UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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 October 31, 2019
118,943,016

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)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 122,886	$ 104,644
Available for sale securities	22,727	216,996
Inventory	115,987	114,245
Accounts receivable, net	29,654	16,666
Prepaid expenses and other current assets	7,754	15,724
Total current assets	299,008	468,275
Property and equipment, net	12,799	8,023
Operating lease assets	30,141	—
Goodwill	55,053	55,053
Other intangible assets, net	300,312	328,153
Other assets	97,907	137,036
Total assets	$ 795,220	$ 996,540
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 64,362	$ 42,796
Accrued expenses and other current liabilities	126,644	150,917
Debt	—	15,000
Short-term deferred revenue	32,142	56,980
Total current liabilities	223,148	265,693
Deferred rent, net of current portion	—	3,006
Deferred revenue, net of current portion	43,887	55,709
Operating lease liabilities, net of current portion	28,811	—
Deferred tax liabilities	1,752	6,631
Other non-current liabilities	30,060	29,573
Total liabilities	327,658	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 September 30, 2019 and December 31, 2018	—	—
Common stock $0.00001 par value; 175,000,000 shares authorized at September 30, 2019 and December 31, 2018; 118,863,735 and 116,887,518 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	1	1
Additional paid-in capital	1,167,126	1,150,583
Accumulated other comprehensive income (loss)	6	(261)
Accumulated deficit	(699,571)	(514,395)
Total stockholders' equity	467,562	635,928
Total liabilities and stockholders' equity	$ 795,220	$ 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product revenue, net	$ 30,004	$ —	$ 82,204	$ —
License, collaboration and other revenue	61,973	53,169	183,242	147,892
Total revenues	91,977	53,169	265,446	147,892
Cost of goods sold:				
Product	29,162	—	79,888	—
Amortization of intangibles	9,101	—	27,301	—
Total cost of goods sold	38,263	—	107,189	—
Operating expenses:				
Research and development	74,512	70,634	242,557	203,955
Selling, general and administrative	34,178	10,378	104,537	31,940
License expense	929	—	2,560	—
Total operating expenses	109,619	81,012	349,654	235,895
Operating loss	(55,905)	(27,843)	(191,397)	(88,003)
Other income:				
Interest income	228	1,780	1,582	4,417
Other income (expense)	(185)	16	(240)	52
Net loss before income taxes	(55,862)	(26,047)	(190,055)	(83,534)
Benefit from income taxes	(1,277)	—	(4,879)	—
Net loss	$ (54,585)	$ (26,047)	$ (185,176)	$ (83,534)
Net loss per share - basic and diluted	$ (0.46)	$ (0.46)	$ (1.57)	$ (1.54)
Weighted-average number of common shares - basic and diluted	118,863,063	57,027,598	118,071,674	54,207,973
Comprehensive loss:				
Net loss	$ (54,585)	$ (26,047)	$ (185,176)	$ (83,534)
Other comprehensive gain (loss) - unrealized gain (loss) on debt securities	(17)	50	267	33
Total comprehensive loss	$ (54,602)	$ (25,997)	$ (184,909)	$ (83,501)

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
Issuance of common stock, net of issuance costs	—	—	36	—	—	36
Proceeds from sale of stock under employee stock purchase plan	31,199	—	267	—	—	267
Exercise of options	101,478	—	59	—	—	59
Share-based compensation expense	—	—	2,252	—	—	2,252
Unrealized gain/loss	—	—	—	50	—	50
Net income (loss)	—	—	—	—	(26,047)	(26,047)
Balance at September 30, 2018	57,046,563	$ —	$ 597,290	$ (409)	$ (454,341)	$ 142,540
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
Proceeds from sale of stock under employee stock purchase plan	47,553	—	195	—	—	195
Share-based compensation expense	—	—	2,613	—	—	2,613
Restricted stock unit vesting	28,881	—	—	—	—	—
Unrealized gain/loss	—	—	—	(17)	—	(17)
Net income (loss)	—	—	—	—	(54,585)	(54,585)
Balance at September 30, 2019	118,863,735	$ 1	$ 1,167,126	$ 6	$ (699,571)	$ 467,562

See accompanying notes to unaudited condensed consolidated financial statements

AKEBIA THERAPEUTICS, INC.

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

	Nine Months Ended	
	September 30, 2019	**September 30, 2018**
Operating activities:		
Net loss	$ (185,176)	$ (83,534)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,659	638
Amortization of intangibles	27,301	—
Amortization of premium/discount on investments	(795)	(698)
Non-cash interest expense	508	—
Non-cash operating lease expense	(1,673)	—
Fair value write-up of inventory sold	51,604	—
Write-down of inventory to net realizable value	5,968	—
Stock-based compensation	6,991	6,978
Deferred income taxes	(4,879)	—
Changes in operating assets and liabilities:		
Accounts receivable	(12,988)	33,528
Inventory	(28,565)	—
Prepaid expenses and other current assets	9,415	(346)
Other long-term assets	3,145	67
Accounts payable	26,438	5,686
Accrued expense	(29,176)	42,118
Operating lease liabilities	1,577	—
Deferred revenue	(36,660)	(28,101)
Deferred rent	—	(131)
Net cash used in operating activities	(165,306)	(23,795)
Investing activities:		
Purchase of equipment	(6,435)	(776)
Proceeds from the maturities of available for sale securities	130,610	180,091
Proceeds from sales of available for sale securities	64,721	13,000
Purchase of available for sale securities	—	(172,438)
Net cash provided by investing activities	188,896	19,877
Financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	9,035	95,453
Proceeds from the sale of stock under employee stock purchase plan	383	482
Proceeds from the exercise of stock options	560	555
Retirement of treasury stock	(426)	—
Payments on debt	(15,000)	—
Payments on capital lease obligations	—	(13)
Net cash provided by (used in) financing activities	(5,448)	96,477
Increase in cash, cash equivalents, and restricted cash	18,142	92,559
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	$ 125,241	$ 163,996

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 November 11, 2019, the Company entered into a loan agreement, or the Loan Agreement, with Keryx as guarantor, Biopharma Credit plc as collateral agent and lender, or the Collateral Agent, and Biopharma Credit Investments V (Master) LP as lender, or collectively with the Collateral Agent, Pharmakon, pursuant to which term loans in an aggregate principal amount of $100.0 million are available to the Company in two tranches, subject to certain terms and conditions, or the Term Loan. Subject to the satisfaction of certain conditions, the first tranche of $80.0 million, or Tranche A, will be drawn in a single drawing on November 25, 2019, or the Tranche A Funding Date. The second tranche under the Term Loan allows the Company to borrow an additional $20.0 million until December 31, 2020, or Tranche B. Refer to Note 11 to our condensed consolidated financial statements in Part I, Item 1 – Financial Statements (unaudited) for additional details on the Loan Agreement.

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.

The Company expects its cash resources, including funds to be received from its collaborators and $100.0 million upon closing of the Term Loans with Pharmakon, subject to the satisfaction of certain customary conditions, to fund the Company's current operating plan beyond the next twelve months, into the first quarter of 2021. However, on a quarterly basis, the Company is 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, the Company's 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 the Company's control" under the accounting standards, the Company is not permitted to include it in its ASC 205-40 analysis. The result of the Company's ASC 205-40 analysis is that there is "substantial doubt" that the Company will have sufficient funds to satisfy its 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 transactions, 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 nine months ended September 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 people 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 nine months ended September 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 the Company's 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 the 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 the Company will exercise that option.

The Company's 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 its 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. Additionally, credit losses for trade receivables will be also be recorded through an allowance that reflects the Company's current estimate of credit losses expected to be incurred. 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. Based on the composition of the Company's available-for-sale debt securities, trade receivables, and other financial assets, and also taking into account current market conditions and historical credit loss activity, the Company does not expect that the adoption of this standard will have a material impact on the Company's consolidated financial statements and related disclosures.

In 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies the disclosure requirements for fair value measurements. 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 the adoption of the standard will have on its condensed consolidated financial statements and related disclosures.

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 September 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):

	September 30, 2019	September 30, 2018
Cash and cash equivalents	$ 122,886	$ 162,430
Prepaid expenses and other current assets	263	—
Other assets	2,092	1,566
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 125,241	$ 163,996

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 September 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 September 30, 2019 and December 31, 2018.

	Useful Life	September 30, 2019	December 31, 2018
		(in thousands)	
Computer equipment and software	3	$ 1,010	$ 1,593
Furniture and fixtures	5 - 7	2,086	1,170
Equipment	7	2,451	1,780
Leasehold improvements	Shorter of the useful life or remaining lease term (10 years)	10,869	5,324
Office equipment under capital lease	3	—	114
		16,416	9,981
Less accumulated depreciation		(3,617)	(1,958)
Net property and equipment		$ 12,799	$ 8,023

Depreciation expense was approximately $0.6 million and $0.2 million for the three months ended September 30, 2019 and 2018, respectively, and approximately $1.7 million and $0.6 million for the nine months ended September 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 September 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 September 30, 2019 and 2018, the Company incurred approximately $0.5 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 $0.2 million and $0.1 million are reimbursable by Otsuka and recorded as a reduction to research and development expense during the three months ended September 30, 2019 and 2018, respectively. During the three months ended September 30, 2019 and 2018, Otsuka incurred approximately $0.3 million and $0.5 million, respectively, of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.2 million and $0.1 million are reimbursable by the Company and recorded as an increase to research and development expense during each of the three months ended September 30, 2019 and 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 and asset group 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 nine months ended September 30, 2019. There were no impairments to assets measured using Level 3 inputs during the three and nine months ended September 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 $30.0 million and $82.2 million for the three and nine months ended September 30, 2019, respectively. The following table summarizes activity in each of the product revenue allowance and reserve categories for the nine months ended September 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	5,617	73,424	1,835	80,876
Adjustments related to prior period sales	13	1,507	—	1,520
Credits/payments made relating to sales in current year	(4,108)	(21,087)	—	(25,195)
Credits/payments made relating to prior period sales	(1,373)	(46,803)	(1,907)	(50,083)
Balance at September 30, 2019	$ 665	$ 29,902	$ 288	$ 30,855

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 nine months ended September 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 September 30, 2019:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
License, Collaboration and Other Revenue:	(in thousands)		(in thousands)	
MTPC Agreement	$ —	$ —	$ 10,000	$ 9,281
Otsuka U.S. Agreement	39,718	29,030	103,461	75,086
Otsuka International Agreement	20,220	24,114	64,643	63,176
Total Proportional Performance Revenue	$ 59,938	$ 53,144	$ 178,104	$ 147,543
JT and Torii	1,549	—	4,266	—
MTPC Stability Studies	486	25	872	349
Total License, Collaboration and Other Revenue	$ 61,973	$ 53,169	$ 183,242	$ 147,892

	September 30, 2019		
	Short-Term	Long-Term	Total
Deferred Revenue:	(in thousands)		
Otsuka U.S. Agreement	$ 18,873	$ 28,576	$ 47,449
Otsuka International Agreement	13,269	10,632	23,901
Vifor Agreement	—	4,679	4,679
Total	$ 32,142	$ 43,887	$ 76,029

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

Nine Months Ended September 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	$ 134,268	$ (131,651)	$ 4,204
Contract liabilities:				
Deferred revenue	$ 112,689	$ 131,444	$ (168,104)	$ 76,029
Accounts payable	$ 13,492	$ —	$ (13,492)	$ —
Nine Months Ended September 30, 2018				
Contract assets:				
Other current assets	$ —	$ 531	$ (531)	$ —
Accounts receivable(1)	$ 34,186	$ 120,283	$ (153,938)	$ 531
Contract liabilities:				
Deferred revenue	$ 179,624	$ 119,442	$ (147,543)	$ 151,523
Accounts payable	$ —	$ 4,427	$ (1,040)	$ 3,387

(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 September 30, 2018 and 2019 and December 31, 2017 and 2018. 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 September 30, 2019 and December 31, 2018.

During the three and nine months ended September 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 September 30,		Nine Months Ended September 30,	
Revenue Recognized in the Period from:	**2019**	**2018**	**2019**	**2018**
Amounts included in deferred revenue at the beginning of the period	$ 27,095	$ 53,144	$ 60,441	$ 110,974
Performance obligations satisfied in previous periods	$ —	$ —	$ 1,254	$ 6,813

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. MTPC reported top-line data for the two Phase 3 pivotal trials and data from the two supportive Phase 3 studies in March 2019 and 52-week data for the two Phase 3 pivotal trials in November 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 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 relation to the JNDA filing in the third quarter of 2019, 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 also made 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 reimbursed 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 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 September 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) the $10.0 million regulatory milestone relating to the JNDA filing. As of September 30, 2019, all development milestones have been achieved and, other than the $10.0 million regulatory milestone received by the Company related to the filing of the JNDA that was achieved, 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 nine months ended September 30, 2019 as the regulatory milestone was both deemed probable of being achieved and the required performance obligations had been satisfied as of September 30, 2019. The Company recognized approximately $9.3 million during the nine months ended September 30, 2018. The revenue is classified as collaboration revenue in the accompanying unaudited condensed consolidated statements of operations. No revenues were recognized for the three months ended September 30, 2019 and 2018 with respect to the MTPC Agreement. As of September 30, 2019, there is no deferred revenue, no accounts receivable, and no contract assets. There were no asset or liability balances classified as long-term in the unaudited condensed consolidated balance sheet as of September 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 September 30, 2019, the Additional Funding was $26.1 million.

In addition, Otsuka is 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, the Additional Funding for which, as of September 30, 2019, totaled $26.1 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 September 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 September 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 September s 30, 2019 and 2018, the Company recognized revenue totaling approximately $39.7 million and $29.0 million, respectively, and $103.5 million and $75.1 million during the nine months ended September 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 September 30, 2019, there is approximately $47.5 million of deferred revenue related to the Otsuka U.S. Agreement of which $18.9 million is classified as current and $28.6 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 September 30, 2019, there is approximately $1.2 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 September 30, 2019 and 2018, the Company incurred approximately $0.5 million and $0.2 million, respectively, of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement of which approximately $0.2 million and $0.1 million are reimbursable by Otsuka and recorded as a reduction to research and development expense during each of the three months ended September 30, 2019 and 2018, respectively. During the three months ended September 30, 2019 and 2018, Otsuka incurred approximately $0.3 million and $0.5 million of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.2 million and $0.1 million are reimbursable by the Company and recorded as an increase to research and development expense during the three months ended September 30, 2019 and 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$_2$TECT Phase 3 development program or the INNO$_2$VATE 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 September 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 September 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 September 30, 2019 and 2018, the Company recognized revenue totaling approximately $20.2 million and $24.1 million, respectively, and approximately $64.6 million and $63.2 million during the nine months ended September 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 September 30, 2019, there is approximately $23.9 million of deferred revenue related to the Otsuka International Agreement of which $13.3 million is classified as current and $10.6 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 September 30, 2019, there is was approximately $0.6 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 $25.0 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 $25.0 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 nine months ended September 30, 2019, the Company incurred approximately $2.7 million and $7.5 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, the Company's wholly owned subsidiary, remains the contracting party. Under the JT and Torii Sublicense Agreement, JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate hydrate in Japan. JT and Torii are responsible for the future development and commercialization costs in Japan.

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 nine months ended September 30, 2019, the Company recognized $1.5 million and $4.3 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 the Company's 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 September 30, 2019 and December 31, 2018 consisted of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
September 30, 2019				
Cash and cash equivalents	$ 122,886	$ —	$ —	$ 122,886
Available for sale securities:				
Certificates of deposit	$ 245	$ —	$ —	$ 245
U.S. government debt securities	22,476	6	—	22,482
Total available for sale securities	$ 22,721	$ 6	$ —	$ 22,727
Total cash, cash equivalents, and available for sale securities	$ 145,607	$ 6	$ —	$ 145,613

	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 September 30, 2019, by contractual maturity, was as follows:

Due in one year or less	$ 22,727
Due after one year	—
Total available for sale securities	$ 22,727

There were no realized gains or losses on available for sale securities for the three and nine months ended September 30, 2019 and 2018. Additionally, the Company did not have any available for sale securities that were in an unrealized loss position as of September 30, 2019. 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 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)			
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

As noted above, there were no securities as of September 30, 2019 that were in an unrealized loss position. There were 51 securities as of December 31, 2018, 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.

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 September 30, 2019 and December 31, 2018 are summarized below:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
September 30, 2019				
Assets:				
Cash and cash equivalents	$ 122,886	$ —	$ —	$ 122,886
Certificates of deposit	—	245	—	245
U.S. government debt securities	—	22,482	—	22,482
	$ 122,886	$ 22,727	$ —	$ 145,613

	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 September 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:

	September 30, 2019	December 31, 2018
	(in thousands)	
Raw materials	$ 2,824	$ 1,880
Work in process	152,208	215,122
Finished goods	45,863	18,182
Total inventory	$ 200,895	$ 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.

	September 30, 2019	December 31, 2018
	(in thousands)	
Balance Sheet Classification:		
Inventory	$ 115,987	$ 114,245
Other assets	84,908	120,939
Total inventory	$ 200,895	$ 235,184

Inventory amounts written down as a result of excess, obsolescence, scrap or other reasons and charged to cost of goods sold totaled $2.9 million and $6.0 million during the three and nine months ended September 30, 2019. The Company did not have any inventory write-offs during the three and nine months ended September 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 September 30, 2019 and December 31, 2018 (in thousands):

	September 30, 2019				
	Gross Carrying Value	Accumulated Amortization	ASC 842 Adjustment	Total	Estimated useful life
Acquired intangible assets:					
Developed product rights for Auryxia	$ 329,130	$ (28,818)	$ —	$ 300,312	9 Years
Favorable lease	545	(5)	(540)	—	N/A
Total	$ 329,675	$ (28,823)	$ (540)	$ 300,312	

	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 $27.3 million in amortization expense related to the developed product rights for Auryxia during the three and nine months ended September 30, 2019, respectively. Estimated future amortization expense for the intangible asset as of September 30, 2019 is as follows (in thousands):

	Total
2019	$ 9,100
2020	36,402
2021	36,401
2022	36,402
2023	36,401
Thereafter	145,606
	$ 300,312

Goodwill

Goodwill was $55.1 million as of September 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 September 30, 2019 and December 31, 2018 are as follows:

	September 30, 2019	December 31, 2018
	(in thousands)	
Accrued clinical expenses	$ 66,194	$ 71,881
Product revenue allowances	28,408	22,861
Accrued bonus	7,740	9,537
Lease liability	4,884	—
Accrued commercial manufacturing	3,352	6,383
Royalties	2,697	2,430
Professional fees	2,393	2,367
Accrued payroll	1,208	2,255
Accrued vacation	926	1,088
Accrued severance	79	3,962
Merger costs	—	16,071
Accrued other	8,763	12,082
Total accrued expenses	$ 126,644	$ 150,917

11. Debt

Term Loans

On November 11, 2019, the Company entered into a loan agreement, or the Loan Agreement, with Keryx as guarantor, BioPharma Credit PLC as collateral agent and a lender, or the Collateral Agent, and BioPharma Credit Investments V (Master) LP as a lender, collectively Pharmakon, pursuant to which term loans in an aggregate principal amount of $100.0 million are made available to the Company in two tranches, subject to certain terms and conditions, or the Term Loans. Subject to the satisfaction of certain conditions, the first tranche of $80.0 million, or Tranche A, will be drawn in a single drawing on November 25, 2019, or the Tranche A Funding Date. The second tranche, available until December 31, 2020, allows the Company to borrow, at its option, an additional $20.0 million, or Tranche B. The date on which Tranche B is drawn, the Tranche B Funding Date, and each of the Tranche A Funding Date and the Tranche B Funding Date, a Funding Date.

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

The Term Loans bear interest at a floating rate per annum equal to the three-month LIBOR rate plus 7.50%, subject to a 2.00% LIBOR floor and a 3.35% LIBOR cap, payable quarterly in arrears. The Term Loans will mature on the fifth anniversary of the Tranche A Funding Date, or the Maturity Date. The Company will repay the principal under the Term Loans in equal quarterly payments starting on the 33rd-month anniversary of the applicable Funding Date or, if certain conditions are met, it will have the option to repay the principal in equal quarterly payments starting on the 48th-month anniversary of the applicable Funding Date, or collectively the Amortization Schedule. Under certain circumstances, unless certain liquidity conditions are met, the Maturity Date may decrease by up to one year, and the Amortization Schedule may correspondingly commence up to one year earlier.

On the Tranche A Funding Date, the Company will pay to Pharmakon a facility fee equal to 2.00% of the aggregate principal amount of the Term Loans. The Loan Agreement permits voluntary prepayment at any time in whole or in part, subject to a prepayment premium. The prepayment premium would be 2.00% of the principal amount being prepaid prior to the third anniversary of the applicable Funding Date, 1.00% on or after the third anniversary, but prior to the fourth anniversary, of the applicable Funding Date, and 0.50% on or after the fourth anniversary of the applicable Funding Date but prior to the Maturity Date, and a make-whole premium on or prior to the second anniversary of the applicable Funding Date in an amount equal to foregone interest through the second anniversary of the applicable Funding Date. A change of control triggers a mandatory prepayment of the Term Loans.

The Loan Agreement contains customary representations, warranties, events of default and covenants of the Company and its subsidiaries, including maintaining, on an annual basis, a minimum liquidity threshold starting in 2021, and on a quarterly basis, a minimum net sales threshold for Auryxia starting in the fourth quarter of 2020. If an event of default occurs and is continuing under the Loan Agreement, the Collateral Agent is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

Revolving Line of Credit

Keryx, the Company's wholly owned subsidiary following the Merger, had 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. 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 had 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 were independent of Keryx's obligations, and separate actions may be brought against the Company.

