any third party.

4. Confidentiality.

In order to carry out the Services, it may be necessary for Consultant to receive certain information proprietary or confidential to Akebia or to third parties to whom Akebia has confidentiality obligations. The term "Confidential Information" includes, without limitation, any technical, scientific, trade, research, manufacturing, marketing, supplier or other information, financing plans, business plans, financial data, customer lists, projects, economic information, systems, plans, procedures, operations, techniques, patent applications, trade secrets, know-how, inventions, technical data or specifications, testing methods, research and development activities, marketing strategies, Personal Information (as defined in Section 22), or the terms of this Agreement that may be disclosed by or on behalf of Akebia to Consultant in connection with the Services, as well as materials and deliverables developed by Consultant in the performance of the Services, regardless of whether such information is specifically designated as confidential and regardless of whether such information is in written, oral, electronic, or other form. Consultant agrees not to use to his own or any other person's advantage or to disclose to any person or entity any Confidential Information. Except with respect to Personal Information, the foregoing non-disclosure obligations shall not apply to information that: (i) is already in the possession of Consultant without obligation of confidentiality (as shown by written records not derived from Akebia), (ii) was in the public domain at the time it was disclosed to Consultant or subsequent to disclosure becomes part of the public domain through no fault of Consultant, (iii) becomes known to Consultant without restriction from a source other than Akebia without breach of this Agreement and otherwise not in violation of Akebia's rights, or (iv) is disclosed pursuant to a requirement of a governmental body, provided, however, that Consultant shall provide prompt notice thereof to enable Akebia to seek a protective order or otherwise prevent such disclosure. Information shall not be deemed to be in public domain simply because one or more component portions thereof are in the public domain. Upon request of Akebia, the Consultant shall promptly return to Akebia or destroy all originals, copies, and summaries of documents, materials, and other tangible manifestations of Confidential Information in the possession or control of Consultant.

5. Independent Contractor.

It is understood and agreed between the Parties that, during the period Consultant renders the Services hereunder, all of his activities shall be undertaken and performed as an independent contractor and not as an employee of Akebia for purposes of the activities performed under this Agreement. Consultant, and his representatives, shall not in any way

represent himself to be an employee, partner, joint venturer, agent, or officer of or with Akebia. Consultant is not authorized to act or attempt to act, or represent himself, directly or by implication, as an agent of Akebia or in any manner assume or create or attempt to assume or create any obligation or responsibility, express or implied, on behalf of, or in the name of, Akebia or to bind Akebia in any manner. Consultant will be solely and unconditionally responsible for any and all federal, state, or local taxes, social security withholding, and other self-employment tax obligations with respect to payments made to Consultant under this Agreement. Except as expressly provided for herein, by virtue of this Agreement or the consulting relationship contemplated herein, Consultant shall not be entitled to any Company-provided employee benefits, coverages, or privileges, including (without limitation) health and life insurance, pension plans, 401(k) plans, stock options, or bonus plans.

6. Assignment and Subcontracting.

Consultant may not assign this Agreement or subcontract his obligations hereunder to another person or entity without the express written permission of Akebia.

7. Term and Termination.

(a) Term. This Agreement shall commence as of the Effective Date and will expire on the later of: (i) one (1) year from the Effective Date, or (ii) the completion of all Services under all Statement(s) of Work executed by the parties prior to the first anniversary of the Effective Date ("Term"). This Agreement may be extended by mutual written agreement of the parties or earlier terminated in accordance with Section 7(b).

(b) Termination for Convenience. Company shall have the right to terminate the Agreement at any time for any reason on ten (10) days' prior written notice. Consultant shall have the right to terminate the Agreement at any time for any reason on thirty (30) days' prior written notice.

(c) Effect of Termination. Upon termination of this Agreement, neither Party shall have any further obligations under this Agreement, except that any liabilities accrued through the date of termination and Sections 3, 4, 5, 7(d), 8, 12, 15, 16, 17, 20, 21, 22 and **Exhibit D** shall survive termination or expiration of this Agreement. Section 11 shall survive for 2 years following the termination or expiration of this Agreement.

(d) Upon expiration or termination of this Agreement, Consultant will terminate all Services in progress in an orderly manner as soon as practical and in accordance with a schedule agreed to by Akebia, unless Akebia specifies in the notice of termination that Services in progress should be completed. Consultant will deliver to Akebia any materials, developments and deliverables in its possession or control and all deliverables and developments made through expiration or termination. Consultant will also return to Akebia or destroy all originals, copies, and summaries of documents, materials, and other tangible manifestations of Personal Information in the possession or control of Consultant.

