Akebia Therapeutics, Inc.
Form 10-Q
August 08, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended June 30, 2017

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number 001-36352

AKEBIA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	20-8756903 (I.R.S. Employer Identification No.)
245 First Street, Suite 1100, Cambridge, MA (Address of Principal Executive Offices)	02142 (Zip Code)

(617) 871-2098

(Registrant’s Telephone Number, Including Area Code)

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 Date 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 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 July 31, 2017
Common Stock, $0.00001 par value	47,151,429

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that are being made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, or PSLRA, with the intention of obtaining the benefits of the "safe harbor" provisions of the PSLRA. Forward-looking statements involve risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- the projected timing of (1) our clinical programs for vadadustat, (2) submission of marketing applications for vadadustat, and (3) preclinical development of AKB-5169 and other product candidates;
- enrollment in the PRO_2TECT and $INNO_2VATE$ clinical programs;
- our development program for vadadustat, including the FO_2RWARD and $TRILO_2GY$ clinical studies, and our other product candidates;
- our anticipated funding from our collaborations;
- the timing or likelihood of regulatory filings and approvals, including any labeling or other restrictions;
- our plans to commercialize vadadustat, if it is approved;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our competitive position;
- our intellectual property position;
- developments and projections relating to our competitors and our industry;
- our estimates regarding expenses (including those associated with the PRO_2TECT and $INNO_2VATE$ clinical programs), future revenue, capital requirements and needs for additional financing; and
- other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

All forward-looking statements in this Quarterly Report on Form 10-Q involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A. Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business, and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainty and may prove inaccurate. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

Akebia Therapeutics, Inc.

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except share and per share data)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$125,390	$ 187,335
Available for sale securities	195,825	73,008
Unbilled receivable	—	33,823
Prepaid expenses and other current assets	11,174	2,155
Total current assets	332,389	296,321
Property and equipment, net	2,934	2,612
Other assets	1,499	1,283
Total assets	$336,822	$ 300,216
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$10,212	$ 2,039
Accrued expenses	28,851	30,261
Short-term deferred revenue	142,346	81,968
Short-term deferred rent	182	—
Total current liabilities	181,591	114,268
Deferred rent, net of current portion	2,678	2,480
Deferred revenue, net of current portion	95,531	115,321
Other non-current liabilities	24	27
Total liabilities	279,824	232,096
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock $0.00001 par value, 25,000,000 shares authorized at June 30, 2017 and December 31, 2016; 0 shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock: $0.00001 par value; 175,000,000 shares authorized at June 30, 2017 and December 31, 2016; 42,490,957 and 38,615,709 shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively	—	—
Additional paid-in capital	420,448	365,298
Accumulated other comprehensive loss	(254)	(42)

Accumulated deficit	(363,196)	(297,136)
Total stockholders' equity	56,998	68,120
Total liabilities and stockholders' equity	$336,822	$ 300,216

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Collaboration revenue	$28,520	$—	$49,385	$—
Operating expenses:				
Research and development	43,751	30,877	103,800	51,112
General and administrative	6,905	5,311	12,693	11,122
Total operating expenses	50,656	36,188	116,493	62,234
Operating loss	(22,136)	(36,188)	(67,108)	(62,234)
Other income (expense):				
Interest income	608	270	1,044	504
Other income	10	139	4	153
Net loss	$(21,518)	$(35,779)	$(66,060)	$(61,577)
Net loss per share - basic and diluted	$(0.53)	$(0.95)	$(1.66)	$(1.65)
Weighted-average number of common shares - basic and diluted	40,819,957	37,811,056	39,795,282	37,342,324
Comprehensive loss:				
Net loss	$(21,518)	$(35,779)	$(66,060)	$(61,577)
Other comprehensive loss - unrealized loss on securities	(75)	63	(254)	37
Comprehensive loss	$(21,593)	$(35,716)	$(66,314)	$(61,540)

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Six months ended	
	June 30, 2017	June 30, 2016
Operating activities:		
Net loss	$(66,060)	$(61,577)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	253	78
Amortization of premium/discount on investments	389	287
Stock-based compensation - equity awards	4,522	2,473
Fair value of warrants issued for license	3,413	—
Changes in operating assets and liabilities:		
Unbilled receivable	33,823	—
Prepaid expenses and other current assets	(9,019)	(1,311)
Other long-term assets	(79)	—
Accounts payable	8,173	2,830
Accrued expense	(1,547)	6,362
Deferred revenue	40,588	40,000
Deferred rent	380	1,337
Net cash provided by (used in) operating activities	14,836	(9,521)
Investing activities:		
Purchase of equipment	(575)	(1,358)
Proceeds from the maturities of available for sale securities	54,118	64,874
Purchase of available for sale securities	(177,536)	(118,684)
Net cash used in investing activities	(123,993)	(55,168)
Financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	46,912	60,869
Proceeds from the sale of stock under employee stock purchase plan	125	105
Proceeds from the exercise of stock options	178	120
Payments on capital lease obligations	(3)	(6)
Net cash provided by financing activities	47,212	61,088
Decrease in cash and cash equivalents	(61,945)	(3,601)
Cash and cash equivalents at beginning of the period	187,335	49,778
Cash and cash equivalents at end of the period	$125,390	$46,177
Non-cash financing activities		
Unpaid follow-on offering costs	$137	$131

See accompanying notes to unaudited condensed consolidated financial statements

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Akebia Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

June 30, 2017

1. Nature of Organization and Operations

The Company is a biopharmaceutical company focused on developing and delivering novel therapeutics for patients based on hypoxia-inducible factor, or HIF, biology, and building our pipeline while leveraging our development and commercial expertise in renal disease. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body, as well as other important metabolic functions. Pharmacologic modulation of the HIF pathway may have broad therapeutic applications. The Company's lead product candidate, vadadustat, is an oral therapy in Phase 3 development, which has the potential to set a new standard of care in the treatment of anemia associated with chronic kidney disease (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 address serious diseases.

The Company's operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing its technology, identifying potential product candidates and undertaking preclinical and clinical studies. The Company has not generated any product revenue to date and may never generate any product revenue in the future. The Company's product candidates are subject to long development cycles and the Company may be unsuccessful in its efforts to develop, obtain regulatory approval for or market its product candidates.

The Company is subject to a number of risks including possible failure of preclinical testing or clinical trials, reliance on contract manufacturing organizations, the need to obtain marketing approval for its product candidates, the development of new technological innovations by competitors, the need to successfully commercialize and gain market acceptance of any of the Company's products that are approved and uncertainty around intellectual property matters. If the Company does not successfully commercialize any of its products, it will be unable to generate product revenue or achieve profitability.

The Company believes that its existing cash resources of approximately $321.2 million at June 30, 2017, together with the net proceeds from the follow-on public offering in July 2017 of approximately $62.6 million and committed funding from its collaboration partners, will be sufficient to allow the Company to fund its current operating plan into the second quarter of 2019, and as a result, through at least twelve months from the filing of the Company's 2017 second quarter Form 10-Q. There can be no assurance, however, that the current operating plan will be achieved in the time frame anticipated by the Company, or that its cash resources will fund the Company's operating plan for the period anticipated by the Company or that additional funding will be available on terms acceptable to the Company, or at all. We will require additional capital for the further development of our existing product candidates and will need to raise additional funds sooner to pursue development activities related to additional product candidates. If and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity, debt offerings, or strategic transactions.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying 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. These condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (U.S. GAAP). 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 (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

In the quarter ended June 30, 2017, we identified and corrected an immaterial error in the amount of research and development expenses related to our global Phase 3 study of vadadustat. This adjustment also affected the amount of revenue recognized pursuant to our license and collaboration agreements with Otsuka. The adjustments impact our results of operations in each quarter of 2016 and the first quarter of 2017. We concluded the effect of these adjustments was not material to our consolidated financial statements for any prior period.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard-setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

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 lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. The amendments in this ASU are effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years. Early application is permitted for all entities. 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.

In May 2014, the FASB, issued 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. The new standard provides a five-step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. In August 2015, the FASB deferred the effective date of the new revenue standard from January 1, 2017 to January 1, 2018. Early adoption is permitted any time after the original effective date, which for us is January 1, 2017. The Company intends to adopt the new standard on January 1, 2018. The standard allows for adoption using a full retrospective method or a modified retrospective method. The Company's historical revenue has been derived from its collaboration agreements with Mitsubishi Tanabe Pharma Corporation, or MTPC and Otsuka Pharmaceutical Co. Ltd., or Otsuka. These arrangements contain multiple-elements and have been accounted for pursuant to ASC Topic 605 25, Revenue Recognition Multiple Element Arrangements (ASC 605 25). As of June 30, 2017, the Company has not commenced revenue recognition under the MTPC arrangement as the Company is not yet able to determine all of its deliverables and the total amount of arrangement consideration. The new revenue standard provides guidance in assessing what comprises the distinct service being provided to a customer that may have implications to our performance obligations and unit of account identified in our three existing collaborations which could be defined differently under the new guidance. As a result, there could be changes to the timing of revenue recognition upon adoption of the new standard. The Company is currently assessing the impact of the new revenue recognition standard on its collaboration agreements with MTPC and Otsuka and evaluating which method it will adopt.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company views its operations and manages its business in one operating segment, which is the business of developing and commercializing proprietary therapeutics based on HIF biology.

Derivative Financial Instruments

The Company accounts for warrants and other derivative financial instruments as either equity or liabilities in accordance with ASC Topic 815, Derivatives and Hedging (ASC 815) based upon the characteristics and provisions of each instrument. Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative

liabilities and other derivative financial instruments that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and will be revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. The warrant issued by the Company in connection with the Janssen Pharmaceutica NV Research and License Agreement, the Janssen Agreement, is classified as equity in the Company's condensed consolidated balance sheet. (See Note 7).