Availability under the Line of Credit was 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 September 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 $29.4 million in available borrowing base as of September 30, 2019.

The principal amount outstanding under the Loan and Security Agreement bore 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 was payable monthly. Principal amounts borrowed under the Line of Credit may have been repaid and, prior to the maturity date, re-borrowed, subject to the terms and conditions set forth in 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 paid to SVB a fee equal to 1.00% of the Line of Credit. Keryx was 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. Pursuant to the terms of the Loan and Security Agreement, Keryx was required to pay a termination fee of 2.00% of the Line of Credit, if the Loan and Security Agreement was terminated prior to the maturity date of July 18, 2020, subject to certain exceptions. The Company terminated the Loan and Security Agreement, the Unconditional Guaranty, and the Security Agreement on November 7, 2019, and Keryx paid SVB a termination fee of $0.8 million.

During the three and nine months ended September 30, 2019, the Company recognized approximately $37,000 and $0.4 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 September 30, 2019, the warrant remains outstanding and expires on February 9, 2022.

13. Stockholders' Equity

Authorized and Outstanding Capital Stock

As of September 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 118,863,735 and 116,887,518 shares were issued and outstanding at September 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 September 30, 2019 and December 31, 2018.

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 1,228,900 options to purchase Akebia Shares were granted during the nine months ended September 30, 2019, of which 1,208,100 options to purchase Akebia Shares remained outstanding at September 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 nine months ended September 30, 2019, the Company granted 2,028,625 options to purchase Akebia Shares to employees under the 2014 Plan, 1,228,900 options to purchase Akebia Shares to employees under the Inducement Award Program, 4,430,945 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 September 30, 2019 of the Company's common stock available for future issuance under the ESPP is 5,715,992. 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:

	September 30, 2019	December 31, 2018
Common stock options and RSUs outstanding (1)	12,618,799	9,309,204
Shares available for issuance under Akebia equity plans (2)	4,684,048	4,526,563
Warrant to purchase common stock	509,611	509,611
Shares available for issuance under the ESPP (3)	5,715,992	603,522
Total	23,528,450	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 $1.3 million and $1.5 million of stock-based compensation expense related to stock options during the three months ended September 30, 2019 and 2018, respectively, and approximately $3.5 million and $5.1 million during the nine months ended September 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 nine months ended September 30, 2019 and 2018. As of September 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. On September 30, 2019, the Company issued 2,979,400 restricted stock units to employees. RSUs granted by the Company vest in one of the following ways: (i) 100% of each RSU grant vests on either the first or the third anniversary of the grant date, or (ii) 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, or (iii) 50% of each RSU grant vests on the first anniversary and 25% of each RSU grant vests in 6 months increment after the one year anniversary of the grant 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 $0.7 million of stock-based compensation expense related to the Akebia employee RSUs during the three months ended September 30, 2019 and 2018, respectively, and approximately $3.3 million and $1.8 million during the nine months ended September 30, 2019 and 2018, respectively.

Employee Stock Purchase Plan

The first offering period under the ESPP opened on January 2, 2015. The Company issued 87,530 shares during the nine months ended September 30, 2019. The Company recorded approximately $0.1 million and $52,000 of stock-based compensation expense related to the ESPP during the three months ended September 30, 2019 and 2018, respectively, and approximately $0.2 million and $0.2 million during the nine months ended September 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		Nine Months Ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
	(in thousands)		(in thousands)	
Research and development	$ 556	$ 647	$ 2,118	$ 2,090
Selling, general and administrative	2,057	1,605	4,873	4,888
Total	$ 2,613	$ 2,252	$ 6,991	$ 6,978

Compensation expense by type of award:

	Three Months Ended		Nine Months Ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
	(in thousands)		(in thousands)	
Stock options	$ 1,305	$ 1,458	$ 3,490	$ 5,074
Restricted stock units	1,217	742	3,318	1,751
Employee stock purchase plan	91	52	183	153
Total	$ 2,613	$ 2,252	$ 6,991	$ 6,978

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 September 30, 2019 and December 31, 2018, the Company's net deferred tax liability was $1.8 million and $6.6 million, respectively. Deferred tax liabilities can be reduced by deferred tax assets generated by the Company. During the three and nine months ended September 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 $1.3 million and $4.9 million tax benefit for the three and nine months ended September 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 nine months ended September 30, 2019 were $1.7 million and $5.0 million, respectively, and cash paid for amounts included in the measurement of operating lease liabilities for the three and nine months ended September 30, 2019 were $1.7 million and $5.2 million, respectively.

In September 2019, Keryx entered into an agreement to sublease the Boston office space to Foundation Medicine, Inc., or Foundation. The sublease is subject and subordinate to the Boston Lease between Keryx and the landlord. The term of the sublease commenced on October 16, 2019, upon receipt of the required consent from the landlord for the sublease agreement, and expires on February 27, 2023. Foundation is obligated to pay Keryx rent that approximates the rent due from Keryx to its landlord with respect to the Boston Lease. Keryx continues to be obligated for all payment terms pursuant to the Boston Lease, and the Company will guaranty Keryx's obligations under the sublease.

The Company has not entered into any material short-term leases or financing leases as of September 30, 2019.

The total security deposit in connection with the Cambridge Lease is $1.6 million as of September 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 September 30, 2019.

As of September 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	$ 1,296
2020	7,008
2021	7,064
2022	6,735
2023	5,347
Thereafter	13,934
Total	$ 41,384

In arriving at the operating lease liabilities, the Company applied incremental borrowing rates ranging from 5.91% to 6.94%, which were based on the remaining lease term at the date of adoption of ASC 842. As of September 30, 2019, the remaining lease terms ranged from 2.17 years to 6.95 years. As of September 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	$ 41,384
Present value adjustment using incremental borrowing rate	(7,689)
Operating lease liabilities	$ 33,695

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 September 30, 2019, the Company is required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $135.7 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 September 30, 2019, the Company recorded $0.5 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 September 30, 2019, the Company is required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $66.3 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 $INNO_2VATE$ programs, the total remaining contract costs as of September 30, 2019 were approximately $76.9 million, of which Otsuka reimburses a significant portion back to the Company. 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 $52.7 million at September 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 September 30,	
	2019	**2018**
Warrant	509,611	509,611
Outstanding stock options	7,808,382	3,957,940
Unvested restricted stock units	4,810,417	893,850
Total	13,128,410	5,361,401

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 people 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 $30.0 million and $82.2 million in revenue from product sales during the three and nine months ended September 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 $54.6 million and $26.0 million for the three months ended September 30, 2019 and 2018, respectively, and $185.2 million and $83.5 million for the nine months ended September 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, $INNO_2VATE$, and other studies, 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 transactions, 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 September 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 collaborations with Otsuka and MTPC and any other collaborations into which we may enter, as well as commercial sales of Auryxia in the U.S., and royalty revenue from JT and Torii.

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 from the date of the Merger.

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 September 30, 2019, we have incurred $996.3 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 September 30, 2019 and 2018

	Three Months Ended		Increase
	September 30, 2019	September 30, 2018	(Decrease)
		(In Thousands)	
Revenues:			
Product revenue, net	$ 30,004	$ —	$ 30,004
License, collaboration and other revenue	61,973	53,169	8,804
Total revenues	91,977	53,169	38,808
Cost of goods sold:			
Product	29,162	—	29,162
Amortization of intangibles	9,101	—	9,101
Total cost of goods sold	38,263	—	38,263
Operating expenses:			
Research and development	74,512	70,634	3,878
Selling, general and administrative	34,178	10,378	23,800
License expense	929	—	929
Total operating expenses	109,619	81,012	28,607
Operating loss	(55,905)	(27,843)	28,062
Other income, net	43	1,796	(1,753)
Net loss before income taxes	(55,862)	(26,047)	29,815
Benefit from income taxes	(1,277)	—	1,277
Net loss	$ (54,585)	$ (26,047)	$ 28,538

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 $30.0 million for the three months ended September 30, 2019. During the three months ended September 30, 2019, the average net sales price per unit (after accounting for fees, rebates, chargebacks, and other discounts or reserves) increased slightly as compared to the three months ended September 30, 2018.

Net U.S Auryxia product revenue for the three months ended September 30, 2018, as reported in the Keryx Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018 prior to the Merger, was $26.6 million. The increase in net product revenue for the three months ended September 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. On October 15, 2019, we filed a complaint in the United States District Court for the District of Massachusetts against CMS and the U.S. Department of Health and Human Services challenging CMS's decision that Auryxia would no longer be covered by Medicare for the IDA Indication and CMS's related decision that imposed a prior authorization requirement for Auryxia in the Hyperphosphatemia Indication. See Part II, Item 1. Legal Proceedings for further information. 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 and the CMS decision have had and will continue to have an adverse impact on the sales of Auryxia for the Hyperphosphatemia Indication and the IDA Indication, and ultimately on the timing and number of prescriptions and Auryxia product revenue. Sales of Auryxia for the Hyperphosphatemia Indication and the IDA Indication have been negatively impacted, and may continue to be negatively affected, as a result of the CMS decision. Even if we are successful in overturning the CMS decision, the negative impact that the original decision had on the growth of sales of Auryxia for the Hyperphosphatemia Indication and the IDA Indication will continue, although less significantly than if the CMS decision is not overturned.

License, Collaboration and Other Revenue. License, collaboration and other revenue was $62.0 million for the three months ended September 30, 2019 compared to $53.2 million for the three months ended September 30, 2018. We recognized $59.9 million in collaboration revenue for the three months ended September 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. We recognized $53.1 million in collaboration revenue for the three months ended September 30, 2018 from our cost sharing arrangement under the Otsuka U.S. Agreement, which commenced in December 2016, and the Otsuka International Agreement, which commenced in April 2017. The increase in revenue between the two periods was primarily attributable to an additional $6.8 million of revenue recognized under the Otsuka U.S. Agreement, primarily driven by $15.5 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, partially offset by a decrease in reimbursable expenses associated to the Otsuka collaboration agreements. The remaining increase is primarily due to 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, as there were no comparable revenues in the third quarter of 2018.

Cost of Goods Sold - Product. Cost of goods sold of $29.2 million for the three months ended September 30, 2019 consists primarily of costs associated with the manufacturing of Auryxia and a $18.0 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 September 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 September 30, 2019 was $9.1 million. This increase as compared to the three months ended September 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 $74.5 million for the three months ended September 30, 2019, compared to $70.6 million for the three months ended September 30, 2018, an increase of $3.9 million. The increase was primarily due to the following:

	(in millions)
Other supporting clinical and preclinical activities and regulatory activities	$ 2.6
Manufacture of drug substance and drug product	0.6
PRO_2TECT and $INNO_2VATE$ Phase 3 program	(6.3)
Total decrease related to the continued development of vadadustat	(3.1)
Headcount, consulting and facilities	3.8
Other research	4.2
Other	(1.0)
Total other increases	7.0
Total net increase	$ 3.9

The decrease in the costs related to the development of vadadustat is primarily attributable to a decrease in external costs related to the continued advancement of the PRO$_2$TECT and INNO$_2$VATE Phase 3 program, for which we completed enrollment in the third quarter of 2019. The aggregate decrease in costs was partially offset by an increase in external costs related to other vadadustat clinical and preclinical activities as well as regulatory activities and the manufacture of drug substance and drug product. The decrease in vadadustat research and development expenses were offset by increases in other research and 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 $34.2 million for the three months ended September 30, 2019, compared to $10.4 million for the three months ended September 30, 2018. The increase of $23.8 million was primarily due to commercialization costs associated with Auryxia as there were no comparable commercialization costs in the third quarter of 2018, and an increase in costs to support our research and development programs. 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 $0.2 million for the three months ended September 30, 2019 and $1.8 million for the three months ended September 30, 2018. The decrease in other income, net was primarily due to lower interest income caused by lower average investment balances in the third quarter of 2019.

Benefit from Income Taxes. Benefit from income taxes was $1.3 million for the three months ended September 30, 2019 due to a decrease in our net deferred tax liabilities, or DTLs. During the three months ended September 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 September 30, 2019.

Comparison of the Nine Months Ended September 30, 2019 and 2018

	Nine Months Ended		Increase
	September 30, 2019	September 30, 2018	(Decrease)
	(In Thousands)		
Revenues:			
Product revenue, net	$ 82,204	$ —	$ 82,204
License, collaboration and other revenue	183,242	147,892	35,350
Total revenues	265,446	147,892	117,554
Cost of goods sold:			
Product	79,888	—	79,888
Amortization of intangibles	27,301	—	27,301
Total cost of goods sold	107,189	—	107,189
Operating expenses:			
Research and development	242,557	203,955	38,602
Selling, general and administrative	104,537	31,940	72,597
License expense	2,560	—	2,560
Total operating expenses	349,654	235,895	113,759
Operating loss	(191,397)	(88,003)	103,394
Other income, net	1,342	4,469	(3,127)
Net loss before income taxes	(190,055)	(83,534)	106,521
Benefit from income taxes	(4,879)	—	4,879
Net loss	$ (185,176)	$ (83,534)	$ 101,642

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 $82.2 million for the nine months ended September 30, 2019. During the nine months ended September 30, 2019, the average net sales price per unit (after accounting for fees, rebates, chargebacks, and other discounts or reserves) increased slightly as compared to the nine months ended September 30, 2018.

Net U.S Auryxia product revenue for the nine months ended September 30, 2018, as reported in the Keryx Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018 prior to the Merger, was $71.3 million. The increase in net product revenue for the nine months ended September 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. On October 15, 2019, we filed a complaint in the United States District Court for the District of Massachusetts against CMS and the U.S. Department of Health and Human Services challenging CMS's decision that Auryxia would no longer be covered by Medicare for the IDA Indication and CMS's related decision that imposed a prior authorization requirement for Auryxia in the Hyperphosphatemia Indication. While we believe that the vast majority of the Medicare prescriptions written for Auryxia today are for the Hyperphosphatemia Indication and therefore will continue to be covered by Medicare with prior authorization, the prior authorization requirement and the CMS decision have had and will continue to have an adverse impact on the sales of Auryxia for the Hyperphosphatemia Indication and the IDA Indication, and ultimately on the timing and number of prescriptions and Auryxia product revenue. Sales of Auryxia for the Hyperphosphatemia Indication and the IDA Indication have been negatively impacted, and may continue to be negatively affected, as a result of the CMS decision. Even if we are successful in overturning the CMS decision, the negative impact that the original decision had on the growth of sales of Auryxia for the Hyperphosphatemia Indication and the IDA Indication will continue, although less significantly than if the CMS decision is not overturned.

License, Collaboration and Other Revenue. License, collaboration and other revenue was $183.2 million for the nine months ended September 30, 2019 compared to $147.9 million for the nine months ended September 30, 2018. We recognized $178.1 million in collaboration revenue for the nine months ended September 30, 2019 from our cost sharing arrangement under the Otsuka U.S. Agreement, the Otsuka International Agreement, and our collaboration agreement with MTPC, or the MTPC Agreement. We recognized $147.5 million in collaboration revenue for the nine months ended September 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 $28.3 million of revenue recognized under the Otsuka U.S. Agreement, primarily driven by $26.1 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). The remaining increase is primarily due to 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, as there were no comparable revenues in the nine months ended September 30, 2018.

Cost of Goods Sold - Product. Cost of goods sold of $79.9 million for the nine months ended September 30, 2019 consists primarily of costs associated with the manufacturing of Auryxia and a $51.6 million charge related to the fair-value inventory step-up from the application of purchase accounting. This increase as compared to the nine months ended September 30, 2018 was due to costs associated with Auryxia, as there were no comparable costs in the first nine months 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 nine months ended September 30, 2019 was $27.3 million. This increase as compared to the nine months ended September 30, 2018 was due to costs associated with Auryxia, as there were no comparable costs in the first nine months of 2018.

Research and Development Expenses. Research and development expenses were $242.6 million for the nine months ended September 30, 2019, compared to $204.0 million for the nine months ended September 30, 2018, an increase of $38.6 million. The increase was primarily due to the following:

	(in millions)
Other supporting clinical and preclinical activities and regulatory activities	$ 8.0
PRO_2TECT and $INNO_2VATE$ Phase 3 program	7.3
Manufacture of drug substance and drug product	(0.4)
Japan Phase 2 studies	(1.4)
Total increase related to the continued development of vadadustat	13.5
Headcount, consulting and facilities	13.6
Other research	6.5
Other	5.0
Total other increases	25.1
Total net increase	$ 38.6

The increase in the costs related to the development of vadadustat is primarily attributable to an increase in external costs related to other supporting clinical and preclinical activities, as well as regulatory activities, and the continued advancement of the PRO_2TECT and $INNO_2VATE$ Phase 3 program, including ongoing enrollment. This increase in costs related to the development of vadadustat was partially offset by a decrease in costs related to the manufacture of drug substance and drug product and 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 and other research 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 $104.5 million for the nine months ended September 30, 2019, compared to $31.9 million for the nine months ended September 30, 2018. The increase of $72.6 million was primarily due to commercialization costs associated with Auryxia as there were no comparable commercialization costs during the first nine months of 2018, and an increase in costs to support our research and development programs. 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 $1.5 million for the nine months ended September 30, 2019 and $4.5 million for the nine months ended September 30, 2018. The decrease in other income, net was primarily due to lower interest income caused by lower average investment balances during the first nine months of 2019 and interest expense associated to our Line of Credit with SVB, which we did not have during the nine months ended September 30, 2018.

Benefit from Income Taxes. Benefit from income taxes was $4.9 million for the nine months ended September 30, 2019 due to a decrease in our net DTLs. During the nine months ended September 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 nine months ended September 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 September 30, 2019, we had an accumulated deficit of $699.6 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 September 30, 2019, we had cash and cash equivalents and available for sale securities of approximately $145.6 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:

	Nine Months Ended	
	September 30, 2019	**September 30, 2018**
	(In Thousands)	
Net cash provided by (used in):		
Operating activities	$ (165,306)	$ (23,795)
Investing activities	188,896	19,877
Financing activities	(5,448)	96,477
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ 18,142	$ 92,559

Operating Activities. Net cash used in operating activities of $165.3 million for the nine months ended September 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 $51.6 million, amortization of intangibles of $27.3 million, and stock-based compensation expense of $7.0 million.

The net cash used in operating activities of $23.8 million for the nine months ended September 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 $151.4 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 $7.0 million.

Investing Activities. Net cash provided by investing activities for the nine months ended September 30, 2019 was $188.9 million and was comprised primarily of proceeds from the maturities of available for sale securities of $130.6 million and proceeds from the sales of available for sale securities of $64.7 million, partially offset by purchases of equipment of $6.4 million.

Net cash provided by investing activities for the nine months ended September 30, 2018 was $19.9 million and was comprised primarily of proceeds from the maturities of available for sale securities of $180.1 million and proceeds from the sales of available for sale securities of $13.0 million, offset by the purchases of available for sale securities of $172.4 million and purchases of equipment of $0.8 million.

Financing Activities. Net cash used in financing activities for the nine months ended September 30, 2019 was $5.5 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 nine months ended September 30, 2018 was $96.5 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 funds to be received from our collaborators, and $100.0 million upon closing of the Term Loans with Pharmakon, subject to the satisfaction of certain customary conditions, to fund our current operating plan beyond the next twelve months, into the first quarter of 2021. 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 transactions, 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 on February 27, 2023. The total monthly lease payments under the base rent are approximately $136,000 and are subject to annual rent escalations.

During the third quarter of 2019, all remaining employees based in our Boston, Massachusetts office moved to our corporate headquarters in Cambridge, Massachusetts. In September 2019, Keryx entered into an agreement to sublease the Boston office space to Foundation Medicine, Inc., or Foundation. The sublease is subject and subordinate to the Boston Lease between Keryx and the landlord. The term of the sublease commenced on October 16, 2019, upon receipt of the required consent from the landlord for the sublease agreement, and expires on February 27, 2023. Foundation is obligated to pay Keryx rent that approximates the rent due from us to Keryx's landlord with respect to the Boston Lease. Keryx continues to be obligated for all payment terms pursuant to the Boston Lease, and we will guaranty Keryx's obligations under the sublease.

Term Loans

On November 11, 2019, we entered into a loan agreement, or the Loan Agreement, with Keryx as guarantor, BioPharma Credit PLC as collateral agent and a lender, or the Collateral Agent, and BioPharma Credit Investments V (Master) LP as a lender, collectively Pharmakon, pursuant to which term loans in an aggregate principal amount of $100.0 million are made available to us in two tranches, subject to certain terms and conditions, or the Term Loans. Subject to the satisfaction of certain conditions, the first tranche of $80.0 million, or Tranche A, will be drawn in a single drawing on November 25, 2019, or the Tranche A Funding Date. The second tranche, available until December 31, 2020, allows us to borrow, at our option, an additional $20.0 million, or Tranche B. The date on which Tranche B is drawn, the Tranche B Funding Date, and each of the Tranche A Funding Date and the Tranche B Funding Date, a Funding Date.

Proceeds from the Term Loans may be used for general corporate purposes. As a condition to the funding of Tranche A, we and Keryx are obligated to enter into a Guaranty and Security Agreement with the Collateral Agent, or the Guaranty and Security Agreement, on the Tranche A Funding Date. Pursuant to the Guaranty and Security Agreement, our obligations under the Term Loans will be unconditionally guaranteed by Keryx, or the Guarantee. Additionally, our and Keryx's obligations under the Term Loans and the Guarantee will be secured by a first priority lien on certain assets of ours and Keryx's, including Auryxia and certain related assets, cash, and certain equity interests held by us and Keryx, collectively the Collateral.