8. Use of Names/Publicity.

Consultant shall not use Akebia's name or the name of its employees or consultants in any advertising, sales or promotional material and Consultant shall not originate any publicity, news release, or other public announcement, written or oral, whether to the public press or otherwise, relating to this Agreement or to performance of the Services hereunder without Akebia's prior written consent.

9. Conflicting Obligations.

Consultant represents that he is under no obligation to any third party that would prevent Consultant from carrying out his duties and obligations under this Agreement or which is inconsistent with the provisions contained herein, such as confidentiality obligations. Consultant represents that he has no financial interest in the outcome of the Services and agrees to avoid having any such a financial interest during the term of this Agreement.

10. Conflicts of Interest.

During the Term of this Agreement, Consultant will not, without Akebia's prior written consent, directly or indirectly: (i) render any service to any person or entity that competes with the Business of the Company ("Competing Company"), *provided*, *however*, that Consultant may render services to a business unit or division of a Competing Company if such business unit or division does not compete with the Business of the Company; or (ii) alone or as a partner, joint venturer, officer, director, employee, consultant, agent, independent contractor or stockholder of any company or business, engage in any business activity that directly or indirectly competes with any of the products being developed, marketed, distributed, planned, sold or otherwise provided by the Company at such time. For the purposes of this Agreement, the "Business of the Company" means the research, development, licensing and/or commercialization of one or more products or product candidates (i) related to the treatment of anemia and related conditions and/or (ii) based on hypoxia-inducible factor (HIF) biology or hypoxia-inducible factor prolyl hydroxylase (HIF-PH) biology and/or (iii) related to the treatment of hyperphosphatemia and/or the control of serum phosphorus levels.

If Consultant is a faculty member, employee of, or affiliated with, a university or hospital, governmental agency, public authority, or any other similar employer that imposes restrictions on employees providing outside consulting services ("Institution"), Consultant represents and warrants that pursuant to Institution's policies, Consultant is permitted to enter into this Agreement. If Consultant's Institution requires Consultant to disclose to it any proposed consulting agreements, Consultant has made such disclosure. If Institution's prior approval of this Agreement is required by Institution policies, Consultant has obtained such approval, and if required pursuant to the policies of the Institution, such approval is evidenced by the Institution's signature to this Agreement. Further, in performing the Services, Consultant agrees not to utilize Institution facilities, space, materials, resources, or intellectual property.

11. Transparency.

Whenever the Consultant writes or speaks in public about a matter that relates to the Services or Akebia product(s), or serves on a committee or governing board that assists in developing clinical practice guidelines, makes decisions about reimbursement for Akebia product(s) (e.g., a formulary committee), Consultant shall: (i) disclose to said committee the existence and nature of his relationship with Akebia, and (ii) Consultant shall follow the procedures set forth by the committee of which he is a member, which may include recusing oneself from decisions relating to the products for which he has provided services to Akebia.

12. Non-Referral.

The Parties agree that Consultant is under no obligation to solicit, refer, or solicit referrals of patients for any Akebia business. Consultant is not required to use Akebia's products and will not receive any benefit of any kind for making any referrals nor suffer any detriment for not making such referrals. The Parties further agree that no amount paid hereunder is intended to be, nor shall be construed as, an inducement or payment for referral of, or recommending referral of, patients for any Akebia business by Consultant to Akebia (or its affiliates) or by Akebia (or its affiliates) to Consultant. In addition, the fees paid hereunder, including, but not limited to the Compensation, do not include any discount, rebate, kickback, or other reduction in charge. The sole purpose of the Compensation paid to Consultant hereunder is to pay fair market value for the Services provided by Consultant to Akebia hereunder, and to reimburse legitimate out-of-pocket expenses. The Parties represent and warrant that the Compensation was determined by the Parties through good faith and arms' length bargaining, constitutes fair market value for the Services, and has not been determined in a manner that takes into account the volume or value of any business between the Parties.

13. Representations and Warranties of Consultant.

Consultant represents and warrants as follows:

a) Consultant has not been or is under consideration to be, excluded, suspended, or debarred from, or otherwise declared ineligible to participate in, federal or state healthcare programs, procurement or non-procurement programs, any governmental program in any jurisdiction, or any other activities or programs related to the Services contemplated by this Agreement. Further, if Akebia consents to Consultant's employment or engagement of any other person or entity to perform any Services under this Agreement, Consultant represents that he has no knowledge of such person or entity having been suspended, debarred or excluded. Consultant will notify Akebia immediately in writing upon receipt of notice of any such debarment or any threatened or scheduled debarment proceedings involving Consultant or any of his employees or contractors.

b) Consultant is the individual he represents himself/herself to be and that Consultant will independently comply with IRCA's (as defined below) requirements.

