Akebia Therapeutics, Inc.
Form 10-Q
May 09, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 April 30, 2018
Common Stock, $0.00001 par value	56,883,214

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:

- 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 presentation 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.

These forward-looking statements involve risks and uncertainties, including those that are described in Part II, Item 1A. Risk Factors included in this Quarterly Report on Form 10-Q and elsewhere in this Quarterly Report on Form 10-Q, that could cause our actual results, financial condition, performance or achievements to be materially different from those indicated in these forward-looking statements. Given these risks and uncertainties, you should not place undue reliance on these forward-looking statements. Forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q. Except as required by law, we assume no obligation to publicly update or revise these forward-looking statements for any reason.

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.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except share and per share data)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$158,171	$ 70,156
Available for sale securities	234,858	247,636
Accounts receivable	35,852	34,216
Prepaid expenses and other current assets	8,100	6,348
Total current assets	436,981	358,356
Property and equipment, net	3,714	3,617
Other assets	2,018	2,274
Total assets	$442,713	$ 364,247
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$17,880	$ 6,998
Accrued expenses	54,947	52,441
Short-term deferred revenue	78,592	81,667
Total current liabilities	151,419	141,106
Deferred rent, net of current portion	2,535	2,588
Deferred revenue, net of current portion	91,641	97,957
Other non-current liabilities	21	22
Total liabilities	245,616	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 March 31, 2018 and December 31, 2017	—	—
Common stock: $0.00001 par value; 175,000,000 shares authorized at March 31, 2018 and December 31, 2017; 56,857,470 and 47,612,619 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	1	—
Additional paid-in capital	591,871	493,823
Accumulated other comprehensive loss	(550)	(442)
Accumulated deficit	(394,225)	(370,807)
Total stockholders' equity	197,097	122,574
Total liabilities and stockholders' equity	$442,713	$ 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 March 31,	
	2018	2017
Collaboration revenue	$45,930	$20,865
Operating expenses:		
Research and development	61,404	60,049
General and administrative	9,024	5,788
Total operating expenses	70,428	65,837
Operating loss	(24,498)	(44,972)
Other income (expense):		
Interest income	1,076	435
Other income (expense)	4	(6)
Net loss	$(23,418)	$(44,543)
Net loss per share - basic and diluted	$(0.48)	$(1.15)
Weighted-average number of common shares - basic and diluted	48,613,565	38,759,221
Comprehensive loss:		
Net loss	$(23,418)	$(44,543)
Other comprehensive loss - unrealized loss on debt securities	(108)	(179)
Total comprehensive loss	$(23,526)	$(44,722)

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Three Months Ended	
	March 31, 2018	March 31, 2017
Operating activities:		
Net loss	$(23,418)	$(44,543)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	199	135
Amortization of premium/discount on investments	(60)	191
Stock-based compensation	2,232	2,016
Fair value of warrants issued for license	—	3,413
Changes in operating assets and liabilities:		
Accounts receivable	(1,636)	33,823
Prepaid expenses and other current assets	(1,496)	(1,093)
Other long-term assets	—	(1)
Accounts payable	10,882	13,044
Accrued expense	2,399	3,998
Deferred revenue	(9,391)	(20,866)
Deferred rent	(41)	355
Net cash used in operating activities	(20,330)	(9,528)
Investing activities:		
Purchase of equipment	(296)	(427)
Proceeds from the maturities of available for sale securities	56,330	24,490
Proceeds from sales of available for sale securities	4,999	—
Purchase of available for sale securities	(48,599)	(116,366)
Net cash provided by (used in) investing activities	12,434	(92,303)
Financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	95,511	1,555
Proceeds from the sale of stock under employee stock purchase plan	218	125
Proceeds from the exercise of stock options	183	68
Payments on capital lease obligations	(1)	(2)
Net cash provided by financing activities	95,911	1,746
Increase (decrease) in cash, cash equivalents, and restricted cash	88,015	(100,085)
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	$159,452	$88,531
Non-cash financing activities		
Unpaid follow-on offering costs	$95	$10

See accompanying notes to unaudited condensed consolidated financial statements

6

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.