The Term Loans bear interest at a floating rate per annum equal to the three-month LIBOR rate plus 7.50%, subject to a 2.00% LIBOR floor and a 3.35% LIBOR cap, payable quarterly in arrears. The Term Loans will mature on the fifth anniversary of the Tranche A Funding Date, or the Maturity Date. We will repay the principal under the Term Loans in equal quarterly payments starting on the 33rd-month anniversary of the applicable Funding Date or, if certain conditions are met, it will have the option to repay the principal in equal quarterly payments starting on the 48th-month anniversary of the applicable Funding Date, or collectively the Amortization Schedule. Under certain circumstances, unless certain liquidity conditions are met, the Maturity Date may decrease by up to one year, and the Amortization Schedule may correspondingly commence up to one year earlier.

On the Tranche A Funding Date, we will pay to Pharmakon a facility fee equal to 2.00% of the aggregate principal amount of the Term Loans. The Loan Agreement permits voluntary prepayment at any time in whole or in part, subject to a prepayment premium. The prepayment premium would be 2.00% of the principal amount being prepaid prior to the third anniversary of the applicable Funding Date, 1.00% on or after the third anniversary, but prior to the fourth anniversary, of the applicable Funding Date, and 0.50% on or after the fourth anniversary of the applicable Funding Date but prior to the Maturity Date, and a make-whole premium on or prior to the second anniversary of the applicable Funding Date in an amount equal to foregone interest through the second anniversary of the applicable Funding Date. A change of control triggers a mandatory prepayment of the Term Loans.

The Loan Agreement contains customary representations, warranties, events of default and covenants of ours and our subsidiaries, including maintaining, on an annual basis, a minimum liquidity threshold starting in 2021, and on a quarterly basis, a minimum net sales threshold for Auryxia starting in the fourth quarter of 2020. If an event of default occurs and is continuing under the Loan Agreement, the Collateral Agent is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

The foregoing description of the Loan Agreement does not purport to be complete and is qualified in its entirety by reference to the Loan Agreement, a copy of which we intend to file as an exhibit to our Annual Report on Form 10-K for the year ending December 31, 2019.

Revolving Line of Credit

Keryx, our wholly owned subsidiary following the Merger, had 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. 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 had 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 were independent of Keryx's obligations, and separate actions were able to be brought against us.

Availability under the Line of Credit was 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 September 30, 2019 and December 31, 2018, there was $0 and $15.0 million outstanding, respectively, under the Line of Credit and we had approximately $29.4 million in available borrowing base as of September 30, 2019.

The principal amount outstanding under the revolving line bore 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 was payable monthly. Principal amounts borrowed under the Line of Credit were able to be repaid and, prior to the maturity date, re-borrowed, subject to the terms and conditions set forth in 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 paid to SVB a fee equal to 1.00% of the Line of Credit. Keryx was 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. Pursuant to the terms of the Loan and Security Agreement, Keryx was required to pay a termination fee of 2.00% of the Line of Credit, if the revolving line was terminated prior to the maturity date of July 18, 2020, subject to certain exceptions. On November 7, 2019, we terminated the Loan and Security Agreement, the Unconditional Guaranty, and the Security Agreement and paid a termination fee of $0.8 million to SVB.

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 September 30, 2019, we are required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $135.7 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 September 30, 2019, we recorded $0.5 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 September 30, 2019, we are required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $66.3 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 September 30, 2019 were approximately $76.9 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 $52.7 million as of September 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 September 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 nine months ended September 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 September 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 September 30, 2019 and 2018, we incurred approximately $0.5 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 $0.2 million and $0.1 million are reimbursable by Otsuka and recorded as a reduction to research and development expense during each of the three months ended September 30, 2019 and 2018. During the three months ended September 30, 2019 and 2018, Otsuka incurred approximately $0.3 million and $0.5 million, respectively, of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.2 million and $0.1 million are reimbursable by us and recorded as an increase to research and development expense during the three months ended September 30, 2019 and 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 September 30, 2019, and December 31, 2018, we had cash and cash equivalents and available-for-sale securities of $145.6 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 September 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 September 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 September 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.

CMS Litigation

On October 15, 2019, we filed a complaint in the United States District Court for the District of Massachusetts, or the Massachusetts District Court, against Centers for Medicare & Medicaid Services, or CMS, the U.S. Department of Health and Human Services, Alex M. Azar II in his official capacity as Secretary of Health and Human Services, and Seema Verma in her official capacity as administrator for CMS challenging CMS's decision that Auryxia would no longer be covered by Medicare for the treatment of iron deficiency anemia, or IDA, in adult patients with chronic kidney disease, or CKD, not on dialysis, or the IDA Indication, and CMS's related decision that imposed a prior authorization requirement for Auryxia in the treatment of adult patients with CKD on dialysis, or the Hyperphosphatemia Indication. On October 29, 2019, we filed a motion for a preliminary injunction asking the court to provide relief while the lawsuit is pending, specifically, to restore coverage for Auryxia when used for the IDA Indication, and to remove the prior authorization requirement for Auryxia when used for the Hyperphosphatemia Indication. In the alternative, we filed a motion for summary judgment with the court asking it to decide the case on the merits now in our favor.

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 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 20, 2019.

On December 10, 2018, a 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 sought 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 sought 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. On October 24, 2019, the Delaware Chancery Court issued a written decision granting inspection, denying the plaintiff's request for costs and expenses, and directing the parties to confer on the proper scope of the inspection.

Shareholder Litigation Relating to Auryxia Supply

Four putative class action lawsuits were 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 sought 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.

On September 23, 2019, the Massachusetts District Court issued a Memorandum and Order denying plaintiff's motion for class certification, granting defendants' motion for judgment on the pleadings, and denying plaintiff's motion for leave to further amend his Complaint. That same day, the Massachusetts District Court entered a final judgment in favor of defendants on all claims. On September 24, 2019, plaintiff filed a notice of appeal. Plaintiff's appeal brief is due December 4, 2019, and defendants' brief is due thirty days thereafter. The First Circuit has not yet set an oral argument date for the appeal.

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, and that stay remains in effect. All of the complaints seek unspecified damages, interest, attorneys' fees, and other costs. It is expected that such complaints would be dismissed if the above-mentioned ruling of the Massachusetts District Court entering judgment for the defendants in the case brought under the securities laws stands; however, as discussed above, we are awaiting the outcome of the appeal of that judgment.

We deny any allegations of wrongdoing and intend to continue vigorously defending 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 any associated appeals, 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 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. On August 26, 2019, Keryx filed an amended complaint against the Lupin Defendants in the Delaware District Court arising from the Lupin Defendants' ANDA filings with the FDA. On September 19, 2019, the Delaware District court set a trial date for February 8, 2021.

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, and the Watson Defendants 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 September 17, 2019, Keryx received from Par a supplemental Paragraph IV certification notice letter regarding its ANDA. On October 16, 2019, Keryx received from Mylan 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. On September 6, 2019 and September 9, 2019, the Southern New York District Court and the Delaware District Court, respectively, entered a stipulation and order of dismissal filed by the parties to dismiss the actions against Par.

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. Oral proceedings in the appeal are scheduled for June 19, 2020.

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. 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 September 26, 2019, the JPO conducted an invalidation trial for JP5474872 and JP4845728.

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. In September 2019, we and Otsuka filed an Amended Particulars of Claim to include FibroGen’s European Patent No. 1487472, or the ’472 EP Patent (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 $185.2 million for the nine months ended September 30, 2019. As of September 30, 2019, we had an accumulated deficit of $699.6 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 and $INNO_2VATE$ and other additional ongoing or planned studies with respect to vadadustat, 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 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 have entered into a loan agreement, or the Loan Agreement, with Keryx as guarantor, BioPharma Credit PLC as collateral agent and a lender, or the Collateral Agent, and BioPharma Credit Investments V (Master) LP as a lender, collectively Pharmakon, pursuant to which term loans in an aggregate principal amount of $100 million are made available to us in two tranches, subject to certain terms and conditions, or the Term Loans. See Note 11 to our condensed consolidated financial statements in Part I, Item 1 – Financial Statements (unaudited) for additional information regarding our obligations under the Loan Agreement. We expect our cash resources, including funds to be received from our collaborators, and $100.0 million, upon closing of the Term Loans, subject to the satisfaction of customary conditions, to fund our current operating plan beyond the next twelve months, into the first quarter of 2021. 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 September 30, 2019, our cash and cash equivalents and available for sale securities were $145.6 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 September 30, 2019, we expect the remaining external aggregate contract research organization, or CRO, costs of PRO_2TECT and $INNO_2$VATE, which have enrolled 7,436 subjects, to be in the range of $95.0 million to $120.0 million; the estimated costs for PRO_2TECT and $INNO_2$VATE could increase significantly due to a number of factors, including accrual of major adverse cardiovascular events, or MACE, detection of unexpected safety signals, 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 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 committed research and development funding from our collaborators and the receipt of a regulatory milestone from MTPC, assuming approval of vadadustat in Japan, and $100 million, upon closing of the Term Loans, subject to the satisfaction of customary conditions, to fund our current operating plan beyond the next twelve months, into the first quarter of 2021. 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 transactions, 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. For more information, see the risk factor titled "*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*."

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 Loan Agreement with Pharmakon could adversely affect our financial condition and restrict our operations.

Our Loan Agreement with Pharmakon contains affirmative and negative covenants applicable to us and our subsidiaries, including maintaining, on an annual basis, a minimum liquidity threshold starting in 2021, and on a quarterly basis, a minimum net sales threshold for Auryxia starting in the fourth quarter of 2020. Failure to maintain compliance with this financial covenant could result in an event of default under the Loan Agreement.

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

The Loan Agreement permits voluntary prepayment at any time in whole or in part, subject to prepayment premiums and make-whole premiums prior to certain dates. Upon a change of control, mandatory prepayment provisions require the Company to prepay the principal amount outstanding, the applicable prepayment premium and make-whole premium and accrued and unpaid interest.

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

- obligating us to negative covenants restricting our activities, including limitations on transferring certain of our assets, engaging in certain transactions, incurring certain additional indebtedness, creating certain liens, paying dividends or making certain other distributions and making certain investments;
- 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 transactions, 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), have filed certain complaints for patent infringement relating to such ANDAs, and have entered into a settlement and license agreement with one such ANDA filer. See Part II, Item 1. Legal Proceedings for further information relating to the ANDAs, lawsuits and settlement. 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. On October 15, 2019, we filed a complaint in the United States District Court for the District of Massachusetts against CMS and the U.S. Department of Health and Human Services challenging CMS's decision that Auryxia would no longer be covered by Medicare for the IDA Indication and CMS's related decision that imposed a prior authorization requirement for Auryxia in the Hyperphosphatemia 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 and the CMS decision have had and may continue to have an adverse impact on market acceptance of Auryxia, sales of Auryxia for the Hyperphosphatemia Indication and the IDA Indication, respectively, and ultimately on the timing and number of prescriptions and Auryxia product revenue, and may influence physicians' prescribing decisions. Sales of Auryxia for the Hyperphosphatemia Indication and the IDA Indication have been negatively impacted, and may continue to be negatively affected, as a result of the CMS decision. Even if we are successful in overturning the CMS decision, the negative impact that the original decision had on the growth of sales of Auryxia for the Hyperphosphatemia Indication and the IDA Indication will continue, although less significantly than if the CMS decision is not overturned. 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 in 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 formulated a commercial plan for Fexeric in Europe with Panion & BF Biotech, Inc., or Panion, the licensor of our rights to ferric citrate. 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 agents 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 for the treatment of IDA may impact the market for Auryxia, such as Shield Therapeutics' Feraccru® (ferric maltol) and Accrufer® (ferric maltol), which is available in Europe for IDA and which is approved in the United States for IDA, respectively.

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. In addition, roxadustat is approved in Japan for the treatment of anemia associated with CKD in patients on dialysis and in China for the treatment of anemia caused by CKD in patients on dialysis and not on dialysis, and is available for sale in China. 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. Other product candidates may launch in certain Asian markets next year. 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. 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. 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 and conducting studies 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 our collaboration partner, MTPC, submitted a JNDA for vadadustat for the treatment of anemia due to CKD in July 2019 in 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 conducted 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 has enrolled 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 had 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 was extended to October 31, 2019. On October 28, 2019, that deadline was extended from October 31, 2019 to January 31, 2020 to allow the parties to continue to negotiate a withdrawal agreement. The United Kingdom could leave the European Union earlier if Parliament approves the withdrawal, but that has proven to be extremely difficult to date. 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. On July 24, 2019, Boris Johnson, who has previously suggested that the country should leave the European Union without an agreement, was appointed Prime Minister of the United Kingdom.

Since a significant proportion of the regulatory framework in the United Kingdom is derived from EU directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the EU. For example, the British government has begun negotiating the terms of the United Kingdom's withdrawal from the European Union. It is unclear what impact Brexit may have, if any, on the development and commercialization of our product candidates, although the first practical effects of Brexit on healthcare were felt in November 2017 when European Union member states voted to move the EMA, the European Union's regulatory body, from London to Amsterdam. Operations in Amsterdam commenced in March 2019, and the move itself may cause significant disruption to the regulatory approval process in Europe. 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 occur, 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. However, in a subsequent filing, the U.S. Department of Justice contended that the ACA should be invalidated only in the states that are suing, rather than all states. 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), have filed certain complaints for patent infringement relating to such ANDAs, and have entered into a settlement and license agreement with one such ANDA filer. See Part II, Item 1. Legal Proceedings for further information relating to the ANDAs, lawsuits and settlement.

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 $3.20 on November 12, 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 September 30, 2019, we believe that our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, approximately 2.5% 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 Internal Revenue Code, or Section 382, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. On December 12, 2018, we completed the Merger, which we believe has resulted in a change in control under Section 382. Future changes in our stock ownership, many of which are outside of our control, could result in an additional ownership change under Section 382. As a result, if we generate taxable income, our ability to use our pre-change NOL carryforwards to offset federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. 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 putative 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 legal proceedings.

We are currently subject to putative 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 September 30, 2019, we did not have any sales of unregistered securities.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Term Loans

On November 11, 2019, we entered into a loan agreement, or the Loan Agreement, with Keryx as guarantor, BioPharma Credit PLC as collateral agent and a lender, or the Collateral Agent, and BioPharma Credit Investments V (Master) LP as a lender, collectively Pharmakon, pursuant to which term loans in an aggregate principal amount of $100.0 million are made available to us in two tranches, subject to certain terms and conditions, or the Term Loans. Subject to the satisfaction of certain conditions, the first tranche of $80.0 million, or Tranche A, will be drawn in a single drawing on November 25, 2019, or the Tranche A Funding Date. The second tranche, available until December 31, 2020, allows us to borrow, at our option, an additional $20.0 million, or Tranche B. The date on which Tranche B is drawn, the Tranche B Funding Date, and each of the Tranche A Funding Date and the Tranche B Funding Date, a Funding Date.

Proceeds from the Term Loans may be used for general corporate purposes. As a condition to the funding of Tranche A, we and Keryx are obligated to enter into a Guaranty and Security Agreement with the Collateral Agent, or the Guaranty and Security Agreement, on the Tranche A Funding Date. Pursuant to the Guaranty and Security Agreement, our obligations under the Term Loans will be unconditionally guaranteed by Keryx, or the Guarantee. Additionally, our and Keryx's obligations under the Term Loans and the Guarantee will be secured by a first priority lien on certain assets of ours and Keryx's, including Auryxia® (ferric citrate) and certain related assets, cash, and certain equity interests held by us and Keryx, collectively the Collateral.

The Term Loans bear interest at a floating rate per annum equal to the three-month LIBOR rate plus 7.50%, subject to a 2.00% LIBOR floor and a 3.35% LIBOR cap, payable quarterly in arrears. The Term Loans will mature on the fifth anniversary of the Tranche A Funding Date, or the Maturity Date. We will repay the principal under the Term Loans in equal quarterly payments starting on the 33rd-month anniversary of the applicable Funding Date or, if certain conditions are met, it will have the option to repay the principal in equal quarterly payments starting on the 48th-month anniversary of the applicable Funding Date, or collectively the Amortization Schedule. Under certain circumstances, unless certain liquidity conditions are met, the Maturity Date may decrease by up to one year, and the Amortization Schedule may correspondingly commence up to one year earlier.

On the Tranche A Funding Date, we will pay to Pharmakon a facility fee equal to 2.00% of the aggregate principal amount of the Term Loans. The Loan Agreement permits voluntary prepayment at any time in whole or in part, subject to a prepayment premium. The prepayment premium would be 2.00% of the principal amount being prepaid prior to the third anniversary of the applicable Funding Date, 1.00% on or after the third anniversary, but prior to the fourth anniversary, of the applicable Funding Date, and 0.50% on or after the fourth anniversary of the applicable Funding Date but prior to the Maturity Date, and a make-whole premium on or prior to the second anniversary of the applicable Funding Date in an amount equal to foregone interest through the second anniversary of the applicable Funding Date. A change of control triggers a mandatory prepayment of the Term Loans.

The Loan Agreement contains customary representations, warranties, events of default and covenants of ours and our subsidiaries, including maintaining, on an annual basis, a minimum liquidity threshold starting in 2021, and on a quarterly basis, a minimum net sales threshold for Auryxia starting in the fourth quarter of 2020. If an event of default occurs and is continuing under the Loan Agreement, the Collateral Agent is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

Revolving Line of Credit

We terminated the Loan and Security Agreement with Silicon Valley Bank, or SVB, the Unconditional Guaranty, and the Security Agreement with SVB, or, collectively, the SVB Loan Agreements, on November 7, 2019, and paid SVB a termination fee of $0.8

million. The summary of the material terms of the SVB Loan Agreements set forth in note 11 to the notes to financial statements is incorporated herein by reference.

The foregoing information is included for the purpose of providing the disclosures required under "Item 1.01 – Entry into a Material Definitive Agreement," "Item 1.02 – Termination of 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.

The foregoing description of the Loan Agreement does not purport to be complete and is qualified in its entirety by reference to such agreement, a copy of which we expect to file as an exhibit to our Annual Report on Form 10-K for the year ending December 31, 2019.

The representations, warranties and covenants contained in the Loan Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to such agreement, 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 agreement. The representations and warranties may have been made for the purposes of allocating contractual risk between the parties to such agreement 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 agreement 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 ours 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 agreement, 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 Junes 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*	Sublease, dated as of September 9, 2019, by and between Keryx Biopharmaceuticals, Inc. and Foundation Medicine, Inc.
10.2*#	Waiver and First Amendment to Loan Security and Security Agreement, dated as of July 31, 2019, by and between Keryx Biopharmaceuticals, Inc. and Silicon Valley Bank.
10.3*#	Security Agreement, dated as of August 7, 2019, by and between Akebia Therapeutics, Inc. and Silicon Valley Bank.
10.4*	Unconditional Guaranty, dates as August 7, 2019, by and between Akebia Therapeutics, Inc. and Silicon Valley Bank.
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: November 12, 2019

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

Date: November 12, 2019

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

SUBLEASE

This instrument is a Sublease (this "**Sublease**") dated as of September 9, 2019 between **KERYX BIOPHARMACEUTICALS, INC.**, a Delaware corporation ("**Sublessor**"), and **FOUNDATION MEDICINE, INC.**, a Delaware corporation ("**Sublessee**").

The parties to this instrument hereby agree with each other as follows:

ARTICLE 1
SUMMARY OF BASIC SUBLEASE PROVISIONS

1.1 BASIC DATA

ALL CAPITALIZED TERMS USED HEREIN SHALL HAVE THE MEANINGS ASCRIBED TO THEM IN THE PRIME LEASE (hereinafter defined) UNLESS OTHERWISE DEFINED HEREIN.

Commencement Date:	The date that is the later of (i) the date that Prime Lessor provides its written consent to this Sublease, and (ii) September 15, 2019 (the "**Estimated Commencement Date**"), subject to Section 2.1.2 below.
Sublessor:	Keryx Biopharmaceuticals, Inc.
Sublessee:	Foundation Medicine, Inc.
Mailing Address of Sublessor:	245 First Street Cambridge, MA 02142
Mailing Address of Sublessee:	150 Second Street 1st Floor Cambridge, MA 02141
Permitted Uses:	General office use, and for no other purpose.
Premises:	Suite 1200, comprising the entire (12th) floor of the building commonly known as One Marina Park Drive, Boston, Massachusetts (the "**Building**") and consisting of 27,323 rentable square feet, as shown on the space plan attached hereto as Exhibit A.
Prime Lease:	That certain Office Lease dated as of as of April 29, 2015, by and between Fallon Cornerstone One MPD LLC and Sublessor.
Prime Lessor:	Fallon Cornerstone One MPD LLC.

Base Rent:

Period	Monthly Installment of Rent	Annual Rental Rate Per Rentable Square Foot
Rent Commencement Date – Last day of the 12th full calendar month of the Term (Year 1)	$146,861.13	$64.50
First day of the 13th full calendar month of the Term – Last day of the 24th full calendar month of the Term (Year 2)	$149,138.04	$65.50
First day of the 25th full calendar month of the Term – Last day of the 36th full calendar month of the Term (Year 3)	$151,414.96	$66.50
First day of the 37th full calendar month of the Term – Termination Date (Year 4)	$153,691.88	$67.50

Sublessee's Pro Rata Share: 100% of Tenant's Pro Rata Share, currently 5.80%.