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 and Cash Equivalents

Cash and cash equivalents consist of all cash on hand, deposits and funds invested in available-for-sale securities with original maturities of three months or less at the time of purchase. At June 30, 2017, the Company's cash is primarily in money market funds. The Company may maintain balances with its banks in excess of federally insured limits.

Investments

Management determines the appropriate classification of securities at the time of purchase and reevaluates such designation as of each balance sheet date. Currently, the Company classifies all securities as available-for-sale which are included in current assets as they are intended to fund current operations. The Company carries available-for-sale securities at fair value. The Company conducts periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. When assessing whether a decline in the fair value of a security is other-than-temporary, the Company considers the fair market value of the security, the duration of the security's decline, and prospects for the underlying business. Based on these considerations, the Company did not identify any other-than-temporary unrealized losses at June 30, 2017. 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 10) and any other collaborations the Company may enter into.

Multiple-Element Arrangements

The Company recognizes revenue in accordance with ASC Topic 605, Revenue Recognition (ASC 605). Accordingly, revenue is recognized for each unit of accounting when all of the following criteria are met:

- Persuasive evidence of an arrangement exists;
- Delivery has occurred or services have been rendered;
- The seller's price to the buyer is fixed or determinable; and
- Collectability is reasonably assured.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified in current liabilities. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Revenue recognition from our MTPC collaboration will commence when all criteria as required under ASC 605 have been satisfied. Therefore, collaboration revenue in the current period is generated exclusively from our collaborations agreements with Otsuka. The terms of these arrangements contain multiple deliverables, which include at inception:

(i) license, (ii) development services, (iii) rights to future intellectual property and (iv) joint committee services. Non-refundable payments to the Company under these arrangements include: (i) up-front fee, (ii) payments for development services and (iii) payments based on the achievement of certain milestones. Also, under the Otsuka U.S. Agreement, the Company and Otsuka share costs incurred with respect to jointly conducted medical affairs and commercialization and non-promotional activities under the collaboration. Additionally, the Company may receive its share of net sales and bear its share of shared costs from the sale of products containing or comprising vadadustat in the United States through its U.S. collaboration with Otsuka. The Company will recognize revenue related to amounts allocated to the License Unit of Accounting on a proportional performance basis as the underlying services are performed.

The Company evaluates multiple element arrangements based on the guidance in ASC 605 25. Pursuant to the guidance in ASC 605 25, the Company evaluates multiple element arrangements to determine (i) the deliverables included in the arrangement and (ii) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires the Company to make judgments about the individual deliverables and whether such deliverables are separable from the other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered item(s) has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. In assessing whether an item has standalone value, the Company considers factors such as the research, development, manufacturing and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can use the other deliverable(s) for their intended purpose without the receipt of the remaining deliverable(s), whether the value of the deliverable is dependent on the undelivered item and whether there are other vendors that can provide the undelivered item(s). The Company's collaboration arrangements do not contain a general right of return relative to delivered item(s).

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. The Company determines the selling price for a unit of accounting following the hierarchy of evidence prescribed by ASC 605-25. Accordingly, the Company determines the estimated selling price for units of accounting within each arrangement using vendor specific objective evidence (VSOE) of selling price, if available, third party evidence (TPE) of selling price if VSOE is not available, or best estimate of selling price (BESP) if neither VSOE nor TPE is available. Determining the BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, the Company considers applicable market conditions and relevant entity specific factors, including factors that were contemplated in negotiating the agreement with the customer and estimated costs. The Company validates the BESP for units of accounting by evaluating whether changes in the key assumptions used to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting.

The Company recognizes arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605 are satisfied for that particular unit of accounting. The Company recognizes as revenue arrangement consideration attributed to licenses that have standalone value from other deliverables to be provided in an arrangement upon delivery. The Company recognizes as revenue arrangement consideration attributed to licenses that do not have standalone value from the other deliverables to be provided in an arrangement over the contractual or estimated performance period associated with the undelivered elements included in the combined unit of accounting, which is typically the term of the Company's development obligations. If there is no discernible pattern of performance and/or objectively measurable performance measures do not exist, then the Company recognizes revenue under the arrangement on a straight line basis over the period the Company is expected to complete its performance obligations. Conversely, if the pattern of performance in which the service is provided to the customer can be determined and objectively measurable performance measures exist, then the Company recognizes revenue under the arrangement using the proportional performance method. Revenue recognized is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight line method or proportional performance method, as applicable, as of the period ending date.

The Company recognizes revenue associated with milestones in accordance with the provisions of ASC Topic 605-28, Revenue Recognition-Milestone Method. Accordingly, at the inception of an arrangement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (i) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from its performance to achieve the milestone, (ii) the consideration relates solely to past performance and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific,

clinical, regulatory, commercial, and other risks that must be overcome to achieve the respective milestone and the level of effort and investment required to achieve the respective milestone in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. Milestones that are considered substantive are recognized as revenue in their entirety upon achievement, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive are recognized as revenue upon achievement if there are no remaining performance obligations or over the remaining period of performance if there are remaining performance obligations, assuming all other revenue recognition criteria are met. Revenue from commercial milestone payments will be accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

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 Topic 605-45, Revenue Recognition—Principal Agent Considerations (ASC 605-45) 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. To the extent 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 605-45.

Patents

Costs incurred in connection with the application for and issuance of patents are expensed as incurred.

Income Taxes

Income taxes are recorded in accordance with FASB Topic 740, Income Taxes (ASC 740), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of June 30, 2017 and 2016, the Company does not have any significant uncertain tax positions. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with ASC Topic 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all stock-based payments to employees, including grants of employee stock options, restricted stock, restricted stock units, or RSUs, and modifications to existing stock awards, to be recognized in the statements of operations and comprehensive loss based on their fair values. The Company accounts for stock-based awards to non-employees in accordance with ASC Topic 505-50, Equity-Based Payments to Non-Employees (ASC 505-50), which requires the fair value of the award to be re-measured at fair value until a performance commitment is reached or counterparty performance is complete. The Company’s stock-based awards are comprised of stock options, shares of restricted stock, shares of common stock and warrants. The Company estimates the fair value of options granted using the Black-Scholes option pricing model. The Company uses a blend of its stock price and the quoted market price of comparable public companies to determine the fair value

of restricted stock awards and common stock awards.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of company-specific historical and implied volatility data for trading the Company's stock in the public market, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. During 2017, the Company began to estimate its volatility by using a blend of its stock price history for the length of time it has market data for its stock and the historical volatility of similar public companies for the expected term of each grant. The Company is in the product development stage with no product revenue and the representative group of companies has certain similar characteristics to the Company. The Company believes the group selected has sufficient similar economic and industry characteristics, and includes companies that are most representative of the Company. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to

calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock, which is similar to the Company's peer group.

The Company's stock-based awards are subject to service based vesting conditions. Compensation expense related to awards to employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Consistent with the guidance in ASC 505- 50, compensation expense related to awards to non-employees with service-based vesting conditions is recognized on a straight-line basis based on the then-current fair value at each financial reporting date prior to the measurement date over the associated service period of the award, which is generally the vesting term.

The Company adopted ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, effective in the first quarter of the year ended December 31, 2017. Prior to adoption, share-based compensation expense was recognized on a straight line basis, net of estimated forfeitures, such that expense was recognized only for share-based awards that are expected to vest. A forfeiture rate was estimated annually and revised, if necessary, in subsequent periods if actual forfeitures differed from initial estimates. Upon adoption, the Company will no longer apply a forfeiture rate and instead will account for forfeitures as they occur.

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 4). 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.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash and investments are the only financial instruments that potentially subject the Company to concentrations of credit risk. The Company maintains its cash with high quality, accredited financial institutions and, accordingly, such funds are subject to minimal credit risk. The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Net Loss per Share

Basic net loss per share is calculated by dividing net loss by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, preferred stock, stock options, warrants, unvested 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.

Property and Equipment

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

The following is the summary of property and equipment and related accumulated depreciation as of June 30, 2017 and December 31, 2016.

	Useful Life	June 30, 2017	December 31, 2016
		(in thousands)	
Computer equipment and software	3	$495	$ 476
Furniture and fixtures	5	800	729
Equipment	7	72	50
Leasehold improvements	Shorter of the useful life or remaining lease term (10 years)	2,226	1,763
Office equipment under capital lease	3	36	36
		3,629	3,054
Less accumulated depreciation		(695)	(442)
Net property and equipment		$2,934	$ 2,612

Depreciation expense, including expense associated with assets under capital leases, was approximately $0.1 million and $46,000 for the three months ended June 30, 2017 and 2016, respectively and approximately $0.3 and $0.1 million for the six months ended June 30, 2017 and 2016, respectively.

3. Strategic Collaborations and Other Significant Agreements

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, the Company's product candidate for the treatment of anemia related to chronic kidney disease, in Japan and certain other Asian countries, collectively, the Territory.

Pursuant to the MTPC Agreement, MTPC has an exclusive license to develop and commercialize vadadustat in the Territory. In addition, the Company will supply vadadustat for both clinical and commercial use in the Territory. The countries included in the Territory are Japan, Taiwan, South Korea, Singapore, Malaysia, India, Indonesia, East Timor, Mongolia, the Philippines, Vietnam, Laos, Cambodia, Thailand, Brunei, Myanmar, Nepal, Sri Lanka, Bangladesh, Bhutan, Maldives, Palau and Tonga and their territories.

