Akebia Therapeutics, Inc.
Form 10-Q
November 08, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2018

OR

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

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.

Class	Outstanding at October 31, 2018
Common Stock, $0.00001 par value	57,059,063

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. These forward-looking statements may be accompanied by words such as "anticipate," "believe," "build," "can," "contemplate," "continue," "could," "designed," "estimate," "expect," "forecast," "futu "likely," "may," "plan," "possible," "potential," "predict," "strategy," "seek," "target," "will," "would," and other words and te meaning. These forward-looking statements include, but are not limited to, statements about:

- our expectations with respect to (i) the closing of our proposed merger, or the Merger, with Keryx Biopharmaceuticals, Inc., or Keryx, including with respect to matters of timing, shareholder approval by our and Keryx's shareholders, regulatory approval and other closing conditions, (ii) the anticipated financial impact and potential benefits to us related to the Merger, (iii) integration of the businesses assuming completion of the Merger, and (iv) other matters related to the Merger;
- the potential therapeutic applications of the HIF pathway;
- our pipeline, including its potential, and our research activities;
- the potential therapeutic benefits, safety profile, and effectiveness of our product candidates, including the potential for vadadustat to set a new standard of care in the treatment of anemia due to chronic kidney disease;
- the potential indications and market potential and acceptance of our product candidates;
- our competitive position, including estimates, developments and projections relating to our competitors and their products and product candidates, and our industry;
- our expectations, projections and estimates regarding our costs, expenses, revenues, capital requirements, need for additional capital, financing our future cash needs, capital resources, cash flows, financial performance, profitability, tax obligations, liquidity, growth, contractual obligations, the period of time our cash resources and collaboration funding will fund our current operating plan, internal control over financial reporting, and disclosure controls and procedures;
- the timing of the availability and disclosure of clinical trial data and results;
- our and our collaborators' strategy, plans and expectations with respect to the development, manufacturing, commercialization, launch, marketing and sale of our product candidates, and the associated timing thereof;
- the designs of our studies, and the type of information and data expected from our studies and the expected benefits thereof;
- the timing of or likelihood of regulatory filings and approvals, including labeling or other restrictions;
- 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 our collaborators and licensees, and the anticipated arrangements and benefits under our collaboration and license agreements;
- 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;
- expected reliance on third parties;
- 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; and
- 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.

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 and in the Risk Factors section of our definitive proxy statement/prospectus relating to the Merger that was filed with the U.S. Securities and Exchange Commission on October 30, 2018, 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 the proposed Merger or any other 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.

Akebia Therapeutics, Inc.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except share and per share data)

	September 30, 2018	December 31, 2017 (as revised)
Assets		
Current assets:		
Cash and cash equivalents	$ 162,430	$ 70,156
Available for sale securities	227,714	247,636
Accounts receivable	688	34,216
Prepaid expenses and other current assets	6,694	6,348
Total current assets	397,526	358,356
Property and equipment, net	3,808	3,617
Other assets	2,492	2,274
Total assets	$ 403,826	$ 364,247
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 12,684	$ 6,998
Accrued expenses	94,616	52,441
Short-term deferred revenue	70,099	81,667
Total current liabilities	177,399	141,106
Deferred rent, net of current portion	2,421	2,588
Deferred revenue, net of current portion	81,424	97,957
Other non-current liabilities	41	22
Total liabilities	261,285	241,673
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock $0.00001 par value, 25,000,000 shares authorized; 0 shares issued and outstanding at September 30, 2018 and December 31, 2017	—	—
Common stock: $0.00001 par value; 175,000,000 shares authorized at September 30, 2018 and December 31, 2017; 57,046,563 and 47,612,619 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	1	—
Additional paid-in capital	597,290	493,823
Accumulated other comprehensive loss	(409)	(442)
Accumulated deficit	(454,341)	(370,807)
Total stockholders' equity	142,541	122,574

Total liabilities and stockholders' equity	$ 403,826	$ 364,247

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Collaboration revenue	$53,169	$41,283	$147,892	$90,668
Operating expenses:				
Research and development	70,634	58,711	203,955	162,511
General and administrative	10,378	6,748	31,940	19,441
Total operating expenses	81,012	65,459	235,895	181,952
Operating loss	(27,843)	(24,176)	(88,003)	(91,284)
Other income:				
Interest income	1,780	842	4,417	1,886
Other income	16	200	52	204
Net loss	$(26,047)	$(23,134)	$(83,534)	$(89,194)
Net loss per share - basic and diluted	$(0.46)	$(0.49)	$(1.54)	$(2.11)
Weighted-average number of common shares - basic and diluted	57,027,598	46,938,618	54,207,973	42,202,560
Comprehensive loss:				
Net loss	$(26,047)	$(23,134)	$(83,534)	$(89,194)
Other comprehensive gain (loss) - unrealized gain (loss) on debt securities	50	73	33	(181)
Total comprehensive loss	$(25,997)	$(23,061)	$(83,501)	$(89,375)

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Nine Months Ended	
	September 30, 2018	September 30, 2017 (as revised)
Operating activities:		
Net loss	$(83,534)	$ (89,194)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	638	420
Amortization of premium/discount on investments	(698)	543
Stock-based compensation	6,978	6,674
Fair value of warrants issued for license	—	3,413
Changes in operating assets and liabilities:		
Accounts receivable	33,528	33,542
Prepaid expenses and other current assets	(346)	(1,797)
Other long-term assets	67	(4)
Accounts payable	5,686	6,666
Accrued expense	42,118	(8,834)
Deferred revenue	(28,101)	8,443
Deferred rent	(131)	347
Net cash used in operating activities	(23,795)	(39,781)
Investing activities:		
Purchase of equipment	(776)	(1,172)
Proceeds from the maturities of available for sale securities	180,091	97,868
Proceeds from sales of available for sale securities	13,000	—
Purchase of available for sale securities	(172,438)	(265,648)
Net cash provided by (used in) investing activities	19,877	(168,952)
Financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	95,453	109,541
Proceeds from the sale of stock under employee stock purchase plan	482	352
Proceeds from the exercise of stock options	555	1,108
Payments on capital lease obligations	(13)	(4)
Net cash provided by financing activities	96,477	110,997
Increase (decrease) in cash, cash equivalents, and restricted cash	92,559	(97,736)
Cash, cash equivalents, and restricted cash at beginning of the period	71,437	188,616
Cash, cash equivalents, and restricted cash at end of the period	$163,996	$ 90,880

See accompanying notes to unaudited condensed consolidated financial statements

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Akebia Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

1. Nature of Organization and Operations

The Company is a biopharmaceutical company focused on developing and commercializing novel therapeutics for patients based on hypoxia-inducible factor, or HIF, biology, and building its pipeline while leveraging its development and commercial expertise in renal disease. HIF is the primary regulator of the production of red blood cells in the body, as well as other important metabolic functions. Pharmacologic modulation of the HIF pathway may have broad therapeutic applications. The Company's lead product candidate, vadadustat, is an oral therapy in Phase 3 development, and has the potential to set a new standard of care in the treatment of anemia due to chronic kidney disease, or CKD. The Company's management team has extensive experience in developing and commercializing drugs for the treatment of renal and metabolic disorders, as well as a deep understanding of HIF biology. This unique combination of HIF and renal expertise is enabling the Company to advance a pipeline of HIF-based therapies to potentially address serious diseases.

Since inception, the Company has devoted most of its resources to research and development, including its preclinical and clinical development activities, raising capital, and providing general and administrative support. 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. The Company has not generated any product revenue to date and may never generate any product revenue in the future.

The Company believes that its existing cash, cash equivalents, and available for sale securities of approximately $390.1 million at September 30, 2018, together with the committed funding from its collaboration partners, will be sufficient to allow the Company to fund its current operating plan through the first quarter of 2020 and, as a result, through at least twelve months from the filing of the Company's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018. 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. The Company will require additional capital for the further development of its existing product candidates and will need to raise additional funds to pursue development activities related to additional product candidates; however, there can be no assurances that additional funding will be available on terms acceptable to the Company, or at all. If and until the Company can generate a sufficient amount of revenue from its products, it expects to finance future cash needs through public or private equity or debt offerings, payments from its collaborators, strategic transactions, or a combination of these approaches.

On June 28, 2018, the Company entered into an Agreement and Plan of Merger, which was amended on October 1, 2018, or the Merger Agreement, with Keryx Biopharmaceuticals, Inc., or Keryx, and Alpha Therapeutics Merger Sub, Inc., a direct, wholly owned subsidiary of the Company, or the Merger Sub., pursuant to which the Merger Sub shall be merged with and into Keryx, with Keryx surviving as a wholly owned subsidiary of the Company, subject to the satisfaction or waiver of the conditions specified in the Merger Agreement, or the Merger.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, each share of common stock of Keryx issued and outstanding immediately prior to the effective time of the Merger will be cancelled and converted into the right to receive 0.37433, or the Exchange Multiplier, fully paid and non-assessable

shares of common stock of the Company. The Merger Agreement also provides that at the effective time of the Merger, each share of Keryx common stock that is subject to an outstanding Keryx restricted stock award issued under a Keryx equity plan, or Keryx Restricted Shares, other than those Keryx Restricted Shares that accelerate or lapse as a result of the completion of the Merger, will convert into restricted stock unit awards, or RSUs, of the Company, the number of which will be adjusted in accordance with the Exchange Multiplier, and in accordance with the terms of the Merger Agreement. In addition, each outstanding and unexercised option to acquire Keryx common stock granted under the Keryx equity plan will be converted into an option to acquire shares of the Company's common stock, with the number of shares and exercise price adjusted by the Exchange Multiplier, in accordance with the terms of the Merger Agreement. The foregoing exchange is expected to result in implied equity ownership in the combined company of 49.4 percent for the Company shareholders and 50.6 percent for Keryx shareholders on a fully-diluted basis, calculated based on the companies' fully diluted market capitalizations as of the date of signing of the Merger Agreement and also taking into account the 4,000,000 additional shares of Keryx common stock that are expected to be issued to Keryx's significant shareholder, Baupost Group Securities, L.L.C., or Baupost, prior to consummation of the Merger, as described below.

The Merger is expected to be completed by the end of 2018 and is subject to the satisfaction of customary closing conditions including, among other things, (i) approval by the affirmative vote of the holders of a majority of the votes cast affirmatively or negatively, at the Company's shareholders' meeting in favor of the issuance of Company common stock in connection with the Merger, (ii) the adoption of the Merger Agreement by the affirmative vote of the holders of a majority of all outstanding shares of Keryx common stock entitled to vote thereon and (iii) the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, which waiting period was terminated by the Federal Trade Commission on August 21, 2018. The Company's obligation to consummate the Merger is also subject to the conversion of Keryx's Zero Coupon Convertible Senior Notes due 2021, or Senior Notes, pursuant to the terms of the Notes Conversion Agreement entered into by the Company, Keryx and Baupost. The Merger Agreement provides for certain termination rights for both the Company and Keryx. Upon termination of the Merger under certain specified circumstances, the Company or Keryx may be required to pay the other party a termination fee of $22.0 million.

Keryx, headquartered in Boston, Massachusetts, is focused on the development and commercialization of medicines for people with kidney disease. Keryx's proprietary product, Auryxia® (ferric citrate) tablets, is approved by the U.S. Food and Drug Administration, or FDA, for two indications: (1) the control of serum phosphorus levels in adult patients with chronic kidney disease on dialysis and (2) the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis.

Simultaneously with the execution of the Merger Agreement, the Company entered into a Voting Agreement with Baupost and the Notes Conversion Agreement with Baupost and Keryx. Pursuant to the Voting Agreement, Baupost agreed, among other things, to vote its shares in favor of the adoption of the Merger Agreement and against any alternative proposal and against approval of any proposal made in opposition to, in competition with, or inconsistent with, the Merger Agreement or the Merger or any other transactions contemplated by the Merger Agreement. Pursuant to the Notes Conversion Agreement, Baupost agreed to convert Keryx's Senior Notes into 35,582,335 shares of Keryx common stock in accordance with the terms of the governing indenture immediately prior to the effective time of the Merger, conditioned upon the issuance to Baupost of an additional 4,000,000 shares of Keryx common stock. The Notes Conversion Agreement provides that the Company will execute a registration rights agreement with Baupost, to provide customary registration rights for any shares of Company common stock held by Baupost if and when the Merger is consummated.

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 United States of America, or U.S. GAAP, for interim financial reporting and as required by Regulation S-X, Rule 10-01. Accordingly, they do not include all of the information and footnotes required by 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. Certain amounts in the prior period financial statements have been revised to conform to the presentation of the current period financial statements. See "New Accounting Pronouncements – Recently Adopted" below for a discussion of certain revisions to prior period financial statements made in connection with the Company's adoption of

new revenue recognition guidance retroactive to January 1, 2016. Otherwise, these reclassifications had no significant effects on the previously reported net loss. Interim results for the three and nine months ended September 30, 2018 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2018 or any other future period.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Akebia Therapeutics Securities Corporation, Akebia Europe Limited and the Merger Sub. 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 proprietary therapeutics based on HIF biology. 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, 2017 filed with the Securities and Exchange Commission on March 12, 2018, or the 2017 Annual Report on Form 10-K.

The significant accounting policies used in preparation of these unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2018 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's 2017 Annual Report on Form 10-K and are updated below as necessary.

New Accounting Pronouncements – Recently Adopted

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606), a new revenue recognition standard which amends revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. This ASU supersedes the revenue recognition requirements in ASC Topic 605, Revenue Recognition. In 2015 and 2016, the FASB issued additional ASUs related to Topic 606, or ASC 606, that delayed the effective date of the guidance and clarified various aspects of the new revenue guidance, including principal versus agent considerations, identifying performance obligations, and licensing, and they include other improvements and practical expedients. The Company adopted this new standard on January 1, 2018 using the full retrospective transition method, and has elected to use the following practical expedients that are permitted under the rules of the adoption, which have been applied consistently to all contracts within all reporting periods presented:

- For all reporting periods presented before January 1, 2018, the Company has not disclosed the amount of the transaction price allocated to the remaining performance obligations or an explanation of when the Company expects to recognize the amount as revenue.
- The Company has not adjusted the promised amount of consideration for the effects of a significant financing component when the Company expects, at contract inception, that the period between when the entity transfers a promised good or a service to a customer and when the customer pays for that good or service will be one year or less.
- 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.

The Company, as a result of adopting ASC 606 on January 1, 2018, has revised its comparative financial statements for the prior year as if ASC 606 had been effective for that period, as set forth below. No changes for the adoption of ASC 606 were deemed necessary for the year ended December 31, 2016 and applicable interim periods within the year.

With respect to the collaboration agreements with Otsuka Pharmaceutical Co. Ltd., or Otsuka, and Mitsubishi Tanabe Pharma Corporation, or MTPC, the Company concluded that there was no impact to revenue for the three and nine months ended September 30, 2017 after the adoption of ASC 606. As a result, there is no change to the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2017.

The changes shown in the table below relate to the Company's collaboration agreement with MTPC and the impact of when milestone payments can be recognized under the new standard as well as the period over which this revenue is recognized. Under ASC 605-28, Revenue Recognition-Milestone Method, the Company evaluates at contract inception whether each milestone is substantive. Substantive milestones are recognized as revenue in their entirety upon achievement, assuming all other revenue recognition criteria are met. Therefore, a $4.0 million MTPC development milestone, which was deemed to be substantive, would have been recognized in its entirety in the first quarter of 2018, when the milestone event occurred. Under ASC 606, these substantive milestone payments would be classified as variable consideration and included in the allocable transaction price over the remaining period of performance when it is probable that a significant reversal in the cumulative amount of revenue recognized would not occur. Under ASC 606, this resulted in the $4.0 million MTPC development milestone being included in the allocable consideration, of which $3.2 million was recognized as revenue in 2017 under the proportional performance method utilized for revenue recognition of the MTPC allocable consideration. For further discussion of the adoption of this standard, see Note 3.

	December 31, 2017 (in thousands)

	As revised under ASC 606	As originally reported under ASC 605	Effect of change
Short-term deferred revenue	$81,667	$84,910	$(3,243)
Accumulated deficit	$(370,807)	$(374,050)	$3,243

In October 2016, the FASB issued ASU 2016-18, Restricted Cash, which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally describes as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017, and interim periods within those years, using a retrospective transition method to each period presented, with early adoption permitted. The ASU requires the application of a retrospective transition method to each period presented. The Company elected to adopt this ASU effective January 1, 2018. The adoption of this guidance resulted in the relocation of $1.3 million in restricted cash from cash used in operating activities to cash, cash equivalents, and restricted cash at the beginning of the period in the unaudited condensed consolidated statement of cash flows for each of the nine months ended September 30, 2018 and 2017.

New Accounting Pronouncements – Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires entities to recognize right-of-use assets and lease liabilities for leases with lease terms of more than 12 months on their balance sheets and provide enhanced disclosures. In July 2018, the FASB issued additional ASUs related to Topic 842, or ASC 842, that clarified various aspects of the new lease guidance, including how to record certain transition adjustments, as well as other improvements and practical expedients. ASC 842 is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities; however, the Company has elected to not early adopt. ASC 842 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently evaluating the impact of this new standard on its consolidated financial statements and related disclosures; however, it expects the adoption of this new guidance will result in the Company recording additional assets and corresponding liabilities on its consolidated balance sheets. The Company plans to adopt ASC 842 using the modified retrospective approach with the cumulative effect of adoption recognized to retained earnings on January 1, 2019.

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, stock-based compensation expense, revenue and income taxes.

Cash, Cash Equivalents, and Restricted Cash

Cash and cash equivalents consist of all cash on hand, deposits and funds invested in available-for-sale securities with original maturities of three months or less at the time of purchase. At September 30, 2018, 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 is included in “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 consolidated balance sheet that sum to the total of the amounts reported in the unaudited condensed consolidated statement of cash flows (in thousands):

	September 30, 2018	September 30, 2017
Cash and cash equivalents	$ 162,430	$ 89,599
Other assets	1,566	1,281
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$ 163,996	$ 90,880

Restricted cash represents amounts required for security deposits under our office and lab space lease agreement.

Investments

Management determines the appropriate classification of securities at the time of purchase and reevaluates such designation as of each balance sheet date. Currently, the Company classifies all securities as available for sale which are included in current assets as they are intended to fund current operations. The Company carries available for sale securities at fair value. The Company conducts periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. When assessing whether a decline in the fair value of a security is other-than-temporary, the Company considers the fair market value of the security, the duration of the security's decline, and prospects for the underlying business. Based on these considerations, the Company did not identify any other-than-temporary unrealized losses at September 30, 2018. Unrealized losses on available for sale securities that are determined to be temporary, and not related to credit loss, are recorded in accumulated other comprehensive loss, a component of stockholders' equity. The amortized cost of debt securities in this category reflects amortization of premiums and accretion of discounts to maturity computed under the effective interest method. The Company includes this amortization in the caption "Interest income" within the consolidated statements of operations and comprehensive loss. The Company also includes in net investment income, realized gains and losses and declines in value determined to be other than temporary. The Company bases the cost of securities sold upon the specific identification method and includes interest and dividends on securities in interest income.