14. Compliance with Laws and Industry Standards.

Consultant shall perform the Services with requisite care, skill and diligence, and in compliance with all applicable federal and state laws and regulations and industry codes and standards, including but not limited to: (i) the Foreign Corrupt Practices Act of 1977, and the UK Bribery Act, the 1997 OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, and other local anti-corruption and anti-bribery laws, (ii) federal and state anti-kickback laws and regulations and laws governing payments to and relationships with healthcare professionals, including 42 U.S.C. §1320a-7b(b); (iii) federal Food and Drug Administration laws, regulations and guidance, including the federal Food, Drug, and Cosmetic Act and the Prescription Drug Marketing Act, (iv) federal and state securities laws, meaning that Consultant acknowledges that Akebia is a publicly traded company and by virtue of his work for Akebia, Consultant may qualify as an "insider" or have access to information that is material and not public, such that federal and state securities laws that prohibit the purchase, sale, or pledge of Akebia stock while in possession of any material, non-public information, may apply to Consultant; (v) applicable Good Laboratory Practices ("GLP"), Good Clinical Practices ("GCP") and/or Good Manufacturing Practices ("GMP"); and (vi) European Union ("EU") Data Protection Laws, U.S. federal and state privacy and data protection laws, including, but not limited to, the federal Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act, and Chapter 93H of the Massachusetts General Laws, and their implementing regulations (the "Privacy Laws"). In addition, Consultant will comply with (i) all Akebia policies and procedures that have been communicated to Consultant in writing; and (ii) as applicable, the Immigration Reform and Control Act of 1986 ("IRCA") to ensure Consultant is authorized to perform the necessary work in the U.S.

15. Indemnification.

(a) Indemnification by Consultant: Consultant will indemnify, defend and hold harmless Akebia, its affiliates, and its and their respective officers, directors, employees and agents against any third party claims and any fines or penalties imposed under applicable law or regulation, including reasonable attorneys' fees for defending those claims or the imposition of such fines or penalties, to the extent such claims, fines, or penalties arise out of or relate to Consultant's performance of the Services; Consultant's negligence, willful misconduct or breach of this Agreement; Consultant's violation of applicable law or regulation; or Consultant's infringement of any patent, copyright, trademark, trade secret or other proprietary right of any third party.

(b) Indemnification by Akebia: Akebia will indemnify, defend, and hold harmless Consultant against any third party claims and any fines or penalties imposed under applicable law or regulation, including reasonable attorneys' fees for defending those claims or the imposition of such fines or penalties, to the extent such claims, fines, or penalties arise out of or relate to the use of the Services or deliverables by Akebia; Akebia's negligence, willful misconduct or breach of this Agreement; or Akebia's violation of applicable law or regulation.

(c) Each Party must notify the other Party within thirty (30) days after receipt of any claims made or any fines or penalties for which the other party might be liable under this section. The indemnifying party will have the sole right to defend, negotiate, and settle such claims or penalty proceedings. The indemnified party will be entitled to

participate in the defense of such matter and to employ counsel at its expense to assist in such defense; provided, however, that the indemnifying party will have final decision-making authority regarding all aspects of the defense of the claim/proceeding. The indemnified party will provide the indemnifying party with such information and assistance as the indemnifying party may reasonably request, at the expense of the indemnifying party. Neither Party will be responsible or bound by any settlement of any claim or suit or penalty proceeding made without its prior written consent; provided, however, that the indemnified party will not unreasonably withhold or delay such consent.

16. Notices.

Any notice required or permitted under this Agreement shall be in writing delivered by express mail or express delivery service and shall be addressed to the Party at the address indicated below or at such other address as the addressee shall have last furnished in writing to the addressor and shall be effective upon receipt by the addressee. All notices to Akebia shall be marked: Attention: Legal Department. Notices to Consultant shall be sent to the most recent address of record for Consultant.

17. Governing Law/Disputes.

This Agreement shall be governed by the laws of the Commonwealth of Massachusetts, without giving effect to the conflict or choice of law provisions thereof. Consultant acknowledges that, because Akebia is headquartered in Massachusetts, and he will have regular interaction with Company representatives based in Massachusetts, any dispute concerning this Agreement shall be heard by a court of competent jurisdiction within Massachusetts. Consultant acknowledges that he is subject to the personal jurisdiction of the Massachusetts courts in any county where Akebia has operations or facilities.