In consideration for the exclusive license and other rights contained in the MTPC Agreement, MTPC will make payments totaling up to $350.0 million to fund the vadadustat global Phase 3 program, including up to $100.0 million in upfront and development payments, of which $40.0 million was received in January 2016. To the extent Japanese patients are included in the Phase 3 program, MTPC will fund up the balance of $60.0 million of development costs (Global Scenario).

If Japanese patients are not included in the Phase 3 program (Local Scenario), MTPC would be responsible for the costs of local development in Japan and would make no additional funding payments for the Phase 3 program. In addition, $20.0 million of the $40.0 million received in 2016 would be used to fund local development of vadadustat in Japan. The Company is currently conducting Phase 2 studies in Japan and will, if under the Local Scenario, apply the $20.0 million against the Phase 2 costs already incurred, and MTPC will reimburse the Company for costs in excess of $20.0 million to complete the studies.

The final determination of whether Japanese patients can be included in the Phase 3 program will be made by the Company and MTPC, in consultation with the Pharmaceuticals and Medical Devices Agency, PMDA, following the results of our Phase 2 studies being conducted in Japan, which is expected in the second half of 2017.

The Company is also eligible to receive up to approximately $250.0 million in additional payments based upon achievement of certain development, regulatory and sales milestones, as well as tiered double-digit royalty payments on sales of vadadustat in the Territory.

The Company and MTPC have established a joint steering committee pursuant to the agreement to oversee development and commercialization of vadadustat in the 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: expiration of the last-to-expire patent covering vadadustat in such country in the Territory; expiration of marketing or regulatory exclusivity in such country in the Territory; or ten years after the first commercial sale of vadadustat in such country in the 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.

Revenue Recognition

The Company has evaluated all of the development, regulatory and sales milestones that may be received in connection with the MTPC Agreement. In evaluating if a milestone is substantive, the Company assesses whether: (i) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) the consideration relates solely to past performance, and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. All development and regulatory milestones are considered substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone as well as the level of effort and investment required. Accordingly, such amounts will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. The total aggregate amount of development milestones is $10.0 million and the total aggregate amount of approval milestones is up to $65.0 million. All sales milestones, up to $175.0 million, will be accounted for in the same manner as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

As of June 30, 2017, the Company cannot determine all of its deliverables or the total amount of consideration to be received for which revenue will be recognized until it knows whether vadadustat will be developed for the Japan market under a Global Scenario or under a Local Scenario. Given the uncertainty around both deliverables and the total consideration to be received, in accordance with the provisions of ASC 605-25, as of June 30, 2017, we concluded that we lack sufficient persuasive evidence of an arrangement until these uncertainties are resolved (that is,

there is uncertainty regarding our rights and obligations under the arrangement). Under a Global Scenario, our deliverable will be a Services Deliverable as we will be required to include Japanese subjects in our ongoing global Phase 3 study. Under a Local Scenario, our deliverable will be a Supply Deliverable as we will not include Japanese subjects in our ongoing Phase 3 program, but will instead provide clinical supply of vadadustat to MTPC in order for MTPC to conduct a local study. The final determination will be made by the Company and MTPC in consultation with the PMDA following the results of our Phase 2 studies being conducted in Japan. Revenue recognition for the MTPC Agreement will commence when all criteria as required under ASC 605 have been satisfied, which the Company expects will be in the second half of 2017. Therefore, the $40.0 million payment received in January 2016 is recorded as deferred revenue in the accompanying consolidated balance sheets.

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

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 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 that are necessary through the filing for regulatory 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 the 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. In support of the potential commercialization of vadadustat, the parties will establish a joint commercialization committee, or JCC, which will be comprised of an equal number of representatives from the Company and Otsuka. Among other responsibilities, the JCC will manage the activities and progress under the commercialization and non-promotional activities plan and all other sales and marketing activities. The Company has retained the final decision making authority with respect to all development matters, 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 upon the date on which the Company has 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 $153.6 million or more. 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. Either party's share of the medical affairs and/or commercialization activities may be increased at such party's request upon mutual agreement of 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.

In addition, Otsuka would be required to make certain milestone payments to the Company upon the achievement of specified development, regulatory and commercial events. More specifically, the Company is eligible to receive up to $125.0 million in development milestone payments and up to $65.0 million in regulatory milestone payments for the first product to achieve the associated event. Moreover, the Company is eligible for up to $575.0 million in commercial milestone payments associated with aggregate sales of all 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, consequently, Otsuka has no further right to elect to exercise this option.

Unless earlier terminated, the 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. 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 US Agreement in accordance with the provisions of ASC 605-25. The Company's arrangement with Otsuka contains the following deliverables: (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 units of accounting in connection with its obligations under the Otsuka U.S. Agreement. Factors considered in making the assessment of standalone value included, among other things, the capabilities of the collaboration partner, whether any other vendor sells the item separately, whether the value of the deliverable is dependent on the other elements in the arrangement, whether there are other vendors that can provide the items and if the customer could use the item for its intended purpose without the other deliverables in the arrangement. Additionally, the Otsuka U.S. Agreement does not include a general right of return. The three units of accounting identified in connection with the Company's obligations under the Otsuka U.S. Agreement are as follows:

(i) License and Development Services Combined (License Unit of Accounting)

The License Deliverable does not qualify for separation from the Development Services Deliverable, due to the contractual limitations inherent in the license conveyed. More specifically, Otsuka does not have the contractual 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 is 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 on a standalone basis.

(ii) Rights to Future Intellectual Property

The License Deliverable and the Development Services Deliverable qualify for separation 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 qualifies for separation 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.

(iii) Joint Committee Services

The License Deliverable and Development Services Deliverable qualify for separation 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 has standalone value 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.

The Company has determined that neither VSOE of selling price nor TPE of selling price is available for any of the units of accounting identified at inception of the arrangement with Otsuka. Accordingly, the selling price of each unit of accounting was determined based on the Company's BESP. The Company developed the BESP with the objective of determining the price at which it would sell such an item if it were to be sold regularly on a standalone basis. In developing the BESP for the Joint Committee Services Unit of Accounting, the Company considered 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 the BESP for the Rights to Future Intellectual Property Unit of Accounting 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 BESP for the License Unit of Accounting due to the following: (i) the BESP associated with the Rights to Future Intellectual Property Unit of Accounting was determined to be immaterial and (ii) the period of performance and pattern of recognition for the License Unit of Accounting and the Joint Committee Services Unit of Accounting was determined to be similar. The Company has concluded that a change in the key assumptions used to determine the BESP for each unit of accounting would not have a significant impact on the allocation of arrangement consideration.

Allocable arrangement consideration at inception 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) an estimate of the cost share payments to be received with respect to amounts incurred by the Company subsequent to December 31, 2016 of $153.6 million. No amounts were allocated to the Rights to Future Intellectual Property Unit of Accounting because the associated BESP was determined to be immaterial. Due to the similar performance period and recognition pattern between the License Unit of Accounting and the Joint Committee Services Unit of Accounting, the arrangement consideration totaling $312.4 million has been allocated to the License Unit of Accounting and the Joint Committee Services Unit of Accounting 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 Unit of Accounting and the Joint Committee Services Unit of Accounting. Effectively, the Company has treated the arrangement as if the License Unit of Accounting and the Joint Committee Services Unit of Accounting are a single unit of accounting.

The Company has evaluated all of the development, regulatory and commercial milestones that may be received in connection with the Otsuka U.S. Agreement. In evaluating if a milestone is substantive, the Company assesses whether: (i) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) the consideration relates solely to past performance, and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. All development and regulatory milestones are considered substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone as well as the level of effort and investment required. Accordingly, such amounts will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. All commercial milestones will be recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

During the three and six months ended June 30, 2017, the Company recognized revenue totaling approximately $16.6 million and $37.5 million, respectively, with respect to the Otsuka U.S. Agreement. The revenue is classified as collaboration revenue in the accompanying consolidated statement of operations. As of June 30, 2017, there is approximately $119.8 million of deferred revenue related to the Otsuka U.S. Agreement of which $112.3 million is classified as current and $7.5 million is classified as long-term in the accompanying consolidated balance sheet based on the performance period of the underlying obligations. During the three months ended June 30, 2017, the Company did not incur any costs related to the cost-sharing provisions of the Otsuka U.S. Agreement.

The Company determined that the medical affairs and 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 commercial success of the activities. Accordingly, the Company is accounting for the joint medical affairs and commercialization and non-promotional activities in accordance with ASC No. 808, Collaborative Arrangements (ASC 808). Additionally, the medical affairs and commercialization and non-promotional activities were not deemed to be deliverables under ASC No. 605-25, Revenue Recognition–Multiple-Element Arrangements (ASC 605-25). As a result, the activities conducted pursuant to the medical affairs and commercialization and non-promotional activities plans will be accounted for as a component of the related expense in the period incurred.

Otsuka Pharmaceutical Co. Ltd. EU Collaboration and License Agreement

Summary of Agreement

On April 25, 2017, the Company entered into a collaboration and license agreement with Otsuka, the Otsuka EU 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 Territory. Under the terms of the Otsuka EU 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 Territory, subject to the approval by the relevant regulatory authorities.

Under the terms of the Otsuka EU 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 Territory.

Pursuant to the terms of the Otsuka EU 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 $INNO_2VATE$ program, as well as other studies, through the filing for regulatory approval. The current global development plan also includes other derivative and ancillary studies. Under the Otsuka EU 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 Territory. Per the terms of the Otsuka EU Agreement, Otsuka is generally responsible for the conduct of any development activities that may be required for regulatory approval in the Territory or otherwise performed with respect to the 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 EU Agreement, Otsuka is to be solely responsible for the conduct of all medical affairs and commercialization activities in the Territory pursuant to underlying plans as reviewed and discussed by the parties. If approved by the relevant jurisdictional regulatory health authorities in the Territory, the Company will provide vadadustat to Otsuka for commercialization pursuant to a separate supply agreement to be negotiated.

