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 March 31, 2020

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 April 30, 2020
130,265,945

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the potential direct or indirect impact of the coronavirus 2 (SARS-CoV-2) pandemic on our business, operations, and the markets and communities in which we and our partners, collaborators, vendors and customers operate;
- 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 timing, investment and associated activities involved in continued commercialization of Auryxia® (ferric citrate);
- 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;
- the potential therapeutic applications of the hypoxia inducible factor, or HIF, pathway;
- our pipeline, including its potential, and our research and development activities;
- our competitive position, including estimates, developments and projections relating to our competitors and their products and product candidates, and our industry;
- 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;
- our expectations, projections and estimates regarding our capital requirements, need for additional capital, financing our future cash needs, costs, expenses, revenues, capital resources, cash flows, financial performance, profitability, tax obligations, liquidity, growth, contractual obligations, the period of time our cash resources and collaboration funding will fund our current operating plan, internal control over financial reporting and remediation of any deficiencies, 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 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.

Any or all of these forward-looking statements in this Quarterly Report on Form 10-Q may turn out to be inaccurate. These forward-looking statements involve risks and uncertainties, including those that are 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.

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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)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 115,374	$ 147,449
Available for sale securities	—	245
Inventory	111,854	116,349
Accounts receivable, net	104,872	38,864
Prepaid expenses and other current assets	8,656	6,626
Total current assets	340,756	309,533
Property and equipment, net	9,855	10,380
Operating lease assets	28,026	29,038
Goodwill	55,053	55,053
Other intangible assets, net	282,112	291,212
Other assets	71,917	75,985
Total assets	$ 787,719	$ 771,201
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 54,379	$ 39,217
Accrued expenses and other current liabilities	124,887	129,071
Short-term deferred revenue	34,886	39,830
Total current liabilities	214,152	208,118
Deferred revenue, net of current portion	42,799	33,120
Operating lease liabilities, net of current portion	26,207	27,528
Derivative liability	1,740	1,650
Long-term debt, net	76,072	75,805
Other non-current liabilities	30,385	30,223
Total liabilities	391,355	376,444
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock $0.00001 par value, 25,000,000 shares authorized; 0 shares issued and outstanding at March 31, 2020 and December 31, 2019	—	—
Common stock $0.00001 par value; 175,000,000 shares authorized at March 31, 2020 and December 31, 2019; 130,251,440 and 121,674,568 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	1,251,164	1,188,810
Accumulated deficit	(854,801)	(794,054)
Total stockholders' equity	396,364	394,757
Total liabilities and stockholders' equity	$ 787,719	$ 771,201

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 March 31,	
	2020	**2019**
Revenues:		
Product revenue, net	$ 29,209	$ 23,111
License, collaboration and other revenue	59,269	49,555
Total revenues	88,478	72,666
Cost of goods sold:		
Product	18,613	22,157
Amortization of intangibles	9,100	9,100
Total cost of goods sold	27,713	31,257
Operating expenses:		
Research and development	81,231	82,351
Selling, general and administrative	37,983	34,291
License expense	676	736
Total operating expenses	119,890	117,378
Operating loss	(59,125)	(75,969)
Other income (expense):		
Interest income (expense)	(1,972)	869
Other income (expense)	350	(78)
Net loss before income taxes	(60,747)	(75,178)
Benefit from income taxes	—	(2,757)
Net loss	$ (60,747)	$ (72,421)
Net loss per share - basic and diluted	$ (0.47)	$ (0.62)
Weighted-average number of common shares - basic and diluted	128,395,163	117,063,352
Comprehensive loss:		
Net loss	$ (60,747)	$ (72,421)
Other comprehensive gain - unrealized gain on debt securities	—	225
Total comprehensive loss	$ (60,747)	$ (72,196)

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, 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	—	—	—	225	—	225
Net loss	—	—	—	—	(72,421)	(72,421)
Balance at March 31, 2019	117,122,262	$ 1	$ 1,153,230	$ (36)	$ (586,816)	$ 566,379
Balance at December 31, 2019	121,674,568	$ 1	$ 1,188,810	$ —	$ (794,054)	$ 394,757
Issuance of common stock, net of issuance costs	7,973,967	—	56,575	—	—	56,575
Proceeds from sale of stock under employee stock purchase plan	115,024	—	451	—	—	451
Share-based compensation expense	—	—	4,916	—	—	4,916
Exercise of options	64,126	—	412	—	—	412
Restricted stock unit vesting	423,755	—	—	—	—	—
Net loss	—	—	—	—	(60,747)	(60,747)
Balance at March 31, 2020	130,251,440	$ 1	$ 1,251,164	$ —	$ (854,801)	$ 396,364

See accompanying notes to unaudited condensed consolidated financial statements

AKEBIA THERAPEUTICS, INC.

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

	Three Months Ended	
	March 31, 2020	March 31, 2019
Operating activities:		
Net loss	$ (60,747)	$ (72,421)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	525	439
Amortization of intangibles	9,100	9,100
Amortization of premium/discount on investments	—	(477)
Non-cash interest expense	437	169
Non-cash operating lease expense	(647)	(614)
Fair value write-up of inventory sold	11,180	14,586
Write-down of inventory	139	1,664
Stock-based compensation	4,916	2,094
Deferred income taxes	—	(2,757)
Change in fair value of derivative liability	90	—
Changes in operating assets and liabilities:		
Accounts receivable	(66,008)	(31,769)
Inventory	(8,163)	(16,064)
Prepaid expenses and other current assets	(1,898)	1,317
Other long-term assets	46	719
Accounts payable	20,470	(20,746)
Accrued expense	(4,209)	(17,500)
Operating lease liabilities	445	549
Deferred revenue	4,735	(6,218)
Net cash used in operating activities	(89,589)	(137,929)
Investing activities:		
Purchase of equipment	—	(1,928)
Proceeds from the maturities of available for sale securities	245	78,691
Proceeds from sales of available for sale securities	—	33,710
Net cash provided by investing activities	245	110,473
Financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	56,485	—
Proceeds from the sale of stock under employee stock purchase plan	451	188
Proceeds from the exercise of stock options	412	365
Payments on debt	—	(15,000)
Net cash provided by financing activities	57,348	(14,447)
Increase in cash, cash equivalents, and restricted cash	(31,996)	(41,903)
Cash, cash equivalents, and restricted cash at beginning of the period	149,804	107,099
Cash, cash equivalents, and restricted cash at end of the period	$ 117,808	$ 65,196
Non-cash financing activities		
Unpaid offering costs	$ 90	$ —

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 with the purpose of bettering the lives of people living with kidney disease. Akebia's lead investigational product candidate, vadadustat, is an oral therapy in Phase 3 development. 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. The Company's commercial product, Auryxia® (ferric citrate) is currently approved by the U.S. Food and Drug Administration, or FDA, and marketed for two indications in the United States: 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).

Since inception, the Company has devoted most of its resources to research and development, including its preclinical and clinical development activities, 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 following the consummation of a merger with Keryx Biopharmaceuticals, Inc., or Keryx, or the Merger. 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 products or product candidates, it may be unable to achieve profitability.

The Company's management completed its going concern assessment in accordance with ASC 205-40, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, or ASC 205-40. The Company believes that its cash resources will be sufficient to allow the Company to fund its current operating plan through at least the next twelve months from the filing of this Quarterly Report on Form 10-Q, as required by ASC 205-40. There can be no assurance, however, that the current operating plan will be achieved in the time frame anticipated by the Company, or that its cash resources will fund the Company's operating plan for the period anticipated by the Company or that additional funding will be available on terms acceptable to the Company, or at all. 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 months ended March 31, 2020 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2020 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, 2019 filed with the U.S. Securities and Exchange Commission on March 12, 2020, or the 2019 Annual Report on Form 10-K.

The significant accounting policies used in preparation of these unaudited condensed consolidated financial statements for the three months ended March 31, 2020 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's 2019 Annual Report on Form 10-K and are updated below as necessary.

New Accounting Pronouncements – Recently 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. Previously, U.S. GAAP delayed recognition of the full amount of credit losses until the loss was probable of occurring. Under this ASU, the income statement will reflect an entity's current estimate of all expected credit losses. The Company adopted this new standard on January 1, 2020 using the modified retrospective approach, which requires a cumulative-effect adjustment, if any, to the opening balance of retained earnings to be recognized on the date of adoption with prior periods not restated. The cumulative-effect adjustment recorded on January 1, 2020, is not material. Please see the description of the Company's "Credit Losses" accounting policy in the "Significant Accounting Policies" section below.

In August 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. The Company adopted this new standard on January 1, 2020 using the prospective approach for amendments applicable to the Company. The adoption of this standard did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

In August 2018, the FASB issued ASU 2018-15, *Intangible-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract*. This standard clarifies the accounting for implementation costs in cloud computing arrangements. This standard became effective for us on January 1, 2020, and was adopted on a prospective basis. The adoption of this standard did not have a material impact to the Company's unaudited condensed consolidated financial statements and disclosures.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*. This standard makes targeted improvements for collaborative arrangements as follows:

- Clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, *Revenue from Contracts with Customers*, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements;
- Adds unit-of-account guidance to ASC 808, *Collaborative Arrangements*, to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606; and
- Precludes a company from presenting transactions with collaborative arrangement participants that are not directly related to sales to third parties with revenue recognized under ASC 606 if the collaborative arrangement participant is not a customer.

This standard became effective for the Company on January 1, 2020, and did not have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

New Accounting Pronouncements – Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes.* This ASU is effective for fiscal years beginning after December 15, 2020, including interim periods therein, and is applicable to the Company in fiscal year 2021. Early adoption is permitted. ASU 2019-12 requires certain amendments to be applied using a modified retrospective approach, which requires a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption, while other amendments should be applied on a prospective basis. The Company does not expect that the adoption of this standard will have a material impact on the Company's unaudited condensed consolidated financial statements and related disclosures.

Derivative Financial Instruments

The Company accounts for warrants and other derivative financial instruments as either equity or liabilities in accordance with ASC Topic 815, *Derivatives and Hedging*, or ASC 815, based upon the characteristics and provisions of each instrument. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's unaudited condensed consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's unaudited condensed consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. The warrant issued by the Company in connection with the Janssen Pharmaceutica NV Research and License Agreement, the Janssen Agreement, is classified as equity in the Company's unaudited condensed consolidated balance sheet. (See Note 12). The derivative liability recorded in connection with the Company's Loan Agreement with Pharmakon is classified as a liability in the Company's unaudited condensed consolidated balance sheet. (See Note 11).

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, derivative 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. The Company has made estimates of the impact of COVID-19 within the unaudited condensed consolidated financial statements and there may be changes to those estimates in future periods including changes to sales, payer mix, reserves and allowances, intangible assets and goodwill. While the COVID-19 pandemic has not had a material adverse impact on the Company's financial condition, the future impacts of the pandemic and any resulting economic impact is largely unknown and rapidly evolving.

Credit Losses

Available for sale debt securities. Management determines the appropriate classification of securities at the time of purchase and reevaluates such designation as of each balance sheet date. The Company classifies all securities as available for sale and includes them in current assets as they are intended to fund current operations. The Company's investment portfolio at any point in time contains investments in money market mutual funds, U.S. government debt securities, certificates of deposit and corporate debt securities. The Company segments its portfolio based on the underlying risk profiles of the securities and have a zero loss expectation for money market mutual funds, U.S. government debt securities and certificates of deposit. The Company regularly reviews the securities in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. During the quarter ended March 31, 2020, the Company's only available for sales securities consisted of certificates of deposit and therefore the Company did not recognize any credit losses.

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. Cash equivalents are reported at fair value. At March 31, 2020, 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, at March 31, 2019, 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):

	March 31, 2020	March 31, 2019
Cash and cash equivalents	$ 115,374	$ 62,741
Prepaid expenses and other current assets	395	263
Other assets	2,039	2,192
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 117,808	$ 65,196

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 March 31, 2020 and December 31, 2019.

	Useful Life	March 31, 2020	December 31, 2019
		(in thousands)	
Computer equipment and software	3	$ 1,010	$ 1,010
Furniture and fixtures	5 - 7	2,086	2,086
Equipment	7	2,451	2,451
Leasehold improvements	Shorter of the useful life or remaining lease term (10 years)	8,497	8,497
		14,044	14,044
Less accumulated depreciation		(4,189)	(3,664)
Net property and equipment		$ 9,855	$ 10,380

Depreciation expense was approximately $0.5 million and $0.4 million for the three months ended March 31, 2020 and 2019, 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 that it performs 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.

Debt

The Company performs an assessment of all embedded features of a debt instrument to determine if (1) such features should be bifurcated and separately accounted for, and (2) if bifurcation requirements are met, whether such features should be classified and accounted for as equity or liability instruments. If the embedded feature meets the requirements to be bifurcated and accounted for as a liability, the fair value of the embedded feature is measured initially, included as a liability on the unaudited condensed consolidated balance sheet, and re-measured to fair value at each reporting period. Any changes in fair value are recorded in the unaudited condensed consolidated statement of operations. The Company monitors, on an ongoing basis, whether events or circumstances could give rise to a change in the classification of embedded features.

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.

The Company does not include a financing component to its estimated transaction price at contract inception unless it estimates that certain performance obligations will not be satisfied within one year. Additionally, the Company recognizes the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that the Company otherwise would have recognized is one year or less.

Product Revenue, Net

The Company sells Auryxia in the United States, or 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 March 31, 2020. 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 unaudited condensed 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 unaudited condensed 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 collaboration agreements, 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 an out-license and collaboration 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 Otsuka U.S. Agreement, as defined below in Note 4, as a component of the related expense in the period incurred. During the three months ended March 31, 2020 and 2019, the Company incurred approximately $0.5 million and $0.3 million, respectively, of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.3 million and $0.2 million are reimbursable by Otsuka and recorded as a reduction to research and development expense during the three months ended March 31, 2020 and 2019, respectively. During each of the three months ended March 31, 2020 and 2019, Otsuka incurred approximately $0.4 million of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.2 million are reimbursable by the Company and recorded as an increase to research and development expense during each of the three months ended March 31, 2020 and 2019. 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).

Goodwill

The Company allocates any excess purchase price over the fair value of the net tangible and intangible assets acquired in a business combination to goodwill. Goodwill is evaluated for impairment on an annual basis as of October 1, and more frequently if indicators are present or changes in circumstances suggest that impairment may exist.

The Company compares the fair value of its reporting unit to its carrying value. If the carrying value of the net assets assigned to the reporting unit exceeds the fair value of its reporting unit, the Company would record an impairment loss equal to the difference. As described above, the Company operates in one operating segment which the Company considers to be the only reporting unit.

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 and derivative liabilities (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 months ended March 31, 2020 and 2019, respectively. There were no impairments to assets measured using Level 3 inputs during the three months ended March 31, 2020 and 2019, respectively.

The Company's other financial instruments mainly consists of debt (see Note 11).

Net Loss per Share

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

3. Product Revenue and Reserves for Variable Consideration

To date, the Company's only source of product revenue has been product revenue from the U.S. sales of Auryxia, which it began recording on December 12, 2018 following the consummation of the Merger. Total net product revenue was $29.2 million and $23.1 million for the three months ended March 31, 2020 and 2019, respectively. The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2020 and 2019 (in thousands):

	Chargebacks and Discounts	Rebates, Fees and other Deductions	Returns	Total
Balance at December 31, 2019	$ 738	$ 30,552	$ 253	$ 31,543
Current provisions related to sales in current year	2,250	30,519	1,053	33,822
Adjustments related to prior year sales	82	32	—	114
Credits/payments made	(2,353)	(29,024)	(1,051)	(32,428)
Balance at March 31, 2020	$ 717	$ 32,079	$ 255	$ 33,051
Balance at December 31, 2018	$ 516	$ 22,861	$ 360	$ 23,737
Current provisions related to sales in current year	1,486	17,476	870	19,832
Adjustments related to prior year sales	—	156	—	156
Credits/payments made	(1,495)	(17,301)	(947)	(19,743)
Balance at March 31, 2019	$ 507	$ 23,192	$ 283	$ 23,982

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.

Accounts receivable, net related to product sales was approximately $20.2 million and $23.0 million as of March 31, 2020 and December 31, 2019, respectively.

4. License, Collaboration and Other Significant Agreements

During the three months ended March 31, 2020 and 2019, the Company recognized the following revenues from its license, collaboration and other significant agreements and had the following deferred revenue balances as of March 31, 2020:

	Three Months Ended March 31,	
	2020	2019
License, Collaboration and Other Revenue:	(in thousands)	
Otsuka U.S. Agreement	$ 38,577	$ 26,223
Otsuka International Agreement	19,370	21,956
Total Proportional Performance Revenue	$ 57,947	$ 48,179
JT and Torii	1,126	1,228
MTPC Other Revenue	196	148
Total License, Collaboration and Other Revenue	$ 59,269	$ 49,555

	March 31, 2020		
	Short-Term	Long-Term	Total
Deferred Revenue:	(in thousands)		
Otsuka U.S. Agreement	$ 19,090	$ 26,854	$ 45,944
Otsuka International Agreement	11,807	11,266	23,073
MTPC - Supply of Validation Drug Product	3,989	—	3,989
Vifor Agreement	—	4,679	4,679
Total	$ 34,886	$ 42,799	$ 77,685

The following table presents changes in the Company's contract assets and liabilities during the three months ended March 31, 2020 and 2019 (in thousands):

Three Months Ended March 31, 2020	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract assets:				
Accounts receivable(1)	$ 15,822	$ 71,639	$ (2,895)	$ 84,566
Prepaid expenses and other current assets	$ —	$ 546	$ —	$ 546
Contract liabilities:				
Deferred revenue	$ 72,950	$ 65,209	$ (60,474)	$ 77,685
Accrued expenses and other current liabilities	$ —	$ 615	$ —	$ 615
Three Months Ended March 31, 2019				
Contract assets:				
Accounts receivable(1)	$ 1,587	$ 30,387	$ (2,041)	$ 29,933
Contract liabilities:				
Deferred revenue	$ 112,689	$ 41,962	$ (48,180)	$ 106,471
Accounts payable	$ 13,492	$ —	$ (13,492)	$ —

(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 March 31, 2019 and 2020 and December 31, 2018 and 2019. Also excludes accounts receivable related to amounts due to the Company from product sales which are included in the accompanying unaudited condensed consolidated balance sheet as of March 31, 2020 and December 31, 2019.

During the three months ended March 31, 2020 and 2019, 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 March 31,	
Revenue Recognized in the Period from:	2020	2019
Amounts included in deferred revenue at the beginning of the period	$ 10,130	$ 45,179
Performance obligations satisfied in previous periods	$ —	$ 1,254

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. 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 in Japan, 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.

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 is eligible to receive an additional $15.0 million upon regulatory approval of vadadustat in Japan, 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, no additional milestone or royalty payments may ever be received from MTPC.

In September 2017, the Company provided MTPC with an option to use data from the Company's global Phase 3 vadadustat program to obtain regulatory approval for vadadustat in Japan. If exercised, MTPC would make 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 March 31, 2020, 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 March 31, 2020, all development milestones and a $10.0 million regulatory milestone related to the filing of the JNDA have been 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, for which all deliverables have been completed. No revenues were recognized for the three months ended March 31, 2020 and 2019 with respect to the MTPC Agreement. As of March 31, 2020, 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 March 31, 2020.

Supply of Validation Drug Product

The Company is advancing key pre-commercial activities in support of the first regulatory approval of vadadustat expected in Japan this year. As a result, in March 2020, in connection with the MTPC agreement, the Company agreed to supply MTPC with certain vadadustat drug product for commercial use and MTPC agreed to reimburse the Company for certain manufacturing-related expenses. In connection with this arrangement, the Company invoiced the upfront payment of $10.4 million, which it received in the second quarter of 2020. The Company does not recognize revenue under this arrangement until risk of loss passes to MTPC and delivery has occurred. As of March 31, 2020, the Company deferred recognition of all revenues relating to this arrangement and recorded $10.4 million in accounts receivable, $4.0 million in short-term deferred revenue for drug product that was delivered in Q2 2020, and $6.4 million in other current liabilities for drug product that is subject to return by MTPC.

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 United States. 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 United States, 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, while Otsuka may agree to perform certain activities under the global development plan from time to time as agreed by the parties. The current global development plan encompasses all activities with respect to the ongoing PRO$_2$TECT and INNO$_2$VATE 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 $279.9 million or more, depending on the actual costs incurred toward the current global development plan. 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 as set forth in the Otsuka U.S. Agreement or 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 the additional funding as a result of exercising the Otsuka Funding Option, or the Additional Funding, to total approximately $104.2 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 March 31, 2020, the Additional Funding was $60.0 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, as of March 31, 2020, the Company is eligible to receive up to $125.0 million in development milestone payments, up to $65.0 million in regulatory milestone payments for the first product to achieve the associated event, and up to $575.0 million in commercial milestone payments associated with aggregate sales of licensed products. These future milestones are 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 March 31, 2020, totaled $60.0 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 United States 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 United States 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 top-line 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. The Company determined that under ASC 606, the contract was modified in the second quarter of 2019 when the Otsuka Funding Option became effective and the Company became eligible to receive the Additional Funding amount. In connection with the modification, the Company adjusted the transaction price to include the Additional Funding amount as additional variable consideration. The Company constrains the variable consideration to an amount for which a significant revenue reversal is not probable. In the event that there is consideration received by a customer in the form of activities performed by such customer under the global development plan, such consideration is reflected as a reduction to the transaction price as contra revenue rather than as an expense because the associated services are not distinct from the License Performance Obligation.

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 March 31, 2020, the transaction price totaling $438.7 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, and (iii) the estimate of the net cost share consideration to be received of approximately $279.9 million with respect to amounts incurred by the Company subsequent to December 31, 2016 and the Additional Funding. As of March 31, 2020, no development or regulatory milestones have been assessed as probable of being reached and thus have been fully constrained.