In March 2018, the Company completed a follow-on public 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.

The Company believes that its existing cash, cash equivalents, and available for sale securities of approximately $393.0 million at March 31, 2018, together with the committed funding from its collaboration partners, will be sufficient to allow the Company to fund its current operating plan into 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 March 31, 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 our 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 our collaborators, strategic transactions, or a combination of these approaches.

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 months ended March 31, 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 and Akebia Europe Limited. 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 months ended March 31, 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 months ended March 31, 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 months ended March 31, 2017.

Condensed Consolidated Balance Sheets

	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

The changes shown above in the unaudited condensed consolidated balance sheet relate to the Company's MTPC collaboration agreement 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.

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 the three months ended March 31, 2018 and 2017, respectively.

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 on their balance sheets and provide enhanced disclosures. The amendments in ASU 2016-02 are 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. ASU 2016-02 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.

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 March 31, 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 “prepaid expenses and other current assets” and “other assets” in the unaudited condensed consolidated balance sheets. The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported in the consolidated balance sheet that sum to the total of the amounts reported in the unaudited condensed consolidated statement of cash flows (in thousands):

	March 31, 2018	March 31, 2017
Cash and cash equivalents	$158,171	$87,250
Prepaid expenses and other current assets	256	—
Other assets	1,025	1,281
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$159,452	$88,531

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

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 March 31, 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. 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.

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:

(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, "Strategic Collaborations and Other Significant Agreements".

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 regards 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 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 March 31, 2018, the Company incurred approximately $0.4 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 March 31, 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 attributable to common stockholders 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 March 31, 2018 and December 31, 2017.

	Useful Life	March 31, 2018	December 31, 2017
		(in thousands)	
Computer equipment and software	3	$716	$ 630
Furniture and fixtures	5	819	800
Equipment	7	811	628
Leasehold improvements	Shorter of the useful life or remaining lease term (10 years)	2,590	2,582
Office equipment under capital lease	3	36	36
		4,972	4,676
Less accumulated depreciation		(1,258)	(1,059)
Net property and equipment		$3,714	$ 3,617

Depreciation expense, including expense associated with assets under capital leases, was approximately $0.2 million and $0.1 million for the three months ended March 31, 2018 and 2017, respectively.

3. Strategic Collaborations and Other Significant Agreements

For the three months ended March 31, 2018 and 2017, the Company recognized $45.9 million and $20.9 million in collaboration revenue, respectively. The $45.9 million in collaboration revenue for the three months ended March 31, 2018 included $45.7 million of the transaction price for the MTPC Agreement (defined below) and the Company's collaboration agreements with Otsuka (discussed below), all of which are recognized based on a proportional performance method, and $0.2 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 months ended March 31, 2018 and 2017, the Company recognized the following revenues from our strategic collaboration agreements and had the following deferred revenue balances as of March 31, 2018:

	For the Three Months Ended March 31,

	2018	2017
Collaboration revenue:	(in thousands)	
MTPC Agreement	$9,092	$—
Otsuka U.S. Agreement	19,599	20,865
Otsuka International Agreement	16,974	—
Total Proportional Performance Revenue	$45,665	$20,865
MTPC Stability Studies	265	—
Total Collaboration Revenue	$45,930	$20,865

	March 31, 2018		
	Short-Term	Long-Term	Total
Deferred revenue:	(in thousands)		
MTPC Agreement	$—	$ —	$—
Otsuka U.S. Agreement	46,138	50,643	96,781
Otsuka International Agreement	32,454	36,319	68,773
Vifor Agreement	—	4,679	4,679
Total	$78,592	$ 91,641	$170,233

The following table presents changes in the Company's contract assets and liabilities during the three months ended March 31, 2018 and 2017 (in thousands):