The activities under the Otsuka EU Agreement are governed by a JSC formed by up to a specified 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 the other detailed plans setting forth any other development activities that may be conducted under the arrangement. Additionally, the parties established a JDC which is be comprised of up to a specified number of representatives from the Company and Otsuka. Among other responsibilities, the JDC shares information related to, and reviews and discusses activities and progress under, the current global development plan and any other development that may be conducted pursuant to the collaboration. The Company and Otsuka also established a joint manufacturing committee, or JMC, which is comprised of up to a specified 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 up to a specified number of representatives from the Company and Otsuka. Among other responsibilities, the JCC reviews and discusses the activities and progress under the commercialization plan and all other sales and marketing activities. The Company has retained the final decision making authority with respect to all development matters, other than decisions related to certain development matters specific to the Territory. Otsuka has retained the final decision making authority with respect to all commercialization matters, other than decisions related to certain marketing matters.

Under the terms of the Otsuka EU 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. Additionally, 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 $163.6 million. 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 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 EU Agreement. The costs incurred related to any other development activities, which are pursued solely for obtaining or maintaining regulatory approval in the Territory or otherwise performed solely with respect to the 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 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 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 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 EU Agreement that contain material financial consequences to the Company.

Unless earlier terminated, the Otsuka EU Agreement will expire upon the expiration of the royalty term in the last country in the Territory. Either party may terminate the Otsuka EU Agreement in its entirety upon an uncured material breach or insolvency on the part of the other party. Otsuka may terminate the Otsuka EU Agreement in its entirety or for a specific sub-division of the Territory upon 12 months' prior written notice at any time after the release of the first topline data from either the PRO_2TECT Phase 3 development program or the $INNO_2$VATE Phase 3 development program, whichever comes first. In the event of termination of the Otsuka EU 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, 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 EU 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 No. 605-25, Revenue Recognition–Multiple-Element Arrangements (ASC 605-25) solely in reference to the terms and conditions of the Otsuka EU Agreement, while the collaboration arrangement with Otsuka related to the U.S. has continued to be accounted for as a discrete agreement in its own right. The Company evaluated the Otsuka EU Agreement in accordance with the provisions of ASC 605-25. The Company's arrangement with Otsuka related to the Territory contains the following deliverables: (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 (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 units of accounting in connection with its obligation under the Otsuka EU Agreement. Factors considered in making this assessment included, among other things, the capabilities of the collaboration partner, whether any other vendor sells the item separately, whether the value of the deliverable is dependent on the other elements in the arrangement, whether there are other vendors that can provide the items and if the customer could use the item for its intended purpose without the other deliverables in the arrangement. Additionally, the Otsuka EU Agreement does not include a general right of return. The three units of accounting identified in connection with the Company's obligations under the Otsuka EU Agreement are as follows:

(i) License and Development Services Combined (License Unit of Accounting)

The License Deliverable does not qualify for separation from the Development Services Deliverable due to the contractual limitations inherent in the license conveyed. More specifically, Otsuka does not have the contractual 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 is 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 on a standalone basis. Therefore, the License Deliverable does not have standalone value from the Development Services Deliverable. As a result, the License Deliverable and the Development Services Deliverable have been combined as a single unit of accounting (the License Unit of Accounting).

(ii) Rights to Future Intellectual Property

The License Deliverable and the Development Services Deliverable qualify for separation 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 qualifies for separation from the Committee Deliverable because the Committee Services Deliverable has no bearing on the value to be derived from the rights to potential future intellectual property.

(iii) Joint Committee Services

The License Deliverable and the Development Services deliverable qualify for separation 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 qualifies for separation 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.

The Company has determined that neither VSOE of selling price nor TPE of selling price is available for any of the units of accounting identified at inception of the arrangement with Otsuka. Accordingly, the selling price of each unit of accounting was determined based on the Company's BESP. The Company developed the BESP with the objective of determining the price at which it would sell such an item if it were to be sold regularly on a standalone basis. In developing the BESP for the Joint Committee Services Unit of Accounting, the Company considered 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 the BESP for the Rights to Future Intellectual Property Unit of Accounting 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 BESP for the License Unit of Accounting due to the following: (i) the BESP associated with the rights to future intellectual property unit of accounting was determined to be immaterial and (ii) the period of performance and pattern of recognition for the License Unit of Accounting and the joint committee services unit of accounting was determined to be similar. The Company has concluded that a change in the key assumptions used to determine the BESP for each unit of accounting would not have a significant impact on the allocation of arrangement consideration.

Allocable arrangement consideration at inception 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 $163.6 million. No amounts were allocated to the Rights to Future Intellectual Property Unit of Accounting because the associated BESP was determined to be immaterial. Due to the similar performance period and recognition pattern between the License Unit of Accounting and the Joint Committee Services Unit of Accounting, the arrangement consideration totaling $236.7 million has been allocated to the License Unit of Accounting and the Joint Committee Services Unit of Accounting 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 Unit of Accounting and the Joint Committee Services Unit of Accounting. Effectively, the Company has treated the arrangement as if the License Unit of Accounting and the Joint Committee Services Unit of Accounting are a single unit of accounting.

The Company has evaluated all of the development, regulatory and commercial milestones that may be received in connection with the Otsuka EU Agreement. In evaluating if a milestone is substantive, the Company assesses whether: (i) the consideration is commensurate with either the Company's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the Company's performance to achieve the milestone, (ii) the consideration relates solely to past performance, and (iii) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. All development and regulatory milestones are considered substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific, clinical, regulatory, commercial and other risks that must be overcome to achieve the milestone as well as the level of effort and investment required. Accordingly, such amounts will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. All commercial milestones will be accounted for in the same manner as

royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. The Company will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable and the Company has no remaining performance obligations, assuming all other revenue recognition criteria are met.

During the three and six months ended June 30, 2017, the Company recognized revenue totaling approximately $11.9 million with respect to the Otsuka EU Agreement. The revenue is classified as collaboration revenue in the accompanying consolidated statement of operations. As of June 30, 2017, there is approximately $73.4 million of deferred revenue related to the Otsuka EU Agreement of which $30.1 million is classified as current and $43.3 million is classified as long-term in the accompanying consolidated balance sheet based on the performance period of the underlying obligations.

Janssen Pharmaceutica NV Research and License Agreement

Summary of Agreement

In February 2017, the Company entered into a Research and License Agreement, the Janssen Agreement, with Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson and Johnson, Janssen, pursuant to which Janssen granted the Company an exclusive license under certain intellectual property rights to develop and commercialize worldwide certain HIF-PH 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, or IBD.

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 share of the Company's common stock, the fair value of which was approximately $3.4 million, the total of which was recorded in research and development expenses for the three months ended March 31, 2017. 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, 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, 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 (International) Ltd. License Agreement

Summary of Agreement

In May 2017, the Company entered into a License Agreement with Vifor (International) Ltd., or Vifor, the Vifor Agreement, pursuant to which the Company will grant Vifor 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 "Territory").

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 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 in which the Company will receive a majority of the profit from Vifor's sales of vadadustat to FKC in the Territory. 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 Territory, which will be done in collaboration with Otsuka following FDA approval.

Prior to FDA approval of vadadustat, the Company and Vifor will enter into a commercial supply agreement for vadadustat pursuant to which the Company will supply all of Vifor's requirements for vadadustat in the Territory. In addition, Vifor will enter into a supply agreement with FKC that will govern the terms pursuant to which Vifor will supply vadadustat to FKC for use in patients at its dialysis centers. During the term of the Vifor Agreement, Vifor will not sell to FKC or its affiliates any HIF product that competes with vadadustat in the Territory.

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 Territory. Vifor 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's relationship with FKC.

Investment Agreement

In connection with the Vifor Agreement, in May 2017, the Company and Vifor entered into an investment agreement, the Investment Agreement, pursuant to which the Company sold an aggregate of 3,571,429 shares of common stock, the Shares, par value $0.00001 per share, to Vifor at a price per share of $14.00 for a total of $50.0 million dollars. 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 of a $20.0 million milestone upon the occurrence of these two events, in accordance with ASC 605, the Company cannot currently determine the extent of its responsibility to supply all of Vifor's requirements for vadadustat in the Territory. Accordingly, the $4.7 million is recorded as deferred revenue in the accompanying consolidated balance sheets. Upon the satisfaction of the aforementioned conditions, revenue will be recognized as the Company supplies vadadustat to Vifor using a proportional performance method.

Vifor 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 with respect to the Shares. The Shares have not been registered pursuant to Securities Act of 1933, the "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 June 30, 2017 and December 31, 2016 consist of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
June 30, 2017				
Cash and cash equivalents	$125,390	$ —	$ —	$125,390
Available for sale securities:				
Certificates of deposit	$14,855	—	—	$14,855
U.S. Government debt securities	128,413	—	(187)	128,226
Corporate debt securities	52,810		(66)	52,744
Total available for sale securities	$196,078	$ —	$ (253)	$195,825
Total cash, cash equivalents, and available for sale securities	$321,468	$ —	$ (253)	$321,215

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
December 31, 2016				
Cash and cash equivalents	$187,335	$ —	$ —	$187,335
Available for sale securities:				
Certificates of deposit	$12,698	—	—	$12,698
U.S. Government debt securities	50,952	—	(32)	50,920
Corporate debt securities	9,398	—	(8)	9,390
Total available for sale securities	$73,048	$ —	$ (40)	$73,008
Total cash, cash equivalents, and available for sale securities	$260,383	$ —	$ (40)	$260,343

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The estimated fair value of the Company's available for sale securities balance at June 30, 2017, by contractual maturity, is as follows:

Due in one year or less	$191,182
Due after one year	4,643
Total available for sale securities	$195,825

5. Fair Value of Financial Instruments

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

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

Assets measured or disclosed at fair value on a recurring basis as of June30, 2017 and December 31, 2016 are summarized below:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
June 30, 2017				
Assets:				
Cash and cash equivalents	$125,390	$—	$ —	$125,390
Certificates of deposit	—	14,855	—	14,855
U.S. Government debt securities	—	128,226	—	128,226
Corporate debt securities	—	52,744	—	52,744
	$125,390	$195,825	$ —	$321,215

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
December 31, 2016				
Assets:				
Cash and cash equivalents	$187,335	$—	$ —	$187,335
Certificates of deposit	—	12,698	—	12,698

U.S. Government debt securities	—	50,920	—	50,920
Corporate debt securities	—	9,390	—	9,390
	$187,335	$73,008	$ —	$260,343

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

The Company had no assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) at June 30, 2017 and December 31, 2016.