Revenue Recognition

To date, the Company has not generated any revenue from the sales of products. Unless and until the Merger is completed, for the foreseeable future, the Company expects substantially all of its revenues will be generated from its collaborations with MTPC and Otsuka, see Note 3, and any other collaborations the Company may enter into.

ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity 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 an entity determines are within the scope of ASC 606, the entity 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. For a complete discussion of accounting for collaborations and other revenues, see Note 3 below.

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 deliverables represent separate performance obligations or whether they must be accounted for as a combined performance obligation as well as 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 the arrangement, the Company recognizes revenue from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, up-front fees. The Company will evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Milestone Payments

At the inception of each arrangement that includes development milestone payments, 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. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. 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. 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 will re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust 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). To date the Company has not recognized any royalty revenue resulting from its collaboration agreements.

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. The Company recognizes its allocation of the shared costs incurred with respect to the jointly conducted medical affairs and commercialization and non-promotional activities under the U.S. collaboration with Otsuka as a component of the related expense in the period incurred. During the three months ended September 30, 2018, the Company incurred approximately $0.2 million of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, as defined below in Note 3, of which approximately $0.1 million are reimbursable by Otsuka and recorded as a reduction to research and development expense during the three months ended September 30, 2018. During the three months ended September 30, 2018, Otsuka incurred approximately $0.5 million of costs related to the cost-sharing provisions of the

Otsuka U.S. Agreement, of which approximately $0.1 million are reimbursable by the Company and recorded as an increase to research and development expense during the three months ended September 30, 2018. To the extent product revenue is generated from the collaboration, the Company will recognize 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.

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 Topic 820, Fair Value Measurements and Disclosures (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 short-term investments, see Note 5. 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. The rate implicit within the Company's capital lease obligation approximates market interest rates.

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, 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 shares outstanding for the period, including any dilutive effect from outstanding options, warrants, restricted stock and RSUs using the treasury stock method.

Property and Equipment

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

The following is the summary of property and equipment and related accumulated depreciation as of September 30, 2018 and December 31, 2017.

	Useful Life	September 30, 2018	December 31, 2017
		(in thousands)	
Computer equipment and software	3	$914	$ 630
Furniture and fixtures	5	845	800
Equipment	7	1,011	628
Leasehold improvements	Shorter of the useful life or remaining lease term (10 years)	2,621	2,582
Office equipment under capital lease	3	114	36
		5,505	4,676
Less accumulated depreciation		(1,697)	(1,059)
Net property and equipment		$3,808	$ 3,617

Depreciation expense, including expense associated with assets under capital leases, was approximately $0.2 million for each of the three months ended September 30, 2018 and 2017, and approximately $0.6 million and $0.4 million for the nine months ended September 30, 2018 and 2017, respectively.

3. Strategic Collaborations and Other Significant Agreements

The Company recognized $53.2 million and $41.3 million in collaboration revenue for the three months ended September 30, 2018 and 2017, respectively, and approximately $147.9 million and $90.7 million for the nine months ended September 30, 2018 and 2017, respectively. The $53.2 million in collaboration revenue for the three months ended September 30, 2018 included $53.1 million of the transaction price for the Company's collaboration agreements with Otsuka (discussed below), all of which are recognized based on a proportional performance method, and approximately $25,000 for other services related to clinical and regulatory related activities performed by the Company on behalf of MTPC that are not included in the performance obligations identified under the MTPC Agreement. The $147.9 million in collaboration revenue for the nine months ended September 30, 2018 included $147.5 million of the transaction price for the MTPC Agreement and the Company's collaboration agreements with Otsuka and $0.3 million for other services related to clinical and regulatory related activities performed by the Company on behalf of MTPC that are not included in the performance obligations identified under the MTPC Agreement.

During the three and nine months ended September 30, 2018 and 2017, the Company recognized the following revenues from its strategic collaboration agreements and had the following deferred revenue balances as of September 30, 2018:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Collaboration Revenue:	2018	2017	2018	2017
	(in thousands)		(in thousands)	
MTPC Agreement	$—	$—	$9,281	$—
Otsuka U.S. Agreement	29,030	22,519	75,086	60,001
Otsuka International Agreement	24,114	18,764	63,176	30,667
Total Proportional Performance Revenue	$53,144	$41,283	$147,543	$90,668
MTPC Stability Studies	25	—	349	—
Total Collaboration Revenue	$53,169	$41,283	$147,892	$90,668

	September 30, 2018		
Deferred Revenue:	Short-Term	Long-Term	Total
	(in thousands)		
MTPC Agreement	$—	$ —	$—
Otsuka U.S. Agreement	41,152	43,669	84,821
Otsuka International Agreement	28,947	33,076	62,023
Vifor Agreement	—	4,679	4,679
Total	$70,099	$ 81,424	$151,523

The following table presents changes in the Company's contract assets and liabilities during the nine months ended September 30, 2018 and 2017 (in thousands):

Nine Months Ended September 30, 2018	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract assets:				
Other current assets	$—	$531	$(531)	$—
Accounts receivable[1]	$34,186	$120,283	$(153,938)	$531
Contract liabilities				
Deferred revenue	$179,624	$119,442	$(147,543)	$151,523
Accounts payable	$—	$4,427	$(1,040)	$3,387
Nine Months Ended September 30, 2017				
Contract assets - Accounts receivable	$33,823	$9,138	$(42,961)	$—
Contract liabilities - Deferred revenue	$197,289	$99,111	$(90,668)	$205,732

[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. These receivables represented approximately $157,000 and $30,000 of accounts receivables in the accompanying unaudited condensed consolidated balance sheet as of September 30, 2018 and the audited consolidated balance sheet as of December 31, 2017, respectively.

During the three and nine months ended September 30, 2018 and 2017, the Company recognized the following revenues as a result of changes in the contract asset and contract liability balances in the respective periods (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Revenue Recognized in the Period from:	2018	2017	2018	2017
Amounts included in deferred revenue at the beginning of the period	$53,144	$41,026	$110,974	$60,001
Performance obligations satisfied in previous periods	$—	$—	$6,813	$—

Mitsubishi Tanabe Pharma Corporation Collaboration Agreement

Summary of Agreement

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

The Company and MTPC agreed that, instead of including Japanese patients in the Company's global Phase 3 program for vadadustat, MTPC would be the sponsor of a Phase 3 program for vadadustat in Japan. Following consultation with the Japanese Pharmaceuticals and Medical Devices Agency, or the PMDA, MTPC initiated its Phase 3 development program for vadadustat in Japan in the fourth quarter of 2017. MTPC is responsible for the costs of the Phase 3 program in Japan and other studies required there, and will make no funding payments for the global Phase 3 program.

In consideration for the exclusive license and other rights contained in the MTPC Agreement, MTPC is obligated to make payments totaling up to $265.0 million, comprised of a $20.0 million upfront payment, up to $50.0 million in specified development and regulatory milestones, up to $175.0 million in specified commercial milestones, and a $20.0 million advance payment for Phase 2 studies in Japanese patients completed by the Company and reimbursable by MTPC, as well as tiered double-digit royalty payments of up to 20% on sales of vadadustat in the MTPC Territory.

The Company completed its Phase 2 study of vadadustat in non-dialysis dependent, or NDD, Japanese patients in Japan and reported top-line data in the third quarter of 2017. The Company also announced top-line data on its Phase 2 study of vadadustat in dialysis dependent, or DD, Japanese patients in Japan in the first quarter of 2018. The costs of these Phase 2 studies are reimbursable by MTPC. MTPC is obligated to reimburse the Company for costs to complete the Phase 2 studies in excess of the $20.0 million advance payment. The Company incurred approximately $20.5 million in Phase 2 costs through June 30, 2018 and did not incur any additional costs subsequent to June 30, 2018 as the studies have been completed. As a result, MTPC is required to reimburse the Company an additional approximately $0.5 million related to the two Phase 2 studies.

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

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

MTPC is required to make certain milestone payments to the Company aggregating 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 for the first product to achieve the associated event, and up to $175.0 million in commercial milestone payments associated with aggregate sales of all products. Additionally, if vadadustat is commercialized, the Company would be entitled to receive tiered royalty payments in the low double digits based on a percentage of net sales. 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, no additional milestone or royalty payments may ever be received from MTPC.

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

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. 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 two performance obligations identified in connection with the Company's obligations under the MTPC Agreement are as follows:

(i) License, Research and Clinical Supply Performance Obligation

The License Deliverable does not have standalone functionality from the Clinical Supply Deliverable. More specifically, the license delivered to MTPC does not provide the right to manufacture vadadustat. MTPC therefore, is prohibited from manufacturing any licensed product during clinical trials. Accordingly, MTPC must obtain the clinical trial products from the Company, which significantly limits the ability for MTPC to use the license for their intended use in a way that generates economic benefits.

The License Deliverable does not have standalone functionality from the knowledge transfer because MTPC cannot fully utilize the license for its intended purpose without the corresponding information regarding know-how, development data and regulatory materials possessed by the Company.

The License Deliverable does not have standalone functionality from the Research Deliverable because MTPC cannot fully utilize the license for its intended purpose without the performance of the Phase 2 dosing studies. The Phase 2 dosing studies needed to be performed prior to the PMDA approving any Phase 3 study to be performed in the MTPC Territory. Furthermore, MTPC cannot benefit from the Phase 2 dosing studies without the license and the undelivered Phase 3 clinical supply.

The License Deliverable does not have standalone functionality from the clinical supply, knowledge transfer or Phase 2 studies. As a result, the License Deliverable, clinical supply, knowledge transfer and Phase 2 studies do not qualify for separation and have been combined as a single performance obligation (the License, Research and Clinical Supply Performance Obligation).

(ii) Rights to Future Know-How Performance Obligation

The License, Research and Clinical Supply Deliverables combined have standalone functionality from the rights to future know how because MTPC can obtain the value of the License, Research and Clinical Supply Deliverables without receipt of any rights to future know how that may be discovered or developed in the future. As a result, the rights to future know how qualify for separation from the License, Research and Clinical Supply Performance Obligation.

The Company allocates the transaction price to each performance obligation based on the Company's best estimate of the relative standalone selling price. The Company developed a best estimate of the standalone selling price for the Rights to Future Know How Performance Obligation primarily based on the likelihood that additional intellectual property covered by the license conveyed will be developed during the term of the arrangement. 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 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 have been 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 will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

No amounts were allocated to the Rights to Know How Performance Obligation because the associated best estimate of standalone selling price was determined to be immaterial therefore the arrangement consideration will be allocated to the License, Research and Clinical Supply Performance Obligation.

As of September 30, 2018, 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,

and (iv) $10.0 million in development milestones received, comprised of a $6.0 million and a $4.0 million development milestone. All development milestones have been reached and no regulatory milestones have been assessed as probable of being reached as of September 30, 2018. Revenue for the License, Research and Clinical Supply Performance Obligation for the MTPC Agreement is being recognized using a proportional performance method using the Company's delivery of clinical supply of vadadustat to MTPC for the Phase 3 study as the basis. The Company recognized no revenue during the three months ended September 30, 2018, with respect to the MTPC Agreement as all deliverables were completed in the second quarter of 2018, and approximately $9.3 million during the nine months ended September 30, 2018. The revenue is classified as collaboration revenue in the accompanying unaudited condensed consolidated statements of operations. No revenues were recognized for the three and nine months ended September 30, 2017 with respect to the MTPC Agreement. As of September 30, 2018, there is no deferred revenue, approximately $0.5 million in accounts receivable, all of which is in unbilled accounts receivable.

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.

Pursuant to the terms of the Otsuka U.S. Agreement, the Company is responsible for performing all activities related to the development of vadadustat as outlined in the current global development plan. The current global development plan encompasses all activities with respect to the ongoing PRO_2TECT and $INNO_2VATE$ clinical programs through the filing for marketing approval, as well as certain other studies. Under the Otsuka U.S. Agreement, subject to the terms of the Otsuka Funding Option, as described below, the Company controls and retains final decision making authority with respect to the development of vadadustat. 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 will 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. Subject to the terms of the Otsuka Funding Option, as described below, the Company has retained final decision making authority with respect to all development matters, 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 represents 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 $167.5 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 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, if the costs incurred in completing the activities under the current global development plan exceed a certain threshold, or the Cost Threshold, then the Company may elect 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. In such event, the excess of the payments made under such election and Otsuka's allocated share of the current global development costs 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. In addition, decisions regarding certain development matters will be made jointly by the Company and Otsuka in accordance with the procedures set forth in the Otsuka U.S. Agreement. In September 2018, the Company exercised the Otsuka Funding Option, which will be effective when the Cost Threshold is exceeded. The Company estimates that the Cost Threshold will be exceeded in the second quarter of 2019.

In addition, Otsuka would be required to make certain milestone payments to the Company upon the achievement of specified development, regulatory and commercial events. More specifically, the Company is eligible to receive up to $125.0 million in development milestone payments and up to $65.0 million in regulatory milestone payments for the first licensed product to achieve the associated event. Moreover, the Company is eligible for up to $575.0 million in commercial milestone payments associated with aggregate sales of licensed products. 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 U.S. on a product-by-product basis on the date that one or more generic versions of vadadustat first achieves 90% market penetration. Either party may terminate the Otsuka U.S. Agreement in its entirety upon an uncured breach or insolvency on the part of the other party. Otsuka may terminate the Otsuka U.S. Agreement in its entirety upon 12 months' prior written notice at any time after the release of the first topline data from the global Phase 3 development program for vadadustat. In the event of termination of the Otsuka U.S. Agreement, all rights and licensees granted to Otsuka under the Otsuka U.S. Agreement will automatically terminate and the licenses granted to the Company will become freely sublicensable. In addition, the upfront payment, all development costs and milestone payments received by the Company prior to such termination will not be refunded to Otsuka.

Revenue Recognition

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

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

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

The License Deliverable does not have standalone functionality 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 have standalone functionality 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 also has standalone functionality 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 have standalone functionality 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 has standalone functionality 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 will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

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

As of September 30, 2018, the transaction price totaling $326.3 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 cost share payments to be received of approximately $167.5 million with respect to amounts incurred by the Company subsequent to December 31, 2016. As of September 30, 2018, no development or regulatory milestones have been assessed as probable of being reached and thus have been fully constrained.

During the three months ended September 30, 2018 and 2017, the Company recognized revenue totaling approximately $29.0 million and $22.5 million, respectively, and $75.1 million and $60.0 million during the nine months ended September 30, 2018 and 2017, respectively, with respect to the Otsuka U.S. Agreement. The revenue is classified as collaboration revenue in the accompanying condensed consolidated statements of operations. As of September 30, 2018, there is approximately $84.8 million of deferred revenue related to the Otsuka U.S. Agreement of which $41.1 million is classified as current and $43.7 million is classified as long-term in the accompanying condensed consolidated balance sheet based on the performance period of the underlying obligations. Additionally, as of September 30, 2018, there is approximately $1.9 million in contract liabilities (included in accounts payable) in the accompanying unaudited condensed consolidated balance sheet.

The Company determined that the medical affairs, commercialization and non-promotional activities elements of the Otsuka U.S. Agreement represent joint operating activities in which both parties are active participants and of which both parties are exposed to significant risks and rewards that are dependent on the success of the activities. Accordingly, the Company is accounting for the joint medical affairs, commercialization and non-promotional activities in accordance with ASC No. 808, Collaborative Arrangements (ASC 808). Additionally, the Company has determined that in the context of the medical affairs, commercialization and non-promotional activities, Otsuka does not represent a customer as contemplated by ASC 606-10-15, Revenue from Contracts with Customers – Scope and Scope Exceptions. As a result, the activities conducted pursuant to the medical affairs, commercialization and non-promotional activities plans will be accounted for as a component of the related expense in the period incurred. During the three months ended September 30, 2018, the Company incurred approximately $0.2 million of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement of which approximately $0.1 million are reimbursable by Otsuka and recorded as a reduction to research and development expense during the three months ended September 30, 2018. During the three months ended September 30, 2018, Otsuka incurred approximately $0.5 million of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.1 million are reimbursable by the Company and recorded as an increase to research and development expense during the three months ended September 30, 2018.

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

Summary of Agreement

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

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

Pursuant to the terms of the Otsuka International Agreement, the Company is responsible for performing all activities related to the development of vadadustat as outlined in the current global development plan; however, the parties may agree to allocate certain responsibilities to Otsuka. Under the Otsuka International Agreement, and subject to the terms of the Otsuka Funding Option described above, the Company controls and retains final decision-making authority with respect to the development of vadadustat other than with respect to certain development matters specific to the Otsuka International Territory. 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.

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. Subject to the terms of the Otsuka Funding Option described above, the Company has retained final decision making authority with respect to all development matters, other than decisions related to certain development matters specific to the Otsuka International Territory. 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 $176.1 million or more, depending on the actual current global development plan costs incurred. The costs associated with the performance of any mutually agreed upon development activities in addition to those outlined in the current global development plan will be subject to a cost sharing or reimbursement mechanism to be determined by the parties. Otsuka may elect to conduct additional studies of vadadustat in the EU, subject to the Company's right to delay such studies based on its objectives outside the Otsuka International Territory. Otsuka will pay a percentage of the costs of any such studies, and the Company will pay its portion of the costs in the form of a credit against future amounts due to the Company under the Otsuka International Agreement. The costs incurred related to any other development activities, which are pursued solely for obtaining or maintaining marketing approval in the Otsuka International Territory or otherwise performed solely with respect to the Otsuka International Territory that are incremental to the development activities included in the current global development plan, will be borne in their entirety by Otsuka. Otsuka will pay costs incurred with respect to medical affairs and commercialization activities in the Otsuka International Territory.

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

Unless earlier terminated, the Otsuka International Agreement will expire upon the expiration of the royalty term in the last country in the Otsuka International Territory. Either party may terminate the Otsuka International Agreement in its entirety upon an uncured material breach or insolvency on the part of the other party. Otsuka may terminate the Otsuka International Agreement in its entirety or for a specific region in the Otsuka International Territory upon 12 months' prior written notice at any time after the release of the first topline data from either the PRO$_2$TECT Phase 3 development program or the INNO$_2$VATE Phase 3 development program, whichever comes first. In the event of termination of the Otsuka International Agreement, all rights and licensees granted to Otsuka under the Otsuka International Agreement will automatically terminate, and the licenses granted to the Company will become freely sublicensable, but potentially subject to a future royalty. In addition, the upfront payment, all development costs and milestone payments received by the Company prior to such termination will not be eligible for refund to Otsuka.

Revenue Recognition

The Company has accounted for the Otsuka International Agreement separately from the collaboration arrangement with Otsuka with respect to the U.S. due to the lack of interrelationship and interdependence of the elements and payment terms within each of the contracts as they relate to the respective territories. Accordingly, the Company has

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

The Company has identified three performance obligations in connection with its obligation 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 has standalone functionality 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 has standalone functionality 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 has standalone functionality 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 has standalone functionality 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 will re-evaluate the transaction price in each reporting period and as uncertain events are resolved or other changes in circumstances occur.