Three months ended March 31, 2018	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract assets:				
Other current assets	$ —	$ 462	$ —	$ 462
Accounts receivable [1]	$ 34,186	$ 36,061	$ (34,660)	$ 35,587
Contract liabilities - Deferred revenue	$ 179,624	$ 36,274	$ (45,665)	$ 170,233
Three months ended March 31, 2017				
Contract assets - Accounts receivable	$ 33,823	$ —	$ (33,823)	$ —
Contract liabilities - Deferred revenue	$ 197,289	$ —	$ (20,865)	$ 176,424

(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 $265,000 and $30,000 of accounts receivables in the accompanying unaudited condensed consolidated balance sheets as of March 31, 2018 and December 31, 2017, respectively.

During the three months ended March 31, 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):

	For the Three Months Ended March 31,	
Revenue recognized in the period from:	2018	2017
Amounts included in deferred revenue at the beginning of the period	$ 40,845	$ 20,865
Performance obligations satisfied in previous periods	$ —	$ —

Mitsubishi Tanabe Pharma Corporation Collaboration Agreement

Summary of Agreement

On December 11, 2015, the Company and MTPC entered into a collaboration agreement, 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.

In consideration for the exclusive license and other rights contained in the MTPC Agreement, MTPC will 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 up to 20% on sales of vadadustat in the MTPC Territory.

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. The Company recently completed its Phase 2 study of vadadustat in non-dialysis dependent, or NDD, Japanese patients 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. Therefore, of the $40.0 million received by the Company in 2016, $20.0 million related to the upfront payment and the remaining $20.0 million is being applied towards costs already incurred by the Company for the Phase 2 studies. In addition, MTPC will reimburse the Company for costs in excess of $20.0 million to complete the Phase 2 studies. The Company incurred approximately $20.0 million in Phase 2 costs through March 2018 and anticipates incurring an additional approximately $0.5 million in Phase 2 costs through the end of the studies. As a result, MTPC would be required to reimburse the Company an additional approximately $0.5 million related to the two Phase 2 studies.

MTPC initiated its Phase 3 development program for vadadustat in Japan in the fourth quarter of 2017. Pursuant to the terms of the MTPC Agreement, MTPC is responsible for performing all Phase 3 activities relating to the development of vadadustat in the MTPC Territory and 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 the completion of Phase 2 dosing studies as reimbursed by MTPC and 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 is eligible to receive up to $10.0 million in development milestone payments, 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, no milestone or royalty payments may ever be received from MTPC.

In September 2017, the Company agreed to provide 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 Services 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 of $20.0 million, (ii) the estimated cost for the Phase 2 studies of approximately $21.4 million, (iii) a non-substantive milestone of $6.0 million 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 constraint. 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 Services and Clinical Supply Performance Obligation.

During the fourth quarter of 2017, a $4.0 million development milestone associated with the first patient enrolled in the DD-CKD Phase 3 study was deemed probable of being reached and as a result the constraint associated to that milestone was fully removed. During the first quarter of 2018, the transaction price is comprised of: (i) the up-front payment of $20.0 million, (ii) the estimated cost for the Phase 2 studies of approximately $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 milestone received, comprised of a $6.0 million and a $4.0 million development milestone. All development milestones have either been reached or considered probable of being reached and no regulatory milestones have been assessed as probable of being reached as of March 31, 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. During the three months ended March 31, 2018 and 2017, the Company recognized revenue totaling $9.1 million and $0, respectively,

with respect to the MTPC Agreement. The revenue is classified as collaboration revenue in the accompanying unaudited condensed consolidated statements of operations. As of March 31, 2018, there is approximately $0 in deferred revenue, $0.7 million in accounts receivable, of which $0.3 million is in unbilled accounts receivable, and $0.5 million in contract assets (included in prepaid expenses and other current assets). There were no asset or liability balances classified as long-term in the unaudited condensed consolidated balance sheet as of March 31, 2018.