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

6. Accrued Expenses

Accrued expenses are as follows:

	June 30, 2017	December 31, 2016
	(in thousands)	
Accrued clinical expenses	$22,576	$ 23,643
Accrued bonus	1,750	2,995
Accrued professional fees	761	539
Accrued vacation	681	513
Accrued payroll	646	596
Accrued other	2,437	1,975
Total accrued expenses	$28,851	$ 30,261

7. Warrant

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

8. Stockholders' Equity

Authorized and Outstanding Capital Stock

As of June 30, 2017, the authorized capital stock of the Company included 175,000,000 shares of common stock, par value $0.00001 per share, of which 42,490,957 and 38,615,709 shares are issued and outstanding at June 30, 2017 and December 31, 2016, respectively; and 25,000,000 shares of undesignated preferred stock, par value $0.00001 per share, of which 0 shares are issued and outstanding at June 30, 2017 and December 31, 2016.

Equity Plans

On February 28, 2014, the Company's Board of Directors adopted its 2014 Incentive Plan (the "2014 Plan") and its 2014 Employee Stock Purchase Plan (the "ESPP"), which were subsequently approved by its stockholders and became effective upon the closing of the Company's initial public offering IPO on March 25, 2014. The 2014 Plan replaced the 2008 Equity Incentive Plan (as amended, the "2008 Plan"), however, options or other awards granted under the 2008 Plan prior to the adoption of the 2014 Plan that have not been settled or forfeited remain outstanding and effective. In May 2016 the Company's Board of Directors approved an inducement award program that was separate from the Company's equity plans and which, consistent with NASDAQ listing rules, did not require shareholder approval (the

2016 program and similar programs, each an “Inducement Award Program”) under which 350,000 shares were reserved to be issued in 2016 and awards relating to 255,000 shares were granted and remain eligible to vest. The Company continues to grant inducement awards to new hires under a 2017 authorization.

The 2014 Plan allows for the granting of stock options, stock appreciation rights (SARs), restricted stock, unrestricted stock, restricted stock units (RSUs), performance awards and other awards convertible into or otherwise based on shares of our common stock. Dividend equivalents may also be provided in connection with an award under the 2014 Plan. The Company’s employees, officers, directors and consultants and advisors are eligible to receive awards under the 2014 Plan. The Company initially reserved 1,785,000 shares of its common stock for the issuance of awards under the 2014 Plan. The 2014 Plan provides that the number of shares reserved and available for issuance under the 2014 Plan will automatically increase annually on January 1st of each calendar year, by an amount equal to three percent (3%) of the number of shares of stock outstanding on a fully diluted basis as of the close of business on the immediately preceding December 31st (the “2014 Plan Evergreen Provision”). The Company’s Board of Directors may act prior to January 1st of any year to provide that there will be no automatic increase in the number of shares available for grant under the 2014 Plan for that year (or that the increase will be less than the amount that would otherwise have automatically been made). During the first six months of 2017, the Company granted 1,043,900 stock options to employees, of which 324,500 were granted under the Inducement Award program, 439,900 RSUs to employees and 87,500 stock options to directors under the 2014 Plan.

The ESPP provides for the issuance of options to purchase shares of the Company’s common stock to participating employees at a discount to their fair market value. The maximum aggregate number of shares of common stock available for purchase pursuant to the exercise of options granted under the ESPP will be the lesser of (a) 262,500 shares, increased on each anniversary of the adoption of

the ESPP by one percent (1%) of the total shares of common stock then outstanding (the "ESPP Evergreen Provision") and (b) 739,611 shares (which is equal to five percent (5%) of the total shares of common stock outstanding on the date of the adoption of the ESPP on a fully diluted, as converted basis. Under the ESPP, each offering period is six months, at the end of which employees may purchase shares of common stock through payroll deductions made over the term of the offering. The per-share purchase price at the end of each offering period is equal to the lesser of eighty-five percent (85%) of the closing price of our common stock at the beginning or end of the offering period.

Shares Reserved for Future Issuance

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

	June 30, 2017	December 31, 2016
Common stock options and RSU's outstanding	4,856,871	3,579,694
Shares available for issuance under the 2014 Plan [1]	739,579	885,328
Warrant to purchase common stock	509,611	—
Shares available for issuance under the ESPP [2]	677,762	803,105
Total	6,783,823	5,268,127

[1] On January 1, 2017 and January 1, 2016, the shares reserved for future grants under the 2014 Plan increased by 1,265,863 and 986,800 shares, respectively pursuant to the 2014 Plan Evergreen Provision.

[2] On February 28, 2016, the shares reserved for future issuance under the ESPP increased by 273,404 shares pursuant to the ESPP Evergreen Provision.

Stock-Based Compensation

Stock Options

On February 21, 2017, as part of the Company's annual grant of equity, the Company issued 719,400 stock options to employees. In addition, the Company issues stock options to new hires and occasionally to other employees not in connection with the annual grant process. Options granted by the Company vest over periods of between 12 and 48 months, subject, in each case, to the individual's continued service through the applicable vesting date. Options vest in installments of (i) 25% at the one year anniversary and (ii) in either 36 or 48 equal monthly or 12 equal quarterly installments beginning in the thirteenth month after the initial vesting commencement date or grant date, subject to the individual's continuous service with the Company. Options generally expire ten years after the date of grant. The Company recorded approximately $1.7 million and approximately $1.0 million of stock-based compensation expense related to stock options during the three months ended June 30, 2017 and 2016, respectively and approximately $3.3 million and $2.1 million during the six months ended June 30, 2017 and 2016, respectively.

Restricted Stock

On December 23, 2013, the Company issued 450,224 shares of restricted stock to employees and 79,067 shares of restricted stock to non-employees at a grant date fair value of $7.42 per share. The aggregate grant date fair value for the shares of restricted stock issued on December 23, 2013 totaled approximately $3.9 million. The awards of restricted stock contained a performance condition wherein vesting is contingent upon the Company's consummation of a liquidity event, as defined, prior to the fifth anniversary of the date of grant. Certain of the awards of restricted stock have a requisite service period that was complete upon grant. The remainder of the awards of restricted stock have a requisite service period of four years whereby the award vests 25% on the one year anniversary of the Vesting Commencement Date (as defined), then ratably on the first day of each calendar quarter for 12 quarters, subject to

continuous service by the individual and achievement of the performance target. Due to the nature of the performance condition, the Company had concluded that the performance condition was not probable of achievement and therefore, recognition of compensation cost had been deferred until the occurrence of a liquidity event, as defined. Compensation expense related to the restricted stock awards is being recognized over the associated requisite service period which commenced on March 25, 2014. The Company recorded approximately $49,000 and $27,000 of stock-based compensation expense related to restricted stock during the three months ended June 30, 2017 and 2016, respectively and approximately $0.1 million and $13,000 during the six months ended June 30, 2017 and 2016, respectively, as a result of mark to market adjustments related to non-employees.

Restricted Stock Units

On February 21, 2017, as part of the Company's annual grant of equity, the Company issued 423,650 RSUs to employees. In addition, the Company occasionally issues RSUs not in connection with the annual grant process to employees. 100% of each RSU grant vests on the third anniversary of the grant date, subject, in each case, to the individual's continued service through the applicable vesting date. Total stock-compensation expense to be recognized over the life of the RSUs is $2.9 million and will be recognized on a straight-

line basis over the vesting period. The Company recorded approximately $0.6 million and $0.2 million of stock-based compensation expense related to the RSUs during the three months ended June 30, 2017 and 2016, respectively, and approximately $1.1 million and $0.3 million during the six months ended June 30, 2017 and 2016, respectively.

Employee Stock Purchase Plan

The first offering period under the ESPP opened on January 2, 2015. The Company issued 19,317 shares during the first quarter of 2017. The Company recorded approximately $42,000 and $16,000 of stock-based compensation expense related to ESPP during the three months ended June 30, 2017 and 2016, respectively and approximately $0.1 million and $47,000 during the six months ended June 30, 2017 and 2016, respectively.

Stock-Based Compensation Expense Summary

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

	Three months ended		Six months ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
	(in thousands)		(in thousands)	
Research and development	$997	$365	$5,171	$757
General and administrative	1,508	857	2,762	1,716
Total	$2,505	$1,222	$7,933	$2,473

Compensation expense by type of award:

	Three months ended		Six months ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
	(in thousands)		(in thousands)	
Stock options	$1,747	$1,021	$3,322	$2,149
Restricted stock	57	27	65	13
Restricted stock units	659	158	1,050	264
Employee stock purchase plan	42	16	83	47
Warrant	—	—	3,413	—
Total	$2,505	$1,222	$7,933	$2,473

9. Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. There were no significant income tax provisions or benefits for the three months ended June 30, 2017 and 2016. Due to the uncertainty surrounding the realization of the favorable tax attributes in future tax returns, the Company has recorded a full valuation allowance against the Company's otherwise recognizable net deferred tax assets.