Additional Rent:	Sublessee shall pay as additional rent hereunder: (a) Sublessee's Pro Rata Share of all Operating Expenses (as defined in Section 29.N of the Prime Lease), which are in excess of the Operating Expenses for the calendar year 2020; (b) Sublessee's Pro Rata Share of all Taxes (as such term is defined in Section 29.S of the Prime Lease), which are in excess of the Taxes for fiscal year 2020 (*i.e.*, the period beginning July 1, 2019 and ending June 30, 2020); (c) any additional charges, fees, costs or expenses charged by Prime Lessor to Sublessor in connection with Sublessee's use of the Premises for extra services provided by Prime Lessor for which Prime Lessor charges an additional fee or charge; and (d) any other amounts in addition to Base Rent payable by Sublessee to Sublessor in accordance with the terms of this Sublease.
Rent Commencement Date:	One (1) month from the Commencement Date.
Security Deposit:	$734,305.65, subject to adjustment as further provided in Section 12.11 herein.
Sublease Term or Term:	Beginning on the Commencement Date and expiring at midnight on February 27, 2023 (the "**Termination Date**").
Sublessee's Broker:	CB Richard Ellis
Sublessor's Broker:	CB Richard Ellis

ARTICLE 2
PREMISES

2.1 SUBLEASE OF PREMISES

2.1.1 Subject to and provided that Prime Lessor gives Prime Lessor's written consent to the subleasing contemplated by this Sublease, Sublessor hereby subleases to Sublessee, and Sublessee hereby accepts and subleases from Sublessor, the Premises, upon and subject to the terms and provisions of the Prime Lease, all of Sublessor's right, title and interest in and to the Premises, pursuant to the Prime Lease, as both are defined in Section 1.1. Included as part of the Premises sublet hereunder are all of Sublessor's appurtenant rights under the Prime Lease to use the Building Common Areas (as defined in the Prime Lease) of the Project (as defined in the Prime Lease), subject in all events to the Prime Lessor's rights reserved and excepted in the Prime Lease. Notwithstanding anything to the contrary contained herein, Sublessee shall have no right to extend the Sublease Term beyond the Termination Date.

2.1.2 In the event that the Commencement Date does not occur prior to October 15, 2019 due to Sublessor's inability or failure to deliver the Premises to Sublessee in the condition required under this Sublease, then Sublessee shall receive a day-for-day credit of Base Rent for

each day thereafter until the Commencement Date occurs. Subject to the Consent Termination Right provided in Section 12.10, such credit of Base Rent shall be Sublessee's sole and exclusive remedy in the event of a late delivery of the Premises without any liability to Sublessor, and Sublessee shall have no right to terminate this Sublease or be entitled to any damages. Notwithstanding the foregoing, in the event that the Commencement Date does not occur prior to December 31, 2019 due to Sublessor's inability or failure to deliver the Premises to Sublessee in the condition required under this Sublease, then Sublessee may terminate this Sublease by written notice to Sublessor, and if so terminated by Sublessee: (a) the Security Deposit, or any balance thereof, and all deposits and other funds provided to Sublessor by Sublessee in connection with this Sublease, shall promptly be returned to Sublessee and (b) neither Sublessor nor Sublessee shall have any further rights, duties or obligations under this Sublease, except with respect to provisions which expressly survive termination of this Sublease.

2.2 PRIME LEASE

2.2.1 Sublessor hereby represents and warrants that: (i) Sublessor is the tenant under the Prime Lease and has the full right to enter into this Sublease (subject, however, to the Prime Lessor Consent); (ii) the Prime Lease is in full force and effect; (iii) Sublessor has not received from Prime Lessor any written notice of any default on the part of Sublessor as tenant under the Prime Lease which has not been cured, nor has Sublessor given Prime Lessor written notice of any default on the part of Prime Lessor as landlord under the Prime Lease which has not been cured, and, to the best of Sublessor's knowledge, no event or circumstance has occurred that, with notice or passage of time, could constitute such a default; (iv) Sublessor has submitted to Sublessee a true and complete copy of the Prime Lease, a copy of which is attached hereto as Exhibit B, including all amendments, modifications, extension notices, consents, and subordination, non-disturbance and attornment agreements related thereto; and (v) no pending dispute or claim has been asserted between Sublessor and Prime Lessor, Sublessor does not now intend to assert any such claim, and Sublessor knows of no basis to do so. Sublessee warrants and acknowledges that it has reviewed the Prime Lease and is satisfied with the arrangements therein reflected. Sublessee agrees that Sublessee is satisfied with the present condition of the Premises, which Sublessee takes "as is" without any representation or warranty by Sublessor regarding the condition of the Premises (except as provided herein and except that the Premises shall be delivered to Sublessee vacant (except for the FF&E) and in broom clean and good condition, free and clear of any debris) and the fitness of the Premises for any particular use and without any obligation of any kind on Sublessor to make any repairs or improvements thereto in connection with Sublessee's occupancy and with Sublessee's ability to use the Premises on the terms herein set forth.

2.2.2 The Prime Lease is by this reference incorporated into and made a part hereof, except that

(i) all references in the Prime Lease to "Landlord", "Tenant", "Lease" and "Premises" shall be deemed to refer to Sublessor, Sublessee, this Sublease and the Premises subleased hereunder, *except that* all references in the following sections and/or provisions of the Prime Lease to "Landlord", "Tenant", "Lease", and "Premises", respectively, shall be deemed to refer to "Prime Lessor", "Sublessee", this "Sublease" and the "Premises subleased hereunder", respectively (i.e., it is the intention of the parties

that Prime Lessor shall retain all of its rights and obligations under such sections and/or provisions; that Sublessor shall not be entitled to exercise any of Prime Lessor's rights, nor shall be bound by any of Prime Lessor's obligations, under such sections and/or provisions; and that Sublessee shall be entitled to exercise all of Tenant's rights, and shall be bound by all of Tenant's obligations, under such sections and/or provisions):

(a) Section 5.C (Alterations)

(b) Section 5.E (Compliance with ADA)

(c) Section 5.F (Labor Covenant)

(d) Article 7 (Services)

(e) Section 8.B (Landlord's Insurance)

(f) Article 10 (Casualty Damage) (but only with respect to Prime Lessor's duty to restore)

(g) Article 11 (Condemnation)

(h) Sections 12.B (Landlord's Obligations) and 12.E (Outside Services)

(i) Section 17.A (Subordination, Non-Disturbance, Attornment and Mortgagee Protection) (except that Prime Lessor shall have no obligation to obtain a SNDA for this Sublease)

(j) Article 28 (Additional Rights Reserved by Landlord)

(k) Section 30.D (Transfers)

(ii) the following sections and/or provisions of the Prime Lease are expressly excluded from this Sublease (i.e., they shall not be deemed to be incorporated in this Sublease) either because they are inapplicable or because they are superseded by specific provisions hereof:

(a) Article 1 (except for Sections 1.C, 1.D, 1.G, Section 1.M, Section 1.N, Section 1.O, and Section 1.Q)

(b) Article 2 (Premises, Term and Commencement Date)

(c) Article 3 (Rent)

(d) Section 4.A (Payment of Taxes and Operating Expenses) (but only with respect to the reference to January 1, 2017 as a base year for Operating Expenses and July 1, 2016 for a base year for Taxes)

(e) Section 5.A (Delivery of Premises)

(f) Section 5.B (Tenant's Work)

(g) Section 5.C (Alterations) (but only with respect to the references to Tenant's Work, Exhibit B and an administrative/supervision fee)

(h) Section 7.E (Separate Meters) (but only with respect to the first part of the sentence referring to Tenant's Work)

(i) Article 21 (Quiet Enjoyment)

(j) Article 23 (Security Deposit)

(k) Article 24 (Brokerage Commission)

(l) Section 30.C (Notices)

(m) Section 30.F (Tenant Financial Statement)

(n) Article 31 (Right of First Offer)

(o) Exhibit A (Space/Floor Plan Showing Premises)

(p) Exhibits B and B-1 (Tenant's Work and Tenant's Conceptual Space Plan)

(q) Exhibit F (Option to Extend Term)

(r) Exhibit K (Form of Commencement Date Confirmation)

2.2.3 This Sublease is and shall remain subject and subordinate in all respects to the Prime Lease and to all renewals, modifications, consolidations, replacements and extensions thereof. To the extent of any conflict between this Sublease and the Prime Lease, the terms of this Sublease are intended to control. This Section 2.2.3 shall be self-operative and no further instrument of subordination shall be required. In the event of termination or cancellation of the Prime Lease for any reason whatsoever with respect to all or any portion of the Premises, this Sublease shall automatically terminate with respect to all or such portion of the Premises and Sublessee shall have no recourse against Sublessor for a termination or cancellation of the Prime Lease unless such termination arose out of a default under the Prime Lease by Sublessor and not arising out of a default hereunder by Sublessee.

2.2.4 Notwithstanding anything contained in this Sublease to the contrary, Sublessor shall have no obligation during the Sublease Term to provide any services of any nature whatsoever to Sublessee or to, in or for the benefit of the Premises or to expend any money for the preservation or repair of the Premises, or to observe or perform any obligations of Sublessor under this Sublease in any case where such services, expenditures or obligations are required under the Prime Lease to be provided, performed or observed by Prime Lessor for the benefit of

Sublessor with respect to the Premises, and Sublessee agrees to look solely and directly to Prime Lessor for the furnishing of any such services, expenditure of any such sums, or observance or performance of any such Prime Lessor obligations under the Prime Lease to which, or the benefit of which, Sublessee may be entitled under this Sublease, but nothing in the foregoing shall be deemed to exculpate or otherwise release Sublessor from, or prevent Sublessee from looking directly to Sublessor for, any liability arising out of Sublessor's negligence or willful misconduct or the failure of Sublessor to perform its express obligations hereunder, subject to M.G.L. Chapter 186, Section 15. Sublessor shall, however, upon the written request of Sublessee, promptly make written demand upon Prime Lessor and use due diligence and reasonable efforts (excluding litigation), at Sublessor's expense, to (i) cause Prime Lessor to provide any service or otherwise perform any obligation of Prime Lessor under the Prime Lease; and (ii) to obtain Prime Lessor's consent or approval whenever required by the Prime Lease or this Sublease. The immediately foregoing obligations of Sublessor are the only obligations of Sublessor to Sublessee with respect to Prime Lessor's obligations to furnish the services that the Prime Lessor is obligated to provide under the Prime Lease. Notwithstanding any of the foregoing, if, after Sublessor makes such demand, Prime Lessor's cure period under the Prime Lease expires and Prime Lessor continues to fail to perform Prime Lessor's obligations, then Sublessee shall have the right to proceed against Prime Lessor in Sublessee's own name. If Sublessee cannot proceed against Prime Lessor in Sublessee's own name because of lack of privity, non-assignability, or any other reason, Sublessee shall have the right to proceed against Prime Lessor in Sublessor's name (including initiating legal proceedings), provided Sublessee is not then in default under this Sublease beyond any applicable notice or cure period. In any event, Sublessee agrees to indemnify Sublessor and hold Sublessor harmless from and against all loss, cost, damage, expense or liability (including, without limitation, attorneys' fees) which Sublessor may incur by reason of any action brought by Sublessee against Prime Lessor.

2.2.5 Sublessor shall timely make all payments of rent and all other charges due to Prime Lessor under the Prime Lease, provided that Sublessee makes timely payment to Sublessor of all Base Rent and Additional Rent payable under this Sublease.

2.2.6 It is the intention of the parties that Sublessee comply with all of Sublessor's obligations as tenant under the Prime Lease (not excluded under Section 2.2.2 above) with respect to the Premises to the same extent and with the same force and effect as if Sublessee were tenant thereunder, and Sublessee hereby agrees to so comply with all such obligations of Sublessor under the Prime Lease with respect to the Premises.

2.2.7 Sublessee shall have no claim against Sublessor for any default by the Prime Lessor under the Prime Lease. If as a result of any default by Prime Lessor as landlord under the Prime Lease, Sublessor as tenant under the Prime Lease is entitled to any offset or similar rights against Prime Lessor, Sublessee shall be entitled to a fair and equitable share of such offset or similar rights. No default by Prime Lessor under the Prime Lease shall excuse Sublessee from the performance of any of its obligations to be performed under this Sublease or to any reduction in or abatement of any of the rent provided for in this Sublease, unless and only to the extent that Sublessor shall be excused from the performance of a corresponding obligation as the Tenant under the Prime Lease.

2.2.8 Sublessee shall not do anything that would increase Sublessor's obligations to the Prime Lessor under the Prime Lease or that would cause the Prime Lease to be defaulted, terminated or forfeited. Sublessor shall not amend or modify the Prime Lease in any way that would increase Sublessee's obligations or diminish Sublessee's rights under this Sublease, nor shall Sublessor do, nor permit to do or be done, anything that would cause the Prime Lease to be terminated or forfeited.

2.2.9 Sublessor shall promptly give Sublessee a copy of any notice of default, termination or otherwise affecting the existence or validity of this Sublease or relating to any casualty or taking, given by Sublessor or Prime Lessor to the other.

2.2.10 Intentionally omitted.

2.2.11 Sublessor shall not exercise any surrender option provided to it under the Prime Lease, nor otherwise voluntarily terminate the Prime Lease, without Sublessee's prior written consent, except pursuant to a right of termination arising out of casualty or condemnation expressly set forth in the Prime Lease.

2.2.12 Notwithstanding anything to the contrary herein, Sublessor agrees that Sublessee may (at Sublessee's option) interact directly with Prime Lessor in seeking any required consent or in demanding Prime Lessor provide any service or otherwise perform any obligation of Prime Lessor under the Prime Lease, provided that Sublessor is copied on all correspondence from Sublessee to Prime Lessor.

ARTICLE 3
TERM OF SUBLEASE

3.1 TERM

The term of this Sublease shall be for the period specified in Section 1.1 as the Sublease Term.

ARTICLE 4
CONDITION OF PREMISES

4.1 CONDITION OF PREMISES

Sublessor shall deliver the Premises (vacant (except for the FF&E), in broom clean and good condition, free and clear of any debris) to Sublessee on or prior to the Commencement Date. Sublessee acknowledges that it will accept the Premises in its then-existing "as is" condition as of the Commencement Date, and agrees that Sublessor is under no obligation to perform any work upon or alteration to any part of the Premises for Sublessee's use and occupancy thereof. Sublessee shall be responsible for any telephone, telecommunication, security and alarm systems serving the Premises.

4.2 FIXTURES

Sublessee shall be entitled to use all built-in fixtures physically located in the Premises as of the Commencement Date. Sublessee shall, at its expense, maintain and repair such fixtures in good order, repair and condition, reasonable wear and tear and damage by fire or other casualty excluded, and shall surrender all such fixtures to Sublessor in such condition at the end of the Sublease Term.

4.3 PERSONAL PROPERTY AND EQUIPMENT

During the Sublease Term, Sublessee shall have, at no additional cost or charge payable by Sublessee hereunder, an exclusive license to use all personal property, equipment and furnishings located in the Premises as of the date of this Sublease and owned by Sublessor (the "**FF&E**"), except for those items set forth on Exhibit C attached hereto which are excluded from the FF&E, in their "as is" "where is" condition and "with all faults". Notwithstanding the license granted to Sublessee pursuant to this Section 4.3 the FF&E shall remain the property of Sublessor at all times during the Sublease Term, provided, however, that if there shall then be no default by Sublessee hereunder (beyond any applicable notice and cure period), Sublessor shall convey the FF&E to Sublessee at the end of the Term in its then "as is" "where is" condition and "with all faults", without representation, warranty or recourse of any kind, for the sum of $1.00 and Sublessee shall accept the FF&E pursuant to the Bill of Sale attached hereto as Exhibit D, which shall be executed at the time of execution of this Sublease and which shall be deemed null and void and of no force effect in the event of a default of Sublessee hereunder (beyond any applicable notice and cure period). At the expiration of the Sublease Term, Sublessee shall remove such personal property, equipment and furnishings, along with any other personal property and equipment of Sublessee in the Premises, and yield up the Premises to Sublessor in accordance with Article 14 of the Prime Lease and Section 12.12 of this Sublease. Notwithstanding anything in this Section 4.3 to the contrary, in the event the Prime Lease is terminated due to a default of Sublessor thereunder, and provided Sublessee is not then in default under this Sublease beyond any applicable notice and cure period, then Sublessor agrees that it shall promptly convey the FF&E to Sublessee pursuant to the Bill of Sale attached hereto as Exhibit D, except that the effective date of such Bill of Sale shall be the date of the transfer and not the effective date currently specified therein. The terms and provisions of the immediately foregoing sentence shall survive the expiration or earlier termination of this Sublease.

ARTICLE 5
USE, ASSIGNMENT AND SUBLETTING, PARKING AND SIGNAGE

5.1 PERMITTED USE

Sublessee agrees that the Premises shall be used and occupied only for the Permitted Uses specified in Section 1.1. During the Sublease Term and subject to the Prime Lease, Sublessee shall assume and maintain exclusive control of the Premises. Sublessee acknowledges and understands that Sublessee shall be responsible, at its expense, for providing any janitorial, cleaning, equipment and fixture maintenance and security services necessary for Sublessee's use and occupancy of the Premises not otherwise provided by Prime Lessor under the Prime Lease.

5.2 ASSIGNMENT AND SUBLETTING

For the avoidance of doubt, Article 16 of the Prime Lease is fully incorporated herein, and Sublessee shall have the same rights afforded to the Sublessor in Article 16 of the Prime Lease with respect to assignment and subletting, but subject to the consent of (i) Prime Lessor (where applicable under Article 16); and (ii) Sublessor (but only to the extent Prime Lessor's consent is required under the Prime Lease).

5.3 PARKING

Subject to all terms and provisions of the Prime Lease, Sublessee shall have the right to nine (9) parking access devices for unreserved parking spaces in the Parking Garage. Sublessee shall pay Sublessor directly for its use of the parking spaces, and Sublessee acknowledges that the current market rate of such parking spaces is $450.00 per space per month and is subject to adjustment pursuant to the Prime Lease.

5.4 SIGNAGE

Subject to all terms and provisions of the Prime Lease, Sublessee shall have the right, at its sole cost and expense, to identification in the Building directory as well as signage on the entrance to the Premises. If requested by Prime Lessor, Sublessee shall replace Sublessor's existing signage.

ARTICLE 6
RENT

6.1 RENT; ADDITIONAL RENT

(a) The Base Rent and Additional Rent specified in Section 1.1 hereof, and any other charges payable pursuant to this Sublease (the "**Rent**") shall be payable by Sublessee to Sublessor at the Mailing Address of Sublessor as of the Rent Commencement Date (or such other place as Sublessor may from time to time designate by notice to Sublessee).

(b) Beginning on the Rent Commencement Date, Base Rent and Additional Rent shall be payable, in advance, on or before the first (1st) day of each and every calendar month during the Term of this Sublease, except that those certain charges, fees, costs and expenses set forth in subsection (c) of "Additional Rent" in Section 1.1 of this Sublease shall be payable prior to the due date set forth on Prime Lessor's invoice, which invoice Sublessor shall promptly provide to Sublessee upon receipt from Prime Lessor. Promptly after Sublessor and Prime Lessor have made the appropriate adjustments between themselves on account of actual Operating Expenses and real estate taxes, the amounts paid by Sublessee as Sublessee's Pro Rata Share of such estimated installments (as set forth in Section 1.1) shall be adjusted between Sublessor and Sublessee in accordance with the process set forth in Article 4 of the Prime Lease, as such Article 4 is incorporated herein. The parties' obligations hereunder to make such adjustments shall survive the expiration or termination of this Sublease.

(c) Base Rent for any partial month shall be paid by Sublessee to Sublessor at such rate on a prorata basis. Other charges payable by Sublessee with respect to a particular accounting period, shall likewise be prorated.

(d) Sublessee shall be responsible for payment to any utility company for any electrical charges assessed pursuant to Section 7.E of the Prime Lease and allocable to the Premises.

All Rent and other amounts due under this Sublease shall be made without demand, offset or deduction. Sublessee shall be entitled to all rent abatements set forth in the Prime Lease and attributable to the Term which Sublessor has been granted with respect to the Premises.

6.2 LATE PAYMENTS

If any installment of Rent or other charges is not paid on or before the date such payment is due and payable, and if as a result Sublessor is obligated to pay to Prime Lessor the late charges or interest specified in Section 3.D of the Prime Lease or any other late charge or penalty, then Sublessee shall pay to Sublessor a late charge of five percent (5%) of the amount of such payment. In addition, if Sublessee shall fail to make any such payment within ten (10) business days after the due date, such payment shall bear interest at twelve percent (12%) per annum from the date such payment became due to the date of payment thereof by Sublessee; provided, however, that nothing contained herein shall be construed as permitting Sublessor to charge or receive interest in excess of the maximum legal rate than allowed by law. Such late charge and interest shall be due and payable hereunder with the next installment of Base Rent due hereunder.