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 will continue to lead 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 U.S. Food and Drug Administration, or 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 other studies. Under the Otsuka U.S. Agreement, 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 will share information related to, and review and discuss activities and progress under, the current global development plan and any other development that may be conducted pursuant to the collaboration. The Company and Otsuka also established a joint manufacturing committee, or JMC, which is comprised of an equal number of representatives from each of the parties. Among other responsibilities, the JMC oversees the manufacturing plan and related manufacturing activities. In support of the potential commercialization of vadadustat, the parties established a joint commercialization committee, or JCC, which is comprised of an equal number of representatives from the Company and Otsuka. Among other responsibilities, the JCC oversees the activities and progress under the commercialization and non-promotional activities plan and all other sales and marketing activities. The Company has retained final decision making authority with respect to 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. Going forward, Otsuka will contribute a percentage of the remaining costs to be incurred under the current global development plan subsequent to December 31, 2016, commencing in the third quarter of 2017, whereupon the Company had incurred a specified amount of incremental costs. 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 vadadustat global development program. 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, then the Company may elect to require Otsuka to fund a higher percentage of the current global development costs. 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, and 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 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.

Under the Otsuka U.S. Agreement, Otsuka originally had a limited period of time in which it can exercise an option to convert the arrangement from a profit share to a right to receive a mid-single digit royalty on future net sales of commercialized products (the Royalty Conversion Option). On August 4, 2017, Otsuka agreed to waive its right to exercise the Royalty Conversion Option in advance of its expiration, consequently, Otsuka has no further right to elect to exercise this option.

Unless earlier terminated, the Otsuka U.S. Agreement will expire on a country-by-country and 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 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) an estimate of the cost share payments to be received with respect to amounts incurred by the Company subsequent to December 31, 2016 of $106.2 million. No development or regulatory milestones have been included in the transaction price at inception, as all milestone amounts were fully constraint. 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 (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 March 31, 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.

During the three months ended March 31, 2018 and 2017, the Company recognized revenue totaling approximately $19.6 million and $20.9 million, 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 March 31, 2018, there is approximately $96.7 million of deferred revenue related to the Otsuka U.S. Agreement of which $46.1 million is classified as current and $50.6 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 March 31, 2018, there is approximately $18.5 million in accounts receivable in the accompanying 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 March 31, 2018, the Company incurred approximately $0.4 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 March 31, 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 will continue to lead 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. 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 approvals. The current global development plan also includes other derivative and ancillary studies. Under the Otsuka International Agreement, 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. 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. Going forward, Otsuka will contribute a percentage of the remaining costs to be incurred under the current global development plan subsequent to March 31, 2017. 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 global development plan 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 sub-division of 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 it relates 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 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 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 $163.6 million. No development or regulatory milestones have been included in the transaction price at inception, as all milestone amounts were fully constraint. 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 March 31, 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.

During the three months ended March 31, 2018 and 2017, the Company recognized revenue totaling approximately $17.0 million and $0, respectively, with respect to the Otsuka International Agreement. The revenue is classified as

collaboration revenue in the accompanying unaudited condensed consolidated statements of operations. As of March 31, 2018, there is approximately $68.8 million of deferred revenue related to the Otsuka International Agreement of which $32.5 million is classified as current and $36.3 million is classified as long-term in the accompanying unaudited condensed consolidated balance sheet based on the performance period of the underlying obligations. Additionally, as of March 31, 2018, there is approximately $16.7 million in accounts receivable in the accompanying 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. The Janssen Agreement includes a license to develop and commercialize AKB-5169, a preclinical compound in development as an oral treatment for inflammatory bowel disease.

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 expiry of the patents licensed under the Janssen Agreement, the expiry 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 common stock, or the Shares, par

value $0.00001 per share, 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 constraint. 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 its 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 Act and Rule 506 promulgated thereunder.

4. Available For Sale Securities

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

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
March 31, 2018				
Cash and cash equivalents	$158,171	$ —	$ —	$158,171
Available for sale securities:				
Certificates of deposit	$6,080	$ —	$ —	$6,080
U.S. government debt securities	186,099	—	(470)	