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

As of September 30, 2018, the transaction price totaling $249.3 million is comprised of: (i) the up-front payment of $73.0 million, (ii) the cost share payment with respect to amounts incurred by the Company during the quarter ended March 31, 2017 of $0.2 million, and (iii) an estimate of the cost share payments to be received with respect to amounts incurred by the Company subsequent to March 31, 2017 of $176.1 million. As of September 30, 2018, no development or regulatory milestones have been assessed as probable of being reached and thus have been fully constrained.

During the three months ended September 30, 2018 and 2017, the Company recognized revenue totaling approximately $24.1 million and $18.8 million, respectively, and $63.2 million and $30.7 million during the nine months ended September 30, 2018 and 2017, respectively, with respect to the Otsuka International Agreement. The revenue is classified as collaboration revenue in the accompanying unaudited condensed consolidated statements of operations. As of September 30, 2018, there is approximately $62.0 million of deferred revenue related to the Otsuka International Agreement of which $28.9 million is classified as current and $33.1 million is classified as long-term in the accompanying unaudited condensed consolidated balance sheet based on the performance period of the underlying obligations. Additionally, as of September 30, 2018, there is approximately $1.5 million in contract liabilities (included in accounts payable) in the accompanying unaudited condensed consolidated balance sheet.

Janssen Pharmaceutica NV Research and License Agreement

Summary of Agreement

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

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

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

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 the fifth anniversary of the date of issuance. 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 will grant 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, in the United States.

The parties' rights under the Vifor Agreement are conditioned upon the approval of vadadustat for DD-CKD patients by the FDA, inclusion of vadadustat in a bundled reimbursement model, and payment by Vifor Pharma of a $20.0 million milestone upon the occurrence of these two events. The Vifor 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 from Vifor Pharma's sales of vadadustat to FKC 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 retains all 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.

Prior to FDA approval of vadadustat, 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 a supply agreement with FKC that will govern the terms pursuant to which Vifor Pharma will supply vadadustat to FKC for use in patients at its dialysis centers. During the term of the Vifor Agreement, Vifor Pharma will not sell to FKC or its affiliates any HIF product that competes with vadadustat in the United States.

Unless earlier terminated, the Vifor Agreement will expire upon the later of the expiration of all patents that claim or cover vadadustat, or expiration of data or regulatory exclusivity for vadadustat in the United States. Vifor Pharma may terminate the Vifor Agreement in its entirety upon 12 months' prior written notice after the release of the first topline data in the vadadustat global Phase 3 program for dialysis-dependent CKD patients. Either party may terminate the Vifor Agreement in the event of the other party's uncured material breach. The Company may also terminate the Vifor Agreement upon the occurrence of other events, such as for specific violations of the Vifor Agreement or if there are changes in Vifor Pharma's relationship with FKC.

Investment Agreement

In connection with the Vifor Agreement, in May 2017, the Company and Vifor Pharma entered into an investment agreement, or the Investment Agreement, pursuant to which the Company sold an aggregate of 3,571,429 shares of the Company's common stock, or the Shares, to Vifor Pharma at a price per share of $14.00 for a total of $50.0 million. The amount representing the premium over the closing stock price of $12.69 on the date of the transaction, totaling $4.7 million, was determined by the Company to represent consideration related to the Vifor Agreement. As the parties' rights under the Vifor Agreement are conditioned upon (a) the approval of vadadustat for DD-CKD patients by the FDA; (b) inclusion of vadadustat in a bundled reimbursement model; and (c) payment by Vifor Pharma of a $20.0 million milestone upon the occurrence of these two events, in accordance with ASC 606, the Company has determined that the full transaction price is fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including clinical and regulatory risks that must be overcome in order for the parties' rights to become effective and the probability of the $20.0 million milestone being achieved. Accordingly, the $4.7 million continues to be recorded as deferred revenue in the accompanying unaudited condensed consolidated balance sheets. Upon the satisfaction of the aforementioned conditions, revenue will be recognized as the Company supplies vadadustat to Vifor Pharma using a proportional performance method.

Vifor Pharma has 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.

4. Available For Sale Securities

Available for sale securities at September 30, 2018 and December 31, 2017 consist of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
September 30, 2018				
Cash and cash equivalents	$162,430	$ —	$ —	$162,430
Available for sale securities:				
Certificates of deposit	$445	$ —	$ —	$445
U.S. government debt securities	177,181	—	(363)	176,818
Corporate debt securities	50,497	—	(46)	50,451
Total available for sale securities	$228,123	$ —	$ (409)	$227,714
Total cash, cash equivalents, and available for sale securities	$390,553	$ —	$ (409)	$390,144

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
December 31, 2017				
Cash and cash equivalents	$70,156	$ —	$ —	$70,156
Available for sale securities:				
Certificates of deposit	$14,117	$ —	$ —	$14,117
U.S. government debt securities	175,155	—	(352)	174,803
Corporate debt securities	58,806	—	(90)	58,716
Total available for sale securities	$248,078	$ —	$ (442)	$247,636
Total cash, cash equivalents, and available for sale securities	$318,234	$ —	$ (442)	$317,792

The estimated fair value of the Company’s available for sale securities balance at September 30, 2018, by contractual maturity, is as follows:

Due in one year or less	$212,725
Due after one year	14,989
Total available for sale securities	$227,714

There were no realized gains or losses on available for sale securities for the nine months ended September 30, 2018 and 2017. The following table summarizes the Company’s available for sale securities that were in a continuous unrealized loss position, but were not deemed to be other-than temporarily impaired, as of September 30, 2018 and December 31, 2017:

	Unrealized Loss for Less Than 12 Months		Unrealized Loss for 12 Months or More		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)					
September 30, 2018						
Available for sale securities:						
U.S. government debt securities	$(342)	$158,845	$(21)	$14,981	$(363)	$173,826
Corporate debt securities	(38)	42,009	(8)	7,470	(46)	49,479
Total	$(380)	$200,854	$(29)	$22,451	$(409)	$223,305

	Unrealized Loss for Less Than 12 Months		Unrealized Loss for 12 Months or More		Total	
	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value
	(in thousands)					
December 31, 2017						
Available for sale securities:						
U.S. government debt securities	$(343)	$170,812	$(9)	$ 3,991	$(352)	$174,803
Corporate debt securities	(90)	58,716	—	—	(90)	58,716
Total	$(433)	$229,528	$(9)	$ 3,991	$(442)	$233,519

There were 49 securities and 60 securities as of September 30, 2018 and December 31, 2017, respectively, that were in an unrealized loss position. The Company considered the decline in the market value of these securities to be primarily attributable to current economic conditions. The contractual terms of these securities do not permit the issuer to settle the securities at a price less than the amortized cost basis of the investment. As of September 30, 2018, the Company does not intend to sell these securities and it was not more likely than not that the Company would be required to sell these securities before the recovery of their amortized cost basis, which may be at maturity. As a result, the Company did not consider these investments to be other-than-temporarily impaired as of September 30, 2018.

5. Fair Value of Financial Instruments

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

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

Assets measured or disclosed at fair value on a recurring basis as of September 30, 2018 and December 31, 2017 are summarized below:

Fair Value Measurements Using

	Level 1	Level 2	Level 3	Total
	(in thousands)			
September 30, 2018				
Assets:				
Cash and cash equivalents	$162,430	$—	$ —	$162,430
Certificates of deposit	—	445	—	445
U.S. government debt securities	—	176,818	—	176,818
Corporate debt securities	—	50,451	—	50,451
	$162,430	$227,714	$ —	$390,144

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
December 31, 2017				
Assets:				
Cash and cash equivalents	$70,156	$—	$ —	$70,156
Certificates of deposit	—	14,117	—	14,117
U.S. government debt securities	—	174,803	—	174,803
Corporate debt securities	—	58,716	—	58,716
	$70,156	$247,636	$ —	$317,792

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

The Company had no assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) at September 30, 2018 and December 31, 2017.

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

6. Accrued Expenses

Accrued expenses as of September 30, 2018 and December 31, 2017 are as follows:

	September 30, 2018	December 31, 2017
	(in thousands)	
Accrued clinical expenses	$80,315	$ 43,297
Accrued bonus	3,481	3,388
Merger costs	2,084	—
Professional fees	1,537	808
Accrued vacation	858	797
Accrued payroll	398	795
Accrued severance	40	—
Income tax payable	—	987
Accrued other	5,903	2,369
Total accrued expenses	$94,616	$ 52,441

7. 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 the fifth anniversary of the date of issuance. The warrant satisfied the equity classification criteria of ASC 815, and is therefore classified as an equity instrument. The fair value at issuance of $3.4 million was calculated using the Black Scholes option pricing model and was charged to research and development expense as it represented consideration for a license for which the underlying intellectual property was deemed to have no alternative future use. As of September 30, 2018, the warrant remains outstanding and expires on February 9, 2022.

8. Stockholders’ Equity

Authorized and Outstanding Capital Stock

As of September 30, 2018, the authorized capital stock of the Company included 175,000,000 shares of common stock, par value $0.00001 per share, of which 57,046,563 and 47,612,619 shares are issued and outstanding at September 30, 2018 and December 31, 2017, respectively; and 25,000,000 shares of undesignated preferred stock, par value $0.00001 per share, of which 0 shares are issued and outstanding at September 30, 2018 and December 31, 2017.

At-the-Market Facility

In May 2016, the Company established an at-the-market, or ATM, equity offering program pursuant to which it was able to offer and sell up to $75.0 million of common stock at the then current market prices from time to time. In September 2016, the Company commenced sales under this program. Through December 31, 2017, the Company sold 1,080,908 shares of common stock under this program with net proceeds (after deducting commissions and other offering expenses) of $12.1 million, of which 150,023 shares were sold in the nine months ended September 30, 2017 for net proceeds (after deducting commissions and other offering expenses) of approximately $1.6 million. Additionally, the Company sold 694,306 shares in the three months ended March 31, 2018 for net proceeds (after deducting commissions and other offering expenses) of approximately $10.5 million. The Company has not sold any additional shares under this program subsequent to March 31, 2018.

Equity Offering

In March 2018, the Company completed a follow-on public equity offering, whereby the Company sold 8,500,000 shares of common stock at a public offering price of $10.50 per share. The aggregate net proceeds received by the Company from the offering were approximately $84.8 million, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

Equity Plans

On February 28, 2014, the Company's Board of Directors adopted its 2014 Incentive Plan, or the 2014 Plan, and its 2014 Employee Stock Purchase Plan, or the ESPP, which were subsequently approved by its stockholders and became effective upon the closing of the Company's initial public offering on March 25, 2014. The 2014 Plan replaced the 2008 Equity Incentive Plan, as amended, 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. 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, the Inducement Award Program. For 2018, the Company authorized the issuance of up to 750,000 shares for the purpose of granting options to purchase shares of the Company's common stock to new hires under the Inducement Award Program, of which 255,550 options to purchase shares were granted during the nine months ended September 30, 2018 and 249,550 options to purchase shares remain outstanding as of September 30, 2018.

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 our 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 1st of each calendar year, by an amount equal to three percent (3%) of the number of shares of the Company's common stock outstanding on a fully diluted basis as of the close of business on the immediately preceding December 31st, or the 2014 Plan Evergreen Provision. The Company's Board of Directors may act prior to January 1st of any year to provide that there will be no automatic increase in the number of 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). During the nine months ended September 30, 2018, the Company granted 522,200 stock options to employees under the 2014 Plan, 255,550 stock options to employees under the Inducement Award Program, 372,250 RSUs to employees under the 2014 Plan, and 112,500 stock options 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. The maximum aggregate number of shares of common stock available for purchase pursuant to the exercise of options granted under the ESPP will be the lesser of (a) 262,500 shares, increased on each anniversary of the adoption of the ESPP by one percent (1%) of the total shares of common stock then outstanding, the ESPP Evergreen Provision, and (b) 739,611 shares, which is equal to five percent (5%) of the total shares of common stock outstanding on the date of the adoption of the ESPP on a fully diluted, as converted basis. Under the ESPP, each offering period is six months, at the end of which employees may purchase shares of 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 our common stock at the beginning or end of the offering period.

Shares Reserved for Future Issuance

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

	September 30, 2018	December 31, 2017
Common stock options and RSUs outstanding [1]	4,851,790	4,388,752
Shares available for issuance under the 2014 Plan [2]	3,347,957	1,790,600

Warrant to purchase common stock	509,611	509,611
Shares available for issuance under the ESPP [3]	603,522	652,290
Total	9,312,880	7,341,253

[1] Includes awards granted under the 2014 Plan and the Inducement Award Program.

[2] On January 1, 2018, January 1, 2017 and January 1, 2016, the shares of common stock reserved for future grants under the 2014 Plan increased by 1,575,329, 1,265,863 and 986,800 shares, respectively, pursuant to the 2014 Plan Evergreen Provision. Additionally, on December 19, 2017, the Company's Board of Directors approved 750,000 shares for issuance in fiscal year 2018 under the Inducement Award Program.

[3] On February 28, 2016, the shares reserved for future issuance under the ESPP increased by 273,404 shares pursuant to the ESPP Evergreen Provision. There were no increases in the shares reserved for future issuance subsequent to this period as the maximum aggregate number of shares available for purchase had reached its cap of 739,611.

Stock-Based Compensation

Stock Options

On February 28, 2018, as part of the Company's annual grant of equity, the Company issued 522,200 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 on the first day of each calendar quarter 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 $1.5 million and $1.6 million of stock-based compensation expense related to stock options during the three months ended September 30, 2018 and 2017, respectively, and approximately $5.1 million and $4.9 million during the nine months ended September 30, 2018 and 2017, respectively.

Restricted Stock

On December 23, 2013, the Company issued 450,224 shares of restricted stock to employees and 79,067 shares of restricted stock to non-employees at a grant date fair value of $7.42 per share. The aggregate grant date fair value for the shares of restricted stock issued on December 23, 2013 totaled approximately $3.9 million. The Company records stock-based compensation expense for restricted stock awards based on the grant date fair value for employees and the reporting date and upon vesting fair value for non-employees. The fair value of the award is considered the intrinsic value as of each measurement date. Compensation expense related to the restricted stock awards was being recognized over the associated requisite service period. The Company recorded approximately $0.1 million and $0.2 million of stock-based compensation expense related to restricted stock during the three and nine months ended September 30, 2017, respectively. Restricted shares were fully vested as of December 31, 2017 and there were no additional grants of restricted stock during the nine months ended September 30, 2018, as such, there was no stock-based compensation expense related to restricted stock during the three and nine months ended September 30, 2018.

Restricted Stock Units

On February 28, 2018, as part of the Company's annual grant of equity, the Company issued 367,250 RSUs to employees. In addition, the Company occasionally issues RSUs not in connection with the annual grant process to employees. 100% of each RSU grant vests on either the first or the third anniversary of the grant date, subject, in each case, to the individual's continued service through the applicable vesting date. The expense recognized for these awards is based on the grant date fair value of the Company's common stock multiplied by the number of units granted and recognized on a straight-line basis over the vesting period. The Company recorded approximately $0.7 million and $0.4 million of stock-based compensation expense related to the RSUs during the three months ended September 30, 2018 and 2017, respectively, and approximately $1.8 million and $1.5 million during the nine months ended September 30, 2018 and 2017, respectively.

Employee Stock Purchase Plan

The Company issued 48,768 shares during the nine months ended September 30, 2018. The Company recorded approximately $52,000 and $47,000 of stock-based compensation expense related to the ESPP during the three months ended September 30, 2018 and 2017, respectively, and approximately $0.2 million and $0.1 million during the nine months ended September 30, 2018 and 2017, respectively.

Stock-Based Compensation Expense Summary

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

	Three Months Ended		Nine Months Ended		
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017	
	(in thousands)		(in thousands)		
Research and development	$647	$ 569	$2,090	$ 5,741	(1)
General and administrative	1,605	1,584	4,888	4,346	
Total	$2,252	$ 2,153	$6,978	$ 10,087	

(1) This amount includes $3.4 million of fair value related to the warrant issued to Janssen.

Compensation expense by type of award:

	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
	(in thousands)		(in thousands)	
Stock options	$1,458	$ 1,606	$5,074	$ 4,927
Restricted stock	—	93	—	158
Restricted stock units	742	407	1,751	1,458
Employee stock purchase plan	52	47	153	131
Warrant	—	—	—	3,413
Total	$2,252	$ 2,153	$6,978	$ 10,087

9. Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. There were no significant income tax provisions or benefits for the three and nine months ended September 30, 2018 and 2017. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets.

As noted in Note 2, effective January 1, 2018, the Company adopted ASC 606, using the full retrospective transition method. Under this method, the Company has revised its consolidated financial statements for the year ended December 31, 2017, and applicable interim periods within those years, as if ASC 606 had been effective for those periods. The adoption of this guidance did not have a significant impact on the Company's related tax disclosures.

For the year ended December 31, 2017, the Company had taxable income primarily due to timing differences. The income was fully offset with available net operating losses, NOLs, for regular federal and state tax purposes. The Company did have a tax liability for Alternative Minimum Tax in 2017 of approximately $0.8 million; however, due to tax reform, the amount is fully refundable through 2021, and thus the net result is that the Company generated an income tax receivable of approximately $0.8 million rather than a tax expense for the year ended December 31, 2017. During the second quarter of 2018, the Company paid the $0.8 million tax liability, as such, the Company's unaudited condensed consolidated balance sheet included a tax receivable of approximately $0.8 million, which is included in other assets, and no tax payable as of September 30, 2018.

The Tax Cuts and Jobs Act, which was signed on December 22, 2017, made significant change in U.S. tax law including a reduction in U.S. corporate tax rate from 35% to 21% for tax years beginning after December 31, 2017. As a result of the enacted law, the Company was required to revalue deferred tax assets and liabilities existing as of December 31, 2017 from the 35% federal rate in effect through the end of 2017, to the new 21% rate. As a result of the change in law, the Company recorded a $43.0 million reduction in the deferred tax asset and corresponding valuation allowance as of December 31, 2017.

In accordance with SAB 118, the Company has determined that its deferred tax asset value and associated valuation allowance reduction is a provisional amount and a reasonable estimate at December 31, 2017. The final impact may

differ from this provisional amount due to, among other things, changes in interpretations and assumptions we have made thus far and the issuance of additional regulatory or other guidance. During the nine months ended September 30, 2018, we did not identify any additional adjustments necessary to the deferred tax asset value and associated valuation allowance recorded at December 31, 2017. We expect to complete the final impact within the measurement period.

10. 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 Lease. Under the Third Amendment to 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 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 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 will commence in February 2019 and are subject to annual rent escalations, commencing in September 2019.

Committed landlord contributions included in the Lease totaled $3,289,170, including $1,142,010 in leasehold improvements not yet utilized. The landlord contributions are being accounted for as a deferred lease incentive and reduction in monthly rent expense over the term of the Lease. The term of the Lease with respect to the office space expires on September 11, 2026, with one five year extension option available. The term of the Lease with respect to the lab space expires on November 30, 2021, with an extension option for one additional period of two years. Under the Fifth Amendment, the total security deposit in connection with the Lease increased by $0.5 million from $1.3 million to $1.8 million. In May 2018, the security deposit was reduced by $0.2 million to $1.6 million, which remains in effect as of September 30, 2018 and is in the form of a letter of credit, all of which is included in other current assets in the Company’s condensed consolidated balance sheets as of September 30, 2018.