ARTICLE 7
ALTERATIONS, FIXTURES AND EQUIPMENT

7.1 ALTERATIONS

Sublessee shall not make any alterations, installations, and improvements to the Premises without, to the extent required under the Prime Lease, first obtaining the prior consent of both Sublessor and Prime Lessor and any such alterations, installations and improvements shall comply with Article 5 of the Prime Lease. Notwithstanding the foregoing, if Prime Lessor consents to any alterations, installations and improvements by Sublessee, Sublessor shall automatically be deemed to have given such consent under this Sublease. Subject to Section 2.2.4, Sublessor shall not be responsible for the failure or refusal of Prime Lessor to consent to such improvements. Any such approved alterations, installations or improvements shall be done at Sublessee's sole expense, in a good and workmanlike manner and in compliance with all applicable laws and codes and the applicable requirements of the Prime Lease, including without limitation the payment of any administrative/supervision fee to Prime Lessor as provided in Article 5 of the Prime Lease. Sublessee shall request at the time of its request for consent to Prime Lessor for such alterations, for a determination from Prime Lessor as to whether such proposed alterations shall require removal at the end of the Term and, if Prime Lessor requires such removal, Sublessee shall be responsible for completing such removal and to repair any damage to the Premises caused by such removal as required in Article 5 of the Prime Lease.

ARTICLE 8
SUBLESSEE'S AND SUBLESSOR'S RISK

8.1 SUBLESSEE'S RISK

Sublessee agrees to use and occupy the Premises at Sublessee's own risk; and to the fullest extent permitted by law, Sublessor shall have no responsibility or liability for any loss of or damage to fixtures or other personal property of Sublessee, or of those claiming by, through or under Sublessee, including without limitation, any loss or damage from the breaking, bursting, crossing, stopping or leaking of electric cables and wires, and water, gas, sewer or steam pipes or like matters. In no event shall Sublessor be liable for any consequential, special, punitive or indirect loss or damage which Sublessee may incur or suffer in connection with this Sublease or any services to be performed or provided hereto.

In addition to, and not in limitation of, any indemnity obligation of Sublessee under this Sublease (which includes, without limitation, any terms or provisions of the Prime Lease which may be incorporated into this Sublease and are applicable to Sublessee pursuant to Section 2.2 hereof), Sublessee shall indemnify and hold harmless Sublessor and Sublessor's members, managing agent, partners, officers, directors, shareholders and employees against and from any and all claims arising from or related to the following: (a) Sublessee's use of the Premises or any activity done, permitted or suffered by Sublessee in, on or about the Premises during the Sublease Term; (b) any act or omission by Sublessee or Sublessee's agents, employees, students, directors, invitees or independent contractors (collectively, "**Sublessee's Agents**") in connection with or related to this Sublease or the Premises, except to the extent caused by Sublessor's gross negligence or willful misconduct. If any action or proceeding is brought against Sublessor or Prime Lessor by reason of any such claim, upon written notice from Sublessor, Sublessee shall defend the same at Sublessee's expense with counsel designated by Sublessee's insurer or otherwise reasonably satisfactory to Sublessor. The indemnification obligations of Sublessee shall survive the termination or expiration of this Sublease.

ARTICLE 9
SUBLESSOR'S ACCESS TO PREMISES

9.1 SUBLESSOR'S RIGHT OF ACCESS

If Sublessee fails to undertake any necessary repairs or maintenance to the Premises within the applicable notice and cure period provided for in the Prime Lease, Sublessor shall have the right to enter the Premises at all reasonable hours for the purpose of making such repairs or performing such maintenance, provided such repairs or maintenance are performed in a fashion and at times that will minimize disruption to Sublessee's business in the Premises to the greatest extent reasonably practicable, and will not disrupt Sublessee's access to the Premises.

ARTICLE 10
INSURANCE

10.1 SUBLESSEE'S INSURANCE

Sublessee shall carry and maintain, throughout the term hereof, at its own cost and expense, the insurance required under Article 8 of the Prime Lease. Such insurance shall name as additional insureds both Sublessor and Prime Lessor and if available, shall contain a waiver of any rights of subrogation to any cause of action against Sublessor, Sublessee and Prime Lessor.

ARTICLE 11
CASUALTY

11.1 CASUALTY AND RESTORATION; EMINENT DOMAIN

If the Premises, or any part thereof, shall be damaged or destroyed by fire or other casualty or subject to a taking by eminent domain then Sublessee shall promptly notify Prime Lessor and Sublessor. Under the Prime Lease, the Prime Lessor is obligated to repair or restore the Premises in the case of a casualty to the extent and in the manner set forth in Article 10 of the Prime Lease. With respect to an eminent domain taking, the Prime Lease shall terminate pursuant to Article 11 thereof. If Prime Lessor abates Sublessor's rent with respect to the Premises as a result, then Rent and other charges hereunder shall be similarly abated for so long as Sublessor is entitled to and receives an abatement under the Prime Lease. If damage is of the type which entitles Prime Lessor or Sublessor to terminate the Prime Lease and either such party so elects to terminate the Prime Lease, then the Prime Lease shall cease and come to an end and this Sublease shall similarly terminate. Sublessee acknowledges that Sublessor shall, in no event, have any obligation whatsoever to rebuild or restore any damage to the Premises.

ARTICLE 12
MISCELLANEOUS PROVISIONS

12.1 WAIVER

Failure on the part of either party to complain of any action or non-action on the part of the other, no matter how long the same may continue, shall never be deemed to be a waiver by such party of any of its rights hereunder. Further, it is agreed that no waiver of any of the provisions hereof by either party shall be construed as a waiver of any of the other provisions hereof and that a waiver at any time of any of the provisions hereof shall not be construed as a waiver at any subsequent time of the same provisions. The consent to or approval of any action by either party requiring such consent or approval shall not be deemed to waive or render unnecessary such consent to or approval of any subsequent similar act by such party.

12.2 COVENANT OF QUIET ENJOYMENT

Sublessee, provided it observes, keeps, and performs all of the terms and provisions of this Sublease on Sublessee's part to be observed, kept, and performed, shall lawfully, peaceably, and quietly have, hold, occupy, and enjoy the Premises during the Sublease Term without hindrance or ejection by Sublessor or by any person lawfully claiming under Sublessor, but

subject to force majeure; the foregoing covenant of quiet enjoyment is given in lieu of any other covenant, whether express or implied.

12.3 INDEPENDENT COVENANTS

The obligations of Sublessor and Sublessee, respectively, under this Sublease are agreed by the parties to be independent covenants. If Sublessor fails to perform any obligation under this Sublease required to be performed by Sublessor, Sublessee shall have no right, except as otherwise provided herein, to (i) terminate this Sublease; (ii) avail itself of self-help or to perform any obligation of Sublessor; (iii) any abatement or withholding of Rent, or of any other charges or sums payable by Sublessee under this Sublease; or (iv) any right of setoff.

12.4 INVALIDITY OF PARTICULAR PROVISIONS

If any term or provision of this Sublease, or the application thereof to any person or circumstance, shall, to any extent, be invalid or unenforceable, the remainder of this Sublease, or the application of such term or provision to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby, and each term and provision of this Sublease shall be valid and be enforced to the fullest extent permitted by law.

12.5 BROKERS

Each party represents and warrants to the other that it has not directly or indirectly dealt, with respect to the Premises and this Sublease with any broker other than the Brokers identified in Section 1.1 (the "**Brokers**") in connection with this Sublease and the transactions contemplated hereby. Sublessee shall save harmless and indemnify Sublessor against any claims by anyone with whom it has so dealt or by whom its attention was called to the Premises, excluding the Brokers, for a commission arising out of the execution and delivery of this Sublease or out of negotiations between Sublessor and Sublessee with respect to space in the Building. Sublessor shall save harmless and indemnify Sublessee against any claims by anyone with whom it has so dealt or by whom its attention was called to the Premises, including the Brokers, for a commission arising out of the execution and delivery of this Sublease or out of negotiations between Sublessor and Sublessee with respect to space in the Building. Sublessor agrees to pay the Brokers the commission with respect to this Sublease set forth in a separate agreement between Sublessor and the Brokers.

12.6 PROVISIONS BINDING, ETC.

Except as herein otherwise expressly provided, the terms hereof shall be binding upon and shall inure to the benefit of the heirs, legal representatives, successors and assigns, respectively, of Sublessor and Sublessee. Each term and each provision of this Sublease to be performed by Sublessee and Sublessor shall be construed to be both a covenant and a condition. The reference contained to the successors and assigns of Sublessee is not intended to constitute a consent to assignment by Sublessee, but has reference only to those instances in which Sublessor shall have given its consent to a particular assignment if such consent is required by the provisions of this Sublease. Sublessor warrants that Sublessor is a duly existing and valid Delaware corporation qualified to do business in Massachusetts, that Sublessor has duly

executed and delivered this Sublease, that the execution and delivery of, and the performance by Sublessor of its obligations under this Sublease are within the powers of Sublessor and have been duly authorized by all requisite corporate action, and that this Sublease is a valid and binding obligation of Sublessor in accordance with its terms. Sublessee warrants that Sublessee is a duly existing and valid Delaware corporation qualified to do business in Massachusetts, that Sublessee has duly executed and delivered this Sublease, that the execution and delivery of, and the performance by Sublessee of its obligations under this Sublease are within the powers of Sublessee and have been duly authorized by all requisite corporate action, and that this Sublease is a valid and binding obligation of Sublessee in accordance with its terms.

12.7 NO RECORDING

Sublessee agrees not to record this Sublease or any notice thereof.

12.8 NOTICES

Whenever by the terms of this Sublease notice, demand or other communication shall or may be given, either to Sublessor or to Sublessee, the same shall be adequately given if in writing and delivered by hand or sent by registered or certified mail, postage prepaid or by reputable overnight delivery service or by facsimile or email:

If intended for Sublessor, addressed to it at the Mailing Address of Sublessor set forth in Section 1.1, and at all times with a courtesy copy to: Stephanie Dubanowitz, Anderson & Kreiger LLP, 50 Milk Street, Boston, Massachusetts 02109, Fax: 617-621-6651.

If intended for Sublessee, addressed to it at the Mailing Address of Sublessee set forth in Section 1.1. with a copy to: Laurie C. Nelson, Ropes & Gray LLP, 1211 Avenue of the Americas, New York, New York 10036, Email: Laurie.Nelson@ropesgray.com.

The effective date of any such notice shall be (i) by (a) facsimile - the date of such facsimile as evidenced in the successful facsimile transmission report or (b) email, the date the email is sent; provided such facsimile or email must be followed up in a hard copy by next-day delivery by a reputable overnight delivery service; (ii) five (5) days following the date mailed for certified or registered letters; (iii) two (2) days following the date mailed for overnight letters; or (iv) when delivered, if in person. The above addresses may be changed at any time by giving prompt written notice as provided above.

12.9 COUNTERPARTS

This Sublease may be executed in any number of counterparts which together shall constitute one and the same instrument. Telecopied or other electronically transmitted signatures (e.g. portable document format ("**pdf**")) may be used in place of original signatures on this Sublease. Each party to this Sublease intends to be bound by the signatures on the telecopied or electronically transmitted document, are aware that the other party will rely on the telecopied or electronically transmitted signatures, and hereby waive any defenses to the enforcement of the terms of this Sublease based on the form of signature to this Sublease.

12.10 PRIME LESSOR CONSENT

Notwithstanding anything herein to the contrary, this Sublease shall not be effective until and unless Prime Lessor has given its consent hereto (the "**Prime Lessor Consent**") on substantially the form attached to the Prime Lease as Exhibit C; provided, however, that Exhibit C shall be modified to provide that Prime Lessor expressly consents to the terms and provisions of Section 2.2 herein. Sublessor shall not be responsible for the failure or refusal of Prime Lessor to provide the Prime Lessor Consent. In the event the Prime Lessor Consent is not received within forty-five (45) days of the full execution of this Sublease, Sublessee shall have the option to terminate this Sublease upon written notice to Sublessor (the "**Consent Termination Right**"), and if so terminated by Sublessee: (a) the Security Deposit, or any balance thereof, and all deposits and other funds provided to Sublessor by Sublessee in connection with this Sublease, shall be returned to Sublessee within fifteen (15) days thereafter, and (b) neither Sublessor nor Sublessee shall have any further rights, duties, or obligations under this Sublease, except with respect to the provisions which expressly survive the termination of this Sublease. Notwithstanding the foregoing, Sublessor shall promptly provide notice to Prime Lessor as required under the Prime Lease to obtain the Prime Lessor Consent, and Sublessor and Sublessee shall reasonably and promptly cooperate with any request for information made by Prime Lessor in connection with providing the Prime Lessor Consent.

12.11 SECURITY DEPOSIT

Sublessee shall deposit with Sublessor upon execution of this Sublease the Security Deposit set forth in Section 1.1 for the faithful performance and observance by Sublessee of the terms and provisions of this Sublease. If Sublessee defaults on any of its obligations under this Sublease beyond any applicable notice and cure periods, Sublessor may draw down on the Security Deposit to the extent required for the payment of Rent, Additional Rent or any other sum as to which Sublessee is in default, or any sum which Sublessor may expend or may be required to expend by reason of Sublessee's default. In the event that Sublessor does draw down on the Security Deposit, Sublessee shall within ten (10) days after receiving notice from Sublessor, replenish the Security Deposit by the amount Sublessor withdrew therefrom and failure to do so within such ten (10) day period shall constitute a default under this Sublease. Sublessor shall return any unapplied portion of the Security Deposit to Sublessee within thirty (30) days after the termination or earlier expiration of this Sublease.

The Security Deposit shall be in the form of a clean, irrevocable, non-documentary and unconditional letter of credit in the amount of the Security Deposit (the "**Letter of Credit**") issued by and drawable upon any commercial bank, trust company, national banking association or savings and loan association with offices for banking and drawing purposes in Boston, Massachusetts or other location provided such bank allows drawing by facsimile (the "**Issuing Bank**"), which has outstanding unsecured, uninsured and unguaranteed indebtedness, that is then rated, without regard to qualification of such rating by symbols such as "+" or "-" or numerical notation, "Aa" or better by Moody's Investors Service and "AA" or better by Standard & Poor's Ratings Service (and is not on credit-watch with negative implications), and has combined capital, surplus and undivided profits of not less than $1,000,000,000. The Letter of Credit shall (i) name Sublessor as beneficiary, (ii) be in the amount of the Security Deposit, (iii)

have a term of not less than one year, (iv) permit multiple drawings, (v) be fully transferable by Sublessor multiple times without the consent of Sublessee and without the payment of any fees or charges, (vi) be payable to Sublessor or an authorized representative of Sublessor upon presentation of only the Letter of Credit and a sight draft and a certification of Sublessor (acceptable to Sublessor in its sole discretion) as to the existence of an event of default of Sublessee, and (vii) otherwise be in form and content reasonably satisfactory to Sublessor. If upon any transfer of the Letter of Credit, any fees or charges shall be so imposed, then such fees or charges shall be payable solely by Sublessee and the Letter of Credit shall so specify. The Letter of Credit shall provide that it shall be deemed automatically renewed, without amendment, for consecutive periods of one year each thereafter during the Term through the date that is at least ninety (90) days after the last day of the Term of this Sublease, unless the Issuing Bank sends a notice (the "**Non-Renewal Notice**") to Sublessor by certified mail, return receipt requested, not less than thirty (30) days prior to the then-current expiration date of the Letter of Credit, stating that the Issuing Bank has elected not to renew the Letter of Credit. Sublessor shall have the right, upon receipt of a Non-Renewal Notice, to draw the full amount of the Letter of Credit, by sight draft on the Issuing Bank, and shall thereafter hold or apply the cash proceeds of the Letter of Credit pursuant to the terms of this Section 12.11. The Letter of Credit shall state that drafts drawn under and in compliance with the terms of the Letter of Credit will be duly honored upon presentation to the Issuing Bank at an office location in Boston, Massachusetts or other location by facsimile. The Letter of Credit shall be subject in all respects to the International Standby Practices current as of the date of this Sublease, International Chamber of Commerce Publication No. 590.

Provided that no default by Sublessee under this Sublease beyond any applicable notice or cure period occurs at any time prior to the second (2nd) anniversary of the Rent Commencement Date (the "**SD Reduction Obligation**"), then Sublessee, no later than forty-five (45) days after the second (2nd) anniversary of the Rent Commencement Date, may notify Sublessor in writing that it wishes to decrease the Security Deposit to $440,583.39 (the "**Reduced Security Deposit**"). Within ten (10) business days following Sublessor's receipt of such notice, Sublessor shall (y) confirm in writing that the SD Reduction Obligation has been satisfied and that the Security Deposit shall be deemed to equal the Reduced Security Deposit or (z) notify Sublessee that the SD Reduction Obligation has not been satisfied. Upon Sublessor's confirmation that the SD Reduction Obligation has been satisfied, Sublessee may provide to Sublessor, and Sublessor shall accept, a replacement letter of credit in the amount of the Reduced Security Deposit in the form required herein.

Notwithstanding the foregoing, from the date of execution of this Sublease until the date that is sixty (60) days after such execution date, the Security Deposit shall be in the form of cash. Prior to the expiration of such sixty (60) day period, Sublessee shall provide to Sublessor the Security Deposit in the form of the Letter of Credit described above. Promptly upon Sublessor's receipt of the Letter of Credit, it will return any applied balance of the cash Security Deposit to Sublessee.

12.12 SURRENDER

On the expiration or sooner termination of the Sublease Term, Sublessee: (a) shall remove all signage bearing Sublessee's name on the Premises that is required to be removed

pursuant to the Prime Lease and repair any damage caused by such removal; (b) shall remove all personal property of Sublessee, including the FF&E; (c) shall remove the Alterations installed by Sublessee after the Commencement Date that Sublessor requires Sublessee to remove at the time of Sublessor and Prime Lessor's consent to the same; and (d) shall quit and surrender possession of the Premises to Sublessor and deliver possession of the Premises to Sublessor in the order and condition as the same were in on the Commencement Date, reasonable wear and tear excepted.

12.13 INTENTIONALLY OMITTED

12.14 LIMITATION OF SUBLESSEE'S LIABILITY

In no event shall any officer, director, member or employee of Sublessee ever be personally liable for any obligation of Sublessee under this Sublease, nor shall Sublessee ever be liable for any consequential, special, punitive or indirect loss or damage under this Sublease, except to the extent provided for in Article 15 (Holding Over) and Article 27 (Hazardous Materials) of the Prime Lease.

12.15 GUARANTY

Sublessor is a wholly owned subsidiary of Akebia Therapeutics, Inc. ("**Guarantor**") and Guarantor does hereby unconditionally and irrevocably guarantee to Sublessee that it will cause Sublessor to perform all of the obligations of Sublessor as set forth in this Sublease. If for any reason any provision of this Sublease shall not be performed by Sublessor as herein required, provided Sublessee is not in default under this Sublease beyond any applicable notice and cure periods, Guarantor will perform, or cause the performance of each such provision. Guarantor agrees to pay, promptly upon receipt of a final, non-appealable judgment from a court of competent jurisdiction, Sublessee's actual, out-of-pocket costs and expenses, including but not limited to reasonable attorneys' fees, costs and disbursements incurred in any effort to enforce Guarantor's obligations hereunder. This Section 12.15 shall apply to the Sublease, any extension, renewal, modification or amendment thereof, and to any assignment, to the extent such assignment is permitted under this Sublease.

[Signatures to appear on next page.]

EXECUTED UNDER SEAL, in any number of counterpart copies, each of which counterpart copies shall be an original for all purposes, as of the day and year first above written.

Sublessor: **KERYX BIOPHARMACEUTICALS, INC.**, a Delaware corporation

By /s/ Jason A. Amello
Name: Jason A. Amello
Its: Chief Financial Officer

Sublessee: **FOUNDATION MEDICINE, INC.**, a Delaware corporation

By /s/ Konstantin Fiedler
Name: Konstantin Fiedler
Its: COO

Guarantor (for the limited purpose of acknowledging and agreeing to Section 12.15 of this Sublease):

AKEBIA THERAPEUTICS, INC., a Delaware corporation

By /s/ Jason A. Amello
Name: Jason A. Amello
Its: Chief Financial Officer

By _____
Name:
Its:

Exhibit A
(Description/Floor Plan of Premises)
See attached.

Exhibit B
Copy of Prime Lease
See attached.

Exhibit C
List of Excluded Personal Property

Exhibit D
Bill of Sale

Exhibit 10.2

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.

WAIVER AND FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

This **WAIVER AND FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT** (this "**Agreement**") is entered into as of this 31st day of July, 2019, by and between SILICON VALLEY BANK ("**Bank**") and KERYX BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Borrower**").

RECITALS

A. Bank and Borrower have entered into that certain Loan and Security Agreement dated as of July 18, 2018 (as may be amended, modified, restated, replaced or supplemented from time to time, the "**Loan Agreement**"). Bank has extended credit to Borrower for the purposes permitted in the Loan Agreement.

B. Borrower previously entered into a certain Agreement and Plan of Merger dated June 28, 2018 by and among Borrower, Akebia Therapeutics, Inc. ("**Akebia**"), and Alpha Therapeutics Merger Sub, Inc., as amended on October 1, 2018, pursuant to which Borrower became a wholly owned subsidiary of Akebia (the "**Acquisition**").

C. As a condition to Bank's consent to the Acquisition, Akebia agreed to become a co-obligor of the Obligations under the Loan Agreement, and to pledge collateral to secure Akebia's Obligations to Bank.

D. In connection therewith, Borrower has requested that Bank (i) waive certain Events of Default that have occurred prior to the date hereof, and (ii) amend the Loan Agreement to make other certain revisions to the Loan Agreement, as more fully set forth herein.

E. Bank has agreed to waive certain Events of Default and to so amend certain provisions of the Loan Agreement, but only to the extent, in accordance with the terms, subject to the conditions and in reliance upon the representations and warranties set forth below.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing recitals and other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

1. Definitions. Capitalized terms used but not defined in this Agreement shall have the meanings given to them in the Loan Agreement.