18. Survivability.

If any part of this Agreement shall be held unenforceable, the remainder of the Agreement shall nevertheless remain in full force and effect and the unenforceable provision shall be construed by the court in such a manner as to be held enforceable while giving maximum effect to the intended meaning.

19. Entire Agreement.

This Agreement represents the entire and integrated agreement between Akebia and Consultant with respect to the subject matter hereof and supersedes and terminates all prior negotiations, representations, or agreements, either written or oral. This Agreement may be amended only by written instrument signed by both Parties.

20. Public Disclosure.

By signing this Agreement, Consultant acknowledges that Akebia or Akebia's collaboration partners may publicly disclose information concerning the relationship between Akebia and Consultant, including, but not limited to, Consultant's name and the

Compensation, travel, lodging and meals costs, and other transfers of value provided to Consultant by Akebia, in order to enable Akebia or its collaboration partners to fully comply with any public or other reporting requirements imposed by applicable laws, regulations and industry codes, and that such information may be publicly posted on a governmental or Akebia website.

21. Waiver.

No waiver of any term, provision, or condition of this Agreement in any one or more instances will be deemed to be or construed as a further or continuing waiver of any other term, provision, or condition of this Agreement. Any such waiver must be evidenced by an instrument in writing executed by Consultant and, in the case of Akebia, by a duly authorized signatory.

22. Data Security.

Consultant will maintain (and, as applicable, cause any subcontractors permitted in accordance with Section 6 to maintain) data security procedures and other safeguards that are compliant with applicable Privacy Laws and consistent with industry standards, against the accidental, unlawful or unauthorized access to or acquisition, use, disclosure, destruction, loss, or alteration of Akebia's Confidential Information (a "Data Breach"). In the event that Consultant, in the course of providing Services to Akebia, receives, creates, stores, maintains, processes or otherwise has access to "Personal Information" (meaning any information relating to an identified or identifiable natural person that is protected by applicable Privacy Laws, including, but not limited to, an individual's name and social security number, driver's license number or financial number, health information, and personal data, as further defined in such Privacy Laws), then Consultant shall implement and maintain appropriate technical and organizational measures, reflected in written security policies, to protect such Personal Information against a Data Breach and otherwise safeguard this information in accordance with these laws, and to the extent that Consultant experiences, becomes aware of, or suspects a Data Breach with respect to Personal Information in connection with this Agreement or any Statement of Work or amendment hereto, Consultant shall: (i) notify Akebia in writing without undue delay, and in any event, within twenty-four (24) hours of becoming aware of such Data Breach (such notification to include, at minimum, a description of the nature of the Data Breach including the categories of Personal Information and approximate number of individuals affected and records concerned; the likely consequences of the Data Breach; and any measures taken or proposed by Consultant to mitigate or otherwise address the Data Breach); (ii) use Consultant's best endeavors to mitigate the effects and to minimize any damage resulting from the Data Breach; and (iii) to the extent permitted by applicable law, reasonably assist and co-operate with Akebia in investigating, resolving and remediating the Data Breach, including providing Akebia with such further information as may be reasonably requested and coordinating with Akebia any public communication, communication to affected individuals, or response to any regulatory or supervisory authority in respect of the Data Breach.

23. Counterparts.

This Agreement may be executed in more than one counterpart and signature pages may be exchanged by facsimile or email.

[signature page follows]

IN WITNESS, WHEREOF, the Parties have duly executed this Master Consulting Services Agreement as of the Effective Date.

AGREED TO AND ACCEPTED BY:

AKEBIA THERAPEUTICS, INC.		**SCOTT A. CANUTE**	
By:	/s/ John P. Butler	By:	/s/ Scott A Canute
Print Name:	John P. Butler	Date:	6/10/19
Title:	CEO & President	Email:	
Date:	June 10, 2019	Telephone:	

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 8, 2019

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, Jason A. Amello, 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 8, 2019

By: /s/ Jason A. Amello
Jason A. Amello
Senior Vice President, Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the accompanying Quarterly Report of Akebia Therapeutics, Inc. (the Company) on Form 10-Q for the fiscal quarter ended June 30, 2019 (the Report), I, John P. Butler, as Chief Executive Officer and President of the Company, and I, Jason A. Amello, 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 8, 2019

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

Date: August 8, 2019

By: /s/ Jason A. Amello
Jason A. Amello
Senior Vice President, Chief Financial Officer
and Treasurer
(Principal Financial Officer)