10. Commitments and Contingencies

The Company leases approximately 45,362 square feet of office and lab space in Cambridge, Massachusetts under a lease which was most recently amended in July 2016, collectively, the Lease. Total monthly lease payments for base rent are approximately $242,000 per month which is subject to annual rent escalations. In addition to such annual rent escalations, base rent payments for a portion of said premises commenced on January 1, 2017 in the monthly amount of approximately $22,000. Landlord contributions included in the Lease from the landlord totaled $2,169,920, including $70,526 in leasehold improvements not yet utilized. The landlord contributions are being accounted for as a deferred lease incentive and reduction in monthly rent expense over the term of the Lease. The term of the Lease with respect to the office space expires on September 11, 2026, with one five year extension option available. The term of the Lease for the lab space is five years, with an extension option for one additional period of two years. The total security deposit in connection with the Lease of $1,280,857 is included in other assets in the Company's condensed consolidated balance sheets as of June 30, 2017 and December 31, 2016.

The Company recognizes rent expense and records a deferred lease obligation representing the cumulative difference between actual facility lease payments and lease expense recognized ratably over the lease period, which is included in the Company's condensed consolidated balance sheets as of June 30, 2017 and December 31, 2016.

The Company leases office equipment under three year capital leases with payments commencing in February 2014, April 2015 and February 2016, respectively. The capital lease amounts are included in accrued expenses and other liabilities.

At June 30, 2017, the Company's future minimum payments required under these leases are as follows:

	Operating Lease	Lease Payments to be Received from Sublease	Net Operating Lease Payments	Capital Lease	Total
	(in thousands)				
2017	$1,773	$ 129	$ 1,644	$ 4	$1,648
2018	3,545	257	$ 3,288	5	$3,293
2019	3,545	—	$ 3,545	—	$3,545
2020	3,545	—	$ 3,545	—	$3,545
2021	3,510	—	$ 3,510	—	$3,510
Thereafter	14,666	—	$ 14,666	—	$14,666
Total	$30,584	$ 386	$ 30,198	9	$30,207
Less amount representing interest				—	
Present value of minimum lease payments at June 30, 2017				$ 9	

The Company recorded approximately $0.8 million and $0.7 million in rent expense for the three months ended June 30, 2017 and 2016, respectively and approximately $1.6 million and $1.0 million for the six months ended June 30, 2017 and 2016, respectively.

Under the Company's agreement with a subsidiary of Quintiles IMS Holdings, Inc., or Quintiles, to provide services for the PRO_2TECT and $INNO_2$VATE programs, the total remaining contract costs as of June 30, 2017 were approximately $334.7 million. The estimated period of performance for the committed work with Quintiles is through the fourth quarter of 2019. The Company contracts with various other organizations to conduct research and development activities with remaining contract costs to the Company of approximately $26.5 million and $24.9 million at June 30, 2017 and December 31, 2016, respectively. The scope of the services under these research and development contracts can be modified and the contracts cancelled by the Company upon written notice. In some instances, the contracts may be cancelled by the third party upon written notice.

The Company has had a number of positive developments in its opposition and invalidity proceedings against FibroGen, Inc., or FibroGen. With regard to the opposition that the Company filed in Europe against FibroGen's European Patent No. 1463823, or the '823 patent, an oral proceeding took place March 8 and 9, 2016. Following the oral proceeding, the European Opposition Division ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. FibroGen has appealed that decision and the appeal process is expected to take 2 to 3 years. Likewise, with regard to the invalidity proceeding that the Company filed in Japan against certain claims of FibroGen's Japanese Patent No. 4804131, or the '131 patent, which is the Japanese counterpart to the '823 patent, the Japan Patent Office, or JPO, issued a preliminary decision finding all of the challenged claims to be invalid. FibroGen subsequently amended the claims and the JPO accepted the amendments. The resulting FibroGen Japanese '131 patent does not cover vadadustat or any pyridine

carboxamide compounds. To date, FibroGen has been unsuccessful in its attempts to obtain a patent in the United States covering the same claim scope as it obtained initially in Europe and Japan in the ’823 and ’131 patents. In the event FibroGen were to obtain such a patent in the United States, the Company may decide to challenge them like the Company has done in Europe and Japan.

With regard to the opposition that we filed in Europe against FibroGen’s European Patent No. 163333, or the ’333 patent, an oral proceeding took place December 8 and 9, 2016. Following the oral proceeding, the European Opposition Division ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. FibroGen has appealed that decision.

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

inhibitors. Oppositions to the ’155 patent and to the ’153 patent were also filed by Glaxo Group Limited, or Glaxo, and by Bayer Intellectual Property GmbH, Bayer Pharma Aktiengesellschaft, and Bayer Animal Health GmbH. In oral proceedings held on May 29, 2017, the European Opposition Division ruled that the '155 patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. Subsequently, in related oral proceedings held on May 31, 2017 and June 1, 2017 for the '153 patent, FibroGen significantly narrowed the claims to an indication for which vadadustat is not intended to be developed.

The Company’s policy is to record a liability if a loss in a significant legal dispute is considered probable and an amount can be reasonably estimated. The Company provides disclosure when a loss in excess of any reserve is reasonably possible, and the Company is in a position to estimate the potential loss or range of possible loss. Significant judgment is required to assess the likelihood of various potential outcomes and the quantification of loss in those scenarios. The Company’s estimates change as litigation progresses and new information comes to light. Changes in Company estimates could have a material impact on the Company’s results and financial position.

11. Employee Retirement Plan

During 2008, the Company established a retirement plan (the Plan) authorized by Section 401(k) of the Internal Revenue Code. In accordance with the Plan, all employees who have attained the age of 21 are eligible to participate in the Plan as of the first Entry Date, as defined, following their date of employment. Each employee can contribute a percentage of compensation up to a maximum of the statutory limits per year. Company contributions are discretionary and contributions in the amount of approximately $39,000 and $29,000 were made during the three months ended June 30, 2017 and 2016, respectively, and approximately $0.2 million and $0.1 million during the six months ended June 30, 2017 and 2016, respectively.

12. Net Loss per Share

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

	Three months ended		Six months ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016
Warrants	509,611	—	509,611	—
Outstanding stock options	4,027,408	2,753,908	4,027,408	2,753,908
Unvested restricted stock	28,512	159,640	28,512	159,640
Unvested restricted stock units	829,463	396,813	829,463	396,813
Total	5,394,994	3,310,361	5,394,994	3,310,361

13. Subsequent Event

In July 2017, the Company completed a follow-on-public offering whereby the Company sold 4,600,000 shares of common stock, including 600,000 shares of common stock pursuant to the full exercise of an over-allotment granted to the underwriters in connection with the offering, at a price of $14.50 per share. The aggregate net proceeds received by the Company from the offering were approximately $62.6 million, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

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, consequently, Otsuka has no further right to elect to exercise this option.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following information should be read in conjunction with the unaudited financial information and the notes thereto included in this Quarterly Report on Form 10-Q and the condensed consolidated financial statements and notes thereto for the year ended December 31, 2016, and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations, contained in our annual report on Form 10-K filed with the United States Securities and Exchange Commission, or the SEC, on March 6, 2017, which we refer to as our annual report.

This report contains forward-looking statements that are being made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, or PSLRA, with the intention of obtaining the benefits of the “safe harbor” provisions of the PSLRA.

Forward-looking statements involve risks and uncertainties. In this Quarterly Report on Form 10-Q, words such as "may," "will," "expect," "anticipate," "estimate," "intend," and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

Our actual results and the timing of certain events may differ materially from the results discussed, projected, anticipated, or indicated in any forward-looking statements. We caution our readers that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from those expressed or implied by the forward-looking statements contained in this Quarterly Report on Form 10-Q.

The following information, including all forward-looking statements, should be considered in light of factors discussed elsewhere in this Quarterly Report on Form 10-Q, including those risks identified under Part II, Item 1A. Risk Factors.

We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Operating Overview

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

HIF, a pathway involving hundreds of genes, is responsible for orchestrating the body's natural response to lower levels of oxygen, or hypoxia. In response to hypoxia, a coordinated adaptive response occurs resulting in both an increase in red blood cell production, a normal biological process known as erythropoiesis, and enhancement of the delivery of iron to the bone marrow to support erythropoiesis. The significance of the HIF pathway was recognized by the 2016 Albert Lasker Basic Medical Research Award, which honored the three physician-scientists who discovered the HIF pathway and elucidated this primary oxygen sensing mechanism that is essential for survival. HIF protein is constantly being produced under normal oxygen conditions, but is quickly degraded by prolyl hydroxylases, or PH. Under hypoxic conditions, HIF-PH's are inhibited, allowing HIF to stimulate erythropoiesis. These findings have opened up new possibilities for developing therapeutics, such as HIF-PH inhibitors, which have the potential to treat many diseases.

Our lead product candidate, vadadustat, is a HIF-PH inhibitor in Phase 3 development for the treatment of anemia of CKD. Anemia is a serious medical condition in which blood is deficient in hemoglobin, which is critical for delivering oxygen to organs and tissue. Untreated anemia is associated with chronic fatigue, increased risk of progression of multiple diseases and death. Anemia is common in patients with CKD, cancer, heart failure, inflammatory diseases and other critical illnesses.