The Company recognizes rent expense for the space it currently occupies under the Lease and records a deferred lease obligation representing the cumulative difference between actual facility lease payments and lease expense recognized ratably over the lease period, which is included in the Company’s condensed consolidated balance sheets as of September 30, 2018 and December 31, 2017.

At September 30, 2018, the Company’s future minimum payments required under this Lease are as follows:

	Operating Lease (in thousands)
2018	$ 896
2019	5,122
2020	5,325
2021	5,355
2022	4,997
Thereafter	18,991
Total	$ 40,686

The Company recorded approximately $0.8 million in rent expense for each of the three months ended September 30, 2018 and 2017, respectively, and approximately $2.4 million for each of the nine months ended September 30, 2018 and 2017, respectively.

Other Third Party Contracts

Under the Company's agreement with IQVIA, formerly known as Quintiles IMS, to provide contract research organization services for the PRO_2TECT and $INNO_2VATE$ programs, the total remaining contract costs as of September 30, 2018 were approximately $162.9 million. The estimated period of substantive performance for the committed work with IQVIA is through the first half 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 $110.4 million at September 30, 2018. 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.

11. Employee Retirement Plan

During 2008, the Company established a retirement plan, or the 401(k) Plan, authorized by Section 401(k) of the Internal Revenue Code. In accordance with the 401(k) Plan, all employees who have attained the age of 21 are eligible to participate in the 401(k) Plan as of the first Entry Date, as defined therein, following their date of employment. Each employee can contribute a percentage of compensation up to a maximum of the statutory limits per year. Company contributions are discretionary and contributions in the amount of approximately $41,000 and $27,000 were made during the three months ended September 30, 2018 and 2017, respectively, and approximately $0.3 million and $0.2 million during the nine months ended September 30, 2018 and 2017, respectively.

12. Net Loss per Share

The shares in the table below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, due to their anti-dilutive effect:

	As of September 30,	
	2018	2017
Warrant	509,611	509,611
Outstanding stock options	3,957,940	3,743,303
Unvested restricted stock	—	13,982
Unvested restricted stock units	893,850	728,438
Total	5,361,401	4,995,334

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, 2017, or the 2017 Annual Report, including the audited consolidated financial statements and notes thereto contained in our 2017 Annual Report. This discussion and analysis contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Part II, Item 1A. of this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. Unless otherwise stated or the context otherwise requires, we have not reflected in this Quarterly Report on Form 10-Q the changes to our business that may occur if we consummate the pending merger with Keryx Biopharmaceuticals, Inc.

Operating Overview

We are a biopharmaceutical company focused on developing and commercializing novel therapeutics for patients based on hypoxia-inducible factor, or HIF, biology, and building our pipeline while leveraging our development and commercial expertise in renal disease. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body, as well as other important metabolic functions. Pharmacologic modulation of the HIF pathway may have broad therapeutic applications. Our lead product candidate, vadadustat, is an oral therapy in Phase 3 development and has the potential to set a new standard of care in the treatment of anemia due to chronic kidney disease, or CKD. Our management team has extensive experience in developing and commercializing drugs for the treatment of renal and metabolic disorders, as well as a deep understanding of HIF biology. This unique combination of HIF and renal expertise is enabling us to advance a pipeline of HIF-based therapies to potentially address serious diseases.

HIF, a pathway involving hundreds of genes, is the same pathway used by the body to adapt to lower oxygen availability, or hypoxia, such as that experienced with a moderate increase in altitude. At higher altitudes, the body responds to lower oxygen levels by increasing the availability of HIF, which coordinates the interdependent processes of iron utilization and erythropoietin, or EPO, production to increase RBC production and, ultimately, improve oxygen delivery. The significance of the HIF pathway was recognized by the 2016 Albert Lasker Basic Medical Research Award, which honored the three physician-scientists who discovered the HIF pathway and elucidated this primary oxygen sensing mechanism that is essential for survival. HIF protein is constantly being produced under normal oxygen conditions, but is quickly degraded by prolyl hydroxylases, or PH. Under hypoxic conditions, HIF-PHs are inhibited, allowing HIF to stimulate erythropoiesis. These findings have opened up new possibilities for developing therapeutics, such as HIF-PH inhibitors, which have the potential to treat many diseases.

Our lead product candidate, vadadustat, is a HIF-PH inhibitor, or HIF-PHI, in Phase 3 development for the treatment of anemia due to CKD. Anemia is common in patients with CKD, and its prevalence increases as CKD progresses. Anemia is a condition characterized by abnormally low levels of hemoglobin. Hemoglobin is contained within RBCs and carries oxygen to other parts of the body. If there are too few RBCs or if hemoglobin levels are low, the cells in the body will not get enough oxygen. In patients with CKD, anemia results from inadequate EPO levels, which negatively affect RBC production. In addition, iron, which is essential to RBC production, may be deficient in patients with CKD. Left untreated, anemia significantly accelerates overall deterioration of patient health with increased morbidity and mortality. Based on third party prevalence data and company estimates, approximately 37 million people in the United States have CKD and approximately 5.7 million of these individuals suffer from anemia. Anemia from CKD is currently treated by injectable recombinant human erythropoiesis-stimulating agents, or injectable ESAs, such as EPOGEN® (epoetin alfa) and Aranesp® (darbepoetin alfa), or with iron supplementation or RBC transfusion. Based on publicly available information on ESA sales and market data compiled by a third-party vendor, global sales of injectable ESAs for all uses were estimated to be approximately $6.2 billion in 2017. The vast majority of these sales were for the treatment of anemia due to CKD.

When administered to a patient, injectable ESAs provide supra-physiological levels of exogenous EPO to stimulate production of RBCs. While injectable ESAs can be effective in raising hemoglobin levels, they have the potential to cause significant side effects, and need to be injected subcutaneously or intravenously. In particular, injectable ESAs may lead to thrombosis, stroke, myocardial infarction and death. These safety concerns, which became evident starting in 2006, have led to a significant reduction in the use of injectable ESAs. Today, anemia is either not treated or inadequately treated in the majority of non-dialysis dependent, or NDD, CKD patients. There is an unmet need for treatment options for patients with anemia due to CKD that offer an improved safety profile and such agents would have significant market potential.

Vadadustat is designed to stimulate erythropoiesis and effectively treat renal anemia while avoiding the supra-physiologic EPO levels previously observed with injectable ESAs. In addition, vadadustat, if approved, would provide patients with an oral treatment option, rather than an injection. For these reasons, we believe that vadadustat has the potential to set a new standard of care for the treatment of anemia due to CKD.

Phase 1 and Phase 2 data led us to the design of our Phase 3 clinical program for vadadustat. The vadadustat Phase 3 program in dialysis dependent, or DD, CKD patients with anemia, called INNO$_2$VATE, and in NDD-CKD patients with anemia, called PRO$_2$TECT, is designed to enroll up to approximately 7,300 patients evaluating once daily oral dosing of vadadustat against an injectable ESA active comparator, darbepoetin alfa. The enrollment numbers and the completion of INNO$_2$VATE and PRO$_2$TECT will be driven by the accrual of major adverse cardiovascular events, or MACE. In August 2016, the first patient was dosed in INNO$_2$VATE, and the first patient was dosed in PRO$_2$TECT in December 2015. As of September 30, 2018, we expect the remaining external aggregate contract research organization, or CRO, costs of INNO$_2$VATE and PRO$_2$TECT to be in the range of $250.0 million to $280.0 million. We are targeting full enrollment of INNO$_2$VATE by the end of 2018 and full enrollment of PRO$_2$TECT in 2019. We anticipate reporting top-line clinical data for the INNO$_2$VATE studies in the first quarter of 2020, subject to the accrual of MACE, and the PRO$_2$TECT studies in mid-2020, subject to the accrual of MACE. Our collaborator, Mitsubishi Tanabe Pharma Corporation, or MTPC, initiated its Phase 3 development program for vadadustat in Japan in the fourth quarter of 2017. MTPC expects data read-outs from these studies in 2019.

In June 2018, we initiated study start-up activities for FO$_2$RWARD-2, a Phase 2 clinical study of vadadustat. FO$_2$RWARD-2 includes once-daily and three-times weekly dosing, data to inform ESA-switching protocols, and a broad dialysis population that is inclusive of patients with anemia due to CKD who are on dialysis and do not adequately respond to injectable ESA, known as hyporesponders. Hyporesponders represent approximately 10-15% of patients with anemia due to DD-CKD, yet they account for 30-40% of total injectable ESA use. These patients have demonstrated a persistently higher risk of mortality than non-hyporesponders and represent a high unmet need. Given its differentiated mechanism of action, we believe that vadadustat may provide a treatment option for these patients. We expect to report top-line clinical data from FO$_2$RWARD-2 in 2019. We expect to initiate an additional Phase 3 clinical study of vadadustat, TRILO$_2$GY-2, in 2019. We believe FO$_2$RWARD-2 and TRILO$_2$GY-2 will provide additional characterization and differentiation of vadadustat and further strengthen our commercial position if vadadustat is approved for marketing.

We have completed a thorough QT, or TQT, study in accordance with FDA guidance. The study showed that vadadustat does not alter cardiac repolarization intervals in normal healthy volunteers following a single dose of up to 1,200 mg. In addition, a drug-drug interaction, or DDI, study was conducted to evaluate the effect of vadadustat on celecoxib, a substrate for the hepatic cytochrome P450 enzyme CYP2C9. Based on this study it was concluded that vadadustat does not inhibit CYP2C9 to any appreciable extent. Therefore, no clinically significant effect of vadadustat on drugs that are CYP2C9 substrates would be expected through this specific mechanism. Additional DDI studies are ongoing. Initial results from a DDI study with rosuvastatin, a BCRP and OATP1B1/OATP1B3 substrate, demonstrated a moderate drug interaction with an approximately 2- to 3-fold increase in exposure to rosuvastatin. These results indicate that vadadustat has the potential to interact with other substrates of BCRP and OATP1B1/OATP1B3. This is being further evaluated in Part 2 of the study, with sulfasalazine and pravastatin, substrates of BCRP and OATP1B1/OATP1B3, respectively.

If vadadustat is approved by the U.S. Food and Drug Administration, or FDA, and our proposed merger with Keryx Biopharmaceuticals, Inc., or the Merger, is consummated, we plan to utilize the commercial organization of the combined company in the United States while leveraging our collaboration with Otsuka Pharmaceutical Co. Ltd., or Otsuka, and its well-established 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 MTPC exclusive rights to commercialize vadadustat, subject to marketing approvals. In May 2017, we entered into an exclusive license agreement with Vifor (International) Ltd., or Vifor Pharma, where Fresenius Kidney Care Group LLC, or FKC, which operates dialysis clinics in the United States, would purchase vadadustat from Vifor Pharma, subject to the approval of vadadustat by the FDA as well as the inclusion of vadadustat in a bundled reimbursement model. During the term of the license agreement, Vifor Pharma may not sell to FKC or its affiliates any HIF product that competes with vadadustat in the United States.

In addition to vadadustat, we are developing a HIF-based portfolio of other product candidates that target serious diseases of high unmet need. Our portfolio includes product candidates developed internally as well as in-licensed product candidates. In February 2017, we signed an exclusive agreement with Janssen Pharmaceutica NV, or Janssen, a subsidiary of Johnson & Johnson, of the Janssen Agreement, for access to an extensive library of well-characterized HIF pathway compounds with potential applications across multiple therapeutic areas.

Since our inception in 2007, we have devoted the largest portion of our resources to our development efforts relating to vadadustat, including preparing for and conducting clinical studies of vadadustat, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through equity offerings and strategic collaborations.

We have never been profitable and have incurred net losses in each year since inception. Our net losses were $83.5 million and $89.2 million for the nine months ended September 30, 2018 and 2017, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant operating expenses and increased operating losses for at least the next several years, without taking into account the potential impact of the Merger. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- conduct our development program of vadadustat for the treatment of anemia due to CKD, including PRO_2TECT, $INNO_2VATE$, FO_2RWARD-2 and $TRILO_2GY$-2, and develop plans for and conduct the preclinical and clinical development of any other potential product candidates;
- seek marketing approvals for our product candidates that successfully complete clinical studies and maintain such marketing approvals, including complying with any post-marketing regulatory requirements;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- initiate additional preclinical, clinical or other studies for vadadustat and any other product candidates;
- seek to discover and develop additional product candidates;
- engage in transactions, including strategic transactions, merger, collaboration, acquisition and licensing arrangements, pursuant to which we would market and develop commercial products, or develop other product candidates and technologies;
- make royalty, milestone or other payments under our license agreement with Janssen and any future in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- continue to create additional infrastructure and expend additional resources to support our operations as a public company, including any additional infrastructure and resources necessary to support a transition from our status as an emerging growth company;
- complete the Merger, subject to satisfying closing conditions, including obtaining applicable shareholder and regulatory approvals, integrate with Keryx following successful completion of the Merger, and seek to satisfy contractual and regulatory obligations following closing of the Merger; and
- experience any delays or encounter issues with any of the above.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. We have no manufacturing facilities, and all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize CROs to carry out our clinical development activities, and we do not yet have a sales organization. If we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. If and until we can generate a sufficient amount of revenue from product sales, we expect to finance future cash needs through public or private equity or debt offerings, payments from our collaborators, 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 one or more of our product candidates. Any of these events could significantly harm our business, financial condition and prospects. The foregoing paragraph does not take into account the potential impact of the Merger.

Through September 2018, we raised approximately $468.4 million of net proceeds from the sale of equity including $377.4 million from various underwritten public offerings, $41.0 million from an at-the-market, or ATM, offerings, pursuant to sales agreements with Cantor Fitzgerald & Co and $50.0 million from the sale of 3,571,429 shares of common stock to Vifor Pharma. At the inception of our collaboration agreements with Otsuka and MTPC, they

committed to approximately $573.0 million or more in upfront payments and cost-share funding, the latter of which we generally continue to receive on a quarterly prepaid basis. Of these commitments, we received approximately $272.0 million at the onset of the collaboration agreements.

Pending Business Combination

On June 28, 2018, we entered into an Agreement and Plan of Merger, which was amended on October 1, 2018, or the Merger Agreement, with Keryx Biopharmaceuticals, Inc., or Keryx, and Alpha Therapeutics Merger Sub, Inc., a direct, wholly owned subsidiary of Akebia, or the Merger Sub., pursuant to which the Merger Sub shall be merged with and into Keryx, with Keryx surviving as a wholly owned subsidiary of Akebia, subject to the satisfaction or waiver of the conditions specified in the Merger Agreement.

Subject to the terms and conditions of the Merger Agreement, at the effective time of the Merger, each share of common stock of Keryx issued and outstanding immediately prior to the effective time of the Merger will be cancelled and converted into the right to receive 0.37433, or the Exchange Multiplier, fully paid and non-assessable shares of common stock of Akebia. The Merger Agreement also provides that at the effective time of the Merger, each share of Keryx common stock that is subject to an outstanding Keryx restricted stock award issued under a Keryx equity plan, or Keryx Restricted Shares, other than those Keryx Restricted Shares that accelerate or lapse as a result of the completion of the Merger, will convert into restricted stock unit awards, or RSUs, of Akebia, the number of which will be adjusted in accordance with the Exchange Multiplier, and in accordance with the terms of the Merger Agreement. In addition, each outstanding and unexercised option to acquire Keryx common stock granted under the Keryx equity plan will be converted into an option to acquire shares of Akebia's common stock, with the number of shares and exercise price adjusted by the Exchange Multiplier, in accordance with the terms of the Merger Agreement. The foregoing exchange is expected to result in implied equity ownership in the combined company of 49.4 percent for Akebia shareholders and 50.6 percent for Keryx shareholders on a fully-diluted basis, calculated based on the companies' fully diluted market capitalizations as of the date of signing of the Merger Agreement and also taking into account the 4,000,000 additional shares of Keryx common stock that are expected to be issued to Keryx's significant shareholder, Baupost Group Securities, L.L.C., or Baupost, prior to consummation of the Merger, as described below.

The Merger is expected to be completed by the end of 2018 and is subject to the satisfaction of customary closing conditions including, among other things, (i) approval by the affirmative vote of the holders of a majority of the votes cast affirmatively and negatively, at Akebia's shareholders' meeting in favor of the issuance Akebia common stock in connection with the Merger, (ii) the adoption of the Merger Agreement by the affirmative vote of the holders of a majority of all outstanding shares of Keryx common stock entitled to vote thereon and (iii) the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, which waiting period was terminated by the Federal Trade Commission on August 21, 2018. Akebia's obligation to consummate the Merger is also subject to the conversion of Keryx's Zero Coupon Convertible Senior Notes due 2021 pursuant to the terms of the Notes Conversion Agreement entered into by the Company, Keryx and Baupost. The Merger Agreement provides for certain termination rights for both the Company and Keryx. Upon termination of the Merger under certain specified circumstances, the Company or Keryx may be required to pay the other party a termination fee of $22.0 million.

Keryx, headquartered in Boston, Massachusetts, is focused on the development and commercialization of medicines for people with kidney disease. Keryx's proprietary product, Auryxia® (ferric citrate) tablets, is approved by the U.S. Food and Drug Administration, or FDA, for two indications: (1) the control of serum phosphorus levels in adult patients with chronic kidney disease on dialysis and (2) the treatment of iron deficiency anemia in adult patients with chronic kidney disease not on dialysis.

Simultaneously with the execution of the Merger Agreement, we entered into a Voting Agreement with Baupost and the Notes Conversion Agreement with Baupost and Keryx. Pursuant to the Voting Agreement, Baupost agreed, among other things, to vote its shares in favor of the adoption of the Merger Agreement and against any alternative proposal and against approval of any proposal made in opposition to, in competition with, or inconsistent with, the Merger Agreement or the Merger or any other transactions contemplated by the Merger Agreement. Pursuant to the Notes Conversion Agreement, Baupost agreed to convert Keryx's Zero Coupon Convertible Senior Notes due 2021 into 35,582,335 shares of Keryx common stock in accordance with the terms of the governing indenture immediately prior

to the effective time of the Merger, conditioned upon the issuance to Baupost of an additional 4,000,000 shares of Keryx common stock. The Notes Conversion Agreement provides that we will execute a registration rights agreement with Baupost, to provide customary registration rights for any shares of Company common stock held by Baupost if and when the Merger is consummated.

We have operated and, unless and until the Merger is successfully completed, will continue to operate independently of Keryx.

Financial Overview

Revenue

To date, we have not generated any revenue from the sales of products. Our revenues have been derived from collaboration revenues, which include license and milestone revenues and cost-sharing revenue, generated through collaboration and license agreements with partners for the development and commercialization of vadadustat. 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.

Unless and until we complete the Merger, for the foreseeable future, we expect substantially all of our revenue will be generated from our collaborations with Otsuka and MTPC and any other collaborations into which we may enter. MTPC has licensed the rights to develop and commercialize vadadustat in Japan and certain other Asian countries, or the MTPC Territory. Otsuka has agreed to co-exclusively collaborate with respect to the development and commercialization of vadadustat in the United States. Additionally, Otsuka has also licensed the rights to develop and commercialize vadadustat in the European Union, Russia, China, Australia, Canada, the Middle East and certain other countries, or the Otsuka International Territory.