During the three months ended March 31, 2020 and 2019, the Company recognized revenue totaling approximately $38.6 million and $26.2 million, 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 March 31, 2020, there is approximately $45.9 million of deferred revenue related to the Otsuka U.S. Agreement of which $19.1 million is classified as current and $26.8 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 March 31, 2020 and December 31, 2019, there is approximately $49.3 million and $8.9 million, respectively, in accounts receivable in the accompanying unaudited condensed consolidated balance sheet. As of March 31, 2020, there is also $0.4 million in prepaid expenses and other current assets and $0.4 million in accrued expenses and other current liabilities in the accompanying unaudited condensed consolidated balance sheet. There were no prepaid expenses and other current assets or accrued expenses and other current liabilities in the consolidated balance sheet as of December 31, 2019.

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 March 31, 2020 and 2019, the Company incurred approximately $0.5 million and $0.3 million, respectively, of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement of which approximately $0.3 million and $0.2 million are

reimbursable by Otsuka and recorded as a reduction to research and development expense during each of the three months ended March 31, 2020 and 2019, respectively. During each of the three months ended March 31, 2020 and 2019, Otsuka incurred approximately $0.4 million of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.2 million are reimbursable by the Company and recorded as an increase to research and development expense during each of the three months ended March 31, 2020 and 2019.

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, while Otsuka may agree to perform certain activities under the global development plan from time to time as agreed by the parties. 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 $213.0 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 as set forth in the Otsuka International Agreement or

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, as of March 31, 2020, 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 top-line data from the global Phase 3 development program for vadadustat. 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. In the event that there is consideration received by a customer in the form of activities performed by such customer under the global development plan, such consideration is reflected as a reduction to the transaction price as contra revenue rather than as an expense because the associated services are not distinct from the License Performance Obligation.

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 March 31, 2020, the transaction price totaling $286.2 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 net cost share consideration to be received with respect to amounts incurred by the Company subsequent to March 31, 2017 of $213.0 million. As of March 31, 2020, no development or regulatory milestones have been assessed as probable of being reached and thus have been fully constrained.

During the three months ended March 31, 2020 and 2019, the Company recognized revenue totaling approximately $19.4 million and $22.0 million, 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 March 31, 2020, there is approximately $23.1 million of deferred revenue related to the Otsuka International Agreement of which $11.8 million is classified as current and $11.3 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 March 31, 2020 and December 31, 2019, there is approximately $22.4 million and $4.0 million, respectively, in accounts receivable in the accompanying unaudited condensed consolidated balance sheet. As of March 31, 2020, there is also $0.2 million in prepaid expenses and other current assets and $0.2 million in accrued expenses and other current liabilities in the accompanying unaudited condensed consolidated balance sheet. There were no prepaid expenses and other current assets and accrued expenses and other current liabilities in the consolidated balance sheet as of December 31, 2019.

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, which research term is now expired. During the research term, the Company could designate one or more compounds as candidates for development and commercialization. Once a compound was designated for development and commercialization, the Company was to 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 United States. 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 United States.

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 reimbursed using 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 United States. 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 United States, 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 United States. 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 United States. During the term of the Vifor Amended Agreement, Vifor Pharma is not permitted to sell any HIF product that competes with vadadustat in the United States 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 United States. Vifor Pharma may terminate the Vifor Amended Agreement in its entirety upon 12 months' prior written notice after the release of the first top-line 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) the earlier of a determination by the Centers for Medicare & Medicaid Services that vadadustat will be reimbursed using Medicare's bundled reimbursement model or that vadadustat will be reimbursed using the Transitional Drug Add-On Payment Adjustment; and (c) payment by Vifor Pharma of a $25.0 million milestone upon the occurrence of (a) and (b), 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.

Priority Review Voucher Letter Agreement

On February 14, 2020, the Company entered into a letter agreement, or the Letter Agreement, with Vifor Pharma relating to Vifor Pharma's agreement with a third party to purchase a Priority Review Voucher, or the PRV, issued by the FDA, subject to satisfaction of customary closing conditions, or the PRV Purchase. A PRV entitles the holder to priority review of a New Drug Application, or NDA, or a Biologics License Application for a new drug, which reduces the target FDA review time to six months after official acceptance of the submission, and could lead to expedited approval. Pursuant to the Letter Agreement, Akebia paid Vifor Pharma

$10.0 million in connection with the closing of the PRV Purchase. Vifor Pharma is obligated to retain all rights to, and maintain the validity of, the PRV until Akebia and Vifor Pharma (a) enter into a definitive agreement setting forth the financial and other terms by which Vifor Pharma will assign the PRV to Akebia for use with Akebia's planned NDA for vadadustat for the treatment of anemia due to CKD in both dialysis-dependent and non-dialysis dependent patients, or (b) make a mutual decision to sell the PRV and share the proceeds based on certain terms.

During the quarter ended March 31, 2020, the $10.0 million payment to Vifor Pharma was recorded to research and development expense in the unaudited condensed consolidated statement of operations and as an operating cash outflow in the unaudited condensed consolidated statement of cash flows.

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 Keryx 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.

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. 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.

During the three months ended March 31, 2020 and 2019, the Company recognized approximately $2.5 million and $2.1 million, respectively, in royalty payments due to Panion relating to the Company's sales of Auryxia in the United States and JT and Torii's net sales of Riona in Japan, as the Company is required to pay a mid-single digit percentage of net sales of ferric citrate in the Company's licensed territories to Panion under the terms of the Panion Amended License Agreement.

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

Summary of Agreement

As a result of the Merger, the Company has an Amended and Restated Sublicense Agreement, which was amended in June 2013, with JT and Torii, or the JT and Torii Sublicense Agreement, under which 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 under the JT and Torii Sublicense Agreement terminates upon the expiration of all underlying patent rights. Also, JT and Torii may terminate the JT and Torii Sublicense Agreement with or without cause upon at least six months prior written notice to us. Additionally, either party may terminate the JT and Torii Sublicense Agreement for cause upon 60 days' prior written notice after the breach of any uncured material provision of the JT and Torii 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 each of the three months ended March 31, 2020 and 2019, the Company recognized $1.1 million and $1.2 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'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 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 fair value of the off-market element was $29.5 million.

The 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 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.

6. Available For Sale Securities

Cash, cash equivalents, and available for sale securities at March 31, 2020 and December 31, 2019 consisted of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
March 31, 2020				
Cash and cash equivalents	$ 115,374	$ —	$ —	$ 115,374
Total cash, cash equivalents, and available for sale securities	$ 115,374	$ —	$ —	$ 115,374

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(in thousands)		
December 31, 2019				
Cash and cash equivalents	$ 147,449	$ —	$ —	$ 147,449
Available for sale securities:				
Certificates of deposit	$ 245	—	—	$ 245
Total available for sale securities	$ 245	$ —	$ —	$ 245
Total cash, cash equivalents, and available for sale securities	$ 147,694	$ —	$ —	$ 147,694

The Company did not hold any available for sale securities at March 31, 2020. There were no realized gains or losses on available for sale securities for the three months ended March 31, 2019. Additionally, the Company did not have any available for sale securities that were in an unrealized loss position as of December 31, 2019.

7. Fair Value of Financial Instruments

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

Based on the fair value hierarchy, the Company classifies its cash equivalents and available for sale securities within Level 1 or Level 2. This is because the Company values its cash equivalents and available for sale 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 March 31, 2020 and December 31, 2019 are summarized below:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
March 31, 2020				
Assets:				
Cash and cash equivalents	$ 115,374	$ —	$ —	$ 115,374
	$ 115,374	$ —	$ —	$ 115,374
Liabilities:				
Derivative liability	$ —	$ —	$ 1,740	$ 1,740
	$ —	$ —	$ 1,740	$ 1,740

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
December 31, 2019				
Assets:				
Cash and cash equivalents	$ 147,449	$ —	$ —	$ 147,449
Certificates of deposit	—	245	—	245
	$ 147,449	$ 245	$ —	$ 147,694
Liabilities:				
Derivative liability	$ —	$ —	$ 1,650	$ 1,650
	$ —	$ —	$ 1,650	$ 1,650

The Company's Loan Agreement with Pharmakon (see Note 11) contains certain provisions that change the underlying cash flows of the debt instrument, including a potential extension to the interest-only period dependent on both no event of default having occurred and continuing and on the Company achieving certain regulatory and revenue conditions. The Company also assessed the acceleration of the obligations under the Loan Agreement under an event of default. In addition, under certain circumstances, a default interest rate will apply on all outstanding obligations during the occurrence and continuance of an event of default. In accordance with ASC 815, the Company concluded that these features are not clearly and closely related to the host instrument, and represent a single compound derivative that is required to be re-measured at fair value on a quarterly basis.

The events of default include 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. The Company recorded a derivative liability related to the Company's Loan Agreement with Pharmakon of $1.7 million as of both March 31, 2020 and December 31, 2019, respectively. The Company classified the derivative liability as a non-current liability on the unaudited condensed consolidated balance sheet as of March 31, 2020 and December 31, 2019. The estimated fair value of the derivative liability on both March 31, 2020 and December 31, 2019 was determined using a scenario-based approach and discounted cash flow model that includes principal and interest payments under various scenarios involving clinical development success for vadadustat and various cash flow assumptions. Probabilities surrounding clinical development success were derived using industry benchmarks. Should the Company's assessment of the probabilities around these scenarios change, including for changes in market conditions, there could be a change to the fair value of the derivative liability.

The following table provides a roll-forward of the fair value of the derivative liability (in thousands):

Balance at December 31, 2019	$ 1,650
Change in fair value of derivative liability, recorded as other expense	90
Balance at March 31, 2020	$ 1,740

The Company had no other assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) at March 31, 2020 and December 31, 2019.

Investment securities are exposed to various risks such as interest rate, market and credit risks. When the Company holds investment securities, 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, the Company considers if changes in risks in the near term would result in material changes in the fair value of investments.

8. Inventory

The components of inventory, inclusive of step-up as a result of bringing Keryx's inventory onto Akebia's books at fair value in connection with the Merger, are summarized as follows:

	March 31, 2020	December 31, 2019
	(in thousands)	
Raw materials	$ 1,841	$ 2,278
Work in process	135,474	137,858
Finished goods	36,925	42,096
Total inventory	$ 174,240	$ 182,232

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

	March 31, 2020	December 31, 2019
	(in thousands)	
Balance Sheet Classification:		
Inventory	$ 111,854	$ 116,349
Other assets	62,386	65,883
Total inventory	$ 174,240	$ 182,232

Inventory amounts written down as a result of excess, obsolescence, scrap or other reasons and charged to cost of goods sold totaled $0.1 million and $1.7 million during the three months ended March 31, 2020 and 2019, respectively. 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 March 31, 2020 and December 31, 2019 (in thousands):

	March 31, 2020				
	Gross Carrying Value	Accumulated Amortization	ASC 842 Adjustment	Total	Estimated useful life
Acquired intangible assets:					
Developed product rights for Auryxia	$ 329,130	$ (47,018)	$ —	$ 282,112	9 Years
Favorable lease	545	(5)	(540)	—	N/A
Total	$ 329,675	$ (47,023)	$ (540)	$ 282,112	

	December 31, 2019				
	Gross Carrying Value	Accumulated Amortization	ASC 842 Adjustment	Total	Estimated useful life
Acquired intangible assets:					
Developed product rights for Auryxia	$ 329,130	$ (37,918)	$ —	$ 291,212	9 Years
Favorable lease	545	(5)	(540)	—	N/A
Total	$ 329,675	$ (37,923)	$ (540)	$ 291,212	

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 in amortization expense related to the developed product rights for Auryxia during each of the three months ended March 31, 2020 and 2019. Estimated future amortization expense for the intangible asset as of March 31, 2020 is as follows (in thousands):

	Total
2020	$ 27,302
2021	36,401
2022	36,402
2023	36,401
2024	36,402
Thereafter	109,204
	$ 282,112

Goodwill

Goodwill was $55.1 million as of March 31, 2020 and December 31, 2019, 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 is 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 March 31, 2020 and December 31, 2019 are as follows:

	March 31, 2020	December 31, 2019
	(in thousands)	
Accrued clinical	$ 54,581	$ 61,815
Product revenue allowances	31,225	30,552
Accrued payroll	7,727	12,604
MTPC - Supply of Validation Drug Product	6,441	—
Lease liability	5,096	4,989
Professional fees	3,949	3,444
Accrued commercial manufacturing	2,694	2,680
Royalties	2,459	2,713
Accrued severance	452	725
Accrued other	10,263	9,549
Total accrued expenses	$ 124,887	$ 129,071

11. Debt

Future principal payments on the Term Loans (as defined below) as of March 31, 2020 are as follows (in thousands):

	Principal Payments (in thousands)
2020	$ —
2021	—
2022	7,140
2023	30,354
2024	42,506
Thereafter	—
Total before unamortized discount and issuance costs	80,000
Less: unamortized discount and issuance costs	(3,928)
Total term loans	$ 76,072

Term Loans

On November 11, 2019, the Company, with Keryx as guarantor, entered into a loan agreement, or the Loan Agreement, with BioPharma Credit PLC as collateral agent and a lender, or the Collateral Agent, and BioPharma Credit Investments V (Master) LP as a lender, collectively with the Collateral Agent, 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. The first tranche of $80.0 million, or Tranche A, was drawn 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, subject to the satisfaction of customary conditions. 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. The Company and Keryx entered 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 are unconditionally guaranteed by Keryx, or the Guarantee. Additionally, the obligations of the Company and Keryx under the Term Loans and the Guarantee are secured by a first priority lien on certain assets of the Company and Keryx, including Auryxia and certain related assets, cash, and certain equity interests held by the Company and Keryx, collectively the Collateral.

The Term Loans bear interest 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 paid to Pharmakon a facility fee equal to 2.00% of the aggregate principal amount of the Term Loans, or $2.0 million, in addition to other expenses incurred by Pharmakon and reimbursed by the Company, or Lender Expenses. The Tranche A draw was $77.3 million, net of facility fee, Lender Expenses and issuance costs. 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. Under certain circumstances, a default interest rate will apply on all outstanding obligations during the occurrence and continuance of an event of default. As of March 31, 2020 and December 31, 2019, the Company determined that no events of default had occurred.

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

The events of default include 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. The fair value of the derivative liability related to the Company's Loan Agreement with Pharmakon is $1.7 million as of both March 31, 2020 and December 31, 2019, respectively. The Company classified the derivative liability as a non-current liability on the unaudited condensed consolidated balance sheet as of March 31, 2020.

During the three months ended March 31, 2020, the Company recognized approximately $2.2 million of interest expense related to the Loan Agreement.

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 March 31, 2020, the warrant remains outstanding and expires on February 9, 2022.

13. Stockholders' Equity

Authorized and Outstanding Capital Stock

As of March 31, 2020, the authorized capital stock of the Company included 175,000,000 shares of common stock, par value $0.00001 per share, of which 130,251,440 and 121,674,568 shares were issued and outstanding at March 31, 2020 and December 31, 2019, respectively; and 25,000,000 shares of undesignated preferred stock, par value $0.00001 per share, of which no shares were issued and outstanding at March 31, 2020 and December 31, 2019.

At-the-Market Facility

On November 12, 2019, the Company entered into an Amended and Restated Controlled Equity Offering℠ Sales Agreement with Cantor Fitzgerald & Co. for the offer and sale of common stock at the then current market prices in amounts to be determined from time to time. Also, on November 12, 2019, the Company filed a prospectus supplement pursuant to which it was able to offer and sell up to $75.0 million its common stock at the then current market prices from time to time. In December 2019, the Company commenced sales under this program. Through December 31, 2019, the Company sold 2,684,392 shares of common stock under this program with net proceeds (after deducting commissions and other offering expenses) of $16.8 million. During the three months ended March 31, 2020, the Company sold 7,973,967 shares of common stock under this program with net proceeds (after deducting commissions and other offering expenses) of $56.7 million. On March 12, 2020, the Company filed an additional prospectus supplement, pursuant to which it is able to offer and sell up to $65.0 million in its common stock at current market prices from time to time. During the three months ended March 31, 2020 and through the date of this Quarterly Report on Form 10-Q, the Company did not sell any shares of common stock pursuant to the March 12, 2020 prospectus supplement.

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. During the three months ended March 31, 2020, the Company granted 299,450 options to purchase shares of the Company's common stock to new hires under the Inducement Award Program, of which all 299,450 options to purchase Akebia Shares remained outstanding at March 31, 2020.

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 three months ended March 31, 2020, the Company granted 1,714,800 options to purchase Akebia Shares to employees under the 2014 Plan, 299,450 options to purchase Akebia Shares to employees under the Inducement Award Program, 2,350,400 Akebia RSUs to employees under the 2014 Plan, 479,000 Akebia PSUs to employees under the 2014 plan, no options to purchase Akebia Shares to directors under the 2014 Plan, and no 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 March 31, 2020 of the Company's common stock available for future issuance under the ESPP is 5,600,968. 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:

	March 31, 2020	December 31, 2019
Common stock options and RSUs outstanding (1)	16,107,645	12,195,031
Shares available for issuance under Akebia equity plans (2)	2,740,708	2,983,256
Warrant to purchase common stock	509,611	509,611
Shares available for issuance under the ESPP (3)	5,600,968	5,715,992
Total	24,958,932	21,403,890

(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, 2020, January 1, 2019 and January 1, 2018, the shares reserved for future grants under the 2014 Plan increased by 4,031,376, 3,801,198 and 1,575,329 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 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.

(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 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, 2020, as part of the Company's annual grant of equity, the Company issued 1,714,800 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 $1.6 million and $1.1 million of stock-based compensation expense related to stock options during the three months ended March 31, 2020 and 2019.

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 Merger. The Company did not issue any performance-based options during the three months ended March 31, 2020 and 2019. As of March 31, 2020, the Company had no performance-based options outstanding compared to 46,790 performance-based options outstanding at December 31, 2019. The potential range of shares issuable pursuant to the Company's 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

Service-Based Restricted Stock Units

On February 28, 2020, as part of the Company's annual grant of equity, the Company issued 2,268,000 restricted stock units, or RSUs, to employees. In addition, the Company occasionally issues RSUs not in connection with the annual grant process to employees. Generally, 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, (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 $3.1 million and $0.9 million of stock-based compensation expense related to employee RSUs during the three months ended March 31, 2020 and 2019, respectively.

Performance-Based Restricted Stock Units

On February 28, 2020, as part of the Company's annual grant of equity, the Company issued 479,000 performance-based restricted stock units, or PSUs, to the Company's executives. The PSUs granted by the Company vest in connection with the achievement of specified commercial and regulatory milestones. The PSUs also feature a time-based vesting component. The expense recognized for these awards is based on the grant date fair value of the Company's common stock multiplied by the number of units granted and recognized over time based on the probability of meeting such commercial and regulatory milestones. The Company recorded approximately $0.1 million and $0 of stock-based compensation expense related to employee PSUs during the three months ended March 31, 2020 and 2019, respectively.

Employee Stock Purchase Plan

The first offering period under the ESPP opened on January 2, 2015. The Company issued 115,024 shares during the three months ended March 31, 2020. The Company recorded approximately $0.2 million and $48,000 of stock-based compensation expense related to the ESPP during the three months ended March 31, 2020 and 2019, respectively.

Compensation Expense Summary

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

	Three Months Ended	
	March 31, 2020	March 31, 2019
	(in thousands)	
Research and development	$ 1,542	$ 878
Selling, general and administrative	3,374	1,216
Total	$ 4,916	$ 2,094

Compensation expense by type of award:

	Three Months Ended	
	March 31, 2020	March 31, 2019
	(in thousands)	
Stock options	$ 1,617	$ 1,112
Restricted stock units	3,142	934
Employee stock purchase plan	157	48
Total	$ 4,916	$ 2,094

14. 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, which commenced 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 each of the three months ended March 31, 2020 and 2019 were $1.7 million and cash paid for amounts included in the measurement of operating lease liabilities for each of the three months ended March 31, 2020 and 2019 were $1.7 million.

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 28, 2023. Foundation is obligated to pay Keryx rent that approximates the rent due from Keryx to its landlord with respect to the Boston Lease. Sublease rental income is recorded to other income. 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. Keryx recorded $0.4 million in sublease rental income from Foundation during the three months ended March 31, 2020.

The Company has not entered into any material short-term leases or financing leases as of March 31, 2020.

The total security deposit in connection with the Cambridge Lease is $1.6 million as of March 31, 2020. 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 in the Company's unaudited condensed consolidated balance sheets as of March 31, 2020.

As of March 31, 2020, undiscounted minimum rental commitments under non-cancelable leases, for each of the next five years and total thereafter are as follows:

	Operating Leases	Lease Payments to be Received from Sublease	Net Operating Lease Payments
		(in thousands)	
Remaining 2020	$ 4,820	$ 1,328	$ 3,492
2021	7,064	1,797	$ 5,267
2022	6,735	1,824	$ 4,911
2023	5,347	307	$ 5,040
2024	5,116	—	$ 5,116
Thereafter	8,818	—	$ 8,818
Total	$ 37,900	$ 5,256	$ 32,644

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, which was January 1, 2019. As of March 31, 2020, the remaining lease terms ranged from 1.67 years to 6.45 years. As of March 31, 2020, 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	$ 37,900
Present value adjustment using incremental borrowing rate	(6,596)
Operating lease liabilities	$ 31,304

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 Manufacture and Supply Agreement with BioVectra and the Product Manufacture and Supply and Facility Construction Agreement with BioVectra, 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 March 31, 2020, the Company is required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $135.3 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 fair value of the off-market element. Through March 31, 2020, the Company recorded $0.9 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 March 31, 2020, the Company is required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $53.3 million through the year ending December 31, 2021.

On April 9, 2019, the Company entered into a Supply Agreement with Esteve Química, S.A., or Esteve, or the Esteve Agreement. The Esteve Agreement includes the terms and conditions under which Esteve will manufacture vadadustat drug substance, or API, for commercial use.