More than 30 million people in the United States have CKD, with estimates that over 1.8 million of these patients suffer from anemia. Anemia from CKD is currently treated by injectable recombinant erythropoiesis-stimulating

agents, or rESAs, such as EPOGEN® and Aranesp®, as well as with iron supplementation or red blood cell transfusion. Based on the reported revenues of companies that market and sell rESAs, global sales of injectable rESAs were estimated to be between $6.5 and $7.0 billion in 2015. The vast majority of these sales were for the treatment of anemia associated with renal disease.

rESAs deliver supra-physiological levels of exogenous erythropoietin, or EPO, to stimulate production of RBCs. While injectable rESAs may be effective in raising hemoglobin levels, they carry significant potential side effects, and need to be injected under the skin (subcutaneously) or into a vein (intravenously). In particular, injectable rESAs may lead to thrombosis, stroke, myocardial infarction and death. These safety concerns, which became evident starting in 2006, have led to a significant reduction in the use of injectable rESAs. Today, anemia is either not treated or inadequately treated in the majority of non-dialysis dependent (NDD) CKD patients. We believe that novel treatment options that address these concerns are needed and would have significant market potential. Because it mimics the body’s natural adaptive response to hypoxia, vadadustat’s HIF-PH inhibition may raise hemoglobin levels without causing supra-physiological levels of EPO.

Vadadustat has the potential to set a new standard of care for the treatment of anemia in CKD. Early clinical studies of vadadustat demonstrated that diurnal variation of EPO was maintained resulting in predictable increases in hemoglobin in normal human

volunteers and similar results were seen in NDD-CKD. These data led us to the design of our Phase 3 clinical program. The vadadustat Phase 3 program in NDD-CKD patients with anemia, called PRO_2TECT, and in dialysis dependent (DD) CKD patients with anemia, called $INNO_2VATE$, is designed to enroll up to 6,300 patients evaluating once daily oral dosing of vadadustat against an rESA active comparator, darbepoetin alfa. The enrollment numbers and the completion of the Phase 3 program will be driven by the rate of major adverse cardiovascular events, or MACE. In December 2015 the first patient was dosed in PRO_2TECT, and the first patient was dosed in $INNO_2VATE$ in August 2016. We expect the remaining cost of the Phase 3 program to aggregate in the range of $450.0 million to $480.0 million in external CRO costs for the total program. We expect to report top-line clinical data for the PRO_2TECT study in the second half of 2018 or the first half of 2019 and top-line clinical data for the $INNO_2VATE$ study in the first half of 2019. If the results from our Phase 3 program are favorable, we currently anticipate submitting marketing applications for vadadustat for the treatment of anemia associated with CKD in the United States and Europe in the second half of 2019.

In May 2017, we initiated a Phase 2 study of vadadustat in the rESA hyporesponder population, called FO_2RWARD. Patients who do not adequately respond to rESA treatment represent approximately 10-15% of DD-CKD patients, yet hyporesponders account for 30-40% of total rESA use. These patients have demonstrated a persistently higher risk of mortality than non-hyporesponders, and represent a high unmet need. We believe that, given its differentiated mechanism of action, vadadustat may provide a treatment option for these patients, and we anticipate results from FO_2RWARD in the second half of 2018. We plan to initiate a Phase 3 dosing study, called $TRILO_2GY$, in the second half of 2017 to evaluate three-times weekly dosing of vadadustat in approximately 300 DD-CKD patients receiving hemodialysis using the same active comparator, darbepoetin alfa. This is an important dosing option for dialysis providers, and we previously investigated this dosing regimen in our Phase 2 dialysis study.

If vadadustat is approved by the United States Food and Drug Administration, or FDA, we plan to establish our own commercial organization in the United States while leveraging our collaborations with Otsuka Pharmaceutical Co. Ltd., or Otsuka, and its well-established commercial organization in the United States, Europe, China and other markets. In Japan and other countries in Asia, we plan to commercialize vadadustat through our collaboration with Mitsubishi Tanabe Pharma Corporation, or MTPC. In May 2017, we entered into an exclusive license agreement with Vifor Pharma, or Vifor, to sell vadadustat solely to Fresenius Kidney Care Group LLC Fresenius Medical Care, or FKC, dialysis clinics in the United States upon approval by the FDA and inclusion of vadadustat in a bundled reimbursement model. During the term of the license agreement, Vifor may not sell to FKC or its affiliates any HIF product that competes with vadadustat in the United States.

In addition to vadadustat, we are developing a HIF-based portfolio of product candidates that target serious diseases of high unmet need. Our portfolio includes product candidates developed internally as well as in-licensed product candidates, such as AKB-5169. In February 2017, we signed an exclusive agreement with Janssen Pharmaceutica NV, or Janssen, a subsidiary of Johnson & Johnson, for access to an extensive library of well-characterized HIF pathway compounds with potential applications across multiple therapeutic areas. The lead compound, AKB-5169, is a differentiated preclinical compound in development as an oral treatment for inflammatory bowel disease, or IBD. We intend to complete further preclinical development of this compound with the goal of submitting an Investigational New Drug application to the FDA in 2018.

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

We have never been profitable and have incurred net losses in each year since inception. Our net losses were $66.1 million and $61.6 million for the six months ended June 30, 2017 and 2016, respectively. Substantially all of our net losses resulted from costs incurred in connection with our research and development programs and from general and

administrative costs associated with our operations.

We expect to continue to incur significant operating expenses and increased operating losses for at least the next several years. We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- complete the development of vadadustat for anemia secondary to CKD;
- conduct the FO_2RWARD and TRILO_2GY clinical studies;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- initiate and continue preclinical and clinical development of our HIF compounds and product candidates;
- initiate additional preclinical, clinical or other studies for additional indications for vadadustat;

- seek to discover and develop additional product candidates;
- acquire, in-license and develop other commercial products, product candidates and technologies;
- make royalty, milestone or other payments under any in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- create additional infrastructure to support our operations as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. We have no manufacturing facilities, and all of our manufacturing activities are contracted out to third parties. Additionally, we currently utilize third-party contract research organizations, or CROs, to carry out our clinical development activities, and we do not yet have a sales organization. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will seek to fund our operations through public or private equity or debt financings or other sources including geographic partnerships. However, we may be unable to raise additional funds or enter into other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our products.

Through June 2017, we have raised approximately $255.7 million of net proceeds, including $230.0 million from three underwritten public offerings and $25.7 million of net proceeds in an at-the-market offering, or ATM, pursuant to a Sales Agreement with Cantor Fitzgerald & Co.

In July 2017, we completed a follow-on-public offering whereby we sold 4,600,000 shares of common stock, including 600,000 shares of common stock pursuant to the full exercise of an over-allotment granted to the underwriters in connection with the offering, at a price of $14.50 per share. The aggregate net proceeds received by us from the offering were approximately $62.6 million, net of underwriting discounts and commissions and estimated offering expenses payable by us.

In addition to proceeds from our public offerings, in May 2017, we received $50.0 million from the sale of 3,571,429 shares of common stock to Vifor Pharma. Our collaborators have committed up to $373.0 million or more in license payments and cost-share funding, which the Company continues to receive on a quarterly prepaid basis.

Financial Overview

In the quarter ended June 30, 2017, we identified and corrected an immaterial error in the amount of research and development expenses related to our global Phase 3 study of vadadustat. This adjustment also affected the amount of revenue recognized pursuant to our license and collaboration agreements with Otsuka. The adjustments impact our results of operations in each quarter of 2016 and the first quarter of 2017. We concluded the effect of these adjustments was not material to our consolidated financial statements for any prior period.

Revenue

To date, we have not generated any revenue from the sales of products. Our revenues have been derived from collaboration agreements.

Revenue recognition for our MTPC collaboration commence when all criteria as required under ASC 605 have been satisfied, which the Company expects will be in the second half of 2017. Therefore, collaboration revenue in the current period is generated exclusively from our collaboration arrangements with Otsuka. The terms of the Otsuka U.S. Agreement contain multiple deliverables, which include at inception: (i) license under certain of our intellectual property to develop, perform medical affairs activities with respect to and conduct non-promotional and commercialization activities related to 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). We have identified three units of accounting in connection with our obligations under the U.S. collaboration agreement with Otsuka as follows: (i) License Unit of Accounting, which combines the License Deliverable and the Development Services Deliverable (ii) Rights to Future Intellectual Property Unit of Accounting and (iii) Joint Committee Services Unit of Accounting.

The terms of the Otsuka EU Agreement contain multiple deliverables, which include at inception: (i) license under certain of our intellectual property to develop and commercialization activities related to 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). We have identified three units of accounting in connection with our obligations under the EU collaboration agreement with Otsuka as follows: (i) License Unit of Accounting, which combines the License Deliverable and the Development Services Deliverable (ii) Rights to Future Intellectual Property Unit of Accounting, and (iii) Joint Committee Services Unit of Accounting.

We recognize arrangement consideration allocated to each unit of accounting when all of the revenue recognition criteria in Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 605, Revenue Recognition, or ASC 605, are satisfied for that particular unit of accounting.

The Company will recognize revenue related to amounts allocated to the License Unit of Accounting on a proportional performance basis as the underlying services are performed.

Our ability to generate product revenue and become profitable depends upon our ability to successfully develop and commercialize products. We expect to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from the sale of our products, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce our operations.

For the foreseeable future, we expect substantially all of our revenue will be generated from our collaborations with Otsuka and MTPC and any other collaborations we may enter into.