2. Amendments to Loan Agreement.

2.1 Section 4.2 of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

" **4.2. Priority of Security Interest.** Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral (subject only to Permitted Liens that are permitted pursuant to the terms of this Agreement to have superior priority to Bank's Lien under this Agreement), assuming that Bank has filed a financing statement with the Secretary of State for the State of Delaware. If Borrower shall acquire a commercial tort claim with a value in excess of [**] Dollars ($[**]), Borrower shall promptly notify Bank in a writing signed by Borrower of the general details thereof and,

upon Bank's request, grant to Bank in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Bank."

2.2 Section 5.9 of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

" **5.9 Tax Returns and Payments; Pension Contributions.** Borrower has timely filed all "required tax returns and reports, and Borrower has timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Borrower except (a) to the extent such taxes are being contested in good faith by appropriate proceedings promptly instituted and diligently conducted, so long as such reserve or other appropriate provision, if any, as shall be required in conformity with GAAP shall have been made therefor, or (b) if such taxes, assessments, deposits and contributions do not, individually or in the aggregate, exceed [**] Dollars ($[**]).

To the extent Borrower defers payment of any contested taxes, Borrower shall (i) if such contested amount is in excess of [**] Dollars ($[**]), notify Bank in writing of the commencement of, and any material development in, the proceedings, and (ii) post bonds or take any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a "Permitted Lien." Borrower is unaware of any claims or adjustments proposed for any of Borrower's prior tax years which could result in additional taxes becoming due and payable by Borrower in excess of [**] Dollars ($[**]). Borrower has paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and Borrower has not withdrawn from participation in, and has not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other governmental agency."

2.3 Section 6.1(a) of the Loan Agreement is hereby deleted in its entirety and the following is substituted in its place:

" (a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of formation and maintain qualification in each jurisdiction in which the failure to so maintain or qualify would reasonably be expected to have a material adverse effect on Borrower's business or operations, provided that any Subsidiary may merge or consolidate in accordance with Section 7.3 hereof, or liquidate or dissolve provided that in connection with such dissolution or liquidation all assets and property of any such Subsidiary shall be transferred to Borrower, Akebia or another Subsidiary. Borrower shall comply, and shall have each Subsidiary comply, with all laws, ordinances and regulations to which it is subject, noncompliance with which could reasonably be expected to have a material adverse effect on Borrower's business taken as a whole."

2.4 Section 6.2(c) of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

" (c) within [**] a duly completed Compliance Certificate signed by a Responsible Officer, certifying that as of the end of such quarter, Borrower was in full compliance with all of the terms and conditions of this Agreement, and setting forth calculations showing compliance with the financial covenants set forth in this Agreement and such other information as Bank may reasonably request, including, without limitation, a statement that [**];"

2.5 Section 6.2(d) of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

"(d) at least annually, as soon as available, but no later than [**] following approval by the Board, and within [**] following approval by the Board of any amendments thereto, annual operating budgets in a form of presentation reasonably acceptable to Bank;"

2.6 Sections 6.2(g) and 6.2(h) of the Loan Agreement are hereby deleted in their entirety and the following is inserted in their place:

"(g) a prompt report of any legal actions pending or threatened in writing against Borrower or any of its Subsidiaries that could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of, individually or in the aggregate, [**] Dollars ($[**]) or more;

(h) prompt written notice of any changes to the beneficial ownership information set out in Section 14 of the Perfection Certificate. Borrower understands and acknowledges that Bank relies on such true, accurate and up-to-date beneficial ownership information to meet Bank's regulatory obligations to obtain, verify and record information about the beneficial owners of its legal entity customers; and

(i) promptly, from time to time, such other information regarding Borrower or compliance with the terms of any Loan Documents as reasonably requested by Bank."

2.7 Section 6.3(a) of the Loan Agreement is hereby amended by deleting the first sentence thereof and inserting the following in its place:

"Borrower shall deliver to Bank the reports and schedules of collections and other financial information, as provided in Section 6.2, on forms acceptable to Bank; provided, however, that Borrower's failure to execute and deliver the same shall not affect or limit Bank's Lien and other rights in all of Borrower's Accounts, nor shall Bank's failure to advance or lend against a specific Account affect or limit Bank's Lien and other rights therein."

2.8 Section 6.3(b) of the Loan Agreement is hereby amended by deleting the first sentence thereof and inserting the following in its place:

"Borrower shall promptly (and in any event no later than at the time of the next Compliance Certificate delivered pursuant to Section 6.2(c)) notify Bank of all disputes or claims relating to Accounts involving [**] Dollars ($[**]) or more individually and in the aggregate."

2.9 Section 6.3(e) of the Loan Agreement is hereby deleted in its entirety and inserting the following in its place:

"(e) Returns. Provided no Event of Default has occurred and is continuing, if any Account Debtor returns any Inventory to Borrower with a value, individually or in the aggregate, in excess of [**] Dollars ($[**]), Borrower shall promptly (and in any event no later than at the time of the next Compliance Certificate delivered pursuant to Section 6.2(c)) (i) determine the reason for such return, (ii) issue a credit memorandum to the Account Debtor in the appropriate amount, and (iii) provide a copy of such credit memorandum to Bank, upon request from Bank. In the event any attempted return occurs after the occurrence and during the continuance of any Event of Default, Borrower shall hold the returned Inventory in trust for Bank, and immediately notify Bank of the return of the Inventory."

2.10 Section 6.4 of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

" **6.4 Remittance of Proceeds**. Except as otherwise provided in Section 6.3(c), deliver, in kind, all proceeds arising from the disposition of any Collateral to Bank in the original form in which received by Borrower not later than the following Business Day after receipt by Borrower, to be applied to the Obligations (a) prior to an Event of Default, pursuant to the terms of Section 6.3(c) hereof, and (b) after the occurrence and during the continuance of an Event of Default, pursuant to the terms of Section 9.4 hereof; provided that, if no Event of Default has occurred and is continuing, Borrower shall not be obligated to remit to Bank the proceeds of the sale of worn out or obsolete Equipment disposed of by Borrower in good faith in an arm's length transaction for an aggregate purchase price of [**] Dollars ($[**] (for all such transactions in any fiscal year). Borrower agrees that it will not commingle proceeds of Collateral with any of Borrower's other funds or property (other than any proceeds of the sale of worn out or obsolete Equipment referred to in the immediately preceding sentence), but will hold such proceeds separate and apart from such other funds and property and in an express trust for Bank. Nothing in this Section 6.4 limits the restrictions on disposition of Collateral set forth elsewhere in this Agreement.

2.11 Section 6.8(a) of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

" (a) After the expiration of the Transition Period, maintain all of its and all of its Subsidiaries' operating and depository accounts, securities/investment accounts, and the Cash Collateral Account with Bank and Bank's Affiliates. Notwithstanding the foregoing, Borrower shall be permitted to maintain deposit accounts at [**]. Any Guarantor (other than Akebia) shall maintain all depository, operating and securities/investment accounts with Bank and Bank's Affiliates."

2.12 Section 6.9(b) of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

" (b) Minimum Revenue. Achieve minimum revenue [**], and measured on a [**] set forth in the chart below, as determined by Bank, of at least the following amounts:

[**]	**Minimum Revenue**
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]
[**]	[**]

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

With respect to each period ending after [**], the levels of minimum revenue shall be mutually agreed upon between Borrower and Bank based upon Borrower's Board-approved operating plan and financial projections acceptable to Bank. Borrower's failure to either (1) agree in writing (which agreement shall be set forth in a written amendment to this Agreement) on or before [**], to any such covenant levels proposed by Bank with respect to the calendar year ending [**], or (2) notwithstanding Section 6.2(f) of this Agreement, deliver to Bank, on or before the earlier to occur of (i) [**] or (ii) approval by the Board, Borrower's budgets, sales projections, operating plans and other financial information of Borrower that Bank deems relevant, including, without limitation, Borrower's Board-approved operating budgets, projections and plans, with respect to the calendar year ending [**] for which there shall be no grace or cure period."

2.13 Section 6.9 of the Loan Agreement is hereby amended by inserting the following as new subsection (c):

" (c) Minimum Asset Management Balance. From and after [**], maintain at all times an aggregate balance of at least [**] Dollars ($[**]) (the "Minimum Threshold") in one or more asset management accounts at Bank or Bank's Affiliate (collectively, the "Asset Management Accounts"). [**].

2.14 Section 7.1 of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

" **7.1 Dispositions**. Convey, sell, lease, transfer, assign, or otherwise dispose of (including, without limitation, pursuant to a Division) (collectively, "Transfer"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers [**]."

2.15 The first paragraph of Section 7.2 of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

"(a) Except as expressly permitted in Section 7.3 below, engage in or permit any of its Subsidiaries to engage in any business other than the businesses currently engaged in by Borrower and such Subsidiary, as applicable, or reasonably related thereto; (b) liquidate or dissolve; (c) [**]; or (d) except as expressly permitted in Section 7.3 below, permit or suffer the consummation of any Change in Control."

2.16 Section 7.3 of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

" **7.3 Mergers or Acquisitions.** Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock or property of another Person (including, without limitation, by the formation of any Subsidiary or pursuant to a Division). A Subsidiary may merge or consolidate into another Subsidiary or into Borrower or Akebia."

2.17 Section 8.7 of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

" **8.7 Judgments; Penalties**. One or more fines, penalties or final judgments, orders or decrees for the payment of money in an amount, individually or in the aggregate, of at least [**] Dollars ($[**] shall be rendered against Borrower and/or Akebia, and the same are not, within ten (10) days after the entry, assessment or issuance thereof, discharged, satisfied, or paid, or after execution thereof, stayed or bonded pending appeal, or such judgments are not discharged prior to the expiration of any such stay (provided that no Credit Extensions will be made prior to the satisfaction, payment, discharge, stay, or bonding of such fine, penalty, judgment, order or decree);"

2.18 Section 8.10 of the Loan Agreement is hereby deleted in its entirety and the following is inserted in its place:

" **8.10 Guaranty**. (a) Any guaranty of any Obligations terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any guaranty of the Obligations; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.6, 8.7, 8.8, or 8.11 of this Agreement occurs with respect to any Guarantor, (d) the death, liquidation, winding up, or termination of existence of any Guarantor; or (e) (i) a material impairment in the perfection or priority of Bank's Lien in the collateral provided by Guarantor or in the value of such collateral or (ii) a material adverse change in the general affairs, management, results of operation, condition (financial or otherwise) or the prospect of repayment of the Obligations occurs with respect to any Guarantor; or"

2.19 Section 10 (Notices). The Loan Agreement shall be amended by deleting the following text, appearing in Section 10 thereof:

"with a copy to: *Riemer & Braunstein LLP*
One Center Plaza
Boston, Massachusetts 02108
Attn: David A. Ephraim, Esquire
Fax: (617) 880-3456
Email: DEphraim@riemerlaw.com"

and inserting in lieu thereof the following:

"with a copy to: Morrison & Foerster LLP
200 Clarendon Street, 20th Floor
Boston, Massachusetts 02116
Attn: David A. Ephraim, Esquire
Email: DEphraim@mofo.com"

2.20 Section 13.1 (Definitions). Section 13.1 of the Loan Agreement shall be amended by inserting the following terms and their respective definitions in the appropriate alphabetical order:

" "**Akebia**" is Akebia Therapeutics, Inc., a Delaware corporation.

" "**Akebia Guaranty**" is that certain Unconditional Guaranty to be dated on or within five (5) Business Days of the First Amendment Effective Date, executed by Akebia in favor of Bank."

“ “**Akebia Security Agreement**” is that certain Security Agreement to be dated on or within five (5) Business Days of the First Amendment Effective Date by Akebia in favor of Bank.”

“ “**Division**” means, in reference to any Person which is an entity, the division of such Person into two (2) or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, or any analogous action taken pursuant to any other applicable law with respect to any corporation, limited liability company, partnership or other entity.”

“ “**First Amendment Effective Date**” is July 31, 2019.”

2.21 Section 13.1 (Definitions).

(a) Section 13.1 of the Loan Agreement shall be amended by deleting the following defined terms and its corresponding definitions and inserting the following in their place:

“ “**Guarantor**” is any Person providing a Guaranty in favor of Bank, including without limitation, Akebia.”

“ “**Loan Documents**” are, collectively, this Agreement and any schedules, exhibits, certificates, notices, and any other documents related to this Agreement, the Akebia Guaranty, the Akebia Security Agreement, any Bank Services Agreement, any subordination agreement, any Control Agreement, any landlord consent, and bailee waiver, any note, or notes or guaranties executed by Borrower or any Guarantor, and any other present or future agreement by Borrower and/or any Guarantor with or for the benefit of Bank, all as amended, restated, or otherwise modified.”

2.22 Compliance Certificate. The Compliance Certificate attached to the Loan Agreement as Exhibit B is hereby deleted in its entirety and the Compliance Certificate attached hereto as Exhibit B is inserted in its place.

2.23 Perfection Certificates. From and after the date of this Agreement, the definition of “Perfection Certificate” in the Loan Agreement shall be deemed to mean, collectively, the Perfection Certificate executed and delivered by Borrower in connection with this Agreement, a copy of which is attached hereto as **Exhibit A** and the Perfection Certificate to be delivered by Guarantor within five (5) Business Days following the First Amendment Effective Date pursuant to the Akebia Security Agreement, each as applicable. The references to the “Effective Date” in clause (b) of the definition of Permitted Indebtedness, clause (a) of the definition of Permitted Liens and clause (a) of the definition of Permitted Investments shall be amended to July 31, 2019.”

3. Limitation of Amendments.

3.1 The amendments set forth in Section 2 above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right or remedy which Bank may now have or may have in the future under or in connection with any Loan Document.

3.2 This Agreement shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

4. **Acknowledgement of Default; Waivers**. Borrower acknowledges that it is currently in default under the Loan Agreement as a result of its failure to comply with certain requirements of the Loan Agreement as set forth in the attached **Schedule A** (collectively, the "**Stated Events of Default**"). Borrower acknowledges and agrees that, as a result of the Stated Events of Default, Bank has the right to declare all Obligations due and payable in full and to pursue its rights and remedies pursuant to the Loan Agreement, applicable law, or otherwise. Notwithstanding the foregoing, subject to the satisfaction of the Conditions Precedent set forth below, Bank hereby waives the Stated Events of Default. The foregoing in a one-time waiver related solely to the Stated Events of Default, and is not intended to be, shall not be construed as, a waiver of any other default or Event of Default, or an agreement to do so in the future.

5. **Representations and Warranties.** To induce Bank to enter into this Agreement, Borrower hereby represents and warrants to Bank as follows:

5.1 Immediately after giving effect to this Agreement (a) except as disclosed in the Perfection Certificate, the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred (other than the Stated Events of Default) and is continuing;

5.2 Borrower has the power and due authority to execute and deliver this Agreement; and

5.3 The organizational documents of Borrower delivered to Bank on the Effective Date remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect.

6. **Waiver of Claims; No Defenses of Borrower**. Borrower hereby acknowledges and agrees that it has no offsets, defenses, causes of action, suits, damages, claims, or counterclaims against Bank, or Bank's officers, directors, employees, attorneys, representatives, predecessors, successors, and assigns (collectively, the "**Bank Released Parties**") with respect to the Obligations, the Loan Documents, the Collateral, any contracts, promises, commitments or other agreements to provide, to arrange for, or to obtain loans or other financial accommodations to or for Borrower, or otherwise, and that if Borrower now has, or ever did have, any offsets, defenses, causes of action, suits, damages, claims, or counterclaims against one or more of the Bank Released Parties, whether known or unknown, at law or in equity, from the beginning of the world through this date and through the time of execution of this Amendment (collectively, the "**Released Claims**"), all of them are hereby expressly **WAIVED**, and Borrower hereby **RELEASES** the Bank Released Parties from any liability therefor. Borrower hereby irrevocably agrees to refrain from directly or indirectly asserting any claim or demand or commencing (or causing to be commenced) any suit, action, arbitration or proceeding of any kind, in any court or before any tribunal or arbiter or arbitration panel, against any Bank Released Party as to any Released Claim.

7. **Integration**. This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

8. **Prior Agreement**. The Loan Documents are hereby ratified and reaffirmed and shall remain in full force and effect. This Agreement is not a novation and the terms and conditions of this Agreement shall be in addition to and supplemental to all terms and conditions set forth in the Loan Documents. In the event of any conflict or inconsistency between this Agreement and the terms of such documents, the terms of this Agreement shall be controlling, but such document shall not otherwise be affected or the rights therein impaired.

9. **Counterparts.** This Agreement may be executed in any number of counterparts and all of such counterparts taken together shall be deemed to constitute one and the same instrument.

10. Effectiveness. This Agreement shall be deemed effective upon the satisfaction of each of the following, as determined by Bank in its sole discretion:

10.1 the due execution and delivery to Bank of this Agreement by Borrower;

10.2 Bank shall have received a new Perfection Certificate executed by Borrower in a form and substance acceptable to Bank in all respects;

10.3 Bank shall have received confirmation that Borrower has deposited at least [**] Dollars ($[**]) into an asset management account or deposit account at Bank or Bank's Affiliate; and

10.4 [**].

11. Conditions Subsequent. Within five (5) Business Days following the First Amendment Effective Date, Borrower shall deliver each of the following to Bank:

11.1 Akebia's duly executed acknowledgement page to this Agreement;

11.2 an Unconditional Guaranty executed by Akebia in a form and substance acceptable to Bank in all respects;

11.3 a Security Agreement executed by Akebia in a form and substance acceptable to Bank in all respects;

11.4 a Perfection Certificate executed by Akebia in a form and substance acceptable to Bank in all respects.

Borrower's failure to deliver any of the documents listed in Sections 11.1-11.4 above within five (5) Business Days following the First Amendment Effective Date shall constitute an Event of Default under the Loan Agreement without grace or cure period.

12. Governing Law. This Agreement and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts.

[Signature page follows.]

In Witness Whereof, the parties hereto have caused this Agreement to be duly executed and delivered as of the date first written above.

BANK		**BORROWER**	
SILICON VALLEY BANK		KERYX BIOPHARMACEUTICALS, INC.	
By:	/s/ Clark Hayes	By:	/s/ Jason A. Amello
Name:	Clark Hayes	Name:	Jason A. Amello
Title:	Managing Director	Title:	CFO

ACKNOWLEDGED AND AGREED:

GUARANTOR

AKEBIA THERAPEUTICS, INC.

By:	/s/ Jason A. Amello
Name:	Jason A. Amello
Title:	CFO

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.

SECURITY AGREEMENT

This SECURITY AGREEMENT (this "**Agreement**") is entered into as of August 7, 2019, by and between **SILICON VALLEY BANK**, a California corporation, with its principal place of business at 3003 Tasman Drive, Santa Clara, California 95054 and with a loan production office located at 275 Grove Street, Suite 2-200, Newton, Massachusetts 02466 ("**Bank**") and **AKEBIA THERAPEUTICS, INC.**, a Delaware corporation ("**Debtor**"), with an office located at 245 First Street, Suite 1400, Cambridge, Massachusetts 02142.

RECITALS

Debtor has executed and delivered a certain Unconditional Guaranty of the obligations and liabilities of **KERYX BIOPHARMACEUTICALS, INC.**, a Delaware corporation ("**Borrower**"), to Bank, dated as of the date hereof (as may be amended, restated or otherwise modified from time to time, the "**Guaranty**"). Bank has entered into that certain Loan and Security Agreement by and between Borrower and Bank, dated as of July 18, 2018 (as may be amended, restated, or otherwise modified from time to time, the "**Loan Agreement**"). Borrower has requested that Bank consent to the sale and transfer of certain Collateral (as defined in the Loan Agreement) to Debtor, and Bank has agreed, but only upon the condition that Debtor execute and deliver this Agreement to secure the payment and performance of the obligations and liabilities of Debtor under the Guaranty (the "**Liabilities**") in accordance with the terms of this Agreement.

AGREEMENT

The parties agree as follows:

1. CREATION OF SECURITY INTEREST

1.1 Grant of Security Interest. Debtor hereby grants to Bank, to secure the payment and performance in full of the Liabilities, a continuing security interest in, and pledges to Bank, the property described in **Exhibit A** attached hereto (the "**Collateral**"), wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Debtor represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral (subject only to Permitted Liens that may have superior priority to Bank's Lien).

If this Agreement is terminated, Bank's Lien in the Collateral shall continue until the Liabilities (other than inchoate indemnity obligations) are terminated and repaid in full in cash. Upon payment in full in cash of the Liabilities (other than inchoate indemnity obligations)and at such time as Bank's obligation to make Credit Extensions has terminated, Bank shall, at Debtor's sole cost and expense, release its Liens in the Collateral and all rights therein shall revert to Debtor.

1.2 Financing Statements. This Agreement constitutes an authenticated record which authorizes Bank to file such financing statements as Bank determines appropriate. Debtor hereby authorizes Bank to file financing statements, without notice to Debtor, with all appropriate jurisdictions to perfect or protect Bank's interest or rights hereunder, including a notice that any disposition of the Collateral, by either Debtor or any other Person, shall be deemed to violate the rights of Bank under the Code. Such financing statements may indicate the Collateral as "all assets of the Debtor" or words of similar effect, or as being of an equal or lesser scope, or with greater detail, all in Bank's discretion.

1.3 Delivery of Additional Documentation Required. Debtor shall from time to time execute and deliver to Bank, at the request of Bank, all financing statements and other documents that Bank may reasonably request, in form and substance reasonably satisfactory to Bank, to perfect and continue Bank's security interest in the Collateral. Notwithstanding the foregoing, Debtor shall not be required to deliver to Bank any Control Agreements.