Pursuant to the Esteve Agreement, the Company will provide rolling forecasts to Esteve on a quarterly basis, or the Forecast. The Forecast will reflect the Company's needs for API produced by Esteve over a certain number of months, represented as a quantity of API per calendar quarter. The parties have agreed to a volume-based pricing structure under the Esteve Agreement. The Esteve Agreement has an initial term of four years, beginning April 9, 2019 and ending April 9, 2023. As of March 31, 2020, the Company had a minimum commitment with Esteve for $6.0 million through the first quarter of 2021. Subsequent to March 31, 2020, the minimum commitment with Esteve increased to $13.6 million through the second quarter of 2021.

On March 11, 2020, the Company entered into a Supply Agreement with Patheon Inc., or Patheon, or the Patheon Agreement. The Patheon Agreement includes the terms and conditions under which Patheon will manufacture vadadustat drug product for commercial use. Additionally, on April 2, 2020, the Company entered into a Supply Agreement with STA Pharmaceutical Hong Kong Limited, a subsidiary of Wuxi AppTec, or WuXi STA, or the WuXi STA Agreement. The WuXi STA Agreement includes the terms and conditions under which WuXi STA will manufacture vadadustat API for commercial use. There are no minimum commitments under either supply agreement as of March 31, 2020.

Other Third Party Contracts

Under the Company's agreement with IQVIA to provide contract research organization services for the PRO_2TECT and $INNO_2VATE$ programs, the total remaining contract costs as of March 31, 2020 were approximately $41.1 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 $67.4 million at March 31, 2020. The scope of the services under these research and development contracts can be modified and the contracts cancelled by the Company upon written notice. In some instances, the contracts may be cancelled by the third party upon written notice.

Litigation and Related Matters

From time to time, the Company may become subject to legal proceedings and claims which arise in the ordinary course of its business. Consistent with ASC 450, *Contingencies*, the Company's policy is to record a liability if a loss in a significant legal dispute is considered probable and an amount can be reasonably estimated. The Company provides disclosure when a loss in excess of any reserve is reasonably possible, and if estimable, the Company discloses the potential loss or range of possible loss. Significant judgment is required to assess the likelihood of various potential outcomes and the quantification of loss in those scenarios. The Company's estimates change as litigation progresses and new information comes to light. Changes in Company estimates could have a material impact on the Company's results and financial position. As of March 31, 2020, the Company does not have any significant legal disputes that require a loss liability to be recorded. The Company continually monitors the need for a loss liability for litigation and related matters.

15. 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 March 31,	
	2020	**2019**
Warrant	509,611	509,611
Outstanding stock options	9,371,675	10,261,827
Unvested restricted stock units	6,735,970	2,058,687
Total	16,617,256	12,830,125

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, 2019 filed with the U.S. Securities and Exchange Commission on March 12, 2020, or the 2019 Annual Report on Form 10-K, including the audited consolidated financial statements and notes thereto contained in our 2019 Annual Report on Form 10-K. This discussion and analysis contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Part II, Item 1A. of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements.

Business Overview

We are a biopharmaceutical company with the purpose of bettering the lives of people living with kidney disease. Our portfolio includes a late-stage product candidate and a commercial product:

- ***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 chronic kidney disease, or CKD, in adult patients on dialysis, or DD-CKD, and (2) anemia due to CKD in adult patients not on dialysis, or 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 is designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxia-inducible factor, or HIF, which can lead to red blood cell, or RBC, production and improved oxygen delivery to tissues.
- ***Auryxia*® *(ferric citrate)*** is approved and marketed in the United States for two indications: (1) the control of serum phosphorus levels in adult patients with DD-CKD, or the Hyperphosphatemia Indication, and (2) the treatment of iron deficiency anemia, or IDA, in adult patients with 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).

Vadadustat

Top-line Results from Global Phase 3 INNO$_2$VATE Program

In the second quarter of 2020, we announced positive top-line results from INNO$_2$VATE, the first of our two global Phase 3 cardiovascular outcomes programs. The two INNO$_2$VATE studies (*Correction/Conversion* and *Conversion*), which collectively enrolled 3,923 patients, evaluated the efficacy and safety of vadadustat versus darbepoetin alfa for the treatment of anemia due to CKD in adult patients on dialysis.

Vadadustat achieved the primary and key secondary efficacy endpoint in each of the two INNO$_2$VATE studies, demonstrating non-inferiority to darbepoetin alfa as measured by a mean change in hemoglobin, or Hb, between baseline and the primary evaluation period (weeks 24 to 36) and secondary evaluation period (weeks 40 to 52). Vadadustat also achieved the primary safety endpoint of the INNO$_2$VATE program, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of major adverse cardiovascular events, or MACE, which is the composite of all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke across both INNO$_2$VATE studies. Each analysis was measured against non-inferiority, or NI, margins agreed upon with the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA.

Both INNO$_2$VATE studies are global, multicenter, open label (sponsor blinded), active-controlled (darbepoetin alfa - an injectable erythropoiesis stimulating agent, or ESA), non-inferiority studies.

Primary and Key Secondary Efficacy Endpoint Results

Vadadustat achieved each of the INNO$_2$VATE studies' primary efficacy endpoints of mean change in Hb between baseline and the primary evaluation period (mean Hb from weeks 24 to 36) compared to darbepoetin alfa, in adult patients on dialysis, demonstrating non-inferiority to darbepoetin alfa based on using a non-inferiority margin of -0.75 g/dL prospectively agreed to with FDA and EMA.

In INNO$_2$VATE's *Correction/Conversion* study of incident dialysis patients (n=369):

- ***Primary Efficacy Endpoint Result***: Vadadustat was *non-inferior* to darbepoetin alfa. The least square mean difference in Hb was -0.31 g/dL (95% CI: -0.53, -0.10), achieving the pre-specified non-inferiority criterion of -0.75 g/dL. The mean (SD) Hb level at week 24 to week 36 was 10.36 (1.13) g/dL for vadadustat-treated patients compared to 10.61 (0.94) g/dL for darbepoetin alfa-treated patients.

- ***Key Secondary Efficacy Endpoint Result***: Vadadustat sustained the target Hb efficacy response at weeks 40 to 52 achieving non-inferiority compared to darbepoetin alfa. The least square mean difference in Hb was -0.07 g/dL (95% CI: -0.34, 0.19). The mean (SD) Hb level at week 40 to week 52 was 10.51 (1.19) g/dL for vadadustat treated-patients compared to 10.55 (1.14) g/dL for darbepoetin alfa-treated patients.

In $INNO_2VATE$'s *Conversion* study of dialysis patients (n=3,554):

- ***Primary Efficacy Endpoint Result***: Vadadustat was *non-inferior* to darbepoetin alfa. The least square mean difference in Hb was -0.17 g/dL (95% CI: -0.23, -0.10), achieving the pre-specified non-inferiority criterion of -0.75 g/dL. The mean (SD) Hb level at week 24 to week 36 was 10.36 (1.01) g/dL for vadadustat-treated patients compared to 10.53 (0.96) g/dL for darbepoetin alfa-treated patients.
- ***Key Secondary Efficacy Endpoint Result***: Vadadustat sustained efficacy in the *Conversion* study demonstrating non-inferiority to darbepoetin with a least square mean difference in Hb of -0.18 g/dL (95% CI: -0.25, -0.12). The mean (SD) Hb level at week 40 to week 52 was 10.40 (1.04) g/dL in the vadadustat-treated patients compared to 10.58 (0.98) g/dL for darbepoetin treated patients.

Primary Safety Major Adverse Cardiovascular Events (MACE) Endpoint Result

Vadadustat achieved the $INNO_2VATE$ program's primary safety endpoint of non-inferiority for MACE. In the primary analysis of time to first MACE event, vadadustat demonstrated non-inferiority to darbepoetin alfa using a non-inferiority margin of 1.25 prospectively agreed to by FDA and a non-inferiority margin of 1.3 prospectively agreed to by EMA.

The $INNO_2VATE$ program (*Correction/Conversion* and *Conversion* studies) of dialysis patients (n=3,902):

- Vadadustat was *non-inferior* to darbepoetin alfa. The upper bound of the 95% confidence interval (CI) of the Hazard Ratio (HR) was below the pre-specified non-inferiority margin of 1.25 for primary MACE analysis (HR 0.96, 95% CI: 0.83, 1.11.). MACE is defined as the composite endpoint of all-cause mortality, non-fatal myocardial infarction, or non-fatal stroke.

The incidence of treatment emergent adverse events during the *Correction/Conversion* study in vadadustat treated patients was 83.8% and 85.5 % in darbepoetin alfa treated patients. During the study, the most common treatment emergent adverse events reported in vadadustat/darbepoetin alfa treated patients were hypertension (16.2%/ 12.9%) and diarrhea (10.1%/ 9.7%). Serious treatment emergent adverse events were lower in vadadustat treated patients at 49.7% compared to 56.5% for darbepoetin alfa treated patients. The incidence of treatment emergent adverse events during the *Conversion* study in the vadadustat treated patients was 88.3%, and 89.3% in darbepoetin alfa treated patients. During the study, the most common treatment emergent adverse events reported in vadadustat/darbepoetin alfa treated patients were diarrhea (13.0%/ 10.1%), pneumonia (11.0%/ 9.7%), hypertension (10.6%/ 13.8%), and hyperkalemia (9.0%/ 10.8%). Serious treatment emergent adverse events were slightly lower for vadadustat treated patients at 55.0% and 58.3% for darbepoetin alfa-treated patients.

Regulatory and Commercialization Strategy

We plan to file for regulatory approval in the United States and other regions upon successful completion of the global Phase 3 studies for vadadustat, which includes the PRO_2TECT studies of vadadustat for the treatment of anemia due to CKD in NDD-CKD patients that we expect to read out in mid-2020. In connection with our plan to file for regulatory approval for vadadustat in the United States, we entered into a letter agreement on February 14, 2020, or the Letter Agreement, with Vifor (International) Ltd., or Vifor Pharma, relating to Vifor Pharma's agreement with a third party to purchase a Priority Review Voucher, or the PRV, issued by the FDA subject to satisfaction of customary closing conditions, or the PRV Purchase. A PRV entitles the holder to priority review of a New Drug Application, or NDA, or a Biologics License Application, or BLA, for a new drug, which reduces the target FDA review time to six months after official acceptance of the submission, and could lead to expedited approval. Pursuant to the Letter Agreement, we paid Vifor Pharma $10.0 million in connection with the closing of the PRV Purchase. Vifor Pharma is obligated to retain all rights to, and maintain the validity of, the PRV until we and Vifor Pharma (a) enter into a definitive agreement setting forth the financial and other terms by which Vifor Pharma will assign the PRV to us for use with our planned NDA for vadadustat for the treatment of anemia due to CKD in both DD-CKD and NDD-CKD patients, or (b) make a mutual decision to sell the PRV and share the proceeds based on certain terms.

We plan to commercialize vadadustat, subject to FDA approval, in the United States with our existing nephrology-focused 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 addition, we granted Vifor Pharma an exclusive license to sell vadadustat solely to Fresenius Kidney Care Group LLC, or FKC, which manages approximately

40% of the dialysis patients in the United States, at its U.S. dialysis clinics, and to certain third party dialysis organizations in the United States, approved by us, or Third Party Dialysis Organizations, which account for up to an additional 20% of the dialysis market in the United States. The license granted to Vifor Pharma would be effective upon FDA approval of vadadustat in the DD-CKD indication, the earlier of a determination by the Centers for Medicare & Medicaid Services, or CMS, 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, or TDAPA, and a milestone payment by Vifor Pharma.

Auryxia

We market Auryxia in the United States 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.

Auryxia is our only product approved for sale in the United States and it generated approximately $29.2 million and $23.1 million in revenue from U.S. product sales during the three months ended March 31, 2020 and 2019, respectively. We have funded our operations primarily through equity offerings, strategic collaborations, product revenues and debt.

Operating Overview

We have never been profitable and have incurred net losses in each year since inception. Our net losses were $60.7 million and $72.4 million for the three months ended March 31, 2020 and 2019, respectively. Substantially all of our net losses resulted from costs incurred in connection with 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.

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$_2$TECT and INNO$_2$VATE and other 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 or product candidate, including those that may be in-licensed or acquired;
- continue our integration activities as a result of our merger, or the Merger, with Keryx Biopharmaceuticals, Inc., or Keryx;
- 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 any post-marketing approval studies, Phase 4 studies or any other clinical trials for Auryxia or any other product, including those that may be in-licensed or acquired;
- seek to discover 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 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 the transition from our prior 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 March 31, 2020, we raised approximately $551.3 million of net proceeds from the sale of equity including $377.4 million from various underwritten public offerings, $123.9 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. In addition, on November 11, 2019, we entered into a loan agreement, or the Loan Agreement, with funds managed by Pharmakon Advisors LP, or Pharmakon, pursuant to which term loans in an aggregate principal amount of $100.0 million were made available to us in two tranches, subject to certain terms and conditions, or the Term Loans. On November 25, 2019, we drew down the first tranche of $80.0 million from the Term Loans and received net proceeds of $77.3 million. During the quarter ended March 31, 2020, we raised $56.7 million from ATM offerings. At inception of our collaboration agreements with Otsuka and MTPC, our collaborators committed to an aggregate of 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.

Impacts of COVID-19 Pandemic

The current severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), or COVID-19, pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, patients, customers, collaboration partners, vendors, communities and business operations. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets where the healthcare providers with whom we interact, our partners, our CROs, our contract manufacturing organizations, or CMOs, and our other vendors operate.

To date, we have not experienced any significant adverse impact from COVID-19 on our financial and operational performance and our fundamentals have remained strong. We believe our innovative therapies are critical to dialysis and non-dialysis CKD patients, who are among the most at risk during this pandemic. Continuing to provide and support our therapies is a priority. However, we are continuing to monitor and assess the potential impact of the COVID-19 pandemic on our business and operations, including our sales, supply chain, manufacturing, and clinical trials. We are also mindful of the potential macro-level risks from the impact on the healthcare system to us, our patients, our customers, healthcare providers, our collaboration partners, and our vendors, as well as the potential impact on payer mix.

We have asked all of our office-based employees to work from home since March 13, 2020. In addition, consistent with Centers for Disease Control and Prevention guidance and in accordance with new COVID-19 safety restrictions imposed by many of our customers, we have suspended in-person interactions by our customer-facing personnel with all patients and healthcare providers, including dialysis centers and hospitals. Where possible, we are engaging with healthcare providers and our customers virtually as we seek to continue to support patient care. Given this uncertain environment and the lack of clear visibility, we are actively monitoring the demand for our marketed therapy, including the potential for material declines or changes in prescription trends and in customer orders. While it is possible that we may benefit in the near term if the prior authorization requirement for Auryxia is waived or relaxed consistent with CMS’s guidance for the COVID-19 pandemic, or from any precautionary measures that could be taken by our customers due to the COVID-19 pandemic, such as increasing their levels of stock of Auryxia in anticipation of any supply interruptions from the pandemic, over the longer term, any such advance sales may negatively impact future revenue.

At this time, our third party contract manufacturing partners continue to operate at or near normal levels. While we currently do not anticipate any interruptions in our manufacturing process, we believe that we have inventory to help mitigate the impact should they occur. However, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our contract manufacturing partners' ability to manufacture our marketed product or to have our marketed product reach our markets, which would also impact our inventory reserves.

In terms of our clinical trials, our PRO$_2$TECT studies for vadadustat have advanced significantly and we continue to expect top-line data in mid-2020, as previously disclosed. Our FO$_2$RWARD-2 trial for vadadustat is fully enrolled, and we continue to expect top-line data by year end. COVID-19 precautions are, however, causing a delay in enrolling new clinical trials. We are using remote monitoring and performing remote patient visits, where possible.

Our team has continued to support local and national response efforts to the COVID-19 pandemic by donating supplies and meals to frontline healthcare workers in the Boston area, volunteering to provide medical care at clinics treating COVID-19 patients, and donating to the American Kidney Fund COVID-19 emergency fund to support the needs of kidney patients.

This uncertain COVID-19 environment has presented new risks to our business. While we are working aggressively to mitigate impacts on our business, we are mindful that many of these risks and the impact to the larger healthcare market are outside our control.

For additional information on the various risks posed by the COVID-19 pandemic, please refer to Part II, Item 1A. Risk Factors.

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 United States, 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 and a half 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 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 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 March 31, 2020, we have incurred $1,158.0 million in research and development expenses. We expect to have significant research and development expenditures for the foreseeable future as we continue the development of vadadustat and any other product candidates.

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 for our global Phase 3 clinical program for vadadustat to which the majority of our research and development costs are attributable. A significant portion of our research and development costs have been external costs, which we track on a program-by-program basis. These external costs include fees paid to investigators, consultants, central laboratories and contract research organizations in connection with our clinical trials, and costs related to acquiring and manufacturing clinical trial materials. Our internal research and development costs are primarily personnel-related costs, depreciation and other indirect costs. We do not track our internal research and development expenses on a program-by-program basis as they are deployed across multiple projects under development.

The following table summarizes our external research and development expenses by program, as well as expenses not allocated to programs, for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31, 2020	Three Months Ended March 31, 2019
	(in thousands)	*(in thousands)*
Vadadustat external costs	$ 58,347	$ 66,044
External costs for other programs	3,233	5,492
Total external research and development expenses	61,580	71,536
Headcount, consulting, facilities and other	19,651	10,815
Total research and development expenses	$ 81,231	$ 82,351

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.

Results of Operations

Comparison of the Three Months Ended March 31, 2020 and 2019

	Three Months Ended		Increase (Decrease)
	March 31, 2020	March 31, 2019	
	(In Thousands)		
Revenues:			
Product revenue, net	$ 29,209	$ 23,111	$ 6,098
License, collaboration and other revenue	59,269	49,555	9,714
Total revenues	88,478	72,666	15,812
Cost of goods sold:			
Product	18,613	22,157	(3,544)
Amortization of intangibles	9,100	9,100	—
Total cost of goods sold	27,713	31,257	(3,544)
Operating expenses:			
Research and development	81,231	82,351	(1,120)
Selling, general and administrative	37,983	34,291	3,692
License expense	676	736	(60)
Total operating expenses	119,890	117,378	2,512
Operating loss	(59,125)	(75,969)	(16,844)
Other income (expense), net	(1,622)	791	(2,413)
Net loss before income taxes	(60,747)	(75,178)	(14,431)
Benefit from income taxes	—	(2,757)	(2,757)
Net loss	$ (60,747)	$ (72,421)	$ (11,674)

Product Revenue, Net. Net product revenue is derived from sales of our only commercial product, Auryxia. We distribute our product principally through a limited number of wholesale distributors as well as certain specialty pharmacy providers. Net product revenue was $29.2 million for the three months ended March 31, 2020, compared to net product revenue of $23.1 million for the three months ended March 31,2019. The increase was primarily due to an increase in units sold. We did not experience any significant impact from COVID-19 on net product revenue for the quarter ended March 31, 2020; however, we have no clear visibility on how product demand and payer mix may be impacted in the upcoming weeks and months and therefore, it is not possible to predict whether our future net product revenue will be impacted as a result of COVID-19 going forward.

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 $59.3 million for the three months ended March 31, 2020 compared to $49.6 million for the three months ended March 31, 2019. We recognized $57.9 million in collaboration revenue for the three months ended March 31, 2020 from our cost sharing arrangement under the Otsuka collaboration agreement for the U.S., or the Otsuka U.S. Agreement, and the Otsuka collaboration agreement for certain territories outside the U.S., or the Otsuka International Agreement. We recognized $48.2 million in collaboration revenue for the three months ended March 31, 2019 from our cost sharing arrangement under the Otsuka U.S. Agreement and the Otsuka International Agreement. The increase in revenue between the two periods was attributable to an additional $9.8 million of revenue recognized under both the Otsuka U.S. Agreement and Otsuka International Agreement. We expect our collaboration revenue to decrease in the near term because our top-line data from our INNO$_2$VATE studies have been reported, and our PRO$_2$TECT studies are nearing completion.

Cost of Goods Sold - Product. Cost of goods sold of $18.6 million for the three months ended March 31, 2020 consists primarily of costs associated with the manufacturing of Auryxia and a $11.2 million charge related to the fair-value inventory step-up from the application of purchase accounting. Cost of goods sold of $22.2 million for the three months ended March 31, 2019 consisted primarily of costs associated with the manufacturing of Auryxia and a $14.6 million charge related to the fair-value inventory step-up from the application of purchase accounting. This decrease as compared to the three months ended March 31, 2019 was due to a decrease in the fair-value inventory step-up charge.

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 nine years using a straight-line method. Amortization of intangibles for each of the three months ended March 31, 2020 and 2019 was $9.1 million.

Research and Development Expenses. Research and development expenses were $81.2 million for the three months ended March 31, 2020, compared to $82.4 million for the three months ended March 31, 2019, a decrease of $1.2 million. The decrease was primarily due to the following:

	(in millions)
Vadadustat development expenses	$ (7.7)
Headcount, consulting and facilities	8.4
Other research and development	(1.9)
Total net increase	$ (1.2)

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_2TECT Phase 3 program, for which we completed enrollment in the third quarter of 2019, and the $INNO_2$VATE Phase 3 program, for which we reported top-line data in the second quarter of 2020. 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. The decreases in vadadustat research and development expenses, as well as other research and development expenses, were offset by an increase in headcount and consulting costs to support our research and development programs. Although we expect our research and development expenses in 2020 to decrease because top-line data from our $INNO_2$VATE studies were reported in the second quarter of 2020, and as PRO_2TECT nears top-line data readout, we will 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 $38.0 million for the three months ended March 31, 2020, compared to $34.3 million for the three months ended March 31, 2019. The increase of $3.7 million was primarily due to increases in headcount and consulting costs. In 2020, we expect our selling, general and administrative expenses for our ongoing commercialization of Auryxia and for support of our ongoing research and development and potential commercialization of vadadustat and other product candidates to be relatively consistent with 2019.