Research and Development Expenses

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

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

Research and development costs are expensed as incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and our clinical sites.

We cannot determine with certainty the duration and completion costs of current or future clinical studies of our product candidates or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates that obtain marketing approval. We may never succeed in achieving marketing approval for any of our product candidates.

The duration, costs and timing of clinical studies and development of our product candidates will depend on a variety of factors including, but not limited to, those described in Part II, Item 1A. Risk Factors of this Quarterly Report on Form 10-Q. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, the European Medicines Agency, or the EMA, or other regulatory authorities were to require us to conduct clinical studies in addition to or different from those that we currently anticipate, or if we experience delays in any of our clinical studies, we could be required to expend significant additional financial resources and time on the completion of clinical development.

From inception through September 30, 2018, we have incurred $666.7 million in research and development expenses. We plan to increase our research and development expenditures for the foreseeable future as we continue the

development of vadadustat and any other product candidates. Our current and/or planned research and development activities include the following:

- global development of vadadustat;
- research and development of compounds in our HIF portfolio; and
- diversification of our pipeline in kidney disease and other HIF-modulated diseases.

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

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

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses. Other general and administrative expenses include facility-related costs, fees for directors, accounting and legal services fees, recruiting fees and expenses associated with obtaining and maintaining patents.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also anticipate increased expenses related to finance, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and U.S. Securities and Exchange Commission, or SEC, requirements, and our other costs associated with being a public company. Additionally, we anticipate an increase in payroll and related expenses if and when we prepare for commercial operations, especially in sales and marketing. The foregoing paragraph does not take into account the potential impact of the Merger.

Results of Operations

Comparison of the Three Months Ended September 30, 2018 and 2017

	Three Months Ended September 30,		Increase (Decrease)
	2018	2017	
	(In Thousands)		
Collaboration revenue	$53,169	$ 41,283	$ 11,886
Operating expenses:			
Research and development	70,634	58,711	11,923
General and administrative	10,378	6,748	3,630
Total operating expenses	81,012	65,459	15,553
Loss from operations	(27,843)	(24,176)	3,667
Other income, net	1,796	1,042	754
Net loss	$(26,047)	$ (23,134)	$ 2,913

Collaboration Revenue. Collaboration revenue was $53.2 million for the three months ended September 30, 2018, compared to $41.3 million for the three months ended September 30, 2017, an increase of $11.9 million. We recognized $53.1 million in collaboration revenue for the three months ended September 30, 2018 from our cost sharing arrangements under the Otsuka U.S. Agreement and the Otsuka International Agreement. We recognized $41.3 million in collaboration revenue for the three months ended September 30, 2017 from our cost sharing arrangements under the Otsuka U.S. Agreement and the Otsuka International Agreement, which commenced in December 2016 and April 2017, respectively, and no collaboration revenue from MTPC as the revenue recognition criteria for the MTPC Agreement, as required under ASC 606, had not yet been satisfied. The increase in revenue between the two periods was primarily attributable to an additional $11.9 million of revenue recognized under both the Otsuka U.S. Agreement and Otsuka International Agreement.

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Research and Development Expenses. Research and development expenses were $70.6 million for the three months ended September 30, 2018, compared to $58.7 million for the three months ended September 30, 2017, an increase of $11.9 million. The increase was primarily due to the following:

	(in millions)
PRO$_2$TECT and INNO$_2$VATE Phase 3 program	$ 6.3
Regulatory activities and other clinical and preclinical activities	3.8
Manufacture of drug substance and drug product	2.4
FO$_2$RWARD-2 and TRILO$_2$GY-2 studies[1]	(1.4)
Japan Phase 2 studies	(2.5)
Total increase related to the continued development of vadadustat	8.6
Headcount, consulting and facilities	3.2
Other	0.1
Total other decreases	3.3
Total net increase	$ 11.9

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

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

General and Administrative Expenses. General and administrative expenses were $10.4 million for the three months ended September 30, 2018, compared to $6.7 million for the three months ended September 30, 2017. The increase of $3.6 million was primarily due to an increase in legal and other professional fees related to our proposed merger with Keryx, and an increase in costs to support our research and development programs, including headcount and compensation-related costs. We expect our general and administrative expenses to increase in future periods to support our continued research and development and potential commercialization of vadadustat and other product candidates.

Other Income, Net. Other income, net, was $1.8 million for the three months ended September 30, 2018 and $1.0 million for the three months ended September 30, 2017. Other income, net for the three months ended September 30, 2018 and 2017 is primarily comprised of interest income.

Results of Operations

Comparison of the Nine Months Ended September 30, 2018 and 2017

	Nine Months Ended	Increase

	September 30, 2018	September 30, 2017	Increase (Decrease)
	(In Thousands)		
Collaboration revenue	$147,892	$ 90,668	$ 57,224
Operating expenses:			
Research and development	$203,955	$ 162,511	$ 41,444
General and administrative	31,940	19,441	12,499
Total operating expenses	235,895	181,952	53,943
Loss from operations	(88,003)	(91,284)	$ (3,281)
Other income, net	4,469	2,090	2,379
Net loss	$(83,534)	$ (89,194)	$ (5,660)

Collaboration Revenue. Collaboration revenue was $147.9 million for the nine months ended September 30, 2018, compared to $90.7 million for the nine months ended September 30, 2017, an increase of $57.2 million. We recognized $147.9 million in collaboration revenue for the nine months ended September 30, 2018 from our cost sharing arrangement under the Otsuka U.S. Agreement, Otsuka International Agreement as well as revenue recognized in connection with the MTPC Agreement. We recognized $90.7 million in collaboration revenue for the nine months ended September 30, 2017 from our cost sharing arrangement under the Otsuka U.S. Agreement, which commenced in December 2016, Otsuka International Agreement, which commenced in April 2017, and no collaboration revenue from MTPC as the revenue recognition criteria for the MTPC Agreement, as required under ASC 606, had not yet been satisfied. The increase in revenue between the two periods was primarily attributable to an additional $47.6 million of revenue recognized under both the Otsuka U.S. Agreement and Otsuka International Agreement, as well as $9.3 million of revenue recognized in connection with the MTPC Agreement.

Research and Development Expenses. Research and development expenses were $203.9 million for the nine months ended September 30, 2018, compared to $162.5 million for the nine months ended September 30, 2017, an increase of $41.4 million. The increase was primarily due to the following:

	(in millions)
PRO$_2$TECT and INNO$_2$VATE Phase 3 program	25.0
Manufacture of drug substance and drug product	11.0
Regulatory activities and other clinical and preclinical activities	10.6
FO$_2$RWARD-2 and TRILO$_2$GY-2 studies[1]	(2.9)
Japan Phase 2 studies	(8.1)
Total increase related to the continued development of vadadustat	35.6
Headcount, consulting and facilities	10.1
Janssen license fee	(1.0)
Fair value of warrants issued for Janssen license	(3.4)
Other	0.1
Total other decreases	5.8
Total net increase	$ 41.4

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

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

General and Administrative Expenses. General and administrative expenses were $31.9 million for the nine months ended September 30, 2018, compared to $19.4 million for the nine months ended September 30, 2017. The increase of $12.5 million was primarily due to an increase in legal and other professional fees related to our proposed merger with Keryx, and an increase in costs to support our research and development programs, including headcount and

compensation-related costs. Excluding costs incurred related to our proposed merger with Keryx, we expect our general and administrative expenses to increase in future periods to support our continued research and development and potential commercialization of vadadustat and other product candidates.

Other Income, Net. Other income, net, was $4.5 million for the nine months ended September 30, 2018 and $2.1 million for the nine months ended September 30, 2017. Other income, net for the nine months ended September 30, 2018 and 2017 is primarily comprised of interest income.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception in February 2007, and as of September 30, 2018, we had an accumulated deficit of $454.3 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. The foregoing paragraph does not take into account the potential impact of the Merger.

We have funded our operations principally through sales of our common stock and payments received from our collaboration partners. As of September 30, 2018, we had cash and cash equivalents and available for sale securities of approximately $390.1 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Accordingly, available for sale securities, consisting principally of corporate and government debt securities stated at fair value, are also available as a source of liquidity.

In connection with the Merger, we estimate spending approximately $25.0 million in merger-related costs.

If and when the Merger is completed, we expect the combined entity to have sufficient cash, cash equivalents, and available for sale securities to fund its operating plans through the first quarter of 2020, which is unchanged from Akebia's pre-merger cash runway.

Cash Flows

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

	Nine Months Ended September 30,	
	2018	2017
	(In Thousands)	
Net cash provided by (used in):		
Operating activities	$(23,795)	$ (39,781)
Investing activities	19,877	(168,952)
Financing activities	96,477	110,997
Net (decrease) increase in cash, cash equivalents, and restricted cash	$92,559	$ (97,736)

Operating Activities. The cash used in operating activities in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in the components of working capital. The net cash used in operating activities of $23.8 million for the nine months ended September 30, 2018 was largely driven by our Phase 3 development program for vadadustat, partially offset by receipt of cash from collaboration agreements, including a $4.0 million milestone payment under the MTPC Agreement and $151.4 million in cost-share reimbursements under the Otsuka U.S. Agreement and the Otsuka International Agreement. Additionally, there were adjustments for non-cash items, including stock-based compensation expense of $7.0 million.

The net cash used in operating activities was $39.8 million for the nine months ended September 30, 2017 and consisted primarily of a net loss of $89.2 million adjusted for non-cash items, including stock-based compensation expense of $10.1 million, amortization of premium/discount on investments of $0.5 million, depreciation and amortization of $0.4 million and a net increase in operating assets and liabilities of $38.4 million. The significant items in the change in operating assets and liabilities include an increase in deferred revenue of $8.4 million and a decrease in unbilled receivable of approximately $33.5 million related to unbilled payments from Otsuka received in the first quarter of 2017, an increase in deferred rent of approximately $0.3 million partially offset by a decrease in accounts payable and accrued expenses of approximately $2.2 million and a decrease of approximately $1.8 million in prepaid expenses and other current assets. The net decrease in accounts payable and accrued expenses is primarily driven by clinical and non-clinical study costs associated with vadadustat.

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

Net cash used in investing activities for the nine months ended September 30, 2017 was $169.0 million and was comprised primarily of purchases of available for sale securities of $265.6 million and purchases of equipment of $1.2 million, offset by proceeds from the maturities of available for sale securities of $97.9 million.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2018 was $96.5 million and consisted primarily of net proceeds from the public issuance of common stock, proceeds from the exercise of stock options and proceeds from the sale of stock under our employee stock purchase plan.

Net cash provided by financing activities for the nine months ended September 30, 2017 was $111.0 million and consisted primarily of net proceeds from the public issuance of common stock, proceeds from the exercise of stock options and proceeds from the sale of stock under our employee stock purchase plan.

Operating Capital Requirements

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate revenue from product sales. We do not expect to generate revenue from product sales unless and until we obtain marketing approval of and commercialize one of our current or future product candidates. 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, and begin to commercialize any approved products. We are subject to all risks incident to the development and commercialization of novel therapeutics, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect to continue to incur additional costs associated with operating as a public company, and we anticipate that we will need substantial additional funding in connection with our continuing operations.

We ended the third quarter of 2018 with cash, cash equivalents and available for sale securities of $390.1 million. At the inception of our collaboration agreements with Otsuka and MTPC, they committed to approximately $573.0 million or more in upfront payments and cost-share funding, the latter of which we generally continue to receive on a quarterly prepaid basis. Of these commitments, we received approximately $272.0 million at the onset of the collaboration agreements. We expect our existing cash resources, including the timing of committed research and development funding from our collaborators, to fund our current operating plan through the first quarter of 2020.

We will require additional capital for the further development of our existing product candidates and will need to raise additional funds sooner to pursue development activities related to additional product candidates. If and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity or debt offerings, payments from our collaborators, 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 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 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. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. 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 of this Quarterly Report on Form 10-Q. 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. The foregoing estimates, forecasts and plans do not take into account the potential impact of the Merger.

Contractual Obligations and Commitments

On April 9, 2018, we executed the Fifth Amendment to Lease, or the Fifth Amendment, with CLPF-Cambridge Science Center, LLC, or the Landlord, amending the Lease for our headquarters in Cambridge, Massachusetts. The Fifth Amendment resulted in an increase in our estimated obligations due to our Landlord, which is more fully described in Note 10. Except for the Fifth Amendment, there have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K for the year ended December 31, 2017 that was filed with the SEC on March 12, 2018.

Off-Balance Sheet Arrangements

As of September 30, 2018, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these unaudited condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our unaudited condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue, prepaid and accrued research and development expenses and stock-based compensation. We base our estimates on historical

experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. In making estimates and judgments, management employs critical accounting policies.

During the nine months ended September 30, 2018, there were no material changes to our critical accounting policies, other than as described below, as reported in our Annual Report on Form 10-K for the year ended December 31, 2017, which was filed with the SEC on March 12, 2018.

Revenue

Effective January 1, 2018, we adopted ASC 606, Revenue from Contracts with Customers, using the full retrospective transition method. Under this method, we revised our consolidated financial statements for the year ended December 31, 2017 and applicable interim periods within the year, as if ASC 606 had been effective for those periods. No change for the adoption of ASC 606 was deemed necessary for the year ended December 31, 2016 and applicable interim periods within the year. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under ASC 606, an entity 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 an entity determines are within the scope of ASC 606, the entity performs the following five steps:

(vi) identify the contract(s) with a customer;
(vii) identify the performance obligations in the contract(s);
(viii) determine the transaction price;
(ix) allocate the transaction price to the performance obligations in the contract(s); and
(x) recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when it is probable that the entity will collect the consideration 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, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for collaborations and other revenues, see Note 3, Strategic Collaborations and Other Significant Agreements.

Collaboration Revenue

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

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under each of our agreements, we implement the five-step model noted above. As part of the accounting for these arrangements, we must develop assumptions that require judgment to determine whether the individual deliverables represent separate performance obligations or whether they must be accounted for as a combined performance obligation as well as 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. We use key assumptions to determine the stand-alone selling price, which may include forecasted revenues, development timelines, reimbursement rates for personnel costs, discount rates, and probabilities of technical and regulatory success. With regard to the MTPC and Otsuka collaboration agreements, we recognize revenue related to amounts allocated to the identified performance obligation on a proportional performance basis as the underlying services are performed.

Licenses of Intellectual Property

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

Milestone Payments

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

Manufacturing Supply Services

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

Royalties

We will recognize sales-based royalties, including milestone payments based on the level of sales, at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all the royalty has been allocated has been satisfied (or partially satisfied). To date, we have not recognized any royalty revenue resulting from our collaboration agreements.

Collaborative Arrangements

We record the elements of our collaboration agreements that represent joint operating activities in accordance with ASC Topic 808, Collaborative Arrangements (ASC 808). Accordingly, the elements of the collaboration agreements that represent activities in which both parties are active participants and to which both parties are exposed to the significant risks and rewards that are dependent on the commercial success of the activities are recorded as collaborative arrangements. We consider the guidance in ASC 606-10-15, Revenue from Contracts with Customers – Scope and Scope Exceptions, in determining the appropriate treatment for the transactions between us and our collaborative partner and the transactions between us and third parties. Generally, the classification of transactions

under the collaborative arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. We recognize our allocation of the shared costs incurred with respect to the jointly conducted medical affairs and commercialization and non-promotional activities under the U.S. collaboration with Otsuka as a component of the related expense in the period incurred. During the three months ended September 30, 2018, we incurred approximately $0.2 million of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.1 million are reimbursable by Otsuka and recorded as a reduction to research and development expense during the three months ended September 30, 2018. During the three months ended September 30, 2018, Otsuka incurred approximately $0.5 million of costs related to the cost-sharing provisions of the Otsuka U.S. Agreement, of which approximately $0.1 million are reimbursable by us and recorded as an increase to research and development expense during the three months ended September 30, 2018. To the extent product revenue is generated from the collaboration, we will recognize our share of the net sales on a gross basis if it is deemed to be the principal in the transactions with customers, or on a net basis if it is instead deemed to be the agent in the transactions with customers, consistent with the guidance in ASC 606.

Recent Accounting Pronouncements

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We chose to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

For a discussion of recent accounting pronouncements, please refer to New Accounting Pronouncements – Recently Adopted and New Accounting Pronouncements – Not Yet Adopted included within Note 2, Summary of Significant Accounting Policies, to our unaudited condensed consolidated financial statements included in this report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are exposed to market risk related to changes in interest rates. As of September 30, 2018 and December 31, 2017, we had cash and cash equivalents and available-for-sale securities of $390.1 million and $317.8 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 SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2018, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving such control objectives. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2018, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

Shareholder Litigation

On October 23, 2018, an alleged shareholder of Keryx Biopharmaceuticals, Inc., or Keryx, filed a putative shareholder class action against Keryx, the members of the Keryx board of directors, Alpha Therapeutics Merger Sub, Inc., our wholly owned subsidiary, or the Merger Sub, and Akebia challenging the disclosures made in connection with the pending merger of Merger Sub with and into Keryx, or the Merger. The lawsuit, Rosenblatt v. Keryx Biopharmaceuticals, Inc., et al., was filed in the United States District Court for the District of Massachusetts. The complaint generally alleges that the registration statement filed in connection with the Merger fails to disclose certain allegedly material information. The alleged omissions relate to (i) certain financial projections for Keryx and Akebia and certain financial analyses performed by Keryx's advisors; (ii) certain terms relating to the engagement of Perella Weinberg Partners by Keryx; and (iii) any alleged negotiations that may have taken place regarding future employment and directorship of the Keryx's officers and directors. The plaintiff asserts claims under Section 14(a) of the Securities Exchange Act and Rule 14a-9 promulgated thereunder against Keryx and the members of the Keryx board of directors, and claims under Section 20(a) of the Exchange Act against the members of the Keryx board of directors, Akebia, and Merger Sub. The plaintiff seeks to enjoin the defendants from proceeding with the Merger and seeks damages in the event the transaction is consummated. We and Keryx believe that the plaintiff's allegations are without merit; however, litigation is inherently uncertain and there can be no assurance that Keryx's or our defense of the action will be successful.

Opposition Proceedings Against Akebia's Patents

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. During the oral proceedings, which took place on April 10, 2013, the Opposition Division of the European Patent Office maintained the '005 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. On February 27, 2018, we withdrew the '005 EP Patent from appeal and filed a divisional patent application to pursue a focused claim set that includes claims for vadadustat, as well as pharmaceutical compositions and methods of treating anemia.

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

Opposition and Invalidity Proceedings Against FibroGen, Inc.