2. REPRESENTATIONS AND WARRANTIES. Except as otherwise expressly set forth in the Perfection Certificate executed by Debtor as of the date of this Agreement, Debtor represents and warrants as follows:

2.1 Due Organization, Authorization; Power and Authority. Debtor is duly existing and in good standing as a Registered Organization in its jurisdiction of formation and is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its business or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a material adverse effect on Debtor's business. In connection with this Agreement, Debtor has delivered to Bank a completed certificate signed by Debtor, entitled "Perfection Certificate" (the "**Perfection Certificate**"). Debtor represents and warrants to Bank that (a) Debtor's exact legal name is that indicated on the Perfection Certificate and on the signature page hereof; (b) Debtor is an organization of the type and is organized in the jurisdiction set forth in the Perfection Certificate; (c) the Perfection Certificate accurately sets forth Debtor's organizational identification number or accurately states that Debtor has none; (d) the Perfection Certificate accurately sets forth Debtor's place of business, or, if more than one, its chief executive office as well as Debtor's mailing address (if different than its chief executive office); (e) Debtor (and each of its predecessors) has not, in the past five (5) years, changed its jurisdiction of formation, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificate pertaining to Debtor and each of its Subsidiaries is accurate and complete (it being understood and agreed that Debtor may from time to time update certain information in the Perfection Certificate after the Effective Date (by delivering a new Perfection Certificate or by disclosing such updates on a Compliance Certificate) to the extent such updates are resulting from actions, transactions, circumstances or events not prohibited by the terms of this Agreement). If Debtor is not now a Registered Organization but later becomes one, Debtor shall promptly notify Bank of such occurrence and provide Bank with Debtor's organizational identification number.

The execution, delivery and performance by Debtor of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Debtor's organizational documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Debtor or any of its Subsidiaries or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect), or (v) conflict with, contravene, constitute a default or breach under, or result in or permit the termination or acceleration of, any material agreement by which Debtor is bound. Debtor is not in default under any agreement to which it is a party or by which it is bound in which the default could reasonably be expected to have a material adverse effect on Debtor's business.

2.2 Collateral. Debtor has good title to, rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien hereunder, free and clear of any and all Liens except Permitted Liens.

The Collateral is not in the possession of any third party bailee (such as a warehouse) except as otherwise provided in the Perfection Certificate or as permitted pursuant to Section 4.2. None of the components of the Collateral shall be maintained at locations other than as provided in the Perfection Certificate or as permitted pursuant to Section 4.2.

All Inventory is in all material respects of good and marketable quality, free from material defects.

Debtor is the sole owner of the Intellectual Property which it owns or purports to own except for (a) non-exclusive licenses granted to its customers in the ordinary course of business, (b) over-the-counter software that is commercially available to the public, (c) material Intellectual Property licensed to Debtor and noted on the Perfection Certificate, (d) Intellectual Property that constitutes a Permitted Lien, and (e) Intellectual Property that is licensed by Debtor to a third party in an arm's length transaction. Each Patent which it owns or purports to own and which is material to Debtor's business is valid and enforceable, and no part of the Intellectual Property which Debtor owns or purports to own and which is material to Debtor's business has been judged invalid or unenforceable, in whole or in part. To the best of Debtor's knowledge, no claim has been made that any part of the Intellectual Property violates the rights of any third party except to the extent such claim would not reasonably be expected to have a material adverse effect on Debtor's business.

Except as noted on the Perfection Certificate or as otherwise disclosed to Bank pursuant to Section 3.5(b), Debtor is not a party to, nor is it bound by, any Restricted License.

2.3 Litigation. There are no actions or proceedings pending or, to the knowledge of any Responsible Officer, threatened in writing by or against Debtor or any of its Subsidiaries involving more than, individually or in the aggregate, [**] Dollars ($[**]).

2.4 Financial Statements; Financial Condition. All consolidated financial statements for Debtor and any of its Subsidiaries delivered to Bank fairly present in all material respects Debtor's consolidated financial condition and Debtor's consolidated results of operations. There has not been any material deterioration in Debtor's consolidated financial condition since the date of the most recent financial statements submitted to Bank.

2.5 Solvency. The fair salable value of Debtor's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of Debtor's liabilities; Debtor is not left with unreasonably small capital after the transactions in this Agreement; and Debtor is able to pay its debts (including trade debts) as they mature.

2.6 Regulatory Compliance. Debtor is not an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Debtor is not engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Debtor (a) has complied in all material respects with all Requirements of Law, and (b) has not violated any Requirements of Law the violation of which could reasonably be expected to have a material adverse effect on its business. None of Debtor's or any of its Subsidiaries' properties or assets has been used by Debtor or any Subsidiary or, to the best of Debtor's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than legally. Debtor and each of its Subsidiaries have obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

2.7 Subsidiaries; Investments. Debtor does not own any stock, partnership, or other ownership interest or other equity securities except for Permitted Investments.

2.8 Tax Returns and Payments; Pension Contributions. Debtor has timely filed all required tax returns and reports, and Debtor has timely paid all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Debtor except (a) to the extent such taxes are being contested in good faith by appropriate proceedings promptly instituted and diligently conducted, so long as such reserve or other appropriate provision, if any, as shall be required in conformity with GAAP shall have been made therefor, or (b) if such taxes, assessments, deposits and contributions do not, individually or in the aggregate, exceed [**] Dollars ($[**]).

To the extent Debtor defers payment of any contested taxes, Debtor shall (i) if such contested amount is in excess of [**] Dollars ($[**]), notify Bank in writing of the commencement of, and any material development in, the proceedings, and (ii) post bonds or take any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a "Permitted Lien." Debtor is unaware of any claims or adjustments proposed for any of Debtor's prior tax years which could reasonably be expected to result in additional taxes becoming due and payable by Debtor in excess of [**] Dollars ($[**]). Debtor has paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and Debtor has not withdrawn from participation in, and has not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Debtor, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other governmental agency.

2.9 Full Disclosure. No written representation, warranty or other statement of Debtor in any certificate or written statement given to Bank, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Bank, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading in light of the circumstances under which they were made (it being recognized by Bank that the projections and forecasts provided by Debtor in good faith and based upon reasonable assumptions are not viewed

as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results and such differences may be material).

2.10 Definition of "Knowledge." For purposes of the Loan Documents, whenever a representation or warranty is made to Debtor's knowledge or awareness, to the "best of" Debtor's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of any Responsible Officer.

3. AFFIRMATIVE COVENANTS. Debtor shall do all of the following:

3.1 Government Compliance.

(a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of formation and maintain qualification in each jurisdiction in which the failure to so maintain or qualify would reasonably be expected to have a material adverse effect on Debtor's business or operations, provided that any Subsidiary other than Borrower may merge or consolidate in accordance with Section 4.3 hereof, or liquidate or dissolve provided that in connection with such dissolution or liquidation all assets and property of any such Subsidiary shall be transferred to Debtor, Borrower or another Subsidiary. Debtor shall comply, and shall have each Subsidiary comply, with all laws, ordinances and regulations to which it is subject, except for such noncompliance with which could not reasonably be expected to have a material adverse effect on Debtor's and Borrower's business taken as a whole.

(b) Obtain all of the Governmental Approvals necessary for the performance by Debtor of its obligations under the Loan Documents to which it is a party and the grant of a security interest to Bank in all of its property. Debtor shall promptly provide copies of any such obtained Governmental Approvals to Bank.

3.2 Taxes; Pensions. Timely file, and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, state and local taxes, assessments, deposits and contributions owed by Debtor and each of its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of Section 2.8 hereof, and shall deliver to Bank, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms.

3.3 Access to Collateral; Books and Records. At reasonable times, on [**] notice (provided no notice is required if an Event of Default has occurred and is continuing), Bank, or its agents, shall have the right to inspect the Collateral and the right to audit and copy Debtor's Books. In each case, such inspections and audits shall be conducted no more often than [**], unless an Event of Default has occurred and is continuing in which case such inspections and audits shall occur as often as Bank shall determine is necessary. The foregoing inspections and audits shall be conducted at Debtor's expense and the charge therefor shall be [**] Dollars ($[**] (or such higher amount as shall represent Bank's then-current standard charge for the same), plus reasonable and documented out-of-pocket expenses. In the event Debtor and Bank schedule an audit more than eight (8) days in advance, and Debtor cancels or seeks to or reschedules the audit with less than eight (8) days written notice to Bank, then (without limiting any of Bank's rights or remedies) Debtor shall pay Bank a fee of [**] Dollars ($[**] to compensate Bank for the anticipated costs and expenses of the cancellation or rescheduling.

3.4 Insurance.

(a) Keep its business and the Collateral insured for risks and in amounts standard for companies in Debtor's industry and location and as Bank may reasonably request. Insurance policies shall be in a form, with financially sound and reputable insurance companies that are not Affiliates of Debtor, and in amounts that are satisfactory to Bank. All property policies shall have a lender's loss payable endorsement showing Bank as lender loss payee. All liability policies shall show, or have endorsements showing, Bank as an additional insured. Bank shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral.

(b) Ensure that proceeds payable under any property policy are, at Bank's option, payable to Bank on account of the Obligations. Notwithstanding the foregoing, (i) so long as no Event of Default has occurred and is continuing, Debtor shall have the option of applying the proceeds of any casualty policy up to [**] Dollars ($[**]) in the aggregate for all losses under all casualty policies in any [**], toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (A) shall be of reasonably equal or similar value (individually or in the aggregate) as the replaced or repaired Collateral and (B) shall be deemed Collateral in which Bank has been granted a first priority security interest, and (ii) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Bank, be payable to Bank on account of the Obligations.

(c) At Bank's request, Debtor shall deliver certified copies of insurance policies and evidence of all premium payments. Each provider of any such insurance required under this Section 3.4 shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to Bank, that it will give Bank [**] prior written notice before any such policy or policies shall be materially altered or canceled. If Debtor fails to obtain insurance as required under this Section 3.4 or to pay any amount or furnish any required proof of payment to third persons and Bank, Bank may make all or part of such payment or obtain such insurance policies required in this Section 3.4, and take any action under the policies Bank deems prudent.

3.5 Protection of Intellectual Property Rights.

(a) (i) Protect, defend and maintain the validity and enforceability of its Intellectual Property; (ii) promptly advise Bank in writing of material infringements or any other event that could reasonably be expected to materially and adversely affect the value of its Intellectual Property; and (iii) not allow any Intellectual Property material to Debtor's business to be abandoned, forfeited or dedicated to the public without Bank's written consent.

(b) Provide written notice to Bank within thirty (30) days of entering or becoming bound by any Restricted License (other than over-the-counter software that is commercially available to the public). Debtor shall take such steps as Bank reasonably requests to obtain the consent of, or waiver by, any person whose consent or waiver is necessary for (i) any Restricted License to be deemed "Collateral" and for Bank to have a security interest in it that might otherwise be restricted or prohibited by law or by the terms of any such Restricted License, whether now existing or entered into in the future, and (ii) Bank to have the ability in the event of a liquidation of any Collateral to dispose of such Collateral in accordance with Bank's rights and remedies under this Agreement and the other Loan Documents.

3.6 Litigation Cooperation. From the date hereof and continuing through the termination of this Agreement, make available to Bank, without expense to Bank, Debtor and its officers, employees and agents and Debtor's books and records, to the extent that Bank may deem them reasonably necessary to prosecute or defend any third-party suit or proceeding instituted by or against Bank with respect to any Collateral or relating to Debtor.

4. NEGATIVE COVENANTS. Debtor shall not do any of the following without Bank's prior written consent:

4.1 Dispositions. Convey, sell, lease, transfer, assign, or otherwise dispose of (including, without limitation, pursuant to a Division) (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers [**].

4.2 Changes in Business, Management, Control, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses currently engaged in by Debtor and such Subsidiary, as applicable, or reasonably related thereto; (b) liquidate or dissolve; (c) [**]; or (d) permit or suffer the consummation of any Change in Control.

Debtor shall not, without at least thirty (30) days prior written notice to Bank: (1) [**], (2) change its jurisdiction of organization, (3) change its organizational structure or type, (4) change its legal name, or (5) change any organizational number (if any) assigned by its jurisdiction of organization. If Debtor intends to [**]. If Debtor intends to deliver any portion of the Collateral consisting of finished goods valued, individually or in the aggregate,

[**], and Bank and such bailee are not already parties to a bailee agreement governing both the Collateral and the location to which Debtor intends to deliver the Collateral, [**].

4.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries (other than Borrower) to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock or property of another Person (including, without limitation, by the formation of any Subsidiary or pursuant to a Division). A Subsidiary other than Borrower may merge or consolidate into another Subsidiary or into Debtor.

4.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

4.5 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, permit any Collateral not to be subject to the first priority security interest granted herein, or enter into any agreement, document, instrument or other arrangement (except with or in favor of Bank) with any Person which directly or indirectly prohibits or has the effect of prohibiting Debtor or any Subsidiary from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Debtor's or any Subsidiary's Intellectual Property, except as is otherwise permitted in Section 4.1 hereof and the definition of "Permitted Liens" herein.

4.6 Distributions; Investments. (a) Pay any dividends or make any distribution or payment or redeem, retire or purchase any capital stock, provided that Debtor may (i) convert any of its convertible securities into other securities pursuant to the terms of such convertible securities or otherwise in exchange thereof, (ii) pay dividends solely in common stock and/or preferred stock, and (iii) repurchase stock pursuant to the terms of employee stock purchase plans, employee restricted stock agreements, stockholder rights plans, director or consultant stock option plans, or similar plans so long as an Event of Default does not exist at the time of any such repurchase and would not exist after giving effect to any such repurchase, provided that the aggregate amount of all such repurchases does not exceed [**] Dollars ($[**]; or (b) directly or indirectly make any Investment (including, without limitation, by the formation of any Subsidiary) other than Permitted Investments, or permit any of its Subsidiaries to do so.

4.7 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Debtor, except for (a) transactions that are in the ordinary course of Debtor's business, upon fair and reasonable terms that are no less favorable to Debtor than would be obtained in an arm's length transaction with a non-affiliated Person, (b) customary director, officer and employee compensation (including bonuses) and other benefits (including retirement, health, stock option and other benefit plans and indemnification arrangements approved by the relevant board of directors, board of managers or equivalent corporate body), or (c) transactions permitted pursuant to Sections 4.1 or 4.3, or (d) equity investments in Borrower or Subsidiaries to the extent not prohibited by Section 4.2(d).

4.8 Subordinated Debt. (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof, provide for earlier or greater principal, interest, or other payments thereon, or adversely affect the subordination thereof to Obligations owed to Bank.

4.9 Compliance. Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a material adverse effect on Debtor's business, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation

plan which could reasonably be expected to result in any liability of Debtor, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other governmental agency.

5. EVENTS OF DEFAULT

Any one or more of the following events shall constitute an event of default by Debtor under this Agreement (an "**Event of Default**"):

5.1 Guaranty; Loan Documents. If an Event of Default (as defined therein) occurs under the Loan Agreement, the Guaranty or any of the other Loan Documents.

5.2 Payment Default. Debtor fails to pay any of the Liabilities when due upon demand therefor by Bank;

5.3 Covenant Default.

(a) If Debtor fails to perform any obligation under Section 3 of this Agreement, or violates any of the covenants contained in Section 4 of this Agreement; or

(b) If Debtor fails or neglects to perform, keep, or observe any other material term, provision, condition, covenant, or agreement contained in this Agreement, the Guaranty or in any of the other Loan Documents, or in any other present or future agreement between Debtor and Bank and as to any default under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure such default within [**] after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the [**] period or cannot after diligent attempts by Debtor be cured within such [**] period, and such default is likely to be cured within a reasonable time, then Debtor shall have an additional reasonable period (which shall not in any case exceed [**]) to attempt to cure such default, and within such reasonable time period the failure to have cured such default shall not be deemed an Event of Default (provided that no Advances will be made to Borrower during such cure period). Grace periods provided under this Section 5.3 shall not apply, among other things, to any covenants that are required to be satisfied, completed, or tested by a date certain or as set forth in subsection (a) above;

5.4 Attachment; Levy; Restraint on Business. (a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Debtor or of any entity under control of Debtor (including a Subsidiary) on deposit with Bank or any Bank Affiliate, or (ii) a notice of lien, levy, or assessment is filed against any of Debtor's assets by any Governmental Authority, and the same under subclauses (i) and (ii) hereof are not, within [**] after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Advances shall be made during any [**] cure period; and (b) (i) any material portion of Debtor's assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Debtor from conducting any part of its business;

5.5 Insolvency. (a) Debtor is unable to pay its debts (including trade debts) as they become due or otherwise becomes insolvent; (b) Debtor begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Debtor and not dismissed or stayed within [**] (but no Advances shall be made while of any of the conditions described in clause (a) exist and/or until any Insolvency Proceeding is dismissed);

5.6 Other Agreements. If there is a default in any agreement to which Debtor is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of [**] Dollars ($[**] the result of which could reasonably be expected to have a material adverse effect on Borrower's or Debtor's business, taken as a whole;

5.7 Judgments; Penalties. One or more fines, penalties or final judgments, orders or decrees for the payment of money in an amount, individually or in the aggregate, of at least [**] Dollars ($[**]) (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower and/or Debtor, and the same are not, within [**] after the entry, assessment or issuance thereof,

discharged, satisfied, or paid, or after execution thereof, stayed or bonded pending appeal, or such judgments are not discharged prior to the expiration of any such stay (provided that no Credit Extensions will be made prior to the satisfaction, payment, discharge, stay, or bonding of such fine, penalty, judgment, order or decree);;

5.8 Misrepresentations. Debtor or any Person acting for Debtor makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in writing delivered to Bank or to induce Bank to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

5.9 Subordinated Debt. A default or breach occurs under any agreement between Debtor and any creditor of Debtor that signed a subordination agreement, intercreditor agreement, or other similar agreement with Bank, or any creditor that has signed such an agreement with Bank breaches any terms of the agreement;

5.10 Other Guaranties. Any guaranty of any Obligations ceases for any reason to be in full force and effect which could reasonably be expected to have a material adverse effect on the ability of the Debtor and its Subsidiaries, taken as a whole, to repay the Obligations, or any material misrepresentation or material misstatement exists now or later in any warranty or representation by Debtor in connection with Debtor's guaranty of the Obligations, which could reasonably be expected to have a material adverse effect on the ability of the Debtor and its Subsidiaries, taken as a whole, to repay the Obligations.

6. BANK'S RIGHTS AND REMEDIES

6.1 Rights and Remedies. Upon the occurrence and during the continuance of an Event of Default, Bank may, at its election, without notice of its election and without demand, do any one or more of the following, all of which are authorized by Debtor:

(a) declare all Liabilities immediately due and payable (but if an Event of Default described in Section 5.5 occurs all Liabilities are immediately due and payable without any action by Bank);

(b) stop advancing money or extending credit for Borrower's benefit under the Loan Agreement or under any other agreement between Borrower and Bank;

(c) demand that Debtor (i) deposits cash with Bank in an amount equal to the aggregate amount of any letters of credit remaining undrawn, as collateral security for the repayment of any future drawings under such letters of credit, and Debtor shall forthwith deposit and pay such amounts, and (ii) pay in advance all letter of credit fees scheduled to be paid or payable over the remaining term of any letters of credit;

(d) settle or adjust disputes and claims directly with Account Debtors for amounts, on terms and in any order that Bank considers advisable and notify any Person owing Debtor money of Bank's security interest in such funds and verify the amount of such account. Debtor shall collect all payments in trust for Bank and, if requested by Bank, immediately deliver the payments to Bank in the form received from the Account Debtor, with proper endorsements for deposit;

(e) make any payments and do any acts it considers necessary or reasonable to protect its security interest in the Collateral. Debtor shall assemble the Collateral if Bank requests and make it available as Bank designates. Bank may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Debtor grants Bank a license to enter and occupy any of its premises, without charge, to exercise any of Bank's rights or remedies;

(f) apply to the Obligations any (i) balances and deposits of Debtor it holds, or (ii) any amount held by Bank owing to or for the credit or the account of Debtor;

(g) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral. Bank is hereby granted a non-exclusive, royalty-free license or other right to use, without

charge, Debtor's labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Bank's exercise of its rights under this Section 4.1, Debtor's rights under all licenses and all franchise agreements inure to Bank's benefit;

(h) place a "hold" on any account maintained with Bank and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any control agreement or similar agreements providing control of any Collateral;

(i) demand and receive possession of Debtor's books and records including ledgers, federal and state tax returns, records regarding Debtor's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information ("**Debtor's Books**"); and

(j) exercise all rights and remedies available to Bank under the Code, the Loan Documents or at law or equity, including all remedies provided under any applicable law (including disposal of the Collateral pursuant to the terms thereof).

6.2 Remedies Cumulative. Bank's rights and remedies under this Agreement, the Guaranty, the Loan Documents, and all other agreements shall be cumulative. Bank shall have all other rights and remedies not inconsistent herewith as provided under the Code, by law, or in equity. No exercise by Bank of one right or remedy shall be deemed an election, and no waiver by Bank of any Event of Default on Debtor's part shall be deemed a continuing waiver. No delay by Bank shall constitute a waiver, election, or acquiescence by it.

6.3 Demand; Protest. Debtor waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees at any time held by Bank on which Debtor may in any way be liable.