License Expenses. License expense related to royalties due to Auryxia relating to sales of Riona in Japan were $0.7 million for each of the three months ended March 31, 2020 and 2019, respectively.

Other Expense, Net. Other expense, net, was $1.6 million for the three months ended March 31, 2020 compared to other income, net of $0.8 million for the three months ended March 31, 2019. The change to other expense, net was primarily due to interest expense associated with our Term Loans in the three months ended March 31, 2020. We did not have similar expenses during the three months ended March 31, 2019. Other income, net for the three months ended March 31, 2019 was primarily due to interest income on our investments.

Benefit from Income Taxes. There was no benefit from income taxes for the three months ended March 31, 2020. Benefit from income taxes was $2.8 million for the three months ended March 31, 2019 due to a decrease in our net deferred tax liabilities, or DTLs. During the three months ended March 31, 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 March 31, 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 March 31, 2020, we had an accumulated deficit of $854.8 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 expect to raise through public or private equity or debt

transactions, payments from our collaborators, royalty transactions, strategic transactions, or a combination of these approaches. Given the impact from COVID-19 on the U.S. economy and financial markets, there can be no assurance that additional funding will be available on terms acceptable to us, or at all.

We have funded our operations principally through sales of our common stock, payments received from our collaboration partners, debt, and following the Merger, product sales. As of March 31, 2020, we had cash and cash equivalents and available for sale securities of approximately $115.4 million and accounts receivable of $104.9 million. The reduction in cash, cash equivalents and available for sale securities by $32.3 million from December 31, 2019 is primarily due to timing of cash receipts from our collaboration partner, Otsuka, for which $49.5 million was received in April 2020 rather than March 2020. 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:

	Three Months Ended	
	March 31, 2020	**March 31, 2019**
	(In Thousands)	
Net cash provided by (used in):		
Operating activities	$ (89,589)	$ (137,929)
Investing activities	245	110,473
Financing activities	57,348	(14,447)
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (31,996)	$ (41,903)

Operating Activities. Net cash used in operating activities of $89.6 million for the three months ended March 31, 2020 was largely driven by timing of payments on our Phase 3 development program for vadadustat and payments for inventory. These payments were partially offset by adjustments for non-cash items, including the fair value write-up of inventory sold of $11.2 million, amortization of intangibles of $9.1 million, and stock-based compensation expense of $4.9 million.

Net cash used in operating activities of $137.9 million for the three months ended March 31, 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 $14.6 million, amortization of intangibles of $9.1 million, and stock-based compensation expense of $2.1 million.

Investing Activities. Net cash provided by investing activities for the three months ended March 31, 2020 was $0.2 million and was comprised entirely of proceeds from the maturities of available for sale securities.

Net cash provided by investing activities for the three months ended March 31, 2019 was $110.5 million and was comprised primarily of proceeds from the maturities of available for sale securities of $78.7 million and proceeds from the sales of available for sale securities of $33.7 million, partially offset by purchases of equipment of $1.9 million.

Financing Activities. Net cash provided by financing activities for the three months ended March 31, 2020 was $57.3 million and consisted primarily of proceeds from the public issuance of common stock of $56.5 million, proceeds from the exercise of stock options and proceeds from the sale of stock under our employee stock purchase plan.

Net cash used in financing activities for the three months ended March 31, 2019 was $14.4 million and consisted primarily of payments on loans payable of $15.0 million, partially offset by proceeds from the exercise of stock options and proceeds from the sale of stock under our employee stock purchase plan.

Operating Capital Requirements

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.

As of March 31, 2020, we had cash, cash equivalents and available for sale securities of $115.4 million and accounts receivable of $104.9 million. At the inception of our collaboration agreements with Otsuka and MTPC, our collaborators committed to an aggregate of approximately $573.0 million or more in cost-share funding, of which we received approximately $272.0 million at the onset of the collaborations, and the remainder of which we generally continue to receive on a quarterly prepaid basis, and through license payments. We expect our cash resources and the receipt of a $15.0 million regulatory milestone from MTPC, assuming approval of vadadustat in Japan, to fund our current operating plan well into 2021.

We will require additional capital for the development and potential commercialization of our existing product candidates, further commercialization of Auryxia and would 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, which commenced 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 28, 2023. The total monthly lease payments under the base rent are approximately $136,000 and are subject to annual rent escalations.

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 28, 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, Akebia, with Keryx as guarantor, entered into a loan agreement, or the Loan Agreement, with BioPharma Credit PLC as collateral agent and a lender, or the Collateral Agent, and BioPharma Credit Investments V (Master) LP as a lender, collectively with the Collateral Agent, Pharmakon, pursuant to which term loans in an aggregate principal amount of $100.0 million were made available to us in two tranches, subject to certain terms and conditions, or the Term Loans. The first tranche of $80.0 million, or Tranche A, was drawn 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, subject to the satisfaction of customary conditions. 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. We and Keryx entered 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 are unconditionally guaranteed by Keryx, or the Guarantee. Additionally, our and Keryx's obligations under the Term Loans and the Guarantee are 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 paid to Pharmakon a facility fee equal to 2.00% of the aggregate principal amount of the Term Loans, or $2.0 million, in addition to other expenses incurred by Pharmakon and reimbursed by us, or Lender Expenses. The Tranche A draw was $77.3 million, net of facility fee, Lender Expenses and issuance costs. 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. Under certain circumstances, a default interest rate will apply on all outstanding obligations during the occurrence and continuance of an event of default. As of March 31, 2020, we determined that no events of default had occurred.

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

Manufacturing Agreements

As a result of the Merger, our contractual obligations 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 Manufacture and Supply Agreement with BioVectra and the Product Manufacture and Supply and Facility Construction Agreement with BioVectra, 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 March 31, 2020, we are required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $135.3 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 March 31, 2020, we recorded $0.9 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 March 31, 2020, we are required to purchase a minimum quantity of drug substance for Auryxia annually at a total cost of approximately $53.3 million through the year ended December 31, 2021.

On April 9, 2019, we entered into a Supply Agreement with Esteve Química, S.A., or Esteve, or the Esteve Agreement. The Esteve Agreement includes the terms and conditions under which Esteve will manufacture vadadustat drug substance, or API, for commercial use.

Pursuant to the Esteve Agreement, we will provide rolling forecasts to Esteve on a quarterly basis, or the Forecast. The Forecast will reflect our needs for API produced by Esteve over a certain number of months, represented as a quantity of API per calendar quarter. The parties have agreed to a volume-based pricing structure under the Esteve Agreement. The Esteve Agreement has an initial term of four years, beginning April 9, 2019 and ending April 9, 2023. As of March 31, 2020, we had a minimum commitment with Esteve for $6.0 million through the first quarter of 2021. Subsequent to March 31, 2020, our minimum commitment with Esteve increased to $13.6 million through the second quarter of 2021.

On March 11, 2020, we entered into a Supply Agreement with Patheon Inc., or Patheon, or the Patheon Agreement. The Patheon Agreement includes the terms and conditions under which Patheon will manufacture vadadustat drug product for commercial use. Additionally, on April 2, 2020, we entered into a Supply Agreement with STA Pharmaceutical Hong Kong Limited, a subsidiary of Wuxi AppTec, or WuXi STA, or the WuXi STA Agreement. The WuXi STA Agreement includes the terms and conditions under which WuXi STA will manufacture vadadustat API for commercial use. There were no minimum commitments under either supply agreement as of March 31, 2020.

Other Third Party Contracts

Under our agreement with IQVIA to provide contract research organization services for the PRO_2TECT and $INNO_2VATE$ programs, the total remaining contract costs as of March 31, 2020 were approximately $41.1 million, of which Otsuka reimburses a significant portion back to us. 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 $67.4 million as of March 31, 2020. 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 March 31, 2020, 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 three months ended March 31, 2020, there were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K.

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 March 31, 2020 and December 31, 2019, we had cash and cash equivalents and available for sale securities of $115.4 million and $147.7 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.

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 March 31, 2020, 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. Based on our evaluation, our management concluded that, as of March 31, 2020, our disclosure controls and procedures were not effective because our internal controls over financial reporting were not adequate due to the material weakness described below.

During the fourth quarter of fiscal 2019, we identified a material weakness in our internal control over financial reporting related to our inventory process. Specifically, we did not design and maintain effective controls over the completeness, accuracy, presentation and disclosure of inventory related to (i) the review of inventory unit and valuation reconciliations, (ii) the annual validation of the inventory costing and (iii) the periodic assessment of inventory expiry and related reserves.

During fiscal 2020, we are enhancing our system of internal controls over financial reporting to remediate the material weakness described above with the following remediation efforts: (i) providing training to individuals with internal control responsibilities including review documentation requirements, (ii) evaluating alignment of resources and enhanced management review and monitoring inventory controls, (iii) reviewing current inventory process and procedures to identify opportunities to enhance their design and operation and (iv) designing controls that address the completeness and accuracy of any key reports utilized in the execution of internal controls. We will also be performing control testing throughout the year to validate the operating effectiveness of internal controls over financial reporting to gain assurance that such controls are present and functioning as designed.

As the revised and enhanced controls need to be in operation for a sufficient period of time and be tested to ensure that the controls are operating as designed, management has concluded that the material weakness cannot be considered remediated as of March 31, 2020.

Changes in Internal Control over Financial Reporting

During the quarter ended March 31, 2020, we implemented certain internal controls in connection with our remediation efforts described above. There have been no other 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.

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 European Patent Office, or 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 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 chronic kidney disease, or 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. An oral proceeding for the appeal is scheduled for July 2020.

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. An oral proceeding for the appeal is scheduled for July 2020.

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. An oral proceeding for the appeal is scheduled for July 2020.

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 November 11, 2019, the JPO conducted an invalidation trial for JP5474741. On February 10, 2020, the JPO issued a pre-notice of a trial decision for JP4845728, which invalidated all claims except two claims in amended form. On March 11, 2020, the JPO issued a pre-notice of a trial decision for JP5474872, which invalidated all claims except one claim in amended form. On April 2, 2020, the JPO issued a pre-notice of a trial decision for JP5474741, which invalidated all claims except two claims in amended form. We do not believe these decisions will prevent our collaboration partner MTPC from launching vadadustat for the treatment of anemia due to CKD in Japan.

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’s six HIF-related patents in the UK: the ’823 EP Patent (UK), the ’333 EP Patent (UK), the ’153 EP Patent (UK), the ’155 EP Patent (UK), European Patent (UK) No. 2,289,531, or the ’531 EP Patent (UK), and European Patent (UK) No. 2,298,301, or the ’301 EP Patent (UK). In May 2019, Astellas Pharma Inc., or Astellas, the exclusive licensee of FibroGen’s HIF-related patents, sued Akebia and Otsuka 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). On February 28, 2020, the parties agreed to dismiss the ’472 EP Patent (UK) from the trial.

A trial was conducted on March 2-19, 2020. On April 20, 2020, the Patents Court of the UK issued a judgment in favor of Akebia, which invalidated all the claims at issue in each of the ’823 EP Patent (UK), the ’333 EP Patent (UK), the ’153 EP Patent (UK), the ’155 EP Patent (UK) and the ’301 EP Patent (UK). The ’531 EP Patent (UK) was amended to a single claim to recite one specific compound; this claim was held to be valid but not infringed by vadadustat.

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 United States District Court for the District of Delaware, or 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 the Teva Defendants, 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 April 27, 2020, the Delaware District Court conducted a Markman hearing concerning certain claim construction issues with respect to four Orange Book-listed patents, and issued an order in favor of Keryx.

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 terminate the actions against Par.

On April 30, 2020, Keryx and Panion entered into a settlement and license agreement with Teva and Watson resolving patent litigation brought by Keryx and Panion in response to Teva and Watson's ANDAs 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 Teva and Watson 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 Watson and Teva regarding Auryxia patents pending in the Delaware District Court. The settlement and license agreement is confidential and subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice. On May 4, 2020, the Delaware District Court entered a stipulation and order of dismissal filed by the parties to terminate the action against Teva and Watson.

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 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. On February 4, 2020, the court denied our request for a preliminary injunction. We filed an expedited appeal with the Court of Appeals for the First Circuit challenging the district court's denial of our motion for a preliminary injunction. The appeal is currently pending.

Shareholder Litigation Relating to Auryxia Supply

Four putative class action lawsuits were filed against Keryx Biopharmaceuticals, Inc., or 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 Securities Exchange Act of 1934, as amended, or 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, which is currently pending.

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.

Other Matters

On June 28, 2018, we entered into an Agreement and Plan of Merger with Keryx and Alpha Therapeutics Merger Sub, Inc., or the Merger Sub, pursuant to which the Merger Sub 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), 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 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 alleged 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 related 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 sought 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 and with prejudice on August 2, 2019. On April 15, 2020, the Delaware District Court granted the defendants' motion and dismissed the Consolidated Action in its entirety.

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.

We deny any allegations of wrongdoing and intend to continue vigorously defending against the shareholder lawsuits described in this Legal Proceedings 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.

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 the COVID-19 Pandemic

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

Since being reported in 2019, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), or COVID-19, has spread to every state in the United States and to multiple countries, including those in which our patients reside and in which we, the healthcare providers with whom we interact, our partners, our contract research organizations, or CROs, our contract manufacturing organizations, or CMOs, and our other vendors operate. On March 11, 2020, the World Health Organization declared COVID-19 a pandemic. The pandemic has had adverse effects on financial markets, general commercial activity and the world economy.

In response to the pandemic, on March 13, 2020, the United States declared a national emergency, and federal, state, local and foreign governments have put in place, quarantines, executive orders, shelter-in-place orders and other restrictions in order to control the spread of the disease. Such orders or restrictions, or the perception that such orders or restrictions could occur, have resulted in business closures, work stoppages, slowdowns and delays, work-from-home policies, travel restrictions, and cancellation or postponement of events, among other effects that have and may continue to negatively impact productivity and disrupt our operations and those of the healthcare providers with whom we interact, our partners, our CROs, our CMOs and our other vendors. We have asked all of our office-based employees to work remotely. We have also asked all of our customer-facing employees, including the members of our sales force, to suspend in-person interactions with patients and healthcare providers, including dialysis centers and hospitals, and instead, connect with customers virtually wherever possible. Furthermore, healthcare facilities have restricted access for non-patients, including the members of our sales force. While most of our office-based operations can be performed remotely, there is

no guarantee that we will be as effective while working remotely because our team is dispersed, many employees may have additional personal needs to attend to (such as looking after children as a result of school closures or family members who may become sick), and employees may become sick themselves and be unable to work. Further, our increased reliance on remote access to our information systems increases our exposure to potential cybersecurity breaches.

Although we may benefit in the near term if the prior authorization requirement for Auryxia is waived or relaxed consistent with Centers for Medicare & Medicaid Services', or CMS's, guidance for the COVID-19 pandemic, or from any precautionary measures taken by our customers due to the COVID-19 pandemic, such as increasing their levels of stock of Auryxia in anticipation of any further interruptions from the pandemic, the inability of our customer-facing employees to have in-person interactions with patients and healthcare providers could negatively impact our access to healthcare providers and, ultimately, our sales.

Moreover, our future success and profitability substantially depends on the management skills of our executives and certain other key employees. The unanticipated loss or unavailability of key employees due to the pandemic could harm our ability to operate our business or execute our business strategy. We may not be successful in finding and integrating suitable successors in the event of key employee loss or unavailability.

In addition, the pandemic may result in disruptions to or closures of CMO facilities and other vendors in our supply chain on which we rely for the supply of our product and product candidates, which could lead to delays or disruptions in supply and an increase in inventory write-offs due to expiry. Although we continue to expect the top-line data readouts of our PRO_2TECT studies in mid-2020 as previously disclosed, the pandemic has resulted in closures of clinical trial sites on which we rely for the completion of certain other clinical trials and may delay enrollment of certain planned and ongoing clinical trials. Further, the pandemic could also potentially affect the business of the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or the EMA, the Japanese Pharmaceuticals and Medical Devices Agency, or the PMDA, or other health authorities, which could result in delays in meetings, reviews and approvals relating to our product candidates. Any decision by the FDA, EMA, PMDA or other health authorities to delay meeting with us or our collaboration partners in light of COVID-19 could have a material adverse effect on clinical trials of our product candidates or on our efforts to obtain marketing approvals for our product candidates, which could increase our operating expenses and have a material adverse effect on our financial results, including the timing and amount of future regulatory milestones we could receive from our partners.

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

The pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, that could impact our ability to raise additional funds and has also impacted, and may continue to impact, the volatility of our stock price and trading in our stock. Moreover, it is possible the pandemic will significantly impact economies worldwide, which could result in adverse effects on our business and operations. Even after the COVID-19 pandemic has been contained or mitigated, we may continue to experience adverse impacts to our business as a result of any economic recession or depression that has occurred or may occur in the future.

The global impact of COVID-19 continues to rapidly evolve, and we will continue to monitor the situation closely. In particular, areas we are monitoring include possible changes in our commercial revenue payer mix, change in overall product sales, possible changes in reserves and allowances, and negative trends that could indicate goodwill and intangible assets to be impaired. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

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, or the Merger, whereby Keryx Biopharmaceuticals, Inc., or Keryx, became a wholly owned subsidiary of ours, commercialization. We have financed our operations primarily through sales of equity securities, our strategic collaborations and, following the Merger, product revenues and debt. 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 $60.7 million for the three months ended March 31, 2020. As of March 31, 2020, we had an accumulated deficit of $854.8 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 marketing approvals for our product candidates after completion of clinical studies and the timing of such approvals, and maintaining marketing approvals for Auryxia or any other product;
- 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, if approved, 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;
- the size of any market in which Auryxia, vadadustat and any other product or product candidate, including those that may be in-licensed or acquired, receives approval and obtaining adequate market share in those markets;
- addressing any competing products;
- identifying, assessing, acquiring, in-licensing 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 other 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 or product candidate, including those that may be in-licensed or acquired;

- 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 any post-marketing approval studies, Phase 4 studies or any other clinical trials for Auryxia or any other product, including those that may be in-licensed or acquired;
- seek to discover 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 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 the transition from our prior 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 our legal proceedings, as described under Part II, Item 1. Legal Proceedings, or any other such legal proceedings brought by or against us in the future.

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

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 products or product candidates that may receive marketing approval, including those that may be in-licensed or acquired. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Our expenses could increase beyond expectations if we are required by the FDA, the 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 commercialization. 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 products or product candidates that may be approved in the future, including those that may be in-licensed or acquired, 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.

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 March 31, 2020, our cash and cash equivalents and available for sale securities were $115.4 million. We expect to continue to expend substantial amounts for the foreseeable future continuing the commercialization of Auryxia and developing and commercializing vadadustat, if approved, and any other products or product candidates, including those that may be in-licensed or acquired. 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 March 31, 2020, we expect the remaining external aggregate contract research organization, or CRO, costs of PRO_2TECT and $INNO_2$VATE, which have enrolled 7,436 patients, to be in the range of $45.0 million to $60.0 million; the estimated costs for PRO_2TECT could increase significantly due to a number of factors, including 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; we reported top-line data for the $INNO_2$VATE studies in the second quarter of 2020, and we continue to incur costs to close out the program;
- the cost and timing of commercialization activities for Auryxia, vadadustat and any other products or product candidates, including those that may be in-licensed or acquired, 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 or any other product, including those that may be in-licensed or acquired;
- the cost of conducting clinical studies or any post-marketing approval studies, Phase 4 studies or any other clinical trials for Auryxia;
- the outcome of our efforts to obtain marketing approval for vadadustat in the United States, Europe and in other jurisdictions and any other product candidates, including those that may be in-licensed or acquired;
- 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 products or product candidates, including those that may be in-licensed or acquired;
- the cost of securing and validating commercial manufacturing of vadadustat and any other product candidates, including those that may be in-licensed or acquired, and maintaining our manufacturing arrangements for Auryxia or any other products, including those that may be in-licensed or acquired, or securing and validating additional arrangements;
- the costs involved in preparing, filing and prosecuting patent applications and maintaining, defending and enforcing our intellectual property rights, including litigation costs, and the outcome of such litigation;
- the costs involved in any legal proceedings to which we are a party;
- 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 the transition from our prior 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 and the receipt of a $15.0 million regulatory milestone from MTPC, assuming approval of vadadustat in Japan, to fund our current operating plan well into 2021. We have based these estimates on assumptions that may prove to be wrong due to a variety of factors, including due to the effects of the COVID-19 pandemic, 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.

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 products or 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 products or 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.

We entered into a loan agreement, or the Loan Agreement, with Pharmakon, pursuant to which term loans in an aggregate principal amount of $100.0 million, or the Term Loans, were made available to us in two tranches. The first tranche of $80 million closed on November 25, 2019, and we have the option to draw down the second tranche of $20.0 million on or before December 31, 2020, subject to the satisfaction of customary conditions. See Note 11 to our unaudited condensed consolidated financial statements in Part I, Item 1. Financial Statements (unaudited) for additional information regarding our obligations under the Loan Agreement. 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 these covenants 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 of the Term Loans, 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 us to prepay the principal amount outstanding, the applicable prepayment premium and make-whole premium and accrued and unpaid interest.

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

- restricting our activities, including limitations on transferring certain of our assets, engaging in certain transactions, 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 a smaller amount of debt or competitors with comparable debt at more favorable interest rates; and
- limiting our ability to borrow additional amounts for working capital, capital expenditures, research and development efforts, acquisitions, debt service requirements, execution of our business strategy and other purposes.

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

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 products or 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 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 the Merger. 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 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 was a putative class action lawsuit filed by purported Keryx shareholders challenging the disclosures made in connection with the Merger, which was dismissed in April 2020. In addition, a stockholder of Keryx filed a complaint against Keryx pursuant to Section 220 of the Delaware General Corporation Law, which 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). 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.