We filed an opposition in Europe against FibroGen, Inc.'s, or FibroGen's, European Patent No. 1463823, or the '823 EP Patent, and an oral proceeding took place March 8 and 9, 2016. Following the oral proceeding, the European Opposition Division 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, 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 European Patent Office, respectively, requesting the patents be revoked in their entirety. These related patents claim, among other things, various compounds that either stabilize HIF or inhibit a HIF hydroxylase or a HIF prolyl hydroxylase, or HIF-PH, for treating or preventing various conditions, including, among other things, iron deficiency, microcytosis associated with iron deficiency, anemia of chronic disease, anemia wherein the subject has a transferrin saturation of less than 20%, anemia refractory to treatment with exogenously administered erythropoietin and microcytosis in microcytic anemia. Such method of use patents do not prevent persons from using the compound for other uses, including any previously known use of the compound. In particular, these patents do not claim methods of using any of our product candidates for purposes of inhibiting HIF-PH for the treatment of anemia due to CKD. While we do not believe these patents will prevent us from commercializing vadadustat for the treatment of anemia due to CKD, we filed these oppositions to provide us and our collaborators with maximum flexibility for developing vadadustat and our pipeline of HIF-PHIs.

Oppositions to the ’155 EP Patent and the ’153 EP Patent were also filed in the European Patent Office 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 European Opposition Division ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. On December 9, 2016, FibroGen filed a notice to appeal the decision to revoke the ’333 EP Patent.

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

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

On 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, 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, Akebia 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.

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. Unless otherwise stated or the context otherwise requires, the following risks do not reflect the changes to our business that may occur if we consummate the proposed merger with Keryx. See also the Risk Factors section of our preliminary Registration Statement on Form S-4 filed with the U.S. Securities and Exchange Commission on October 1, 2018.

Risks Related to our Proposed Merger with Keryx

There can be no assurance that the proposed merger with Keryx will be consummated. The announcement and pendency of the merger, or the failure of the merger to be consummated, could have an adverse effect on our stock price, business, financial condition, results of operations or prospects.

On June 28, 2018, we, Alpha Therapeutics Merger Sub, Inc., a direct, wholly owned subsidiary of ours, or the Merger Sub, and Keryx Biopharmaceuticals, Inc., or Keryx, entered into an Agreement and Plan of Merger, which was amended on October 1, 2018, or the Merger Agreement, pursuant to which Merger Sub shall be merged with and into Keryx, with Keryx surviving as a wholly owned subsidiary of ours, or the Merger. Consummation of the Merger is subject to approval by our shareholders and Keryx’s shareholders, receipt of certain regulatory approvals and other conditions specified in the Merger Agreement. As a result, there can be no assurance that the Merger will be consummated.

Further, the announcement and pendency of the Merger could disrupt our business, in any of the following ways, among others:

- our employees may experience uncertainty about their future roles with the combined company, which might adversely affect our ability to retain and hire employees;
- the attention of our management may be directed toward completion of the Merger, integration planning and transaction-related considerations and may be diverted from our day-to-day business operations;
- vendors, suppliers or others may seek to modify or terminate their business relationship with us;
- we and our directors and Keryx could become subject to lawsuits relating to the Merger; and
- we may experience negative reactions from our shareholders, patients enrolled in our studies and the medical community, among others.

These disruptions could be exacerbated by a delay in the completion of the Merger or termination of the Merger Agreement. Additionally, if the Merger is not consummated, we will have incurred significant costs and diverted the time and attention of management. A failure to consummate the Merger may also result in negative publicity, litigation against us or our directors and officers, and a negative impression of the Company in the financial markets. The occurrence of any of these events individually or in combination could have a material adverse effect on our financial statements and stock price.

We may be unable to fully realize the expected benefits from the Merger.

We expect to achieve substantial operating and capital synergies and cost savings as a result of the Merger. 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 combined company following the Merger, 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 the Merger and/or the resulting combined company. 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 will become responsible for Keryx's liabilities and obligations, including with respect to legal, financial, regulatory and compliance matters. 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. 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. For example, the Centers for Medicare & Medicaid Services, or CMS, recently communicated to Medicare Part D sponsors that Keryx's marketed product, Auryxia, is considered by CMS as a covered Part D drug when it is used for its FDA-approved indication for the control of serum phosphorus levels. CMS also indicated that it does not consider Auryxia covered under Part D when it is used solely for the treatment of iron deficiency anemia in patients with chronic kidney disease, or CKD, not on dialysis, which is Auryxia's other FDA-approved indication. As a result, CMS currently expects Part D sponsors to utilize a prior authorization edit or other process for all Auryxia prescriptions for Medicare beneficiaries to ensure that Auryxia is being used for a Part D covered indication. Keryx expects Part D sponsors will implement a prior authorization edit for Auryxia no later than January 2019. Keryx is engaging in discussions with CMS and Part D sponsors on this matter as Keryx believes that Auryxia should qualify for coverage under Part D of the CMS regulations when it is used for the treatment of iron deficiency anemia in patients with CKD not on dialysis. While Keryx believes that the vast majority of the Part D prescriptions written for Auryxia today are for the control of serum phosphorus levels and therefore will continue to be covered by Part D plans with prior authorization, Keryx cannot predict the impact of these changes on Keryx's operations and they could have a material adverse effect on Keryx's results of operations going forward.

Even if we successfully consummate the Merger and integrate the businesses, there can be no assurance that the Merger will result in the realization of the full benefit of the anticipated synergies and cost savings or that these benefits will be realized within the expected time frames or at all. In addition, by engaging in the Merger, we may forego or delay pursuit of other opportunities that may have proven to have greater commercial potential.

If generic products that compete with Keryx's marketed product, Auryxia, or any future product of the combined company are approved and launched, the combined company's business, financial position or results of operations would be adversely affected.

Although composition and use of Auryxia are currently claimed by 14 issued patents that are listed in the FDA's Orange Book, we cannot assure you that third parties will not attempt to invalidate or design around the patents or assert that they are invalid or otherwise unenforceable or not infringed and introduce generic equivalents of Auryxia or any future product of the combined company. Third parties may seek to introduce generic equivalents of Auryxia, provided they receive FDA approval and can show that their products do not infringe Keryx's patents or that its patents are invalid or unenforceable. 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. Generic competition for Auryxia or any future product of the combined company could have a material adverse effect on the combined company's sales, results of operations and financial condition.

On October 31, 2018, Keryx received a Paragraph IV certification notice letter regarding an Abbreviated New Drug Application, or ANDA, submitted to the FDA by Lupin Atlantis Holdings SA, or Lupin, requesting approval to market, sell and use a generic version of the Auryxia tablets (210 mg iron per tablet). In its notice letter, Lupin alleges that Keryx's U.S. Patents Nos. 5,753,706; 7,767,851; 8,093,423; 8,299,298; 8,338,642; 8,609,896; 8,754,257; 8,754,258; 8,846,976; 8,901,349; 9,050,316; 9,328,133; 9,387,191; and 9,757,416, which cover the approved drug substance, drug product and/or methods of using Auryxia, are invalid, unenforceable and/or will not be infringed by Lupin's manufacture, use or sale of the product described in its ANDA. Keryx is currently reviewing the notice letter and intends to vigorously enforce its intellectual property rights relating to Auryxia. By statute, Keryx has 45 days from receipt of the notice letter to initiate a patent infringement lawsuit against Lupin. Such a lawsuit would automatically preclude the FDA from approving Lupin's ANDA until the earlier of 30 months from October 31, 2018 or entry of a district court decision finding the patents invalid, unenforceable or not infringed.

On November 6, 2018, Keryx received a Paragraph IV certification notice letter regarding ANDA submitted to the FDA by Teva Pharmaceuticals USA, Inc., or Teva, requesting approval to market, sell and use a generic version of the Auryxia tablets (210 mg iron per tablet). In its notice letter, Teva alleges that Keryx's U.S. Patents Nos. 7,767,851; 8,093,423; 8,299,298; 8,338,642; 8,609,896; 8,754,257; 8,754,258; 8,846,976; 8,901,349; 9,050,316; 9,328,133; 9,387,191; and 9,757,416, which cover the approved drug substance, drug product and/or methods of using Auryxia, are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of the product described in its ANDA. Keryx is currently reviewing the notice letter and intends to vigorously enforce its intellectual property rights relating to Auryxia. By statute, Keryx has 45 days from receipt of the notice letter to initiate a patent infringement lawsuit against Teva. Such a lawsuit would automatically preclude the FDA from approving Teva's ANDA until the earlier of 30 months from November 6, 2018 or entry of a district court decision finding the patents invalid, unenforceable or not infringed.

Litigation to enforce or defend intellectual property rights is complex, costly and involves significant management time. If Keryx's Orange Book listed patents are successfully challenged by Lupin, Teva or any other third party and a generic version of Auryxia is approved and launched, revenue from Auryxia could decline significantly.

While the Merger Agreement is in effect, we are subject to restrictions on our business activities.

While the Merger Agreement is in effect, we are subject to restrictions on our business activities and must generally operate our business in the ordinary course consistent with past practice, subject to certain exceptions. These restrictions could prevent us from pursuing attractive business opportunities that may arise prior to the consummation of the Merger and are generally outside the ordinary course of business, and otherwise have a material adverse effect on us. Although we may be able to pursue such activities with Keryx's consent, Keryx may not be willing to provide its consent for us to do so.

A delay in completing the Merger may reduce or eliminate the expected benefits from the Merger.

The Merger is subject to a number of conditions, some of which are beyond our control, which could prevent, delay or otherwise materially adversely affect its completion. We cannot predict whether and when the conditions will be satisfied. A delay in completing the Merger could cause the combined company to not realize some or all of the synergies and other benefits it expects to achieve if the Merger is successfully completed within its expected time frame. Because the Merger Agreement contains certain restrictions on the conduct of our business, if the Merger is delayed, these restrictions could adversely affect our ability to execute business strategies or pursue attractive business opportunities. In addition, a delay could cause management to focus on completion of the Merger instead of on other opportunities that could be beneficial to us or our day-to-day business operations.

Failure to consummate the Merger could negatively impact our future stock price, operations and financial results.

If the Merger is not consummated for any reason, we may be subjected to a number of material risks, including the following:

- our business may be adversely impacted by the failure to pursue other beneficial opportunities due to the focus of our management on the Merger;
- the market price of our shares may decline to the extent that current market prices reflect a market assumption that the Merger will be consummated and will be beneficial to the value of our business after the Merger closes;
    - if the Merger Agreement is terminated under certain specified circumstances, we will be required to pay Keryx a termination fee of $22.0 million. We will also be required to pay Keryx the termination fee in the event we sign or consummate an Acquisition Proposal, as defined in the Merger Agreement, within twelve months following the termination of the Merger Agreement under certain circumstances;
- we may have to pay certain costs related to the Merger, such as legal, accounting, financial advisory, printing and mailing fees, which must be paid regardless of whether the Merger is consummated;

- we will need to address the consequences of any operational decisions made since the signing of the Merger Agreement that may have been impacted by restrictions on our operations imposed by the terms of the Merger Agreement, including decisions to delay or defer capital expenditures;
- our management and personnel will need to return their focus to operating the Company on a stand alone basis, without any of the benefits expected to have been provided by the consummation of the Merger; and
- negative reactions from shareholders, suppliers, employees, patients enrolled in our studies and the medical community.

The occurrence of any of the foregoing events individually or in combination could have a material adverse effect on our financial statements and stock price.

The issuance of shares of our common stock in connection with the Merger, and any future offerings of securities by us, will dilute our shareholders' ownership interest in Akebia and sales of shares of our common stock after the completion of the Merger may cause the market price of our common stock to decline.

The Merger will be financed by the issuance of additional 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 the companies' fully diluted market capitalizations as of the date of signing of the Merger Agreement and also taking into account the 4,000,000 additional Keryx shares expected to be issued to Baupost Group Securities, L.L.C., or Baupost, prior to consummation of the Merger, as more fully described elsewhere in this document. These issuances of additional shares of our common stock will dilute our existing shareholders' ownership interest in the Company, and will reduce our existing shareholders' ownership and voting interest in the Company following the consummation of the Merger. In addition, Keryx shareholders may decide not to hold the shares of our common stock they receive in the Merger and 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 that they receive in the Merger. Such sales of our common stock could result in higher than average trading volume following the closing of the Merger and may cause the market price for our common stock to decline.

Following completion of the Merger, our current shareholders in the aggregate will not have a majority ownership and voting interest in the Company and the structure of our Board of Directors will be different, which may result in our shareholders having less influence on our management and policies.

Our shareholders currently have the right to vote for the election of directors to our Board of Directors and on other matters affecting us. Immediately following the Merger, our shareholders and the Keryx shareholders are expected to own approximately 49.4% and 50.6%, respectively, of our issued and outstanding shares of common stock, calculated based on the companies' fully diluted market capitalizations as of the date of signing of the Merger Agreement and also taking into account the 4,000,000 additional Keryx shares expected to be issued to Baupost prior to consummation of the Merger. In addition, the Merger Agreement provides that as of the closing of the Merger, we must take all necessary corporate action to cause an increase in the size of our Board of Directors to ten directors, comprised of four directors designated by our Board of Directors, each of whom will be a director of the Company immediately prior to the consummation of the Merger and be reasonably acceptable to Keryx, referred to as the Continuing Directors, and five directors designated by the Keryx Board of Directors, each of whom will be a director of Keryx immediately prior to the consummation of the Merger and be reasonably acceptable to us, referred to as the Keryx Designees. In addition, our Board of Directors and the Keryx Board of Directors will designate one additional independent director, who does not currently sit on the Boards of Directors of either Akebia or Keryx, who will serve as the Chairperson of our Board of Directors if and when the Merger is consummated. As a result, our shareholders may have less influence on our management and policies than they currently have.

Consummation of the Merger could result in limitations to our ability to utilize pre-change operating losses to offset future taxable income.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. As the Merger is structured as an all-stock merger, we expect the consummation of the transaction to create a limitation for both Akebia and Keryx’s pre-merger NOLs. Depending on the equity value of both Akebia and Keryx on the date the merger is consummated, the limitations could be restrictive enough to impact our ability to utilize our NOLs to offset future taxable income.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant net losses since inception and anticipate that we will continue to incur significant and increasing net losses for the foreseeable future.

Investment in pharmaceutical product development is highly speculative because it entails upfront capital expenditures and significant risk that a product candidate will fail to gain marketing approval or become commercially viable. Since our inception, we have devoted most of our resources to research and development, including our preclinical and clinical development activities. We have financed our operations primarily through sales of equity securities and our strategic collaborations. To date, we have no products approved for commercial sale and have not generated any revenue from the sale of products. As a result, we are not profitable and have incurred net losses each year since our inception, including net losses of $83.5 million for the nine months ended September 30, 2018. As of September 30, 2018, we had an accumulated deficit of $454.3 million. We do not know whether or when we will generate product revenue or become profitable.

We expect to continue to incur significant expenses and increased 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 ability to obtain funding through equity or debt financings or strategic collaborations. We anticipate that our expenses will increase significantly if and as we:

- conduct our development program of vadadustat for the treatment of anemia due to CKD including PRO_2TECT, $INNO_2VATE$, FO_2RWARD-2 and $TRILO_2GY$-2, and develop plans for and conduct the preclinical and clinical development of any other potential product candidates;
- complete the Merger, subject to satisfying closing conditions, including obtaining applicable shareholder and regulatory approvals, integrate with Keryx following successful completion of the Merger, and seek to satisfy contractual and regulatory obligations following closing of the Merger;
- seek marketing approvals for our product candidates that successfully complete clinical studies, and maintain such marketing approvals, including complying with any post-marketing regulatory requirements;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- initiate additional preclinical, clinical or other studies for vadadustat and any other product candidates;
- seek to discover and develop additional product candidates;
- engage in transactions, including strategic transactions, merger, collaboration, acquisition and licensing arrangements, pursuant to which we would market and develop commercial products, or develop other product candidates and technologies;
- make royalty, milestone or other payments under our license agreement with Janssen Pharmaceutica NV, or Janssen, and any future in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- continue to create additional infrastructure and expend additional resources to support our operations as a public company, including any additional infrastructure and resources necessary to support a transition from our status as an emerging growth company; and
- experience any delays or encounter issues with any of the above.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, 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.

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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 post-marketing requirements for vadadustat and any other product candidates that may receive marketing approval. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have never generated any revenue from product sales, and we may never be profitable.

We have no products approved for commercial sale, have never generated any revenue from product sales, and do not anticipate generating any revenue from product sales unless and until we receive marketing approval for the commercial sale of a product candidate or in-license or acquire an approved product. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict when, if at all, we will be able to achieve profitability. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including the following:

- completing research regarding, and preclinical and clinical development of, our product candidates;
- seeking and obtaining marketing approvals for our product candidates for which we complete clinical studies and the timing of such approvals;
- developing, commercializing and marketing any product candidate or product that may be in-licensed or acquired, including as a result of a successful completion of the Merger;
- developing sustainable and scalable manufacturing processes for our product candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate products and services to support clinical development and the market demand for our product candidates, if approved;
- launching and commercializing our product candidates, either directly or with a collaborator or distributor;
- obtaining sufficient pricing and reimbursement for our product candidates from private and governmental payors;
- obtaining market acceptance of our product candidates as viable treatment options;
- the size of any market in which our product candidates receive approval and adequate market share in those markets;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any transaction into which we may enter, including collaboration, merger, acquisition and licensing arrangements;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other regulatory authorities, or if we otherwise believe it is necessary, to change our manufacturing processes or assays, to amend or replace our study protocols, to repeat any of our clinical trials, to perform studies in addition to, different from or larger than those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates. Even if our product candidates are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. In addition, our ability to generate revenue would be negatively affected if the size of our addressable patient population is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the patient population for treatment is narrowed by competition, physician choice, or payor or treatment guidelines. Even if we are able to generate revenues from the sale of any approved products, 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 September 30, 2018, our cash and cash equivalents and available for sale securities were $390.1 million. We expect to continue to expend substantial amounts for the foreseeable future developing and commercializing vadadustat, if approved, and any other product candidates. These expenditures will include costs associated with research and development, potentially obtaining marketing approvals and having our products manufactured, as well as marketing and selling products approved for sale, if any. In addition, other unanticipated costs may arise, including as a result of our decision to include certain elements in our development programs. Because the outcome of our current and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amount of funding necessary to successfully complete the development and commercialization of our product candidates. Our future capital requirements depend on many factors, including:

- significant costs associated with our global Phase 3 development program for vadadustat for the treatment of anemia due to CKD. As of September 30, 2018, we expect the remaining external aggregate contract research organization, or CRO, costs of PRO_2TECT and $INNO_2$VATE, which are designed to enroll up to 7,300 subjects, to be in the range of $250.0 million to $280.0 million; the estimated costs for PRO_2TECT and $INNO_2$VATE could increase significantly due to a number of factors, including changes in target enrollment and enrollment rates, accrual of major adverse cardiovascular events, or MACE, the addition of new investigative sites, modification of clinical trial protocols, performing other studies in support of the Phase 3 program, choosing to add third-party vendors to support the program, and any other factor that could delay completion of PRO_2TECT and $INNO_2$VATE;
- the results of our meetings with the FDA, the EMA and other regulatory authorities and the consequential effect 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 marketing approvals for vadadustat and any other product candidates that we may develop or acquire, if clinical studies are successful, including to fund the preparation and filing of regulatory submissions with the FDA, the EMA and other regulatory authorities;
- the cost of conducting the FO_2RWARD-2 and $TRILO_2$GY-2 clinical studies;
- the cost, timing and outcome of our efforts to obtain marketing approval for vadadustat in the United States, Europe and in other jurisdictions;
- the scope, progress, results and costs of additional preclinical, clinical, or other studies for vadadustat, as well as any studies of any other product candidates;
- the cost of securing and validating commercial manufacturing of vadadustat;
- the cost and timing of future commercialization activities for our products, if approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- 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; and
- the extent to which we engage in transactions, including collaboration, merger, acquisition and licensing arrangements pursuant to which we would develop and market commercial products, such as the Merger, or develop other product candidates and technologies.