7. CHOICE OF LAW AND VENUE; JURY TRIAL WAIVER

The laws of the Commonwealth of Massachusetts shall apply to this Agreement. DEBTOR ACCEPTS FOR ITSELF AND IN CONNECTION WITH ITS PROPERTIES, UNCONDITIONALLY, THE NON-EXCLUSIVE JURISDICTION OF ANY STATE OR FEDERAL COURT OF COMPETENT JURISDICTION IN THE COMMONWEALTH OF MASSACHUSETTS IN ANY ACTION, SUIT, OR PROCEEDING OF ANY KIND, AGAINST IT WHICH ARISES OUT OF OR BY REASON OF THIS AGREEMENT; PROVIDED, HOWEVER, THAT IF FOR ANY REASON BANK CANNOT AVAIL ITSELF OF THE COURTS OF THE COMMONWEALTH OF MASSACHUSETTS, DEBTOR ACCEPTS JURISDICTION OF THE COURTS AND VENUE IN SANTA CLARA COUNTY, CALIFORNIA. NOTWITHSTANDING THE FOREGOING, BANK SHALL HAVE THE RIGHT TO BRING ANY ACTION OR PROCEEDING AGAINST DEBTOR OR ITS PROPERTY IN THE COURTS OR ANY OTHER JURISDICTION WHICH BANK DEEMS NECESSARY OR APPROPRIATE IN ORDER TO REALIZE ON THE COLLATERAL OR TO OTHERWISE ENFORCE BANK'S RIGHT AGAINST DEBTOR OR ITS PROPERTY.

DEBTOR AND BANK EACH HEREBY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF ANY OF THE LOAN DOCUMENTS OR ANY OF THE TRANSACTIONS CONTEMPLATED THEREIN, INCLUDING CONTRACT CLAIMS, TORT CLAIMS, BREACH OF DUTY CLAIMS, AND ALL OTHER COMMON LAW OR STATUTORY CLAIMS. EACH PARTY RECOGNIZES AND AGREES THAT THE FOREGOING WAIVER CONSTITUTES A MATERIAL INDUCEMENT FOR IT TO ENTER INTO THIS AGREEMENT. EACH PARTY REPRESENTS AND WARRANTS THAT IT HAS REVIEWED THIS WAIVER WITH ITS LEGAL COUNSEL AND THAT IT KNOWINGLY AND VOLUNTARILY WAIVES ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL.

8. GENERAL PROVISIONS

8.1 Successors and Assigns. This Agreement shall bind and inure to the benefit of the respective successors and permitted assigns of each of the parties; provided, however, that neither this Agreement nor any rights hereunder may be assigned by Debtor without Bank's prior written consent, which consent may be granted or withheld in Bank's sole discretion. Bank shall have the right without the consent of or notice to Debtor to sell, transfer, negotiate, or grant participations in all or any part of, or any interest in Bank's obligations, rights and benefits hereunder.

8.2 Indemnification. Debtor shall defend, indemnify and hold harmless Bank and its officers, employees, and agents against: (a) all obligations, demands, claims, and liabilities claimed or asserted by any other party in connection with the transactions contemplated by this Agreement; and (b) all losses or Bank Expenses in any way suffered, incurred, or paid by Bank as a result of or in any way arising out of, following, or consequential to transactions between Bank and Debtor under this Agreement or the other Loan Documents (including without limitation reasonable attorneys' fees and expenses), except for losses caused by Bank's gross negligence or willful misconduct.

8.3 Right of Set-Off. Debtor hereby grants to Bank, a lien, security interest and right of setoff as security for all Liabilities to Bank, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Bank or any entity under the control of Bank or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Bank may set off the same or any part thereof and apply the same to any liability or obligation of Debtor even though unmatured and regardless of the adequacy of any other collateral securing the loan. ANY AND ALL RIGHTS TO REQUIRE BANK TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE LIABILITIES, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF DEBTOR, ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

8.4 Time of Essence. Time is of the essence for the performance of all obligations set forth in this Agreement.

8.5 Severability of Provisions. Each provision of this Agreement shall be severable from every other provision of this Agreement for the purpose of determining the legal enforceability of any specific provision.

8.6 Amendments in Writing, Integration. This Agreement cannot be changed or terminated orally. This Agreement and the other Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.

8.7 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Agreement.

8.8 Survival. All covenants, representations and warranties made in this Agreement shall continue in full force and effect so long as any liabilities and obligations under the Guaranty and this Agreement remain outstanding. The obligations of Debtor to indemnify Bank with respect to the expenses, damages, losses, costs and liabilities described in this Agreement shall survive until all applicable statute of limitations periods with respect to actions that may be brought against Bank have run.

8.9 Amendment of Loan Documents. Debtor authorizes Bank, without notice or demand and without affecting its liability hereunder, from time to time to (a) renew, extend, or otherwise change the terms of the Loan Documents or any part thereof, provided that Debtor or Borrower consents to such changes to the extent required under the applicable Loan Document; (b) take and hold security for the payment of the Loan Documents, and exchange, enforce, waive and release any such security; and (c) apply such security and direct the order or manner of sale thereof as Bank in its sole discretion may determine.

8.10 Debtor Waivers. Debtor waives any right to require Bank to (a) proceed against Borrower, Debtor, any other guarantor or any other person; (b) proceed against or exhaust any security held from Borrower or Debtor; (c) marshal any assets of Borrower or Debtor; or (d) pursue any other remedy in Bank's power whatsoever. Bank may, at its election, exercise or decline or fail to exercise any right or remedy it may have against Borrower or Debtor or any security held by Bank, including without limitation the right to foreclose upon any such security by judicial or nonjudicial sale, without affecting or impairing in any way the liability of Debtor hereunder. Debtor waives any defense arising by reason of any disability or other defense of Borrower or Debtor or by reason of the cessation from any cause whatsoever of the liability of Borrower or Debtor. Debtor waives any setoff, defense or counterclaim that Borrower or Debtor may have against Bank. Debtor waives any defense arising out of the absence, impairment or loss of any right of reimbursement or subrogation or any other rights against Borrower or Debtor. Debtor shall have no right of subrogation or reimbursement, contribution or other rights against Borrower, and Debtor waives any right to enforce any remedy that Bank now has or may hereafter have against Borrower. Debtor waives all rights to participate in any security now or hereafter held by Bank. Debtor waives all presentments, demands for performance, notices of nonperformance, protests, notices of protest, notices of dishonor, and notices of acceptance of this Agreement and of the existence, creation, or incurring of new or additional indebtedness. Debtor assumes the responsibility for being and keeping itself informed of the financial condition of Borrower and of all other circumstances bearing upon the risk of nonpayment of any indebtedness or nonperformance of any obligation of Borrower, warrants to Bank that it will keep so informed, and agrees that absent a request for particular information by Debtor, Bank shall have no duty to advise Debtor of information known to Bank regarding such condition or any such circumstances.

8.11 Insolvency. If Borrower becomes insolvent or is adjudicated bankrupt or files a petition for reorganization, arrangement, composition or similar relief under any present or future provision of the United States Bankruptcy Code, or if such a petition is filed against Borrower, and in any such proceeding some or all of any indebtedness or obligations under the Loan Documents is terminated or rejected or any obligation of Borrower is modified or abrogated, or if Borrower's obligations are otherwise avoided for insolvency, bankruptcy or any similar reason, Debtor agrees that Debtor's liability hereunder shall not thereby be affected or modified and such liability shall continue in full force and effect as if no such action or proceeding had occurred. This Agreement shall continue to be effective or be reinstated, as the case may be, if any payment must be returned by Bank upon the insolvency, bankruptcy or reorganization of Borrower or Debtor, any other person, or otherwise, as though such payment had not been made.

9. DEFINITIONS. Capitalized terms used but not otherwise defined herein shall have the same meaning as in the Loan Agreement, with references to "Borrower" therein being deemed references to "Debtor" to the extent applicable. The foregoing is for definitional purposes only and is not intended to impose any obligations on Guarantor other than those set forth in the Guaranty and this Agreement.

[The remainder of this page is intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as a sealed instrument under the laws of the Commonwealth of Massachusetts as of the date first above written.

("Debtor")

AKEBIA THERAPEUTICS, INC.

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

("Bank")

SILICON VALLEY BANK

By: /s/ Clark Hayes
Name: Clark Hayes
Title: Managing Director

Exhibit 10.4

UNCONDITIONAL GUARANTY

This continuing Unconditional Guaranty ("**Guaranty**") is entered into as of August 7, 2019, by AKEBIA THERAPEUTICS, INC. ("**Guarantor**"), in favor of Silicon Valley Bank ("**Bank**").

RECITALS

A. Bank and KERYX BIOPHARMACEUTICALS, INC., a Delaware corporation ("**Borrower**"), have entered into that certain Loan and Security Agreement dated as of July 18, 2018 (as amended, restated, or otherwise modified from time to time, the "**Loan Agreement**") pursuant to which Bank has agreed to make certain advances of money and to extend certain financial accommodations to Borrower (collectively, the "**Loans**"), subject to the terms and conditions set forth therein. *Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement*.

B. In consideration of the agreement of Bank to make the Loans to Borrower under the Loan Agreement, Guarantor is willing to guaranty the full payment and performance by Borrower of all of its obligations thereunder and under the other Loan Documents, all as further set forth herein.

C. Guarantor is the sole shareholder of Borrower and will obtain substantial direct and indirect benefit from the Loans made by Bank to Borrower under the Loan Agreement.

NOW, THEREFORE, to induce Bank to enter into the Loan Agreement, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, and intending to be legally bound, Guarantor hereby represents, warrants, covenants and agrees as follows:

Section 1. **Guaranty.**

1.1 Unconditional Guaranty of Payment. In consideration of the foregoing, Guarantor hereby irrevocably, absolutely and unconditionally guarantees to Bank the prompt and complete payment and performance when due (whether at stated maturity, by acceleration or otherwise) of all Obligations. Guarantor agrees that it shall execute such other documents or agreements and take such action as Bank shall reasonably request to effect the purposes of this Guaranty.

1.2 Separate Obligations. These obligations are independent of Borrower's obligations and separate actions may be brought against Guarantor (whether action is brought against Borrower or whether Borrower is joined in the action).

Section 2. **Representations and Warranties.**

Guarantor hereby represents and warrants that:

(a) Guarantor (i) is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware; (ii) is duly qualified to do business and is in good standing in every jurisdiction where the nature of its business requires it to be so qualified (except where the failure to so qualify would not have a material adverse effect on Guarantor's condition, financial or otherwise, or on Guarantor's ability to pay or perform the obligations hereunder); and (iii) has all requisite power and authority to execute and deliver this Guaranty and each Loan Document executed and delivered by Guarantor pursuant to the Loan Agreement or this Guaranty and to perform its obligations thereunder and hereunder.

(b) The execution, delivery and performance by Guarantor of this Guaranty (i) are within Guarantor's powers and have been duly authorized by all necessary action; (ii) do not contravene Guarantor's charter documents or any law or any contractual restriction binding on or affecting Guarantor or by which Guarantor's property may be affected; (iii) do not require any authorization or approval or other action by, or any notice to or filing with, any governmental authority or any other Person under any indenture, mortgage, deed of trust, lease, agreement or other instrument to which Guarantor is a party or by which Guarantor or

any of its property is bound, except such as have been obtained or made; and (iv) do not result in the imposition or creation of any Lien upon any property of Guarantor, other than the Lien created pursuant to that certain Security Agreement by and between Bank and Guarantor of even date herewith.

(c) This Guaranty is a valid and binding obligation of Guarantor, enforceable against Guarantor in accordance with its terms, except as the enforceability thereof may be subject to or limited by bankruptcy, insolvency, reorganization, arrangement, moratorium or other similar laws relating to or affecting the rights of creditors generally.

(d) The incurrence of Guarantor's obligations under this Guaranty will not cause Guarantor to (i) become insolvent; (ii) be left with unreasonably small capital for any business or transaction in which Guarantor is presently engaged or plans to be engaged; or (iii) be unable to pay its debts as such debts mature.

Section 3. **General Waivers**. Guarantor waives:

(a) Any right to require Bank to (i) proceed against Borrower or any other person; (ii) proceed against or exhaust any security or (iii) pursue any other remedy. Bank may exercise or not exercise any right or remedy it has against Borrower or any security it holds (including the right to foreclose by judicial or nonjudicial sale) without affecting Guarantor's liability hereunder.

(b) Any defenses from disability or other defense of Borrower or from the cessation of Borrower's liabilities.

(c) Any setoff, defense or counterclaim against Bank.

(d) Any defense from the absence, impairment or loss of any right of reimbursement or subrogation or any other rights against Borrower. Until Borrower's obligations to Bank have been paid and the Borrower's financing arrangements have been terminated, Guarantor has no right of subrogation or reimbursement or other rights against Borrower.

(e) Any right to enforce any remedy that Bank has against Borrower.

(f) Any rights to participate in any security held by Bank.

(g) Any demands for performance, notices of nonperformance or of new or additional indebtedness incurred by Borrower to Bank. Guarantor is responsible for being and keeping itself informed of Borrower's financial condition.

(h) The benefit of any act or omission by Bank which directly or indirectly results in or aids the discharge of Borrower from any of the Obligations by operation of law or otherwise.

Section 4. **Real Property Security Waiver**. Guarantor acknowledges that, to the extent Guarantor has or may have rights of subrogation or reimbursement against Borrower for claims arising out of this Guaranty, those rights may be impaired or destroyed if Bank elects to proceed against any real property security of Borrower by non-judicial foreclosure. That impairment or destruction could, under certain judicial cases and based on equitable principles of estoppel, give rise to a defense by Guarantor against its obligations under this Guaranty. Guarantor waives that defense and any others arising from Bank's election to pursue non-judicial foreclosure. Guarantor waives the benefits, if any, of any statutory or common law rule that may permit a subordinating creditor to assert any defenses of a surety or guarantor, or that may give the subordinating creditor the right to require a senior creditor to marshal assets, and Guarantor agrees that it shall not assert any such defenses or rights**.**

Section 5. **Reinstatement**. Notwithstanding any provision of the Loan Agreement to the contrary, the liability of Guarantor hereunder shall be reinstated and revived and the rights of Bank shall continue if and to the extent that for any reason any payment by or on behalf of Guarantor or Borrower is rescinded or must be otherwise

restored by Bank, whether as a result of any proceedings in bankruptcy or reorganization or otherwise, all as though such amount had not been paid. The determination as to whether any such payment must be rescinded or restored shall be made by Bank in its sole discretion; *provided, however*, that if Bank chooses to contest any such matter at the request of Guarantor, Guarantor agrees to indemnify and hold harmless Bank from all costs and expenses (including, without limitation, reasonable attorneys' fees) of such litigation. To the extent any payment is rescinded or restored, Guarantor's obligations hereunder shall be revived in full force and effect without reduction or discharge for that payment.

Section 6. **No Waiver; Amendments**. No failure on the part of Bank to exercise, no delay in exercising and no course of dealing with respect to, any right hereunder shall operate as a waiver thereof; nor shall any single or partial exercise of any right hereunder preclude any other or further exercise thereof or the exercise of any other right. The remedies herein provided are cumulative and not exclusive of any remedies provided by law. This Guaranty may not be amended or modified except by written agreement between Guarantor and Bank, and no consent or waiver hereunder shall be valid unless in writing and signed by Bank.

Section 7. **Compromise and Settlement**. No compromise, settlement, release, renewal, extension, indulgence, change in, waiver or modification of any of the Obligations or the release or discharge of Borrower from the performance of any of the Obligations shall release or discharge Guarantor from this Guaranty or the performance of the obligations hereunder.

Section 8. **Notice**. Any notice or other communication herein required or permitted to be given shall be in writing and may be delivered in person or sent by email transmission, overnight courier, or by United States mail, registered or certified, return receipt requested, postage prepaid and addressed as follows:

If to Guarantor:	AKEBIA THERAPEUTICS, INC. 245 First Street, Suite 1400 Cambridge, Massachusetts 02142 Attention: Jason Amello, CFO Email:
If to Bank:	SILICON VALLEY BANK 275 Grove Street Suite 2-200 Newton, Massachusetts 02466 Attn: Mr. Clark Hayes Email:
with copies to:	MORRISON & FOERSTER LLP 200 Clarendon Street, 20th Floor Boston, Massachusetts 02114 Attention: David A. Ephraim, Esquire Telephone No.: 617-648-4730 Email: dephraim@mofo.com

or at such other address as may be substituted by notice given as herein provided. Every notice, demand, request, consent, approval, declaration or other communication hereunder shall be deemed to have been duly given or served on the date on which personally delivered or sent by email transmission or three (3) Business Days after the same shall have been deposited in the United States mail. If sent by overnight courier service, the date of delivery shall be deemed to be the next Business Day after deposited with such service.

Section 9. **Entire Agreement**. This Guaranty constitutes and contains the entire agreement of the parties and supersedes any and all prior and contemporaneous agreements, negotiations, correspondence, understandings and communications between Guarantor and Bank, whether written or oral, respecting the subject matter hereof.

Section 10. **Severability**. If any provision of this Guaranty is held to be unenforceable under applicable law for any reason, it shall be adjusted, if possible, rather than voided in order to achieve the intent of Guarantor and Bank to the extent possible. In any event, all other provisions of this Guaranty shall be deemed valid and enforceable to the full extent possible under applicable law.

Section 11. **Subordination of Indebtedness**. Any indebtedness or other obligation of Borrower now or hereafter held by or owing to Guarantor is hereby subordinated in time and right of payment to all obligations of Borrower to Bank, except as such indebtedness or other obligation is expressly permitted to be paid under the Loan Agreement; and such indebtedness of Borrower to Guarantor is assigned to Bank as security for this Guaranty, and if Bank so requests shall be collected, enforced and received by Guarantor in trust for Bank and to be paid over to Bank on account of the Obligations of Borrower to Bank, but without reducing or affecting in any manner the liability of Guarantor under the other provisions of this Guaranty. Any notes now or hereafter evidencing such indebtedness of Borrower to Guarantor shall be marked with a legend that the same are subject to this Guaranty.

Section 12. **Payment of Expenses**. Guarantor shall pay, promptly on demand, all Expenses incurred by Bank in defending and/or enforcing this Guaranty. For purposes hereof, "Expenses" shall mean costs and expenses (including reasonable and documented fees and disbursements of any law firm or other external counsel) for defending and/or enforcing this Guaranty (including those incurred in connection with appeals or proceedings by or against any Guarantor under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief).

Section 13. **Assignment; Governing Law**. This Guaranty shall be binding upon and inure to the benefit of Guarantor and Bank and their respective successors and assigns, except that Guarantor shall not have the right to assign its rights hereunder or any interest herein without the prior written consent of Bank, which may be granted or withheld in Bank's sole discretion. Any such purported assignment by Guarantor without Bank's written consent shall be void. This Guaranty shall be governed by, and construed in accordance with, the laws of the Commonwealth of Massachusetts without regard to principles thereof regarding conflict of laws.

Section 14. **PERSONAL JURISDICTION.** GUARANTOR HEREBY IRREVOCABLY AGREES THAT ANY LEGAL ACTION OR PROCEEDING WITH RESPECT TO THIS GUARANTY OR ANY OF THE AGREEMENTS, DOCUMENTS OR INSTRUMENTS DELIVERED IN CONNECTION HEREWITH MAY BE BROUGHT IN THE STATE AND FEDERAL COURTS LOCATED IN THE COMMONWEALTH OF MASSACHUSETTS AS BANK MAY ELECT (PROVIDED THAT GUARANTOR ACKNOWLEDGES THAT ANY APPEALS FROM THOSE COURTS MAY HAVE TO BE HEARD BY A COURT LOCATED OUTSIDE OF THE COMMONWEALTH OF MASSACHUSETTS), AND, BY EXECUTION AND DELIVERY HEREOF, GUARANTOR ACCEPTS AND CONSENTS TO, GENERALLY AND UNCONDITIONALLY, THE JURISDICTION OF THE AFORESAID COURTS AND AGREES THAT SUCH JURISDICTION SHALL BE EXCLUSIVE, UNLESS WAIVED BY BANK IN WRITING, WITH RESPECT TO ANY ACTION OR PROCEEDING BROUGHT BY GUARANTOR AGAINST BANK. NOTHING HEREIN SHALL LIMIT THE RIGHT OF BANK TO BRING PROCEEDINGS AGAINST GUARANTOR IN THE COURTS OF ANY OTHER JURISDICTION, GUARANTOR HEREBY WAIVES, TO THE FULL EXTENT PERMITTED BY LAW, ANY RIGHT TO STAY OR TO DISMISS ANY ACTION OR PROCEEDING BROUGHT BEFORE SAID COURTS ON THE BASIS OF FORUM NON CONVENIENS.

Section 15. **WAIVER OF JURY TRIAL**. EACH OF BANK AND GUARANTOR HEREBY WAIVES, TO THE FULL EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY WITH RESPECT TO ANY LITIGATION DIRECTLY OR INDIRECTLY ARISING OUT OF, UNDER OR IN CONNECTION WITH THIS GUARANTY. EACH PARTY HERETO (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF ANY OTHER PARTY HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT SUCH OTHER PARTY WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER, AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HERETO HAVE BEEN INDUCED TO ENTER INTO THIS GUARANTY AND ANY RELATED INSTRUMENTS, AS APPLICABLE, BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 15.

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GUARANTOR

AKEBIA THERAPEUTICS, INC.

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

Exhibit 31.1

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

I, John P. Butler, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Akebia Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the Audit Committee of the registrant's Board of Directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 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: November 12, 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 September 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: November 12, 2019

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

Date: November 12, 2019

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