As of March 31, 2020, we had approximately $337.2 million of goodwill and definite lived intangible assets from the Merger. Our definite lived intangible assets are amortized over their estimated useful lives. In accordance with generally accepted accounting principles, or GAAP, we are required annually, or more frequently upon certain indicators of impairment, to review our estimates and assumptions underlying the fair value of our goodwill and our definite lived intangible assets when indicators of impairment are present. Conditions that could indicate impairment and necessitate such a review include, but are not limited to, Auryxia's commercial performance, our inability to execute on our strategic initiatives, and the deterioration of our market capitalization such that it is

significantly below our net book value. To the extent we conclude that goodwill and/or definite lived intangible assets have become impaired, we may be required to incur material write-offs relating to such impairment and any such write-offs could have a material impact on our future operating results and financial position.

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 or 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 and complications 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 the product;
- the success of our physician and patient communications and education programs;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety and efficacy of the product in relation to alternative treatments;
- the timing of receipt of marketing approvals and product launch relative to competing products and potential generic entrants;
- relative convenience and ease of administration;
- the 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 the product 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, or NDA, 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 settlement and license agreements with certain such ANDA filers. See Part II, Item 1. Legal Proceedings for further information relating to the ANDAs, lawsuits and settlements. Although the United States District Court for the District of Delaware conducted a Markman hearing concerning certain claim construction issues with respect to four Orange Book-listed patents, and issued an order in favor of Keryx, we may not ultimately be successful in the ANDA litigation. 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, vadadustat or any other products or product candidates, if 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 or are unable to do so on terms that are favorable to us, we will not be successful in commercializing Auryxia, vadadustat, or any other product or product candidates.

Coverage and reimbursement may be limited or unavailable in certain market segments for Auryxia, vadadustat, or any other products or 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 depends significantly on the availability of adequate coverage and reimbursement from third party payors and may be affected by existing and future healthcare reform measures. Government authorities, third party payors, and pharmacy benefit managers, or PBMs, decide which drugs they will cover, as well as establish formularies or implement other mechanisms to manage utilization of products and determine reimbursement levels. Coverage and reimbursement by a third-party payor or PBM may depend upon a number of factors, including the determination that use of a product is:

- a covered benefit under the health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient; and
- cost effective.

Obtaining coverage and reimbursement approval for a product from a 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, and the timing of commencement of reimbursement by a government payor is dependent on the assignment of codes via the Healthcare Common Procedure Coding System, which codes are assigned on a quarterly basis. Within Medicare, for oral drugs dispensed by pharmacies and also administered in facilities, coverage and reimbursement may vary depending on the setting. The Centers for Medicare & Medicaid Services, or CMS, local Medicare administrative contractors, Medicare Part D plans and/or PBMs operating on behalf of Medicare Part D plans, may have some responsibility for determining the medical necessity of such drugs, and therefore coverage, for different patients. Different reimbursement methodologies may apply, and CMS may have some discretion in interpreting their application in certain settings.

As an oral drug, Auryxia is covered by Medicare 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 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, or HHS, challenging CMS's decision that Auryxia would no longer be covered by Medicare for the IDA Indication and CMS's related decision that imposed the prior authorization requirement for Auryxia in the Hyperphosphatemia Indication. On February 4, 2020, the court denied our request for a preliminary injunction. We filed an expedited appeal with the Court of Appeals for the First Circuit challenging the district court's denial of our motion for a preliminary injunction. The appeal is currently pending. 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 and/or PBMs 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 PBMs, or provide data sufficient to obtain favorable coverage and reimbursement for many reasons, including that we may be at a competitive disadvantage relative to companies with more extensive product lines. In addition, third party payors, PBMs and other entities that purchase our products may impose restrictions on our ability to raise prices for our products over time without incurring additional costs. We cannot be sure that coverage or adequate reimbursement will be available for our product or any of our potential future products. 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 product. If reimbursement is not available or is limited, we may not be able to commercialize certain of our products.

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

As disclosed in our Annual Report on Form 10-K for the year ended December 31, 2019, we had four distributors, 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, 2019. If we are not able to maintain our contracts with these key distributors on favorable terms, on a timely basis or at all, or if there is any adverse change in one or more of these distributors' business practices or financial condition, or such distributors' end users' prescribing practices or clinical protocols, it would adversely impact the market opportunity for Auryxia, our product 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 distributors, 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 a vast majority 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 would 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, if approved, will be reimbursed using the TDAPA followed by reimbursement via the bundled reimbursement model, if vadadustat is neither reimbursed under the TDAPA nor the bundled reimbursement model, 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 or eligibility criteria 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.

The successful commercialization of Auryxia, vadadustat or any other products or product candidates, if approved, will depend in part on the extent to which third party payors and government authorities establish adequate reimbursement levels and pricing policies.

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.

Cost control initiatives may decrease coverage and payment levels for any drug and, in turn, the price that we will be able to charge and/or the volume of our sales. Certain third party payors require prior authorization for, or even refuse to provide, reimbursement for Auryxia, and others may do so in the future with respect to Auryxia, vadadustat and any of our other products or product candidates. In addition, certain third party payors require some form of prior authorization for the administration of ESAs for the treatment of anemia due to CKD within the non-dialysis patient population, and a similar prior authorization may be applicable to the HIF-PHI class for the treatment of anemia due to CKD within the non-dialysis patient population. Our business would be materially adversely affected if we are not able to receive approval for reimbursement from third party payors on a broad, timely or satisfactory basis; if reimbursement is subject to overly broad or restrictive prior authorization requirements; or if reimbursement is not maintained at satisfactory levels or becomes subject to prior authorization. We are unable to predict all changes to the coverage or reimbursement methodologies that will be applied by private or government payors.

In addition, 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.

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 Ibsrela® (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 intravenous iron formulations, including Feraheme® (ferumoxytol injection), Venofer® (iron sucrose injection), Ferrlicit® (sodium ferric gluconate complex in sucrose injection), Injectafer® (ferric carboxymaltose injection), and Triferic® (ferric pyrophosphate citrate).

In addition, other new therapies for the treatment of IDA may impact the market for Auryxia, such as Shield Therapeutics' Feraccru® (ferric maltol), which is available in Europe for IDA and Accrufer® (ferric maltol), which is approved in the United States for IDA.

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 and complications of the 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. The product has launched for the treatment of anemia of CKD in patients on dialysis, or DD-CKD, in Japan and both DD-CKD and for the treatment of anemia of CKD in patients not on dialysis, or NDD-CKD, in China. In January 2020, FibroGen announced the submission of an sNDA for marketing approval for roxadustat for NDD-CKD in Japan. FibroGen announced that the FDA has completed its filing review of its NDA for roxadustat for both DD-CKD and NDD-CKD and set a Prescription Drug User Fee Act date of December 20, 2020. They have stated they expect Astellas to file a marketing authorization application in the European Union, or MAA, for both indications in the second quarter of 2020. 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. GlaxoSmithKline plc and Japan Tobacco International have submitted NDAs for their product candidates for the treatment of renal anemia in Japan. 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 and our current and potential future efforts with respect to the development and commercialization of our products and product candidates outside of the United States subject us to a variety of risks associated with international operations, which could materially adversely affect our business.

Our Japanese sublicensee, 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. 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 healthcare 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 may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third party contractors, such as our CROs, may fail to comply with regulatory requirements, perform effectively, or meet their contractual obligations to us in a timely manner, or at all, or we may fail to communicate effectively or provide the appropriate level of oversight of such third party contractors;
- the supply or quality of our starting materials, drug substance and drug product necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;

- regulators, independent data monitoring committees, or IDMCs, institutional review boards, or IRBs, safety committees, or ethics committees, may require that we suspend or terminate our clinical trials for various reasons, including noncompliance with regulatory requirements, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using our product candidate, or a finding that the participants are being exposed to unacceptable health risks;
- clinical trials of our product candidates may produce negative or inconclusive results, 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 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 patients complete a clinical trial or return for post-treatment follow-up;
- delay or failure in recruiting and enrolling suitable patients 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, good clinical practice, or GCP, and current good manufacturing practice, or cGMP; or
- changes in governmental regulations or administrative actions.

Although we continue to expect the top-line data readouts of our PRO_2TECT studies in mid-2020 as previously disclosed, the COVID-19 pandemic has resulted in closures of clinical trial sites on which we rely for the completion of certain other clinical trials and may delay enrollment of certain planned and ongoing clinical trials.

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.

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 because of concerns about adverse events observed with the current standard of care, competitor products and/or other investigational agents, in each case for the same indications and/or similar patient populations. In addition, patients currently receiving treatment with the current standard of care or a competitor product may be reluctant to participate in a clinical trial with an investigational drug. Finally, competition for clinical trial sites may limit our access to patients appropriate for studies of vadadustat and any other product candidates. As a result, the timeline for recruiting patients and conducting studies may be delayed. These delays could result in increased costs, delays in advancing our development of our 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 patients and will treat patients 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. For example, our positive INNO$_2$VATE Phase 3 data do not ensure that PRO$_2$TECT will demonstrate similar results. 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 any 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 commercial products or product candidates in development that utilize a common mechanism of action could cause us or regulatory authorities to interrupt, delay or halt clinical trials, could result in a more restrictive label or the delay, denial or withdrawal of marketing approval by the FDA or other regulatory authorities, and could lead to potential product liability claims. 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 any 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 any other products or product candidates, could substantially increase our costs, and could significantly impact our ability to successfully commercialize Auryxia, vadadustat or any other products and product candidates and generate revenues.

The patient populations treated with Auryxia and the patients 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 patients 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 patients 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 any other products or 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 any other products or 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 European Union, commonly referred to as Brexit. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. Under the withdrawal agreement, there is a transitional period until December 31, 2020 (extendable up to two years). Discussions between the United Kingdom and the European Union have so far mainly focused on finalizing withdrawal issues and transition agreements but have been extremely difficult to date. To date, only an outline of a trade agreement has been reached. Much remains open, but the Prime Minister has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption. The Prime Minister has also indicated that the United Kingdom will not accept high regulatory alignment with the European Union.

Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from EU directives and regulations, Brexit could materially impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or the 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 of 2003, or PREA. 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. With regard 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. For example, with regard to the Hyperphosphatemia Indication, we did not complete and submit the post-marketing requirement pediatric clinical study report by December 31, 2019, and we received a notification of noncompliance with PREA. We have requested an extension of this deadline. If we are unable to complete these studies successfully, we will need to inform the FDA, have further discussions, and if the FDA finds that we failed to comply with pediatric study requirements, it could initiate proceedings to seize or enjoin the sale of Auryxia, 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, insurance fraud 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.

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. Furthermore, approval of a drug does not ensure successful commercialization. For example, on September 23, 2015, the European Commission, or EC, approved Fexeric for the control of hyperphosphatemia, in adult patients with CKD. Pursuant to the sunset clause under EU law, the EC's approval of Fexeric in the EU was contingent on, among other things, our commencing marketing of Fexeric within three years; although we successfully negotiated an extension to December 23, 2019, we did not commence marketing Fexeric by such date and therefore the Fexeric approval in the EU has ceased to be valid.

If the results of our global Phase 3 studies for vadadustat are positive, we plan to file for regulatory approval in the United States and other regions. In February 2020, we entered into a letter agreement, or the Letter Agreement, with Vifor Pharma relating to Vifor Pharma's agreement with a third party to purchase a Priority Review Voucher issued by the FDA, or the PRV, subject to satisfaction of customary closing conditions, or the PRV Purchase. Although a PRV entitles the holder to priority review of an NDA or a Biologics License Application for a new drug, which reduces the target FDA review time to six months after official acceptance of the submission, the utilization of a PRV does not ensure a faster review or faster approval compared to products considered for approval under conventional FDA procedures, and in any event does not assure ultimate approval by FDA. Furthermore, even if utilization of the PRV enables a faster approval of vadadustat, it may not result in faster commercialization of vadadustat. For more information on risks related to commercialization of vadadustat, see "Risks Related to Commercialization". In addition, pursuant to the Letter Agreement, we paid Vifor Pharma $10.0 million in connection with the closing of the PRV Purchase. Vifor Pharma is obligated to retain all rights to, and maintain the validity of, the PRV until we and Vifor Pharma (a) enter into a definitive agreement setting forth the financial and other terms by which Vifor Pharma will assign the PRV to us for use with our planned NDA for vadadustat for the treatment of anemia due to CKD in both dialysis-dependent and non-dialysis dependent patients, or (b) make a mutual decision to sell the PRV and share the proceeds based on certain terms. We may not come to terms with Vifor Pharma on assigning the PRV to us, and even if we do, we and Vifor Pharma may decide not to use the PRV for vadadustat and, instead, resell it. In the event of resale of the PRV at a price lower than the purchase price, our share of the proceeds from the resale would be lower than our $10.0 million contribution.

In addition, the safety concerns associated with the current standard of care for the indications for which we are seeking marketing approval for our product candidates may affect the FDA's, the EMA's, the PMDA's or other regulatory authorities' review of the safety results of our compounds in development. 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 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.

Risks Related to Government Regulation and Compliance

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 healthcare 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 healthcare 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, such as the California Consumer Privacy Act, or CCPA, as well as state consumer protection laws;
- federal and state laws requiring the submission of accurate product prices and notifications of price increases;
- federal and state securities laws; 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, enforcement actions by regulatory authorities, 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 any other product we may develop, acquire or in-license 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, the Department of Justice and other regulatory and enforcement authorities enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained, as well as the false advertising or misleading promotion of drugs. In 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 guidance from the FDA, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved drug or unapproved uses of an approved drug. We intend to engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. Although we believe we have put in place a robust compliance program and processes designed to ensure that all such activities are performed in a legal and compliant manner, 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, employees 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.

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

The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which took effect across all member states of the 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 when required, 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 sponsors with clinical trial sites in the EEA by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial patients and investigators. 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 patients 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.

In addition, numerous other federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, and storage of personal information. For example, the CCPA went into effect on January 1, 2020, which creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. Failure to comply with these laws, as well as local laws outside of the U.S. in countries where we are conducting clinical trials, 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 products or 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, and violations of the FD&C Act, the federal government pricing laws, and the federal Anti-Kickback Statute trigger liability under the federal False Claims Act;
- 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 (renamed the Open Payments 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 state Medicaid or other programs, or non-governmental third party payors, including private insurers, and which are not preempted by federal laws and often differ from state to state, thus complicating compliance efforts; and
- U.S. state laws restricting interactions with healthcare providers and other members of the healthcare community or requiring pharmaceutical manufacturers to implement certain compliance standards, which vary from state to state.

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

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

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. One of the potential areas for governmental scrutiny involves federal and state requirements for pharmaceutical manufacturers to submit accurate price reports to the government. Because our processes for calculating applicable government prices and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to risk of errors and differing interpretations. In addition, they are subject to review and challenge by the applicable governmental agencies, or potential qui tam complaints, and it is possible that such reviews could result in changes, recalculations, or defense costs that may have adverse legal or financial consequences. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. 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 other products or 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 2% per fiscal year which will remain in effect through 2029 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, HHS proposed regulatory changes in kidney health policy and reimbursement. Any new legislative or regulatory changes may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for Auryxia or 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. On December 18, 2019, that court affirmed the lower court’s ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. 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.

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 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. In addition, on December 23, 2019, the current administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit importation program proposals to FDA for review and approval. Applicants would be required to demonstrate their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, FDA issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

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 healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products or put pressure on our product pricing.

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

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

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 optimize the commercialization of 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 optimization of the 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$_2$TECT clinical program 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. The loss of these manufacturers, their failure to supply us on a timely basis, or their failure to successfully carry out their contractual duties or comply with regulatory requirements could cause delays in our current and future capacity and substantially harm our business.

We do not have any manufacturing facilities and do not expect to independently manufacture any product or product candidates. We currently rely on third party manufacturers to produce all of our commercial, clinical and preclinical 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. 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.

We currently have two suppliers of Auryxia's drug substance, one of them with two approved sites, 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 that could materially and adversely impact our results of operations. We have entered into supply agreements with Esteve Química, S.A. and STA Pharmaceutical Hong Kong Limited, a subsidiary of Wuxi AppTec, for the manufacture of vadadustat drug substance and Patheon Inc. for the manufacture of vadadustat drug product, each, 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. For example, a contract manufacturer may require a substantial financial commitment, including a commitment to fund the purchase of a new facility or equipment. If we are unsuccessful in implementing redundant supply arrangements for commercial quantities of vadadustat, if our commercial supply arrangements for Auryxia or vadadustat 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 for vadadustat and risk that we would not have sufficient quantities of our product candidates and products for clinical trials and commercialization. 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.

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, PMDA 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 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 manufacture our product and product candidates in sufficient quality and quantity, which would delay or prevent us from commercializing approved products and developing our product candidates.

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 depends 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 any 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.

In addition, 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.

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.

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 to 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.

We may incur losses as a result of unforeseen or catastrophic events, including the emergence of a pandemic, terrorist attacks, extreme weather events or other natural disasters.

The occurrence of unforeseen or catastrophic events, including the emergence of a pandemic, such as COVID-19 discussed above, or other widespread health emergency (or concerns over the possibility of such an emergency), terrorist attacks, extreme terrestrial or solar weather events or other natural disasters, could create economic and financial disruptions, and could lead to operational difficulties that could impair our ability to manage our businesses or result in reduced sales or delays in our clinical studies, which could have a material adverse effect on our financial results. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted, which could have a material adverse effect on our business and our financial results.

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.

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 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 settlement and license agreements with certain such ANDA filers. See Part II, Item 1. Legal Proceedings for further information relating to the ANDAs, lawsuits and settlements.

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, licensees or us that seeks damages or an injunction of commercial activities relating to Auryxia, vadadustat or any other product candidates or other technologies could subject us to monetary liability, a temporary or permanent injunction preventing the development, marketing and sale of such products or such technologies, and/or require our licensor, licensees or us to obtain a license to continue to use such products or other technologies. We cannot predict whether our licensor, licensees or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. 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 United States 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 or our licensees may seek and obtain injunctive or other equitable relief, which could effectively block our or their ability to continue to commercialize Auryxia or further develop and commercialize vadadustat or any other product candidates. 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 and CCPA discussed elsewhere in these risk factors and the privacy or security rules under federal, state, or other local laws outside of the U.S. protecting confidential or personal information, that could be expensive to defend and could result in significant fines or other penalties. 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, inadvertent diversion of cash, 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 negative publicity. 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 including the CCPA, harm our competitive position and delay the further development and commercialization of our products and product candidates, or impact our relationships with 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.

We are conducting global clinical trials in countries where corruption is prevalent, and violations of any of these laws by our personnel or by any of our vendors or agents, such as our CROs or CMOs, could have a material adverse impact on our clinical trials and our business and could result in criminal or civil fines and sanctions. We are subject to complex laws that govern our international business practices. These laws include the FCPA, which prohibits U.S. companies and their intermediaries, such as CROs or CMOs, from making improper payments to foreign government officials for the 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.

The laws and regulations referenced above may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. 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 development 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

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 $2.99 on November 13, 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.

According to the most recent filings made under Section 13(d) and 13(g) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, Baupost Group Securities, L.L.C., or Baupost, beneficially owned approximately 14% 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, pursuant to at-the-market offerings, or otherwise could dilute our stockholders, lower the market price of our common stock and impair our ability to raise capital through the sale of equity securities.

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 March 31, 2020, we believe that our directors and executive officers, together with their affiliates, beneficially owned, in the aggregate, approximately 2% of our outstanding common stock. In addition, we have certain significant stockholders, including Baupost, which beneficially owned approximately 14% of our outstanding common stock according to the most recent filings made under Section 13(d) and 13(g) of the Exchange Act. 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 and after December 31, 2019 when we ceased to 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 have and will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly, especially since, as of December 31, 2019, we are no longer an “emerging growth company” and we therefore may no longer 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 are unable to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act or 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 testing by our independent registered public accounting firm, which became 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. For example, as of December 31, 2019, management and our independent registered public accounting firm concluded that our disclosure controls and procedures were not effective because of a material weakness in our internal control over financial reporting relating to our inventory process. During fiscal 2020, we are enhancing our system of internal controls over financial reporting to remediate this material weakness. As the revised and enhanced controls need to be in operation for a sufficient period of time and be tested to ensure that the controls are operating as designed, management has concluded that the material weakness cannot be considered remediated as of March 31, 2020. Even if this material weakness is remediated, our internal control over financial reporting could in the future have material weaknesses, deficiencies or conditions that could require correction or remediation. 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.

We will need to continue to dedicate internal resources, potentially engage outside consultants and maintain a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to remediate control deficiencies and 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. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner each year, we could be subject to sanctions or investigations by the Securities and Exchange Commission, the Nasdaq Stock Market or other regulatory authorities which would require additional financial and management resources and could adversely affect the market price of our common stock. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

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. In addition, the Tax Cuts and Jobs Act, as amended by the Coronavirus Aid, Relief, and Economic Security Act which was enacted on March 27, 2020, includes changes to U.S. federal tax rates and the rules governing net operating loss carryforwards that may significantly impact our ability to utilize our net operating losses to offset taxable income in the future. Future changes in our stock ownership, many of which are outside of our control, could result in an additional ownership change under Section 382. As a result, if we generate taxable income, our ability to use our pre-change NOL carryforwards to offset federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. At the state level, state net operating losses generated in one state cannot be used to offset income generated in another state and there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Furthermore, our ability to utilize our NOLs is conditioned upon our attaining profitability and generating U.S. taxable income. As described above under "—Risks Related to our Financial Position 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 legal proceedings that could result in substantial costs and divert management's attention, and we could be subject to additional legal proceedings.

We are currently subject to legal proceedings 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 March 31, 2020, 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.

Not applicable.

Item 6. Exhibits.