We expect our existing cash resources, including the timing of committed research and development funding from our collaborators, to fund our current operating plan through the first quarter of 2020. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Furthermore, our development milestones may not be achieved, we may not receive the anticipated funding from our collaboration partners, and we may not secure other sources of financing. If and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity or debt offerings, payments from our collaborators, 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 from their day-to-day activities, which may adversely affect our ability to develop and commercialize our 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 one or more of our product candidates. Any of these events could significantly harm our business, financial condition and prospects.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through public or private equity or debt offerings, payments from our collaborators, 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 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 candidates, future revenue streams, research programs or product candidates or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for vadadustat, or any other product candidates that we develop or acquire, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to our Business and the Clinical Development, Regulatory Review and Approval of Vadadustat and our Other Product Candidates

We depend heavily on the success of one 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 product candidate, vadadustat, in clinical development, and our business depends almost entirely on 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 marketing approval or commercialize our product candidates. Our clinical trials may take longer to complete than currently anticipated, or may be delayed, suspended, required to be repeated, prematurely terminated or may not successfully demonstrate safety and/or efficacy for a variety of other reasons, such as:

- the costs are greater than we anticipate;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
-

enrollment in our clinical trials and accrual of MACE events may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;

- our third-party contractors may fail to comply with regulatory requirements, perform effectively, or meet their contractual obligations to us in a timely manner, or at all, or we may fail to communicate effectively or provide the appropriate level of oversight of such third-party contractors;
- the supply or quality of our starting materials, drug substance and drug product necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators, international data monitoring committees, or IDMCs, institutional review boards, or IRBs, safety committees, or ethics committees, may require that we suspend or terminate our clinical trials for various reasons, including noncompliance with regulatory requirements, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using our product candidate, or a finding that the participants are being exposed to unacceptable health risks;

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials, repeat a clinical trial or abandon product development programs;
- lack of adequate funding to continue a clinical trial, including unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials or repeat a clinical trial and increased expenses associated with the services of our CROs and other third parties;
- failure to initiate, delay of or failure to complete a clinical trial as a result of an Investigational New Drug Application, or IND, being placed on clinical hold by the FDA, EMA, the Japanese Pharmaceuticals and Medical Devices Agency, or PMDA, or other regulatory authorities, or for other reasons;
- we may determine to change or expand a clinical trial, including after it has begun;
- clinical trial sites and investigators deviating from the clinical protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial, or failure by us or our CROs to communicate effectively or provide the appropriate level of oversight of such clinical sites and investigators;
- delay or failure in having subjects complete a clinical trial or return for post-treatment follow-up;
- delay or failure in recruiting and enrolling suitable subjects to participate in a clinical trial;
- inability, delay, or failure in identifying and maintaining a sufficient number of clinical trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in reaching agreement with the FDA, EMA, 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, EMA, PMDA or other regulatory authorities may require us to submit additional data or impose further requirements before permitting us to initiate a clinical trial;
- failure to comply with good practice quality guidelines and regulations, or GXP, including good laboratory practice, or GLP, good clinical practice, or GCP, and current good manufacturing practice, or cGMP; or
- changes in governmental regulations or administrative actions.

Many of the factors that cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our product candidates. Further, the FDA, EMA, 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.

If we are required to conduct additional clinical trials, repeat clinical trials or conduct other studies of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other studies, if the results of these trials or tests are not positive or are only modestly positive, or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval for our product candidates at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- 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;
- be subject to additional post-marketing restrictions and/or requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in preclinical and clinical development or receiving the requisite marketing approvals. Our preclinical studies or clinical trials may need to be restructured or may not be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our

competitors to bring products to market before we do. This could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

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

The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by numerous government 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 Pharmaceutical Co. Ltd., or Otsuka, our collaboration partner, are not permitted to market vadadustat in the United States until we receive approval from the FDA, in the European Union until we receive approval from the EMA, or in any other jurisdiction until the requisite approval from regulatory authorities in such jurisdiction is received. Mitsubishi Tanabe Pharma Corporation, or 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, EMA, PMDA or other regulatory authorities. Vadadustat may not be successful in clinical trials or receive marketing approval. Further, vadadustat may not receive marketing approval even if it is successful in clinical trials.

Obtaining marketing approval in the United States and other jurisdictions is a complex, lengthy, expensive and uncertain process that typically takes many years and depends upon numerous factors, including the substantial discretion of the regulatory authorities. Even if our product candidates demonstrate safety and efficacy in clinical studies, the regulatory agencies may not complete their review processes in a timely manner, or we may not be able to obtain marketing approval. In addition, the safety concerns associated with injectable ESAs may affect the FDA's, EMA's, PMDA's or other regulatory authorities' review of the safety results of compounds in development for treatment of the same indications as injectable ESAs, including vadadustat. Further, the policies or regulations, or the type and amount of clinical data necessary to gain approval, may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained marketing approval for any product candidate, and 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 FDA may require us to complete both the $INNO_2VATE$ clinical program and the PRO_2TECT clinical program for vadadustat prior to filing our NDA even if one of these programs finishes in advance of the other;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval;
- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;
- the FDA may not approve the formulation, labeling or specifications we request for vadadustat or any other product candidate;
- the FDA may approve vadadustat or any other product candidate for use only in a small patient population or for fewer or more limited indications than we request;
- the FDA may require that we conduct additional clinical trials or repeat one or more clinical trials;
- the FDA may grant approval contingent on the performance of costly post-marketing clinical trials;

- we, or our CROs or vendors, may fail to comply with GXP;
- the CROs that we retain to conduct our clinical trials may not perform effectively or take actions that adversely impact our clinical trials, or we may fail to communicate effectively or provide the appropriate level of oversight of our CROs;
- we or our third party manufacturers may fail to perform in accordance with the FDA's cGMP requirements;
- the FDA may disagree with inclusion of data obtained from certain regions outside the United States to support the NDA for potential reasons such as differences in clinical practice from United States standards;
- the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials;

- the FDA could deem that our financial relationships with certain principal investigators constitute a conflict of interest, such that the data from those principal investigators may not be used to support our applications;
- an FDA Advisory Committee or other regulatory advisory group or authority could recommend non-approval or restrictions on approval;
- the FDA's decision-making regarding vadadustat and any other product candidates may be impacted by the results of competitors' clinical trials;
- 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 PMDA or other regulatory authorities to delay, limit or deny approval of vadadustat or any other product candidate outside the United States.

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

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

Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends, in part, on the speed at which we can recruit patients to participate in testing our product candidates. Patients may be unwilling to participate in our clinical studies of vadadustat or other product candidates because of concerns about adverse events observed with injectable ESAs, other investigational agents and commercial products in CKD or for other reasons, including competitive clinical studies for similar patient populations. In addition, patients currently receiving treatment with injectable ESAs may be reluctant to participate in a clinical trial with an investigational drug. Finally, competition for clinical trial sites may limit our access to subjects appropriate for studies of vadadustat and any other product candidates. As a result, the timeline for recruiting patients, conducting studies and obtaining marketing approval of vadadustat and any other product candidates may be delayed. These delays could result in increased costs, delays in advancing our development of vadadustat and any other product candidates, or termination of the clinical studies altogether.

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

- severity of the disease under investigation;
- design of the study protocol;
- size and nature of the patient population;
- eligibility criteria for, and design of, the study in question;
- perceived risks and benefits of the product candidate under study, including as a result of adverse effects observed in similar or competing therapies;
- proximity and availability of clinical study sites for prospective patients;
- availability of competing therapies and clinical studies and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to available therapies or other product candidates in development;
- efforts to facilitate timely enrollment in clinical studies;
- clinical trial sites and investigators failing to perform effectively;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

We may not be able to initiate or continue clinical studies if we cannot enroll a sufficient number of eligible patients to participate in the clinical studies required by regulatory agencies. If we have difficulty enrolling a sufficient number of patients to conduct our clinical studies as planned, we may need to delay, limit or terminate on-going 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 currently expect to seek marketing approval of vadadustat for the treatment of anemia due to CKD in markets outside the United States, including the European Union and Japan. Our ability to successfully initiate, enroll and complete a clinical study in any country outside of the United States is subject to numerous additional risks unique to conducting business in jurisdictions outside the United States, including:

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

Data obtained from studies conducted in the United States may not be accepted by the EMA, PMDA and other regulatory authorities outside of the United States. Also, certain jurisdictions require data from studies conducted in their country in order to obtain approval in that country. For example, in Japan, MTPC is conducting a Phase 3 program of vadadustat, which is separate from our global Phase 3 program of vadadustat.

If we 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.

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. On March 29, 2017, the United Kingdom formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. Since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, the withdrawal could materially impact the regulatory regime with respect to the approval of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit

or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occurs, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business.

Positive results from preclinical and clinical studies are not necessarily predictive of the results of any future clinical studies. Furthermore, initial success in our ongoing clinical studies may not be indicative of results obtained when these studies are completed.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies may not be predictive of similar results in humans during clinical trials, successful results from early or small clinical trials may not be replicated in later and larger clinical trials, and successful interim results from ongoing clinical studies may not be indicative of results obtained when those studies are completed. For example, our encouraging preclinical and clinical results for vadadustat thus far do not ensure that the results of any future clinical trials will demonstrate similar results. Our global Phase 3 development program for vadadustat is enrolling a larger number of subjects and will treat subjects for longer periods than our prior trials, which will result in a greater likelihood that adverse events may be observed. 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 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 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, EMA, PMDA or other regulatory authorities. 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.

Our product candidates may cause undesirable side effects or have other properties that delay or prevent their marketing approval or limit their commercial potential.

Undesirable side effects caused by our product candidates or competing products in development that utilize a common mechanism of action could cause us or regulatory authorities to interrupt, delay or halt clinical trials, could result in a more restrictive label or the delay or the denial of marketing approval by the FDA or other regulatory authorities, and could lead to potential product liability claims. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

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

If we or others identify undesirable side effects caused by our 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 additional warnings on the label;
- 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 our products, could substantially increase our costs, and could significantly impact our ability to successfully commercialize our product candidates and generate revenues.

Any product candidate for which we obtain marketing approval will be 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, when and if any of them is approved.

Any marketing approvals that we receive for our product candidates or any other product candidates or products that we may develop or acquire 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. In addition, if the FDA or any other regulatory authority approves any of our product candidates, or any other product candidates or products that we may develop or acquire, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product 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 U.S. federal and state healthcare fraud and abuse and other laws, as well as state consumer protection laws, third party payor actions, shareholder actions and other lawsuits.

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

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

Non-compliance with FDA, EMA, 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 regulation 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.

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. In interim guidance issued by the Office of Information and Regulatory Affairs within the Office of Management and on February 2, 2017, the administration 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.

Risks Related to our Reliance on Third Parties

We rely on third parties to conduct preclinical and clinical studies for our 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 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 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, and would adversely affect our business operations. In addition, if the third parties on whom we rely may fail to perform effectively or terminate their engagement with us, we may need to enter into alternative arrangements, which could delay, perhaps significantly, 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, 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 other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, resulting in additional costs and depriving us of potential product revenue. In addition, we are using an active comparator in our PRO_2TECT and $INNO_2VATE$ clinical programs. If our distributors are unable to obtain sufficient supply of the active comparator for any reason, or supply active comparator to clinical trial sites in a timely manner, our clinical trials may be extended, delayed, suspended or terminated.

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

We do not have any manufacturing facilities and do not expect to independently manufacture our product candidates for research and preclinical and clinical studies or, if our product candidates are approved, for commercial purposes. We currently rely on third party manufacturers to produce all of our preclinical and clinical material supply. We expect to continue to rely on existing or alternative third party manufacturers to supply our ongoing and planned preclinical and clinical trials and for commercial production. We have not yet entered into binding agreements with third party manufacturers to manufacture commercial quantities of vadadustat, and we may not be able to negotiate binding agreements at commercially reasonable terms. Our reliance on third party manufacturers increases the risk that we will not have sufficient quantities of our 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.

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 technology required to manufacture a 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 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 develop and receive marketing approval for product candidates in a timely manner or within budget or, if vadadustat or any other product candidate is approved and marketed, a failure to satisfy patient demand.

The facilities and processes used by our third party manufacturers to manufacture our product candidates will be inspected by the FDA, EMA and other regulatory authorities prior to or after we submit our marketing application. We do not control the manufacturing processes of, and are completely dependent on, our third party manufacturers for compliance with cGMP requirements for manufacture of certain starting materials, drug substance and finished drug product. If our third party manufacturers cannot successfully manufacture material that conforms to our specifications and regulatory requirements, we will not be able to 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, EMA or other regulatory authorities do not approve these facilities for the manufacture of our product candidates, or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to 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 product candidates or products, if approved, operating restrictions or criminal prosecutions, any of which could significantly and adversely affect the supply of our product candidates or products, if approved. 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, if approved, or product candidates and we may incur significant financial harm. In addition, our product candidates and products, if approved, may compete with other product candidates and products for access to third party manufacturing facilities. Certain of these third party manufacturing facilities may be contractually prohibited from manufacturing our product candidates or products, if approved, 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 our product candidates and products, if approved, for us.

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

If we are unable to obtain our product candidates or products, if approved, in sufficient quantities and at sufficient yields, we may experience delays in product development, preclinical or clinical studies, marketing approvals and commercial distribution.

Completion of our preclinical and clinical studies and commercialization of our product candidates require access to facilities to manufacture our product candidates at sufficient yields and at clinical and commercial scale. We have limited experience managing third parties in manufacturing our product candidates or products, if approved, in the volumes that will be necessary to support large-scale clinical trials or commercial sales. Our third party manufacturers

may not meet our expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality.

Our reliance on third party manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third party manufacturers with the expertise, required marketing approvals and facilities to manufacture our bulk starting materials, drug substance and finished drug product on a commercial scale, replacement of a third party manufacturer may be expensive and time-consuming and may cause interruptions in the production of our product candidates or products, if approved. A third party manufacturer may also encounter delays brought on by sudden internal resource constraints, labor disputes, or shifting regulatory protocols. In addition, a contract manufacturer may also require a substantial financial commitment, including but not limited to a commitment to fund the purchase of a new facility or equipment.

Any delay or interruption in our supply of product candidates or products, if approved, could cause delays in our product development, clinical trials, marketing approvals, commercial distribution, or have a material adverse effect on our business, financial condition, results of operations and cash flows.

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

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

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

We currently have redundant supply arrangements in place for the preclinical and clinical supply of vadadustat. We have not yet entered into binding agreements with third party manufacturers to manufacture commercial quantities of vadadustat. While we intend to put redundant supply arrangements in place for commercial manufacturing of vadadustat, we may be unsuccessful in doing so due to a number of factors, including that we may not be able to negotiate binding agreements at commercially reasonable terms. Even if we are ultimately successful in entering into redundant supply arrangements for commercial manufacturing of vadadustat, the timing of such arrangements is uncertain.

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

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

We depend on our collaborations with Otsuka and MTPC for the development and commercialization of vadadustat, and we may depend on collaborations with additional third parties for the development and commercialization of vadadustat and any other product candidates. 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 vadadustat or any other product candidates and our business could be materially harmed.

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 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 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 one or more 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 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 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 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 development and potential commercialization of vadadustat and any other product candidates. For some of our product candidates, including vadadustat, we may decide to enter into additional collaborations for their development and potential commercialization. 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 candidate;
- 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 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 develop our product candidates or bring them to market and generate product revenue.

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

Risks Related to our Intellectual Property

If our efforts to protect our proprietary technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. We will only be able to protect our product candidates, proprietary technologies and their uses from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market.

In July 2011, a third party filed an opposition to our issued European patents, European Patent No. 2044005, or the ’005 EP Patent. 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.

Composition-of-matter patents on the active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any method of use. Method-of-use patents protect the use of a product for the specified method. A method-of-use patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method-of-use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or license may fail to result in issued patents in the United States or in other countries. Our competitors have taken, and we expect that they will continue to undertake, formal efforts to oppose the issuance of claims in our patent applications. We do not control decisions made by the United States Patent and Trademark Office, or US PTO, or equivalent bodies outside the United States. Even if our patents do successfully issue, third parties may challenge the validity, enforceability, inventorship, or scope of these patents, such actions may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. If we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for applications in which all claims are entitled to a priority date before March 16,

2013, an interference proceeding can be provoked by a third-party or instituted by the US PTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law with the passage of the America Invents Act of 2011, which brought into effect significant changes to the U.S. patent laws and introduced new procedures for challenging pending patent applications and issued patents. A primary change under this reform was creating a “first to file” system in the United States. This requires us to be cognizant of the time from invention to filing of a patent application.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how processes, and any other elements of our drug discovery and development process and information or technology that are not covered by patents. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors, collaborators and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential or proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in the market, which could materially adversely affect our business, operating results and financial condition.

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, 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.

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.

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 our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. 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 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 vadadustat; nor do we make any admission that any of such patents are valid, enforceable or infringed. Under U.S. law, a party may be able to patent a discovery of a new way to use a previously known compound, even if such compound itself is patented, provided the newly discovered use is novel and nonobvious. Such a method-of-use patent, however, if valid, only protects the use of a claimed compound for the specified methods claimed in the patent. This type of patent does not prevent persons from using the compound for any previously known use of the compound. Further, this type of patent does not prevent persons from making and marketing the compound for an indication that is outside the scope of the patented method. We are not aware of any valid U.S. patents issued to FibroGen, or any other person, that claim methods of using any of our product candidates for purposes of inhibiting hypoxia-inducible factor prolyl hydroxylases, or HIF-PHs, for the treatment of anemia due to CKD. For example, we are aware of certain patents that have been acquired by FibroGen directed to certain heterocyclic carboxamide compounds that are described as inhibitors of prolyl-4-hydroxylase. Those patents, however, are believed to have expired as of December 2014.

FibroGen has also filed other patent applications in the U.S. and other countries directed to purportedly new methods of using such previously known heterocyclic carboxamide compounds for purposes of treating or affecting specified conditions, and some of these applications have since issued as patents. To the extent any such patents issue or have been issued, we may initiate opposition or other legal proceedings with respect to such patents. We discuss the status of the opposition proceedings against FibroGen's European '823, '153, '155 and '333 EP Patents in Part II, Item 1. Legal Proceedings of this Quarterly Report on Form 10-Q.

There may be other patents of FibroGen or patents of other third parties of which we are currently unaware with claims to compounds, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our drug candidates. Also, because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe.