Exhibits

3.1	Ninth Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on March 28, 2014).
3.2	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*#	Supply Agreement, dated as of March 11, 2020, by and between Akebia Therapeutics, Inc. and Patheon, Inc.
31.1*	Certification of Principal Executive Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Principal Financial Officer Required Under Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. 1350.
101.INS*	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document)
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Filed, or submitted electronically, herewith
\# Indicates portions of the exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K

SIGNATURES

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

AKEBIA THERAPEUTICS, INC.

Date: May 5, 2020

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

Date: May 5, 2020

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

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

Supply Agreement for

vadadustat

PARTIES

PATHEON INC.
a company existing under the laws of Canada, with its principal place of business at [**] ("**Patheon**"),

- and -

AKEBIA THERAPEUTICS, INC.
a company existing under the laws of Delaware, with its principal place of business at 245 First Street, Cambridge, MA 02142 ("**Client**").

With effect from the Effective Date, the parties have agreed to the following terms:

1. Interpretation

1.1 Definitions.

The following terms will, unless the context otherwise requires, have the respective meanings set out below and grammatical variations of these terms will have corresponding meanings:

"**Affiliate**" means:

(a) a business entity which owns, directly or indirectly, a controlling interest in a party; or

(b) a business entity which is controlled by a party, either directly or indirectly; or

(c) a business entity, the controlling interest of which is directly or indirectly common to the majority ownership of a party;

For this definition, "control" means the lawful right to determine (by ownership of shares or otherwise) the election of the majority of directors (or equivalent managers) of a business entity.

For the avoidance of doubt, Keryx Biopharmaceuticals, Inc., a corporation existing under the laws of Delaware, having a principal place of business at 245 First Street, Cambridge, MA 02143 (hereinafter, “Keryx”) is an Affiliate of Akebia under this Agreement;

"**Annual Volume**" means, for the purpose of the Price, Patheon’s assumed volume of Product to be manufactured in any Year as set out in the “Annual Volume Forecast” section of Appendix 1;

“**API**” means the active pharmaceutical ingredient for vadadustat (references to “Active Materials” or “Active Pharmaceutical Ingredient” in documents forming part of this Agreement will mean “API”);

[**]

"**Applicable Laws**" means: (a) for Patheon, the Laws of the jurisdiction where the Manufacturing Site is located; and (b) for Client and the Product, the Laws of all jurisdictions where Product is manufactured, distributed, marketed and sold as these are agreed by the parties in this Agreement;

"**Authority**" means any governmental or regulatory authority, department, body or agency or any court, tribunal, bureau, commission or other similar body, whether federal, state, provincial, county or municipal, with competent jurisdiction over a party, the Manufacturing Services, or the relevant Product (or its use);

"**Business Day**" means a day other than a Saturday, Sunday or a day that is a statutory holiday in Patheon’s resident jurisdiction, Client’s resident jurisdiction, or the jurisdiction where the Manufacturing Site is located;

“**Capital Equipment Agreement**” means the separate agreement that the parties may enter into that addresses the rights and responsibilities of the parties regarding capital equipment and facility modifications that may be required to perform the Manufacturing Services under this Agreement;

"**cGMPs**" means, as applicable, current good manufacturing practices as described in:

(a) Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations;

(b) Commission Directive (EU) 2017/1572 (art. 2); and

(c) Division 2 of Part C of the Food and Drug Regulations (Canada);

together with current final industry-accepted Health Canada, FDA and EMA guidance documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time;

“**Client Intellectual Property**” means Intellectual Property generated or derived by Client, or by Patheon while performing any Manufacturing Services which Intellectual Property is specific to, or dependent upon, the Product;

“**Client-Supplied Components**” means those Components supplied or to be supplied by or on behalf of Client as identified in Appendix 1;

"**Components**" means, collectively, all packaging components, raw materials, ingredients, and other materials (including labels, product inserts and other labelling for the Products) required to manufacture or package Product in accordance with the Processing Instructions, other than the API;

“**Confidential Information**” has the meaning specified in Section 11.1;

“**DEA**” means the Drug Enforcement Administration of the United States Department of Justice;

“**Deficient Product**” has the meaning specified in Section 6.1(a);

“**Disclosing Party**” has the meaning specified in Section 11.1;

“**Effective Date**” means the date of last signature of the parties executing this Agreement;

"**EMA**" means the European Medicines Agency;

"**FDA**" means the United States Food and Drug Administration;

"**Firm Order**" has the meaning specified in Section 5.1(d);

“**Force Majeure**” means an “act of God,” government, or other acts such as war, riot, crime, or strike, earthquake, hurricane, tornado or flooding, caused by facts or circumstances which a party could not reasonably foresee or which, if foreseeable, they could not reasonably avoid [**];

"**Health Canada**" means the department of the Canadian Government known as Health Canada and includes, among other relevant branches, the Therapeutic Products Directorate and the Health Products and Food Branch Inspectorate;

“**Initial Term**” has the meaning specified in Section 8.1;

"**Intellectual Property**" includes, without limitation, rights in patents, patent applications, formulae, trademarks, trademark applications, trade-names, Inventions, copyrights, industrial designs, trade secrets, and know how;

"**Invention**" means information about any innovation, improvement, development, discovery, computer program, device, trade secret, method, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable that are conceived, discovered, invented, developed, created, made or reduced to practice during the provision of the Manufacturing Services;

"**Inventory**" means, at a point in time, all inventories of Components and work-in-process under Patheon’s care or control used for the manufacture or packaging of Product;

[**].

“**Local Currency**” has the meaning specified in Appendix 3;

“**Long Term Forecast**” has the meaning specified in Section 5.1(a);

"**Manufacturing Services**" means the manufacturing, quality control, quality assurance, stability testing, packaging, and related services, as set out in this Agreement, for the manufacture of Product for distribution in the Territory;

"**Manufacturing Site**" means the facility of Patheon located at [**] where the Manufacturing Services will be performed;

“**Minimum Market Requirement**” has the meaning specified in Section 2.1;

"**Minimum Order Quantity**" means, for each manufacturing campaign ordered, the minimum number of units or batches of a Product that Client must purchase, as set out in Appendix 1;

“**Obsolete Stock**” has the meaning specified in Section 5.2(b);

[**];

“**Patheon Intellectual Property**” means Intellectual Property generated or derived by Patheon or its Affiliates before performing any Manufacturing Services, developed by Patheon while performing the Manufacturing Services, or otherwise generated or derived by Patheon in its business, which Intellectual Property is not specific to, or dependent upon, the Product including, without limitation, Inventions and Intellectual Property which may apply to manufacturing processes or the formulation or development of drug products or drug delivery systems unrelated to the specific requirements of the Product;

“**Price or Pricing**” means the fees to be charged by Patheon for:

[**]

as set out in Appendix 1;

"**Processing Instructions**" means the agreed file for the Product which contains documents relating to the Product, including, without limitation:

(a) the Specifications

(b) quality control testing methods for API and Components;

(c) any storage requirements for the API, Components, or Product;

(d) all environmental, health and safety information for the Product including material safety data sheets; and

(e) the finished Product quality control testing methods;

"**Product**" means a product listed in Appendix 1 of this Agreement;

“**Product Claims**” has the meaning specified in Section 6.1(a);

"**Quality Agreement**" means a separate agreement that sets out the quality assurance standards for the Manufacturing Services;

“**Recall**” has the meaning specified in Section 6.2(a);

“**Recipient**” has the meaning specified in Section 11.1;

“**Regulatory Approval**” has the meaning specified in Section 7.5(a);

"**Regulatory Authority**" means the FDA, EMA, and Health Canada and any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical or biopharmaceutical products, including the Products, in the Territory;

"**Release Date**" means in relation to each batch of Product the scheduled date by which the Product will be released by Patheon's quality department (by confirmation or certification) and confirmed by Client's quality department, as agreed in the Quality Agreement, and made available for shipment;

"**Representatives**" means, a party's directors, officers, employees, advisers, agents, consultants, subcontractors, service partners, legal representatives, or other professional advisors;

"**Rolling Forecast**" has the meaning specified in Section 5.1(b);

"**Specifications**" means the file for the Product, which is approved by Client in accordance with the procedures listed in this Agreement and the Quality Agreement including, without limitation:

(a) specifications for API and Components;

(b) manufacturing specifications, directions, and processes;

(c) all environmental, health and safety information for each Product including material safety data sheets; and

(d) the finished Product specifications, packaging specifications and shipping requirements for each Product;

all as updated, amended and revised from time to time in accordance with the terms of this Agreement and the Quality Agreement;

"**Technical Dispute**" has the meaning specified in Section 13.17;

"**Territory**" means worldwide;

"**Third Party Rights**" means the Intellectual Property of any third party;

"**Year**" means, in the first year of this Agreement, the time from the Effective Date up to and including December 31 of the same calendar year, and after that will mean a calendar year.

1.2 Interpretation.

The division of this Agreement into Sections, Subsections, Appendices and Schedules, and the insertion of headings, are for convenience of reference only and will not affect the interpretation of this Agreement. Unless otherwise indicated, any reference in this Agreement to a Section, Appendix or Schedule refers to the specified Section, Appendix or Schedule to this Agreement. In this Agreement, the term "this Agreement" and similar expressions refer to this Agreement as a whole and not to any particular part, Section, Appendix or Schedule of this Agreement. Except as otherwise expressly stated or unless the context otherwise requires, all references to the singular will include the plural and vice versa.

2. Patheon's Manufacturing Services

2.1 Manufacturing Services.

Patheon will perform the Manufacturing Services as set out in this Agreement for the Price and in accordance with the Quality Agreement. Subject to the preceding sentence, Patheon will convert API and Components into Product, and provide supportive Manufacturing Services such as quality assurance (for example quality controls, analytical testing, quality inspection, and stability programs), primary and secondary packaging, and any other related Manufacturing Services as agreed between the parties.

Unless otherwise agreed to in writing by the Parties, subject to any capacity limits as stipulated in Appendix 1, and upon Regulatory Approval to market the Product in the Territory, Client shall purchase from Patheon not less than [**]% of Client's or its Affiliates' global needs for Product for commercial purposes (the "**Minimum Market Requirement**"). [**].

2.2 Subcontracting.

With Client's prior written consent, Patheon may subcontract the Manufacturing Services under this Agreement to any of its Affiliates, as agreed in Appendix 1. Patheon will remain exclusively liable to Client for the performance of any such Affiliate, and any breach of this Agreement or negligence by its Affiliates in the course of performing: (a) subcontracted Manufacturing Services under this Agreement; or (b) obligations under the Quality Agreement. Patheon may also arrange for non-Affiliate subcontractors to perform specific services arising under this Agreement with the consent of Client ("**Third Party Subcontractors**") as agreed between the parties in writing. Patheon will be liable to Client for the failure by any Third Party Subcontractor to perform any part of the subcontracted services. Patheon's liability to Client for Third Party Subcontractors will remain subject to all limitations on Patheon's liability as set out in this Agreement. Patheon will have no liability arising from the performance of services by Third Party Subcontractors: (i) that are chosen and contracted directly by Client; or (ii) that are suppliers or service providers not validated and utilized by Patheon prior to the date the Service is required.

3. Client's Obligations

3.1 Payment.

Client will pay Patheon the applicable Price in accordance with Sections 4 and 5. All cost items that are not included in the Price are subject to additional fees to be paid by Client, as detailed and agreed in writing in advance between Patheon and Client.

3.2 Processing Instructions.

Before the start of commercial manufacturing of Product under this Agreement, Client will give Patheon a copy of the Processing Instructions, which must be accompanied by the Specifications for the applicable API, Component and finished Product Specifications. If the Processing Instructions or

accompanying documents received are amended or no longer reflect those currently approved by the Regulatory Authority, then Client will give Patheon a copy of the revised documents (if applicable, precisely matching the revised Specifications approved by the applicable Regulatory Authority). Upon acceptance of the revised Processing Instructions and accompanying documents, Patheon will give Client a signed and dated receipt indicating Patheon's acceptance. At Patheon's request, Client will provide evidence of the executed original documents submitted by or on behalf of Client to the Regulatory Authority.

3.3 API and Components.

(a) Client will [**] deliver the API and any Client-Supplied Components to the Manufacturing Site [**]. Client's obligation will include [**]. Unless otherwise agreed in writing, Client or Client's designated broker will be the "**Importer**" or "**Importer of Record**" (or equivalent, as understood under Applicable Laws) for API, Client-Supplied Components, drug products and intermediates imported to the Manufacturing Site, and Client is responsible for compliance with Applicable Laws relating to that role. For API or Client-Supplied Components which may be subject to import or export to or from [**], Client agrees that its vendors and carriers will comply with applicable requirements of Applicable Law.

(b) Unless otherwise agreed in writing between the parties, the API and any Client-Supplied Components must be delivered by Client to the Manufacturing Site at least [**] before the scheduled manufacture date for Product covered by a Firm Order in sufficient quantity to enable Patheon to manufacture the agreed quantities of Product. Unless otherwise agreed, Patheon reserves the right to [**]. If (i) Client fails to deliver the API or Client-Supplied Components within the agreed time period, or (ii) such API fails to meet its Specifications, and, [**], Patheon is unable to manufacture Product on the scheduled date because of either scenario described in Section 3.3(b)(i) or 3.3(b)(ii), then [**], unless otherwise agreed.

(c) Patheon will control the unloading of API and Client-Supplied Components arriving at the Manufacturing Site and Client will comply and ensure that its carrier complies with all reasonable directions of Patheon related to such unloading. The API and Client-Supplied Components will be held by Patheon on behalf of Client as set out in this Agreement and the Quality Agreement. The API and Client-Supplied Components will at all times remain the property of Client. Any API and Client-Supplied Components received by Patheon will only be used by Patheon to perform the Manufacturing Services.

(d) Client will [**] that all shipments of API are accompanied by the required documentation as specified in the applicable Quality Agreement.

(e) If Client asks Patheon to qualify an additional supplier for the API or any Component, the parties must agree on the scope of work to be performed by Patheon and the additional fees to be paid by Client. For any API or any Component, this work may include: (i) laboratory testing to confirm the API or Component meets existing Specifications; (ii) manufacture of an experimental batch of Product that will be placed on [**] stability; and (iii) manufacture of [**] validation batches that will be placed on concurrent stability [**]

(f) Patheon will promptly advise Client in accordance with the Quality Agreement if it encounters API or Client-supplied Component problems, including delays or delivery of non-conforming API or Client-supplied Components from a Client designated additional supplier. The parties will cooperate to reduce or eliminate any such supply problems from these additional suppliers. If supply problems persist, [**]. Client will qualify or certify (as appropriate) all Client designated additional suppliers on an annual basis at its expense and will provide Patheon with copies of the relevant annual reports. If Patheon agrees to certify or qualify a Client designated additional supplier on behalf of Client, it will do so for an additional fee payable by Client.

3.4 Packaging and Artwork.

Unless otherwise agreed, Patheon will supply Product in bulk packaging. Client will be responsible for the cost of artwork development and approval of all artwork for the packaging of the Product. Client will be responsible for changes to labels, product inserts, and other packaging for the Product, including obtaining all required approvals. Client will be responsible for the cost of labelling obsolescence as contemplated in Section 5.2. Patheon's name will not appear on the label or anywhere else on the Product unless: (a) required by any Laws; or (b) Patheon consents in writing to the use of its name. For secondary packaging, at least [**] prior to the Release Date of Product for which new or modified artwork is required, Client will provide at no cost to Patheon and in accordance with the applicable Specifications, final camera-ready artwork for all packaging Components to be used in the manufacture of the Product. If applicable, Client will be responsible for the costs associated with complying with any and all regulatory requirements for the labelling and tracking of the manufactured Product, including product serialisation, product data transfer and anti-counterfeiting requirements in the Territory.

4. Price and Price Adjustments

4.1 [**] Pricing.

The Price for the Product will be listed in Appendix 1 of this Agreement and may be adjusted under this Section 4.

4.2 [**] Price Adjustments.

Patheon may adjust the Price [**] as follows:

(a) Inflation. Patheon may adjust the Price for inflation in accordance with Appendix 3.

(b) Currency Fluctuations. If the parties agree in Appendix 1 of this Agreement to invoice in a currency other than the Local Currency for the Manufacturing Site, Patheon will adjust the Price to reflect currency fluctuations. The adjustment will be calculated in accordance with Appendix 3 after all other [**] Price adjustments under this Section 4.2 have been made.

(c) Pricing [**]. Client acknowledges that, except as otherwise limited in Appendix 1: Description of Manufacturing Service and Price, the Price [**] is agreed based upon [**]. Patheon may adjust the Price if [**].

(d) [**] Pricing. The Pricing may be divided into [**]. If applicable, and unless otherwise agreed between the parties, Client will be invoiced during the Year [**]. Within [**] after [**], Patheon will send Client a [**]. If the [**] within [**] after [**] within [**] after termination. The parties will work together in good faith to resolve any disagreement over [**].

For all Price adjustments under this Section 4.2, Patheon will deliver to Client on [**] (unless otherwise agreed in writing) a letter stating the adjusted Pricing to be effective for Product to be delivered on or after [**] including any Firm Orders accepted by Patheon before that date. The parties may agree to defer any such Price adjustment for [**] adjustment.

4.3 Price Adjustments at any Time.

The Prices may be adjusted by Patheon at any time upon written notice to Client as follows:

(a) Extraordinary Increases in Component Costs. If the cost of a Component increases cumulatively by at least [**]% since [**] adjustment as a result of [**], and Patheon has [**] then Patheon will be entitled to request an adjustment of the Price proportionately, and as otherwise agreed in the Appendix 1 of this Agreement. Patheon must provide Client with details of the specific cost drivers causing the invocation of this clause, as well as [**] as per the above. The revised Price will become effective with the first use of the higher cost Component in the manufacture of the Product. For a Price adjustment under this Section 4.3(a), Patheon will deliver to Client a revised Appendix 1. In such an instance, Client will have the right to audit Patheon records (using an independent auditor in the event of third-party confidentiality obligations) in accordance with Section 7.4 to verify such cost drivers [**].

(b) Changes. The scope of the Manufacturing Services is set by the agreed Processing Instructions, the Regulatory Approvals, the Quality Agreement and any assumptions, inclusions, exclusions and other parameters set out in this Agreement. Changes to the scope of the Manufacturing Services and related changes to the Price must be agreed in writing by the parties (using a "**Change of Scope**" agreement, or similar, setting out the agreed activities and costs of implementation) and are subject to the change control provisions of the Quality Agreement. [**].

5. Purchasing Product

5.1 Orders and Forecasts.

(a) Long Term Forecast. On or before [**] of each Year, Client will give Patheon a [**] written forecast of Client's volume requirements for the Product for each of the next [**] ("**Long Term Forecast**"). If Patheon foresees any capacity constraint affecting any portion of the Long Term

Forecast, it will notify Client and the parties will agree on a revised Long Term Forecast within Patheon's expected capacity.

(b) Rolling Forecast. Unless otherwise agreed between the parties, upon Execution of this Agreement, Client will give Patheon a written forecast of the volume of Product that Client expects to order in each of the next [**] (the "**Rolling Forecast**"). The [**] of the Rolling Forecast [**]. Client will provide an updated Rolling Forecast [**] prior to the [**] calendar quarter. Each updated Rolling Forecast supersedes all previous Rolling Forecasts.

(c) Orders. Any purchase order for Product should be provided by Client [**] prior to the end of each [**], for any Product required in the subsequent [**]. For clarity, purchase orders for the [**] would have already been received by Patheon. Each purchase order will specify the purchase order number, quantities by Product type consistent with the batch size outlined in this Agreement, and requested Release Dates for the Product (which must occur at least [**] the date of such purchase order).

(d) Acceptance of Purchase Orders. Provided that a purchase order is consistent with the Rolling Forecast, Patheon will accept the purchase order by sending an acknowledgement to Client, including the confirmed Release Dates. Subject to Section 5.1(c). herein, if Patheon fails to acknowledge receipt of a purchase order within [**], the purchase order will be considered accepted by Patheon. An accepted purchase order will be binding on the parties (a "**Firm Order**"), except that either party may request to change the Release Date of the Product beyond [**] after [**]. The parties will negotiate in good faith and agree on any requested alternative Release Date. Neither party may unreasonably reject an alternative Release Date requested under this Section 5.1(d), but, if the parties cannot agree, the original Release Date confirmed by Patheon will apply.

(e) Cancellation or Postponement. Patheon will determine the manufacturing schedule of all Product covered by Firm Orders. If Client cancels or reduces a Firm Order, or wishes to postpone the applicable Release Date (subject to Section 5.1(d)), Patheon shall [**] Release Date. [**] for the Firm Order.

5.2 Obsolete Stock.

(a) Client understands and acknowledges that Patheon will rely on purchase orders, Firm Orders, the Long Term Forecast and the Rolling Forecast in ordering the Components (other than Client-Supplied Components) required to meet anticipated Firm Orders. Patheon may purchase the Components in sufficient volumes, and reasonably in advance of the expected use of the Component (taking into account lead times), to meet the production requirements for Products covered by anticipated Firm Orders, or to meet the production requirements of any longer period agreed to by the parties.

(b) Client will reimburse Patheon for the cost of Components ordered by Patheon in relation to Firm Orders or under Section 5.2 if the Components have expired or are rendered obsolete

due to [**] during the period (collectively, "**Obsolete Stock**"). This reimbursement will include Patheon's [**].

(c) Non-expired Components not used in the Manufacturing Services within [**] after the forecasted month for which the purchases have been made will be [**] with supporting documentation [**]. If any non-expired Components [**] in Products subsequently manufactured for Client or in third party products manufactured by Patheon, [**] for any costs of [**].

5.3 Storage.

Patheon agrees to store Product, Components, and all other Materials under this Agreement in accordance with cGMP, the Quality Agreement, and the Specifications for the Product and each of the respective Components.

If: (a) Client fails to take possession or arrange for the destruction of Components ordered by Patheon in relation to Firm Orders or under Section 5.2 (a) that are not used in the Manufacturing Services within [**] after the forecasted month for which the purchases have been made or if the Components have expired or are rendered obsolete due to [**] during the period within [**] of receipt of written notice from Patheon identifying the Obsolete Stock; (b) any equipment (other than existing Patheon equipment) is stored at the Manufacturing Site at any time prior to its use in the Manufacturing Services; or (c) Product is not collected by Client within [**] of the Release Date as notified by Patheon, and no other arrangements have been agreed in writing by both parties, Client will pay Patheon [**], per month after that for storing the Obsolete Stock, equipment or Product. Storage fees for Obsolete Stock or Product which contain controlled substances or require refrigeration will be charged at [**] per month. Storage fees for partial pallets are subject to a [**] minimum charge per month.

Patheon may ship Product held by it longer than [**] to Client [**] on [**] written notice to Client. If Patheon is unable to store any material due to capacity constraints, Patheon may use an Affiliate or qualified third party to store (outside the Manufacturing Site) any Client-owned property under this Agreement if permitted under the Quality Agreement. After the limited storage periods stated above, [**].

5.4 Invoices and Payment.

For shipments of Product, Patheon will issue invoices to Client on or after the Release Date of the Product. Otherwise, Patheon will issue invoices for Manufacturing Services on completion or as otherwise agreed in writing under this Agreement. Patheon will also submit to Client, with each shipment of Product, a duplicate copy of the invoice covering the shipment. Invoices will be sent by email to the email address given by Client to Patheon in writing. Each invoice will, to the extent applicable, identify Client's Manufacturing Services, purchase order number, Product numbers, names and quantities, unit price, freight charges, and the total amount to be paid by Client. Client will pay all invoices within [**] of the date of the invoice. If any portion of an invoice is disputed, the parties will use good faith efforts to reconcile the disputed amount as soon as practicable. In the instance where an invoice is disputed, Client shall clearly indicate any portion of the invoice which is not in dispute, whereas Patheon can reissue an invoice solely for the undisputed portion, which Client shall pay per the terms. The disputed portion can be re-invoiced

and reconciled in accordance with this Section 5.4. Interest on undisputed past due accounts will accrue at [**]. Patheon may, on giving [**] notice to Client, [**].

5.5 Delivery and Shipping.

Delivery of Product and any other materials will be made [**] from Patheon's Manufacturing Site on or after the Release Date. Subject to Section 8.3, [**]. If Client fails to collect Product within [**] after the Release Date, and no other storage arrangements have been made and agreed between the parties [**]. Patheon may, in accordance with Client's instructions and as agent for Client, at Client's risk, arrange for shipping (to Client or any third party nominated by Client) to be paid by Client. Client will arrange for insurance and will select the freight carrier used by Patheon to ship Product and may monitor Patheon's shipping and freight activity under this Agreement.

6. Product Claims and Recalls

6.1 Product Claims.

(a) Rejection. Client may reject any manufactured Product that it reasonably considers (by reference to the results of the agreed Specifications) to be deficient based on documentation provided by Patheon or inspection by Client or its designee or testing of delivered Product.

(b) Product Claims.

i. Client may claim a remedy (a "**Product Claim**") for any portion of any batch of Product for which Patheon did not perform the Manufacturing Services in accordance with the agreed Processing Instructions, cGMPs, the Quality Agreement, the Specifications, this Agreement, or Applicable Laws ("**Deficient Product**"). Any Product Claim concerning Deficient Product shall be communicated by Client to Patheon in writing as soon as possible, but in no event later than [**] from its discovery by Client or its designees. For clarification, after the end of the above-mentioned [**] period to issue a Product Claim, neither Client nor its designees shall be entitled to claim that the Product delivered by Patheon constituted Deficient Product. Client shall not be entitled to claim that the Product delivered by Patheon is Deficient Product if Client, or as appropriate, its designees, fail to perform the tests, analysis, inspections and/or reviews of the Product appropriately, reasonably, and in a timely manner consistent with industry standard, and/or complete its related documentation required under Applicable Laws, the Quality Agreement, and/or cGMP.

ii. Patheon shall be liable to Client for Product Claims as specified in Section 6.1(b)(i), but Patheon will have no obligation for any Product Claims to the extent the Deficient Product was caused by: [**]. If after a complete and thorough investigation by the parties as set out in the Quality Agreement and this Section 6.1(b)(ii), it is reasonable to conclude that Patheon manufactured Product in accordance with the agreed Processing Instructions,

cGMP, Applicable Law and the Quality Agreement, but a batch or portion of batch of Product is not released by Client, Client will [**].

(c) Determination of Deficiency. Upon receipt of a Product Claim, Patheon will have [**] to advise Client by notice in writing whether it disagrees with the contents of the Product Claim. If the parties fail to reasonably agree within [**] after Patheon's notice to Client as to whether any Product identified in the Product Claim is Deficient Product, the parties will investigate the matter in accordance with the Quality Agreement. If, after joint and/or independent testing or investigation has been performed, and the parties still cannot agree on the root cause of the Deficient Product, the provisions of Section 13.17 will apply.

(d) Shortages and Price Disputes. Claims for shortages in the amount of Product shipped by Patheon or a Price dispute will be dealt with by reasonable agreement of the parties. Any claim for a shortage or a Price dispute will be considered waived by Client if it has not been presented within [**] of [**].

6.2 Product Recalls and Returns.

(a) Records and Notice. The parties will each maintain records necessary to permit a Recall of any Product delivered to Client or customers of Client. Each party will promptly notify the other of any information which might affect the marketability, safety or effectiveness of the Product or which might result in the Recall or seizure of the Product in accordance with the Quality Agreement. Upon receiving this notice or upon this discovery, each party will stop making any further shipments of any Product in its possession or control until a decision has been made whether a Recall or some other corrective action is necessary. The decision to initiate a Recall or to take some other corrective action, if any, will be made and implemented by Client, with appropriate cooperation from Patheon. "**Recall**" will mean any action by Client to recover title to or possession of quantities of the Product sold or shipped, and/or refrain from selling or shipping to third parties (including, without limitation, the voluntary withdrawal of Product from the market.

(b) Recalls. If: (i) any Regulatory Authority issues a directive, order, or, following the issuance of a safety warning or alert about a Product, a written request that any Product be Recalled; (ii) a court of competent jurisdiction orders a Recall; or (iii) Client determines that any Product should be Recalled or that a "Dear Doctor" letter is required relating the restrictions on the use of any Product, then Patheon will co-operate as reasonably required by Client, in compliance with all Applicable Laws.

(c) Recalled Product. To the extent that a Recall results from or arises from Deficient Product, [**] of the Recall and will [**] to replace the Deficient Product with replacement Products as per Section 10. In all other circumstances, Recalls, returns, or other corrective actions will be made at [**].

(d) Disposition of Deficient Product. Client will not dispose of any damaged, returned, or Deficient Product prior to asserting a Product Claim against Patheon for such Deficient Product, without

Patheon's prior written authorization to do so. Patheon may instruct Client to return the Products to Patheon. In such an instance, Patheon will bear the cost of return and disposition of any Deficient Products. In all other circumstances, Client will bear the cost of return and disposition, including all applicable fees for Manufacturing Services.

7. Co-operation and Regulatory Affairs

7.1 Governance.

Each party will without delay upon execution of this Agreement appoint one of its employees to be a relationship manager responsible for liaison between the parties. The relationship managers will meet on a frequency agreed between the parties to review the current status of the business relationship, including review of key performance indicators such as API delivery, on-time delivery, right first time, and attainment of the Minimum Market Requirement, and manage any issues that arise.

7.2 Governmental Agencies.

Subject to any restrictions in the Quality Agreement, Patheon will permit Client to be present and, if requested by the Regulatory Authority, participate in any visit to or inspection by any Regulatory Authority (if and to the extent it relates in any way to any Product, or the Manufacturing Process). Patheon will give as much advance notice as possible to Client of any such visit or inspection. Unless prohibited by Applicable Law or regulation, Patheon will provide Client with a copy of any report or other written communication received from such Regulatory Authority in connection with such visit or inspection, and any written communication received from any Regulatory Authority relating to the Product, the Manufacturing Site (if it relates to or affects the manufacture of Product) or the manufacturing process, and, unless prohibited by Applicable Law, will consult with Client before responding to each such communication. Patheon will comply with all reasonable requests and comments by Client with respect to all contacts and communications with any Regulatory Authority relating to the Services. Each party may communicate with any Regulatory Authority responsible for granting Regulatory Approval for the Product and any other relevant Authority regarding the Product if the communication is necessary to comply with the terms of this Agreement or the requirements of the Authority or Applicable Laws. Otherwise, the parties will consult each other in relation to regulatory communications relating to the Product in accordance with the Quality Agreement.

7.3 Records.

Patheon will keep records of the manufacture, testing, and shipping of the Product, and retain samples of the Product as are necessary to comply with manufacturing regulatory requirements applicable to Patheon, Applicable Laws, cGMP, this Agreement, and the Quality Agreement. Copies of the records and samples will be retained as, and for the period specified in, the Quality Agreement.

7.4 cGMP and Quality Audits.

Subject to the limits agreed in the Quality Agreement, Patheon will give Client, and any third party authorized by Client to audit on behalf of/or along with the Client, which may include a market authorization holder, reasonable access at agreed times to the areas of the Manufacturing Site in which the Product is manufactured, stored, handled, or shipped to permit Client to verify that the Manufacturing Services are being performed in accordance with the Specifications, cGMPs, this Agreement, the Quality Agreement, and Applicable Laws. If Client wishes to audit Patheon beyond the limitations set forth in this Agreement or the Quality Agreement, except where the audit is required due to Patheon's material breach of this Agreement, the Quality Agreement, cGMPs, Applicable Laws, or manufacture of Product that does not conform to the Specifications, Client will pay to Patheon a fee of [**] for each additional audit day and [**] per audit day for each additional auditor above the duration or number provided in the Quality Agreement. Under no circumstances will: (a) Client have a right of access to Patheon's financial records under this Section 7.4; or (b) any [**] be permitted access to the Manufacturing Site.

7.5 Regulatory Filings.

(a) Regulatory Authority Documentation. Client will provide copies of all relevant documents relating to Regulatory Authority approval for the commercial manufacture, distribution and sale of the Product ("**Regulatory Approval**") to Patheon on request and as required under the Quality Agreement. Patheon will review and verify the accuracy of these documents in accordance with the Quality Agreement.

(b) Deficiencies. If, [**], Patheon determines that any regulatory information given by Client is inaccurate or deficient in any manner whatsoever (the "Regulatory Deficiencies") with respect to the Manufacturing Services to be performed by Patheon, Patheon will notify Client in writing of the Regulatory Deficiencies. The parties will work together to have the Regulatory Deficiencies resolved prior to the date of filing of the relevant application for Regulatory Approval, and in any event before any pre-approval inspection or before the Product is placed on the market if a pre-approval inspection is not performed. In the case of a Regulatory Deficiency communicated after market approval, the parties shall together agree on a resolution to correct such a Regulatory Deficiency,

(c) Inspection by Regulatory Authorities & Deficient Documentation. If Client does not give Patheon the documents requested under this Section 7.5 or the Quality Agreement within the time specified, and if Patheon reasonably believes that Patheon's standing with a Regulatory Authority may be jeopardized as a result, Patheon may, in its sole discretion, delay or postpone any inspection by the Regulatory Authority until Patheon has reviewed the requested documents and is satisfied with their contents.

(d) Pharmacovigilance. Client will be responsible, at its expense, for all pharmacovigilance obligations for the Product in accordance with Applicable Laws and the monitoring and management of post-marketing complaints and queries at its cost (including, without limitation, the cost of assistance required of Patheon under the Quality Agreement). Unless required by Applicable Law, Client will not be obliged to provide Patheon any information or data which it

compiles in carrying out pharmacovigilance obligations or activities. Patheon, at Client's expense, agrees to work in good faith to share information and collaborate in Client investigations related to pharmacovigilance obligations.

(e) Regulatory Filings. Except as otherwise agreed in the Quality Agreement, Patheon will not assume any responsibility for: (a) the submission or cost of any application for Regulatory Approval or related documentation (or the success of those applications), except with respect to Patheon's obligation to provide accurate data and reports to Client; (b) any activity that is required by Applicable Laws for Regulatory Approval (including pharmacovigilance and complaints handling, and preparation and submission of any regular quality or other update) except with respect to Patheon's obligation to provide accurate data and reports to Client; or (c) any dealings with the relevant Regulatory Authority on behalf of Client for Regulatory Approval, unless otherwise agreed between the parties. If a Regulatory Authority, or other governmental body, requires Patheon to incur fees, costs or activities in relation to the Products which Patheon considers unexpected and extraordinary, then Patheon will notify Client in writing and the parties will discuss in good faith appropriate mutually acceptable actions, including [**].

7.6 Release.

The parties agree that the release of the Products for sale or distribution under the applicable marketing approval for the Product will not by itself indicate compliance by Patheon with its obligations relating to the Manufacturing Services. Nothing in this Agreement will remove or limit the authority of the relevant quality functions of the respective parties (as specified by the Quality Agreement) to determine whether the Product will be released for sale or distribution.

8. Term and Termination

8.1 Term.

This Agreement will become effective as of the Effective Date and will continue until June 30, 2023 of the Agreement (the **"Term**"), unless terminated earlier by one of, or both of the parties in accordance with this Section 8. This Agreement will automatically renew after the Term for successive terms of one (1) Year, unless either party gives written notice to the other party of its intention to terminate this Agreement at least eighteen (18) months prior to the end of the then current term.

8.2 Termination for Cause.

(a) Either party may terminate this Agreement upon written notice where the other party has failed to remedy a material breach of this Agreement within [**] (the "**Remediation Period**") following receipt of a written notice of the breach from the aggrieved party that expressly states that it is a notice under this Section 8.2(a) (a "**Breach Notice**").

(b) Client may terminate this Agreement upon 30 days' prior written notice if any Authority takes any action, or raises any objection, that permanently prevents Client from selling the Product in the Territory.

(c) Client may terminate this Agreement upon six months' prior written notice if it intends to no longer order Manufacturing Services for a Product due to the Client's decision to discontinue marketing the Product.

(d) Patheon may terminate this Agreement if payment in full of overdue, undisputed invoices is not received within sixty (60) days following written notice from Patheon.

8.3 Obligations on Termination.

(a) If this Agreement expires or is terminated in whole or in part for any reason, then:

(b) Client will take delivery of and pay for all undelivered Products that are manufactured or packaged in accordance with this Agreement under a Firm Order, at the Price in effect at the time the Firm Order was released;

(c) Client will purchase all Inventory that was purchased (or will be purchased under existing unfulfilled orders for Components), maintained or produced by Patheon in contemplation of filling Firm Orders or in accordance with Section 5.2, at Patheon's cost (including all costs incurred by Patheon for the purchase, handling, and processing of the Inventory);

(d) Unless otherwise agreed by the parties in writing, Client, at its own expense, will remove from the Manufacturing Site, within [**] following the termination or expiration of this Agreement, all unused API and Client-Supplied Components, all applicable Inventory (whether current or obsolete), supplies, undelivered Product, equipment or other moveable property owned by Client related to the Agreement and located at the Manufacturing Site or that is otherwise under Patheon's care and control ("Client Property"). If Client fails to remove Client Property within the [**] period, Client will pay Patheon [**], per month, [**] minimum after that for storing Client Property [**]. Patheon may ship Client Property to Client or to an external warehouse [**]. If Client fails to remove Client Property within [**] following the termination or expiration of this Agreement, Client will [**] the stored Client Property and it will be [**]. If Client asks Patheon to destroy any Client Property, Client will be responsible for the cost of destruction; and

(e) With exception to any termination for a material breach under this Agreement by Patheon, any termination or expiration of this Agreement will not affect any prior outstanding obligations or payments due nor will it prejudice any other remedies that the parties may have under this Agreement or any related Capital Equipment Agreement. Termination or expiration of this Agreement for any reason will not affect the obligations and responsibilities of the parties under Sections 5.1(e), 5.4, 5.5,8.3, 10, 11, 12, 13.15, 13.16 and 13.17, all of which survive any termination or expiration, as well as any other provisions that are by implication or otherwise intended to survive any termination or expiration. If Patheon agrees to provide stability services

following the termination or expiration of this Agreement, the relevant provisions of this Agreement will survive for the agreed duration of those stability services.

(f) No later than [**] following completion or permanent cessation of the Manufacturing Services at the applicable Manufacturing Site, Client will: (a) ensure that any regulatory filings relating to the Product are withdrawn or amended to remove all references to the Manufacturing Site and, as applicable, Patheon or its Affiliates and their facilities (except in an historic context); and (b) provide to Patheon written confirmation of its compliance with this Section. If this time is not sufficient to meet the requirements of certain Regulatory Authorities, despite Client's best efforts, then Patheon may agree to extend the period based on the written reassurances of Client.

8.4 Technology Transfer.

Following expiration or termination of this Agreement for any reason, or at Client's request, within [**] before the end of the Term of this Agreement, Patheon will provide assistance to transfer part or all of Client's manufacturing process, know-how and analytical testing methodology for the Product to Client, or a third party designated by Client ("**Technology Transfer**") to assist Client to manufacture the Product. Patheon will also disclose to Client any Patheon Intellectual Property that is reasonably required to manufacture the Product. Patheon will, upon request of Client, prepare a written proposal to perform the Technology Transfer. Reasonable fees for the Technology Transfer performed by Patheon will be agreed upon by the parties and promptly paid by the Client.

9. Representations, Warranties and Covenants

9.1 Authority.

Each party covenants, represents, and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations under this Agreement.

9.2 Client Warranties.

Client covenants, represents, and warrants that:

i. the Processing Instructions and Specifications for the Product conform to all applicable cGMPs and Applicable Laws;

ii. the Product, if labelled and manufactured in accordance with the Processing Instructions and in compliance with applicable cGMPs, the Quality Agreement and Applicable Laws, may be lawfully sold and distributed in every jurisdiction in which Client markets or intends to market the Product; and

iii. on receipt by Patheon, the API will be adequately contained, packaged, and labelled in accordance with Applicable Laws.

9.3 Patheon Warranties.

Patheon covenants, represents, and warrants that:

(a) Patheon is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.

(b) The execution and delivery of this Agreement by Patheon has been authorized by all requisite corporate or company action. This Agreement is and will remain a valid and binding obligation of Patheon, enforceable in accordance with its terms, subject to Applicable Laws.

(c) it will perform the Manufacturing Services in accordance with the Processing Instructions, cGMPs, the Quality Agreement, this Agreement, and Applicable Laws;

(d) any Patheon Intellectual Property used by Patheon to perform the Manufacturing Services (i) is Patheon's or its Affiliate's unencumbered property, (ii) may be lawfully used by Patheon, and (iii) does not infringe and will not infringe any Third Party Rights;

(e) Patheon has engaged, will engage and will cause its Affiliates involved in rendering Services to engage, employees and permitted subcontractors including consultants with the proper skill, training and experience to provide Manufacturing Services detailed in this Agreement. The foregoing is provided that the involvement of Affiliates of Patheon in providing the Manufacturing Services hereunder shall require Client's prior approval. Before providing Manufacturing Services hereunder, all Patheon personnel must be subject to binding commitments with Patheon under which they have confidentiality obligations with regard to Client's Confidential Information (as defined below) that are consistent with the terms of this Agreement. Patheon will not in the performance of its obligations under this Agreement use the services of any person it knows is debarred or suspended under 21 U.S.C. §335(a) or (b); and

(f) it does not currently have, and it will not hire, as an officer or an employee any person whom it knows has been convicted of a felony under the laws of the United States for conduct relating to the regulation of any drug product under the United States Federal Food, Drug, and Cosmetic Act.

9.4 Permits.

Client will be solely responsible for obtaining or maintaining, on a timely basis, any regulatory approvals for the Product, Processing Instructions or Specifications including, without limitation, all marketing and post-marketing approvals, and any specific approvals referred to in the Quality Agreement that are not the responsibility of Patheon as described therein. Patheon will maintain at all relevant times

when performing the Manufacturing Services all required governmental permits, licenses, approval, and authorities.

9.5 No Warranty.

NEITHER COMPANY MAKES ANY WARRANTY OR CONDITION OF ANY KIND, EITHER EXPRESSED OR IMPLIED, BY FACT OR LAW, OTHER THAN THOSE EXPRESSLY SET OUT IN THIS AGREEMENT. NEITHER PARTY MAKES ANY WARRANTY OR CONDITION OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY WARRANTY OR CONDITION OF MERCHANTABILITY FOR THE PRODUCT.

10. Liability and Remedies

10.1 Consequential and Other Damages.

Except in the event of breach of the parties' obligations of confidentiality under this Agreement, under no circumstances whatsoever will either party be liable to the other for; (a) any special, incidental, consequential (including lost profits, business or goodwill), punitive or indirect damages suffered or incurred by the other party or its affiliates in connection with this Agreement or (b) any reliance damages, including but not limited to costs or expenditures incurred to evaluate the viability of entering into this Agreement or to prepare for performance under this Agreement; or (c) for any other liability, damage, costs, penalty, or expense of any kind incurred by the other party of an indirect or consequential nature, regardless of any notice of the possibility of these damages.

10.2 Limitation of Liability.

(a) Remedies for Deficient Product. If Client makes a Product Claim under Section 6.1 and the parties agree the Product is Deficient Product, or the Product is determined to be Deficient Product under Section 6.1, either of the following will occur, at Client's option:

i. If Patheon is able to manufacture the replacement Product at the Manufacturing Site according to a schedule agreed to by the parties, Patheon shall replace the Deficient Product at Patheon's cost if Deficient Product was previously paid for by Client, or at Client's cost if Deficient Product was not previously paid for by Client. Any replacement of Product under this Section 10.2(i) is contingent upon the receipt by Patheon from Client of all API and Client-Supplied Components required for the manufacture of the replacement Product; or

ii. Patheon will refund 100% of the Price (if previously paid by Client) for the Deficient Product by credit or offset against other amounts due to Patheon under this Agreement. If insufficient Manufacturing Services remain under this Agreement to provide such a credit, whether by function of termination or expiration of the Agreement, such refund shall be paid directly to Client by Patheon.