Third parties, including FibroGen, may in the future claim that our product candidates and other technologies infringe upon their patents and may challenge our ability to commercialize vadadustat. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to 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 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 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 product candidates. Should a license to a third-party patent become necessary, we cannot predict whether we would be able to obtain a license or, if a license were available, whether it would be available on commercially reasonable terms. If such a license is necessary and a license under the applicable patent is unavailable on commercially reasonable terms, or at all, our ability to commercialize our product 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 opposition and invalidity proceedings and may in the future be involved in 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 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 US PTO 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 US PTO 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 US PTO or a foreign patent office may result in substantial costs and distract our management and other employees.

For example, we are currently involved in opposition or invalidation proceedings in the European Patent Office, the Japan Patent Office and the Canadian Federal 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. 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 US PTO and foreign patent agencies in several stages over the lifetime of the patent. The US PTO 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 Commercialization

Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, third-party payors and others in the medical community.

Even if we obtain marketing approval for vadadustat or any other product candidates, these product candidates may not gain market acceptance among physicians, patients, third-party payors, and others in the medical community in the United States or in other countries. In addition, market acceptance of any approved product depends on a number of other factors, including:

- the safety and efficacy of the product, as demonstrated in clinical trials and in the post-marketing setting;
- the prevalence of the disease treated by our product;
- the clinical indications for which the product is approved and the product label approved by regulatory authorities, including any warnings or limitations that may be required on the label as a consequence of potential safety risks associated with the product;
- the countries in which marketing approvals are obtained;
- the claims we and our collaborators are able to make regarding the safety and efficacy of our products;
- the success of our physician and patient communications and education programs;
- acceptance by physicians and patients of the product as a safe and effective treatment and the willingness of the target patient population to try new therapies and of physicians to prescribe new therapies;
- the cost, safety and efficacy of the product in relation to alternative treatments;
- the timing of receipt of marketing approvals and product launch relative to competing products and potential generic entrants;
- the availability of adequate coverage and reimbursement by third-party payors and governmental authorities, including patient cost-sharing programs such as copays and deductibles;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- adverse publicity about our products or favorable publicity about competing products;
- the effectiveness of our and our collaborators' sales, marketing and distribution efforts; and
- the restrictions on the use of our products together with other medications, if any.

Market acceptance of any of our product candidates, if approved, may also depend on factors specific to such candidates. 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 clinics, instead of through third party payors, which we believe could be challenging. In May 2017, we entered into a license agreement, or the Vifor Agreement, pursuant to which we will grant Vifor (International) Ltd., or Vifor Pharma, an exclusive license to sell vadadustat solely to Fresenius Kidney Care Group LLC, or FKC, in the United States, subject to FDA approval and inclusion in the bundle. Under the Vifor Agreement, FKC is not obligated to utilize vadadustat in its clinics. In addition, even if FKC chooses to utilize in vadadustat its clinics in the United States, it is not restricted from utilizing other therapies for anemia due to CKD. The Vifor Agreement does not restrict us from entering into supply agreements with other dialysis clinics, such as DaVita, one of the largest operators of dialysis clinical in the United States; however, the dialysis clinics may not choose to contract with us for vadadustat or they may choose to contract with us for a limited supply of vadadustat. Although we currently believe it likely that vadadustat will be included in the bundle, if vadadustat is not included in the bundle, then the Vifor Agreement will not become effective, and patients would access vadadustat via contracts we negotiate with third party payors for reimbursement of vadadustat, which would be subject to the risks and uncertainties described above.

Market acceptance is critical to our ability to generate significant revenue. In addition, any 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 significant revenue and our business would suffer.

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

We are currently collaborating with Otsuka to develop and commercialize vadadustat in the United States, Europe, China and certain other jurisdictions and with MTPC to develop and commercialize vadadustat in Japan and certain other Asian countries. We do not have a sales or marketing infrastructure, and we have not yet sold, marketed or distributed any products. To achieve commercial success for any product for which we may obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements for sales and marketing services, either by establishing our own or entering into additional geographic collaborations.

There are risks involved with establishing 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 or persuade adequate numbers of physicians to prescribe our products, if approved;
- 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 creating an independent sales and marketing organization.

If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If we are unable to establish our own sales, marketing and distribution capabilities for the United States and Latin America and, as a result, we must enter into arrangements with third parties to perform these services, our profitability, if any, is likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

We will be dependent on Otsuka, MTPC and any future commercialization partners to commercialize vadadustat, when and if it is approved. If Otsuka, MTPC or any future commercialization partner fails to perform under our agreements, our future results could be materially harmed.

We and Otsuka share the obligations to commercialize vadadustat in the United States, subject to obtaining marketing approval from the FDA; however, we are dependent on Otsuka to commercialize vadadustat in Europe, China and certain other territories and on MTPC to commercialize vadadustat in Japan and certain other Asian countries in the event we receive marketing approval in the applicable territories. If either of these collaborators fails to perform their obligations diligently under their agreements with us, including failing to diligently commercialize vadadustat in their territories, our sales potential in these regions may be materially harmed, and we may not have an adequate remedy for such harm under our agreements with either company. Furthermore, if a contractual dispute with either Otsuka or MTPC were to arise, it could result in costly litigation for us and jeopardize important revenue streams, which could materially harm our financial condition.

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

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

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

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. In the United States, there are multiple government and private third party payors with varying coverage and reimbursement levels for pharmaceutical products. Within Medicare, for oral drugs dispensed by pharmacies and also administered in facilities, coverage and reimbursement may vary depending on the setting. The Centers for Medicare & Medicaid Services, or CMS, local Medicare administrative contractors and/or Medicare Part D plans may have some responsibility for determining the medical necessity of such drugs, and therefore coverage, for different patients. Different reimbursement methodologies may apply and CMS may have some discretion in interpreting their application in certain settings. 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 government or private purchasers in order to obtain coverage of such products under federal healthcare programs such as Medicaid.

Additionally, we may be required to enter into contracts with third-party payors offering rebates or discounts on our products in order to obtain favorable formulary status. We may not be able to agree upon commercially reasonable terms with such third-party payors or provide data sufficient to obtain favorable coverage and reimbursement for many reasons, including that we may be at a competitive disadvantage relative to companies with more extensive product lines. We cannot be sure that coverage or adequate reimbursement will be available for any of our product candidates. Even if we obtain coverage for any approved product, third-party payors may not establish adequate reimbursement amounts, which may reduce the demand for our product, and prompt us to have to reduce pricing for the products. If reimbursement is not available or is limited, we may not be able to commercialize certain of our products. In addition, in the United States third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage 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.

In addition, if vadadustat is approved and we are successful in entering into contracts to supply vadadustat to dialysis clinics, such facilities often receive fixed reimbursement for services, drugs and supplies included in the bundle. At this time, we believe that vadadustat, if approved, will likely be included in the bundle. 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. Patient and provider access to adequate coverage and reimbursement by government and private insurance plans is central to the acceptance of any products for which we receive marketing approval.

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

In some countries, including member states of the European Union, 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 European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices, and even, in some instances, render commercialization in a market 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 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 within the country of publication and other countries. 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 candidate 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.

The impact of recent healthcare reform legislation and other changes in the healthcare industry on us is currently unknown, and may adversely affect our business model.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States, Europe, China, Japan and other countries. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions related to healthcare availability or the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

The United States federal and state governments continue to propose and pass legislation intended to reduce the cost of healthcare. One of these reforms was the Health Care Reform Act, which included changes to the coverage and reimbursement of drugs under government healthcare programs, imposed new taxes on manufacturers of branded drugs, expanded health care coverage through Medicaid expansion, and implemented the individual health insurance mandate. Under the current administration, there have been ongoing efforts to modify or repeal all or certain provisions of the Health Care Reform Act. For instance, tax reform legislation was enacted at the end of 2017 that eliminated the individual health insurance mandate, which is expected to increase the number of Americans without comprehensive health insurance. We cannot predict the ultimate content, timing or effect of any changes to the Health Care Reform Act, and significant changes to, or repeal of, the Health Care Reform Act could have a material adverse effect on our business, financial condition and profitability.

Additional legislative actions to control U.S. healthcare costs include the Budget Control Act, which imposed 2% reductions in Medicare payments to providers beginning in 2013. Subsequent legislation extended these reductions through 2025. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented, or any significant taxes or fees that may be imposed on us, as part of any broader deficit reduction effort or legislative replacement to the Budget Control Act, could have an adverse impact on potential revenues we may receive from any approved products.

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

In the United States there is increasing scrutiny of drug prices, and federal or state reforms could impact our ability to establish what we believe is a fair price for our product candidates upon approval, and ultimately diminish our revenue prospects.

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 approved.

Even prior to approval of any of our product candidates, 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 FDA or EMA.

Even before we obtain approval for vadadustat or any other product candidate, certain laws apply to us or may otherwise restrict our activities, including the following:

- laws and regulations governing the conduct of preclinical and clinical studies in the United States and other countries in which we are conducting such studies;

- laws and regulations in the United States and in countries in which we are interacting with health care providers, patients, patient organizations and other constituencies that prohibit promoting a drug prior to approval and/or reimbursement;
- laws and regulations of countries outside the United States that prohibit pharmaceutical companies from promoting prescription drugs to the general public;
- laws, regulations and industry codes that vary from country to country and govern our relationships with health care providers, patients, patient organizations, and other constituencies, prohibit certain types of gifts and entertainment, establish codes of conduct and, in some instances, require disclosure to, or approval by, regulatory authorities for us to engage in arrangements with such constituencies;

- anti-corruption and anti-bribery laws, including the Foreign Corrupt Practices Act, or FCPA, the U.K. Bribery Act and various other anti-corruption laws in countries outside of the United States;
- data privacy laws existing in the European Union 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, and state privacy and data protection laws, as well as state consumer protection laws;
- U.S. federal securities laws restricting the purchase or sale of any securities while in possession of material, non-public information; and
- international trade laws, which are laws that regulate the sale, purchase, import, export, re-export, transfer and shipment of goods, products, materials, services and technology.

Compliance with these and other applicable laws and regulations requires us to expend significant resources. Failure to comply with these laws and regulations may subject us to 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.

Europe has enacted a new data privacy regulation, the General Data Protection Regulation, a violation of which could subject us to significant fines.

In May 2018, a new privacy regime, the General Data Protection Regulation, or GDPR, took effect across all member states of the European Economic Area, or EEA. The GDPR increases our obligations with respect to clinical trials conducted in the EEA by expanding the definition of personal data to include coded data, and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR 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 imposes substantial fines for breaches of data protection requirements, which can be up to four percent of global turnover or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects for breaches of data protection requirements. Compliance with these directives is a rigorous and time-intensive process that may increase our cost of doing business, and the failure to comply with these laws could subject us to significant fines.

If any of our product candidates obtains marketing approval, we will be subject to additional healthcare laws, regulation and enforcement, and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

If we obtain approval for any of our product candidates and begin commercializing them, our operations will be directly, or indirectly through our customers, subject to additional healthcare regulation and enforcement by the U.S. federal government, states and governments in countries outside of the United States in which we conduct our business. In addition to the laws mentioned above, the U.S. laws, and their non-U.S. equivalents, that may affect our ability to operate include:

- 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;
- the U.S. federal anti-kickback law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce the referral for an item or service or the purchasing or ordering of a good or service for which payment may be made under U.S. federal healthcare programs such as Medicare and Medicaid;
- U.S. federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- U.S. 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;

- the so-called "federal sunshine" law, in the United States, which requires pharmaceutical and medical device manufacturers to report certain financial interactions to the federal government for re-disclosure to the public;
- the U.S. federal law known as HIPAA, which, in addition to privacy protections, prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- U.S. state law equivalents of the above U.S. federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state gift ban and transparency laws, which are not preempted by federal laws and often differ from state to state, thus complicating compliance efforts; and
- U.S. state laws restricting interactions with healthcare providers and other members of the healthcare community or requiring pharmaceutical manufacturers to implement certain compliance standards.

Because of the breadth of these U.S. laws, and their non-U.S. equivalents, and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reforms have strengthened these laws. For example, the Health Care Reform Act, among other things, amended the intent requirement of the U.S. federal anti-kickback law. 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.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to, on a corporate or individual basis, penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in healthcare programs in and out of the United States and even imprisonment, any of which could materially adversely affect our ability to operate our business and our financial results. In addition, the cost of implementing sufficient systems, controls, and processes to ensure compliance with all of the aforementioned laws could be significant.

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 candidates. Our objective is to 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.

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), both commercialized by Johnson & Johnson, 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. In addition, there are several other HIF product candidates in various stages of active 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, in collaboration with AstraZeneca PLC, or AstraZeneca, in the United States and China and with Astellas Pharma Inc., or Astellas, in Europe and Asia, Japan Tobacco International, GlaxoSmithKline plc and Bayer HealthCare AG. FibroGen together with Astellas and AstraZeneca are currently in Phase 3 global clinical development of their product candidate, roxadustat. Japan Tobacco International and Bayer HealthCare AG are currently in Phase 3 clinical development of their product candidates in Japan. GlaxoSmithKline plc is currently in Phase 3 global clinical development of its product candidate, daprodustat. Some of these product candidates may launch in certain markets as early as 2019. In addition, certain companies are developing potential new therapies for renal-related diseases that could potentially reduce injectable ESA utilization and thus limit the market potential for vadadustat if they are approved and launched commercially. Other new therapies are in development for the treatment of conditions inclusive of renal anemia that may impact the market for anemia-targeted treatment.

A biosimilar is a biologic product that is approved based on demonstrating that it is highly similar to an existing, FDA-approved branded biologic product. The patents for the existing, branded biologic product must expire in a given market before biosimilars may enter that market without risk of being sued for patent infringement. In addition, an

application for a biosimilar product cannot be approved by the FDA until 12 years after the existing, branded product was approved under a Biologics License Application, or BLA. The patents for epoetin alfa, an injectable ESA, expired in 2004 in the European Union, 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 European Union. In the United States, Pfizer's biosimilar version of injectable ESAs, Retacrit® (epoetin alfa-epbx), was approved by the FDA in May 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 anemia. In particular, these companies have greater experience and expertise in conducting preclinical testing and clinical trials, obtaining marketing approvals to market products, 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.

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 and commercialize, if approved, our product candidates.

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 and certain members of our senior management. The loss of the services of our executives, senior managers or other key employees 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.

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.

Security breaches and unauthorized use of our IT systems and information, or the IT systems or information in the possession of our vendors, 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 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 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 participants and business partners. In particular, we rely on CROs and other third parties to store and manage information from our clinical trials. 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 trial data, 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 new General Data Protection Regulation discussed elsewhere in these risk factors, 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. Likewise, although we believe our 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 vendors or service providers, and we may not have adequate contractual remedies against such vendors and service providers in such event. In the recent past, cyber-attacks have become more prevalent and much harder to detect and defend against, and we might not anticipate or immediately detect such incidents and the damage caused by such incidents.

Such attacks, whether successful or unsuccessful, or other compromises with respect to our information security and the measures we implement to prevent, detect and respond to them, could result in our incurring significant costs related to, for example, rebuilding internal systems, defending against litigation, responding to regulatory inquiries or actions, paying damages or fines, or taking other remedial steps with respect to third parties, divert the attention of our management and key information technology resources, disrupt key business operations, harm our reputation and deter business partners from working with us. A compromise with respect to our information security could lead to public exposure of personal information of our clinical trial patients and others, and publicity about information security. Publicity about vulnerabilities and attempted or successful incursions could damage the integrity of our studies or delay their completion. For example, any loss of clinical trial data could result in delays in our regulatory approval efforts 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 applications or 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.

We are conducting global clinical trials in countries where corruption is prevalent. In addition, we are subject to a variety of import and export trade laws. Violations of any of these laws by our personnel or on the part of 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 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 U.K. Bribery Act applies to our global activities and prohibits bribery of private individuals as well as public officials. The U.K. 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.

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:

- 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;

- U.S. 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 U.K. Bribery Act or country-specific anti-bribery or anti-corruption laws, as well as various import and export laws and regulations;
- laws that require the reporting of true and accurate financial information and data; and
- U.S. securities laws and regulations and their non-U.S. equivalents.

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

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

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our clinical, medical, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. We have entered into a number of strategic collaborations for 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. Our future financial performance and our ability to commercialize vadadustat, if approved, and any other product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train, integrate and retain additional qualified personnel. 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.

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

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop 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, 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 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 candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- a diversion of management's time and our resources;

- substantial monetary awards to study participants or patients;
- product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize any product candidates that we may develop; 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 stage of development and may need to obtain higher levels prior to marketing any of our product candidates. 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.

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 Common Stock

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

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

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

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

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 $5.91 on August 25, 2015 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 and trials, developments related to our regulatory submissions, developments related to our ability to commercialize any 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 our product candidates, 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 any of our product candidates 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, and we could be the target of such litigation in the future.

Provisions in our charter 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 and the Merger Agreement 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 the holders of our common stock or the majority vote of our Board of Directors to amend our Amended and Restated By-Laws; and
- require a supermajority vote of the holders of our common stock to amend the classification of our Board of Directors into three classes 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. See “Risks Related to our Proposed Merger with Keryx” for information relating to the Merger Agreement.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibit a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Any provision of our Ninth Amended and Restated Certificate of Incorporation, our Amended and Restated By-Laws, the Merger Agreement 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.

As described above in the Risks Related to our Proposed Merger with Keryx section, under Section 382 of the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change net operating losses, or NOLs, to offset future taxable income. Future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Section 382 of the Code. Our NOLs may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs. 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. income necessary to utilize our NOLs. A full 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. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our Ninth Amended and Restated Certificate of Incorporation described above. This choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our Ninth Amended and Restated Certificate of Incorporation inapplicable to, or unenforceable with respect to, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

We are currently subject to securities class action litigation in connection with the Merger, which could result in substantial costs and divert management's attention, and we could be subject to additional securities class action and derivative lawsuits.

A purported securities class action was filed against us alleging violation of federal securities laws in connection with the Merger. We believe such claims are without merit and will engage in a vigorous defense of such litigation. In

addition, securities class action and derivative lawsuits have often been 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 securities litigation 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

During the quarter ended September 30, 2018, 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.

The following disclosure is provided in accordance with and in satisfaction of the requirements of Item 2.02 “Results of Operations and Financial Condition” of Form 8-K:

On November 8, 2018, we announced our financial results for the quarter ended September 30, 2018 and commented on certain corporate accomplishments and plans. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 hereto.

The information furnished in Item 5 (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such a filing.

Item 6. Exhibits.

Exhibits

10.1	First Amendment to Agreement and Plan of Merger, dated as of October 1, 2018, by and among Akebia Therapeutics, Inc., Alpha Therapeutics Merger Sub, Inc. and Keryx Biopharmaceuticals, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 1, 2018).
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.
99.1	Press Release issued by Akebia Therapeutics, Inc. on November 8, 2018 (furnished herewith).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

SIGNATURES

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

AKEBIA THERAPEUTICS, INC.

Date: November 8, 2018 By: /s/ John P. Butler
John P. Butler
President and Chief Executive Officer

Date: November 8, 2018 By: /s/ Jason A. Amello
Jason A. Amello
Senior Vice President, Chief Financial Officer and Treasurer