Except for the indemnity set out in Section 10.3 and any claim for expenses related to a Recall under Section 6.2(c), the remedies described in this Section 10.2(a) will be Client's sole remedy in contract, tort, negligence, equity or otherwise, for Deficient Product.

The remedy under this Section 10.2(a), if applicable (including in the case of Recall), will apply only to the extent that the affected Deficient Product is unsold or refunded by Client to an end customer, and returned, destroyed, or otherwise disposed of by Client in accordance with this Agreement.

(b) API. Patheon's liability to Client for [**] API will be calculated using [**].

Except in circumstances arising from Patheon's [**], Patheon's liability to Client in [**] to the API [**].

(c) [**] Liability. In any Year, in addition to the specific remedies under Section 10.2(a) for Deficient Product, each party's [**] to the other party under or in connection with this Agreement [**] (the "**[**]**"). For avoidance of doubt, the [**] shall not apply to [**].

For the avoidance of doubt, this Section 10.2(c) shall in no way affect the amount or calculation of the limitations of liability set forth in [**].

Further, [**]. The remedies under Section 10.2(a), and 10.2(b), if applicable (including in the case of Recall), will apply only to the extent that the affected Deficient Product is unsold or refunded by Client, and returned, destroyed or otherwise disposed of by Client in accordance with this Agreement.

(d) Death, Personal Injury and Fraudulent Misrepresentation. Nothing contained in this Agreement will act to exclude or limit either party's liability for personal injury or death caused by the negligence of either party or fraudulent misrepresentation.

10.3 Patheon Indemnity.

Patheon will indemnify, defend and hold harmless Client, its Affiliates, and its and their respective officers, directors, employees and agents (collectively, the "Client Indemnitees") against any and all losses, damages, liabilities or expenses (including reasonable attorney's fees and other costs of defense) (collectively, "Losses") that any of them may suffer in connection with any and all suits, investigations, claims, or demands of Third Parties (collectively, "Third Party Claims") arising from, relating to or occurring as a result of (a) any Patheon Indemnitee's [**] in performing its obligations under this Agreement; (b) Patheon's violation of any patent, trade secret or other proprietary or intellectual property rights of any Third Party in the performance of the Manufacturing Services; or (c) Patheon's breach of this Agreement, the Quality Agreement, cGMP or Applicable Law; except to the extent that such Third Party Claims are due to any breach by Client of its obligations under this Agreement or [**] of Client.

10.4 Client Indemnity.

Client agrees to indemnify, defend and hold harmless Patheon, its Affiliates, and its and their respective officers, directors, employees and agents (collectively, the "Patheon Indemnitees") against any Losses that any of them may suffer in connection with any Third Party Claims arising from, relating to or occurring as a result of (a) the development, commercialization or use of the Product (including, but not limited to, product liability claims and claims that such Product infringes any Third Party Rights and claims for personal damages or injuries); (b) Client technology transferred to Patheon for the development and/or Manufacturing of the Product not having been generated in compliance with Applicable Laws, or violating any patent, trade secret or other proprietary or intellectual property rights of any Third Party; (c) any Client Indemnitee's [**] in performing obligations under this Agreement; or (d) Client's breach of this Agreement, the Quality Agreement, cGMP or Applicable Law; except to the extent that such Third Party Claims are due to any breach by Patheon of its obligations under this Agreement, any Deficient Product supplied by Patheon, or [**] of Patheon.

10.5 Indemnification Procedures.

Each party must promptly notify the other party after receipt of any Third Party Claims for which the other party might be liable under Section 10.3 or 10.4 hereof, as applicable. The indemnifying party will have the sole right to defend, negotiate, and settle such claims. The indemnified party will be entitled to participate in the defense of such matter [**]; provided, however, that the indemnifying party will have final decision-making authority regarding all aspects of the defense of the claim. The indemnified party will provide the indemnifying party with such information and assistance as the indemnifying party may reasonably request, at the expense of the indemnifying party. Neither party will be responsible or bound by any settlement of any claim or suit made without its prior written consent; provided, however, that the indemnified party will not unreasonably withhold or delay such consent.

10.6 Validation Batches.

Where Product is manufactured by Patheon (or any of its Affiliates) under a separate pharmaceutical development or technology transfer agreement (the "**Development Agreement**") and then released by Patheon for commercial sale or distribution by Client, the performance of the applicable pharmaceutical development or technology transfer services including the manufacture of the Product will be governed by the terms of the Development Agreement and will not be subject to the terms and conditions of this Agreement. The terms of this Agreement will apply to any Product after release by Patheon.

11. Confidentiality

11.1 Confidential Information.

"**Confidential Information**" means any information disclosed by the Disclosing Party to the Recipient (whether disclosed in oral, written, electronic or visual form) that is non-public, confidential or proprietary including, without limitation, information relating to the Disclosing Party's patent and trademark

applications, process designs, process models, drawings, plans, designs, data, databases and extracts therefrom, formulae, methods, know-how and other intellectual property, its clients and its clients' confidential information, finances, marketing, products and processes and all price quotations, manufacturing or professional services proposals, information relating to composition, proprietary technology, and all other information relating to manufacturing capabilities and operations. In addition, all analyses, compilations, studies, reports or other documents prepared by any party's Representatives containing Confidential Information will be considered Confidential Information. Samples or materials provided under this Agreement as well as any and all information derived from the approved analysis of the samples or materials will also constitute Confidential Information. A party's rights and obligations under this Section 11 will apply to any Confidential Information that is disclosed by or received by that party's Representatives. For the purposes of this Section 11, a party receiving Confidential Information under this Agreement (including through its Representatives) is a "**Recipient**", and a party disclosing Confidential Information under this Agreement (including through its Representatives) is the "**Disclosing Party**". The existence, parties to, and terms of this Agreement will be considered Confidential Information.

11.2 Use of Confidential Information.

The Recipient will use the Confidential Information solely for the purpose of meeting its obligations under this Agreement. The Recipient will keep the Confidential Information strictly confidential and will not disclose the Confidential Information in any manner whatsoever, in whole or in part, other than to those of its Representatives who (a) have a need to know the Confidential Information for the purpose of this Agreement; (b) have been advised of the confidential nature of the Confidential Information and (c) have obligations of confidentiality and non-use to the Recipient no less restrictive than those of this Agreement. Recipient will protect the Confidential Information disclosed to it by using reasonable precautions to prevent the unauthorized disclosure, dissemination or use of the Confidential Information, which precautions will not be less than those exercised by Recipient for its own confidential or proprietary Confidential Information of a similar nature.

11.3 Exclusions.

The obligations of confidentiality in this Section 11 will not apply to the extent that Confidential Information:

(a) is or becomes publicly known through no breach of this Agreement by the Recipient or its Representatives;

(b) is in the Recipient's possession at the time of disclosure by the Disclosing Party other than as a result of the Recipient's or Third Party's breach of any legal obligation;

(c) is or becomes known to the Recipient on a non-confidential basis through disclosure by sources, other than the Disclosing Party, having the legal right to disclose the Confidential Information, if the other source is not known by the Recipient to be bound by any obligations (contractual, legal, fiduciary, or otherwise) of confidentiality to the Disclosing Party for the Confidential Information;

(d) is independently developed by the Recipient without use of or reference to the Disclosing Party's Confidential Information as evidenced by Recipient's written records; or

(e) is expressly authorized for release by the written authorization of the Disclosing Party.

Any combination of information which comprises part of the Confidential Information is not exempt from the obligations of confidentiality merely because individual parts of that Confidential Information are covered by exceptions in this Section 11.3, unless the combination itself is covered by any of those exceptions.

11.4 Photographs and Recordings.

Neither party will take any photographs or videos of the other party's facilities, equipment or processes, nor use any other audio or visual recording equipment (such as camera phones) while at the other party's facilities, without that party's express written consent.

11.5 Permitted Disclosure.

Notwithstanding any other provision of this Agreement, the Recipient may disclose Confidential Information of the Disclosing Party to the extent required, as advised by counsel, in response to a valid order of a court or other governmental body or as required by law, regulation or stock exchange rule. In such an instance, the Recipient will advise the Disclosing Party in advance of the disclosure and limit the required disclosure to the extent practicable and permissible by the order, law, regulation or stock exchange rule and any other applicable law, will reasonably cooperate with the Disclosing Party, if required, in seeking an appropriate protective order or other remedy, and will otherwise continue to perform its obligations of confidentiality set out in this Agreement. If any public disclosure is required by law, the parties will consult concerning the form of announcement prior to the public disclosure being made.

11.6 Return or Destruction of Confidential Information.

Upon the written request of the Disclosing Party, the Recipient will promptly return the Confidential Information to the Disclosing Party or, if the Disclosing Party directs, destroy all Confidential Information disclosed in or reduced to tangible form including any copies, summaries, compilations, analyses or other notes derived from the Confidential Information except for one copy which may be maintained by the Recipient for its records. The retained copy will remain subject to all confidentiality provisions contained in this Agreement. Client will not unreasonably require the return of Confidential Information that is necessary or useful to perform the Manufacturing Services.

11.7 Injunctive Relief.

The parties acknowledge that monetary damages may not be sufficient to remedy a breach by either party of this Section 11 and agree that the non-breaching party may be entitled to seek specific performance, injunctive or other equitable relief to prevent breaches of this Section 11 and to specifically enforce this Section 11 in addition to any other remedies available at law or in equity. These remedies will not be the

exclusive remedies for breach of this Section 11 but will be in addition to any and all other remedies available at law or in equity.

12. Intellectual Property

12.1 Proprietary Rights.

(a) For the term of this Agreement, Client grants to Patheon a non-exclusive, paid-up, royalty-free, non-transferable license of Client's Intellectual Property that is necessary in order to perform the Manufacturing Services, solely for the performance of such Manufacturing Services.

(b) All Client Intellectual Property will be the exclusive property of Client. All rights to and interests in Client Intellectual Property will remain solely in Client and, other than as set forth herein, no right or interest therein is transferred or granted to Patheon under this Agreement. Patheon acknowledges and agrees that it does not acquire a license or any other right to Client Intellectual Property except for the limited purpose of carrying out its duties and obligations under this Agreement and that such license will expire upon the expiration or termination of this Agreement.

(c) All Patheon Intellectual Property will be the exclusive property of Patheon. Unless Patheon identifies in advance any specific Patheon Intellectual Property that will be subject to a separate licensing agreement between the parties, Patheon grants to Client a non-exclusive, perpetual, paid-up, royalty-free, transferable license of the Patheon Intellectual Property used by Patheon in the Manufacturing Services for use in relation to manufacturing that Product only.

(d) Each party will be responsible for the costs of filing, prosecution, and maintenance of patents and patent applications on its own Inventions. Notwithstanding the foregoing, Patheon agrees to provide reasonable assistance upon request by Client in any filing, prosecution or maintenance of any patents and patent applications generated as a result of an Invention under this Agreement.

12.2 No Transfer of Intellectual Property.

Neither party has, nor will it acquire, any interest in any of the other party's Intellectual Property unless otherwise expressly agreed to in writing, or as set forth in this Agreement. Neither party will use any Intellectual Property of the other party, except as specifically authorized by the other party or as required for the performance of its obligations under this Agreement.

13. Miscellaneous

13.1 Insurance.

Each party will maintain commercial general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for a period of three years after that. This insurance will have policy limits of not less than: (a) [**] for each occurrence for personal injury or property damage liability; and (b) [**] in the aggregate per annum for product and completed operations liability. If requested, each party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of [**] written notice to the insured of a cancellation of, or material change in, the insurance. If a party is unable to maintain the insurance policies required under this Agreement through no fault of its own, then the party will without delay notify the other party in writing and the parties will in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.

13.2 Independent Contractors.

The parties are independent contractors and this Agreement does not create between the parties any other relationship such as, by way of example only, that of employer and employee, principal and agent, joint-venturers, co-partners, or any similar relationship, the existence of which is expressly denied by the parties.

13.3 No Waiver.

Neither party's failure to require the other party to comply with any provision of this Agreement or will be considered a waiver of the provision or any other provision of this Agreement.

13.4 Assignment.

(a) Patheon may not assign this Agreement or any of its associated rights or obligations without the written consent of Client, this consent not to be unreasonably withheld.

(b) Subject to Section 8.2(e), Client may assign this Agreement or any of its associated rights or obligations without approval from Patheon. Notwithstanding the foregoing, Client will give Patheon prior written notice of any assignment, and any assignee will covenant in writing with Patheon to be bound by the terms of this Agreement, and Client will remain liable under this Agreement.

(c) [**]. Any assignee under this Section 13.4 must execute an agreement with the non-assigning party whereby it agrees to be bound by the obligations of this Agreement owed to that party.

13.5 Exclusivity and Patent Challenges.

The parties acknowledge that Client or its Affiliates shall supply secret and substantial know-how to Patheon for the purposes of this Agreement. In order to protect that know-how, and without prejudice to Patheon's obligations under this Agreement, Patheon agrees that [**] and provided that the Agreement has not expired or terminated:

(a) Patheon shall [**]; and

(b) Patheon shall [**].

Within [**] following the Effective Date of this Agreement, the parties will negotiate in good faith [**] related to the Product under this Agreement [**]. If the parties agree to [**] of the Effective Date of this Agreement [**].

If the parties [**] following the Effective Date, then [**].

In addition, neither [**]. Patheon further agrees that, during the Term, neither Patheon nor any of its Affiliates shall

i. commence or participate in any action or proceeding (including, without limitation, any court action, inter parte review, post-grant review, patent opposition or re-examination proceeding), or otherwise assert in writing any claim, challenging or denying the validity of any of the Client patents, or any claim thereof (each, a "**Patent Challenge**"),

ii. actively assist any other person or entity in bringing, prosecuting or maintaining any Patent Challenge; or

iii. in any country where Client holds Client patent rights, seek marketing authorization, or actively assist any other person or entity to seek marketing authorization of a generic version of vadadustat thereof, including, without limitation, the filing of an Abbreviated New Drug Application or an equivalent thereof within and outside of the United States.

13.6 Force Majeure.

Except as otherwise expressly set forth in this Agreement, neither party will be deemed to have breached this Agreement for failure or delay in fulfilling or performing any obligation under this Agreement when such failure or delay is caused by or results from Force Majeure. The party affected by any Force Majeure will promptly notify the other party, explaining the nature, details and expected duration thereof. Such party will also notify the other party from time to time as to when the affected party reasonably expects to resume performance in whole or in part of its obligations under this Agreement and notify the other party of the cessation of any such event. A party affected by Force Majeure will [**] remedy, remove or mitigate such event and the effects thereof with all reasonable dispatch. Upon termination of the Force Majeure, the performance of any suspended obligation or duty will promptly recommence. In the event that Patheon's failure or delay remains uncured for a period of [**], Client may thereafter terminate this Agreement

immediately upon written notice, and Patheon agrees to provide any assistance required with any necessary technology transfer that Client may require at Client's expense.

13.7 Additional Services.

If Client requests services other than those expressly set out in this Agreement (such as qualification of a new packaging configuration or shipping studies, or validation of alternative batch sizes), or any cost items that are specifically excluded from the Price, Patheon will provide a written quote of the fee for the additional services and Client will advise Patheon whether it wishes to have the additional services performed by Patheon. The scope of work and fees will be agreed in writing by the parties.

13.8 Notices.

Any notice, approval, instruction or other written communication required or permitted under this Agreement will be sufficient if made or given to the other party by personal delivery, confirmed email receipt or by sending the same by first class mail, postage prepaid to the respective addresses or email addresses set out below:

If to Client:

Akebia Therapeutics Inc.
245 First Street, Suite 1100
Cambridge, MA 02142
Attention: Head of vadadustat Manufacturing
CC: General Counsel

If to Patheon:

Patheon Inc.
[**]
Attention: [**]
Email address: [**]

or to any other addresses or email addresses given to the other party in accordance with the terms of this Section 13.8. Notices or written communications made or given by personal delivery will be considered to have been sufficiently made or given when sent (receipt acknowledged), or if mailed, five days after being deposited in the mail, postage prepaid or upon receipt (supported by reasonable written evidence), whichever is sooner.

13.9 Severability.

If any provision of this Agreement is determined by a court of competent jurisdiction to be invalid, illegal, or unenforceable in any respect, that determination will not impair or affect the validity, legality, or enforceability of the remaining provisions, because each provision is separate, severable, and distinct.

13.10 Entire Agreement.

This Agreement, together with its Appendices, Capital Equipment Agreement (if any) and the Quality Agreement, constitutes the full, complete, final and integrated agreement between the parties relating to the subject matter of the Agreement and, with the exception of any outstanding or ongoing statement of work or work order under any preceding agreement (which will continue in full force and effect until the work under such mechanisms are completed or terminated) supersedes all previous written or oral negotiations, commitments, representations, agreements, transactions, or understandings concerning the subject matter of this Agreement. The basis of the parties' agreement is set out expressly and they have not been induced by, nor do they rely on any statement or representation that is not set out in this Agreement. Any modification, amendment, or supplement to this Agreement must be in writing and signed by authorized representatives of both parties. In case of conflict, the prevailing order of documents will be this Agreement and then the Quality Agreement (except that the Quality Agreement will prevail in relation to quality matters).

13.11 Other Terms.

No terms, provisions or conditions of any purchase order or other business form or written authorization used by the parties will have any effect on the rights, duties, or obligations of the parties under or otherwise modify this Agreement, regardless of any failure of a party to object to the terms, provisions, or conditions unless the document specifically refers to this Agreement and is signed by both parties.

13.12 No Third Party Benefit or Right.

Nothing in this Agreement will confer or be construed as conferring on any third party any benefit or the right to enforce any express or implied term of this Agreement (except that Patheon Affiliates acting as subcontractors under this Agreement may enforce Sections 10.1 and 0).

13.13 Execution in Counterparts.

This Agreement may be executed in two or more counterparts, by original or electronic (including "pdf") signature, each of which will be considered an original, but all of which together will constitute one and the same instrument.

13.14 Use of Name.

With exception to any disclosures required by Applicable Law, or disclosures required for securities filings or other required corporate functions, either party may publicly use the other party's name, trademarks or logo or any variations of them, alone or with any other word or words, without the prior written consent of the other party.

13.15 Taxes.

The Prices specified in this Agreement are exclusive of any sales, use, excise, value added tax, or similar taxes, and of any export and import duties which may be levied as a result of the shipment of the Product. It shall be Patheon's sole obligation to report all compensation received by Patheon hereunder for Services as may be required by Applicable Law. Client shall pay all applicable sales and use taxes, including all applicable goods and services tax, value added tax, local taxes, applicable duties, electronic delivery taxes, sales, use and excise taxes, levies and import and export fees (collectively, "Taxes") that are required by law stemming directly from the provision of the Manufacturing Services. Patheon shall reasonably cooperate and assist Client in recovering any non-applicable taxes due to Client. Where any Taxes are paid directly to a tax authority or government by Client, Client shall not deduct this amount from any amount due to Patheon.

13.16 Governing Law and Jurisdiction.

This Agreement, and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with them or their subject matter or formation are governed by the laws of the [**], without regard to any conflicts-of-law principle that directs the application to another jurisdiction's law. Both parties submit to the exclusive jurisdiction of the courts in the applicable location.

13.17 Dispute Resolution.

Negotiation

If any dispute arises out of this Agreement, the parties will first try to resolve it amicably. Any party may send a notice of a dispute to the other. The representatives of each party will meet as necessary in order to resolve the dispute. If the representatives fail to resolve the matter within [**] from the date a dispute notification is received, or if a party fails to appoint a representative as required above:

(a) for Technical Disputes (as defined below) the expert determination procedure may be started by either party;

(b) for all other disputes, each party will refer the dispute immediately to the appropriate senior officers of the respective companies (which may include the Chief Executive Officers) ("Senior Officers") who will meet and discuss as necessary to try to resolve the dispute amicably.

Mediation

If the Senior Officers fail to resolve the dispute, the parties may attempt in good faith to settle the dispute promptly by confidential mediation under procedures to be agreed at that time between the parties, before resorting to litigation. The mediation will take place in [**], and the language of the mediation will be English.

Technical Disputes

In case of any disagreement between the Parties regarding as to whether any Product fails to conform to the Specifications or has otherwise been manufactured in accordance with the Quality Agreement, this Agreement, or cGMP, the quality assurance representatives of the parties will attempt to resolve any such disagreement in good faith. If the disagreement is not resolved in a reasonable time (which will not exceed [**]), a representative sample of the Product and/or relevant documentation will be submitted to an independent testing laboratory of recognized standing in the industry and agreed upon by the parties for tests and final determination of whether or not such product conforms to the Specifications, the Quality Agreement, this Agreement, or cGMP. Such laboratory will use the test methods contained in the applicable Specifications. The determination of conformance by such laboratory will be final and binding on the parties. The fees and expenses of the laboratory will be paid by the party against whom the determination is made.

[Signature page to follow]

This Agreement is signed by the authorized representatives of the parties on the dates shown below and will take effect from the Effective Date.

PATHEON INC.		AKEBIA THERAPEUTICS INC.	
By:	/s/ Don Liscombe	By:	/s/ Jason Amello
Name:	Don Liscombe	Name:	Jason Amello
Title:	Sr Director/General Manager	Title:	SVP, Chief Financial Officer
Date:	09 March 2020	Date:	11-Mar-2020
		By:	/s/ John Butler
		Name:	John Butler
		Title:	CEO
		Date:	11-Mar-2020

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: May 5, 2020

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: May 5, 2020

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 March 31, 2020 (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: May 5, 2020

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

Date: May 5, 2020

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