Research and Development Expenses

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

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

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

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

The duration, costs and timing of clinical studies and development of our product candidates will depend on a variety of factors, including:

- the results of our meetings with the FDA and the EMA and other regulatory authorities and the consequential effect on our study design, study size and resulting operating costs;

- the size, rate of progress, results and costs of completing our global Phase 3 development of vadadustat;
- difficulties or delays in enrolling patients in our clinical trials;
- assuming favorable Phase 3 clinical results, the timing of, and the costs involved in, obtaining regulatory approvals for vadadustat in dialysis and non-dialysis indications, including to fund the preparation and filing of regulatory submissions for vadadustat with the FDA, the EMA and other regulatory authorities, and whether we will seek regulatory approval for both indications simultaneously;
- the cost of conducting the FO_2RWARD and TRILO_2GY clinical studies;
- the cost, timing and outcome of our efforts to obtain marketing approval for vadadustat in the United States, Europe and other regions;

- the scope, progress, results and costs of additional preclinical, clinical, or other studies for additional indications for vadadustat, as well as any studies of AKB-5169 and other product candidates that we may develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory approvals for AKB-5169 and other product candidates that we may develop or acquire, if clinical studies are successful;
- the cost of having our product candidates manufactured and obtaining comparator product for clinical trials;
- the cost and timing of future commercialization activities for our products, if any of our product candidates are approved for marketing, including product manufacturing, marketing, sales and distribution costs;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements; and
- unanticipated changes to laws or regulations applicable to our clinical trials.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA, EMA or another regulatory authority were to require us to conduct clinical studies in addition to or different from those that we currently anticipate, or if we experience significant delays in enrollment in any of our clinical studies, we could be required to expend significant additional financial resources and time on the completion of clinical development.

From inception through June 30, 2017, we have incurred $335.7 million in research and development expenses. We plan to increase our research and development expenditures for the foreseeable future as we continue the development of vadadustat and our other product candidates. Our current and/or planned research and development activities include the following:

- global development of vadadustat, including the PRO2TECT and INNO$_2$VATE clinical programs;
- research and development of compounds in our HIF portfolio, including product candidates such as AKB-5169; and
- diversification of our pipeline in kidney disease and other HIF-modulated diseases.

Our direct research and development expenses consist principally of external costs, such as fees paid to clinical trial sites, consultants, central laboratories and CROs in connection with our clinical studies, and costs related to acquiring and manufacturing clinical study materials.

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

General and Administrative Expenses

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

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also anticipate increased expenses related to finance, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, and our other costs associated with being a public company. Additionally, we anticipate an increase in payroll and related expenses if and when we prepare for commercial operations, especially in sales and marketing.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to prepaid and accrued research and development expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue

We recognize revenue in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 605, Revenue Recognition, or ASC 605. Accordingly, revenue is recognized for each unit of accounting when all of the following criteria are met:

- persuasive evidence of an arrangement exists;
- delivery has occurred or services have been rendered;
- the seller's price to the buyer is fixed or determinable; and
- collectability is reasonably assured.

Amounts received prior to satisfying the revenue recognition criteria are recorded as deferred revenue in our consolidated balance sheets.

Multiple Element Arrangements

Determination of Accounting Units

We analyze multiple element arrangements based on the guidance in ASC Topic 605 25, Revenue Recognition—Multiple Element Arrangements, or ASC 605 25. Pursuant to the guidance in ASC 605 25, we evaluate multiple element arrangements to determine (1) the deliverables included in the arrangement and (2) whether the individual deliverables represent separate units of accounting or whether they must be accounted for as a combined unit of accounting. This evaluation involves subjective determinations and requires management to make judgments about the individual deliverables and whether such deliverables are separate from other aspects of the contractual relationship. Deliverables are considered separate units of accounting provided that: (i) the delivered item(s) has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially within our control. In assessing whether an item under a collaboration has standalone value, we consider factors such as the research, manufacturing, and commercialization capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. We also consider whether our collaboration partner can use the other deliverable(s) for their intended purpose without the receipt of the remaining element(s), whether the value of the deliverable is dependent on the undelivered item(s), and whether there are other vendors that can provide the undelivered element(s).

Options under a collaboration are considered substantive if, at the inception of the arrangement, we are at risk as to whether the collaboration partner will choose to exercise the option. Factors that we consider in evaluating whether an option is substantive include the cost to exercise the option, the overall objective of the arrangement, the benefit the collaboration partner might obtain from the arrangement without exercising the option, and the likelihood the option will be exercised. When an option is considered substantive, we would not consider the option or item underlying the option to be a deliverable at the inception of the arrangement and the associated option fees are not included in allocable consideration, assuming the option is not priced at a significant and incremental discount. Conversely, when an option is not considered substantive, we would consider the option, including other deliverables contingent upon the exercise of the option, to be a deliverable at the inception of the arrangement and a corresponding amount would be included in allocable arrangement consideration. In addition, if the price of the option includes a significant incremental discount, the discount would be included as a deliverable at the inception of the arrangement.

Allocation of Arrangement Consideration

Arrangement consideration that is fixed or determinable is allocated among the separate units of accounting using the relative selling price method. The applicable revenue recognition criteria in ASC 605 are applied to each of the separate units of accounting in determining the appropriate period and pattern of recognition. We determine the selling price of a unit of accounting following the hierarchy of evidence prescribed by ASC 605 25. Accordingly, we determine the estimated selling price for units of accounting within each arrangement using vendor specific objective evidence, or VSOE, of selling price, if available, third party evidence, or TPE, of selling price if VSOE is not available, or best estimate of selling price, or BESP, if neither VSOE or TPE is available. We have only used BESP to estimate selling price, since we have not had VSOE or TPE of selling price for any units of accounting to date. Determining BESP for a unit of accounting requires significant judgment. In developing the BESP for a unit of accounting, we consider applicable market conditions and relevant entity specific factors, including factors that were contemplated in negotiating the applicable agreement and estimated costs. We validate BESP for units of accounting by evaluating whether changes in the key

assumptions used by us to determine the BESP will have a significant effect on the allocation of arrangement consideration between multiple units of accounting.

Pattern of Recognition

We recognize the arrangement's consideration allocated to each unit of accounting when all of the revenue recognition criteria in ASC 605 are satisfied for that particular unit of accounting. We recognize revenue associated with licenses, license options, or the discount related to a license option upon (i) delivery of the license or (ii) the earlier of exercise or expiration of the license option, if the underlying license has standalone value from the other deliverables to be provided after delivering that license. If the license does not have standalone value, the amounts allocated to the license are combined with the related undelivered items as a single unit of accounting.

We recognize the amounts associated with collaboration research and development services, joint research committees, or other services ratably over the associated period of performance. If there is no discernible pattern of performance or objectively measurable performance measures do not exist, then we recognize revenue under the arrangement on a straight line basis over the period that we are expected to complete our performance obligations. Conversely, if the pattern of performance in which the service is provided to the collaboration partner can be determined and objectively measureable performance exists, then we recognize revenue under the arrangement using the proportional performance method. Revenue to be recognized is limited to the lesser of the cumulative amount of payments received or the cumulative revenue earned determined using the straight line method or proportional performance, as applicable, as of the period end date.

Recognition of Milestones and Royalties

At the inception of an arrangement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether: (1) the consideration is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from our performance to achieve the milestone, (2) the consideration relates solely to past performance, and (3) the consideration is reasonably relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as clinical, regulatory, commercial, and other risks that must be overcome to achieve the respective milestones and the level of effort and investment required to achieve the respective milestones in making this assessment. There is considerable judgment involved in determining whether a milestone satisfies all of the criteria required to conclude that a milestone is substantive. In accordance with ASC Topic 605 28, Revenue Recognition—Milestone Method, or ASC 605 28, a clinical or regulatory milestone that is considered substantive will be recognized as revenue in its entirety upon successful accomplishment of the milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive would be recognized as revenue over the remaining period of performance, assuming all other revenue recognition criteria are met. Revenue from a commercial milestone payment will be accounted for as royalties and recorded as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met.

We will recognize royalty revenue in the period of sale of the related product(s), based on the underlying contract terms, provided that the reported sales are reliably measurable, we have no remaining performance obligations, and assuming all other revenue recognition criteria are met.

Prepaid and Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our prepaid and accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or

otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our prepaid and accrued research and development expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated prepaid and accrued research and development expenses include expenses for:

- CROs in connection with clinical studies;
- investigative sites in connection with clinical studies;
- vendors in connection with preclinical development activities; and
- vendors related to product manufacturing, development and distribution of clinical materials.

We base our expenses related to clinical studies on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical studies on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. The scope of services under contracts for research and development activities can be modified and some of the agreements may be cancelled by either party upon written notice. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical study milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed we may report amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates and the amount actually incurred.

Stock-Based Compensation

Stock-Based Awards

We issue stock-based awards to employees and non-employees, generally in the form of stock options, restricted stock, RSUs, shares of common stock and warrants. We account for our stock-based compensation awards in accordance with Financial Accounting Standards Board, (FASB) ASC Topic 718, Compensation—Stock Compensation, or ASC 718. ASC 718 requires all stock-based payments to employees, including grants of employee stock options and restricted stock and modifications to existing stock awards, to be recognized in the statements of operations and comprehensive loss based on their fair values. We account for stock-based awards to non-employees in accordance with ASC Topic 505-50, Equity-Based-Payments to Non-Employees, or ASC 505-50, which requires the fair value of the award to be re-measured at fair value until a performance commitment is reached or counterparty performance is complete. Described below is the methodology we have utilized in measuring stock-based compensation expense. Stock option, common stock and restricted stock values are determined based on a blend of our stock price and the quoted market price of our comparable public companies.

We estimate the fair value of our stock-based awards of options to purchase shares of common stock to employees and non-employees using the Black-Scholes option pricing model, which requires the input of highly subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of the expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of company-specific historical and implied volatility data for trading our stock in the public market, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to our company, including stage of product development and life science industry focus. During 2017, we began to estimate our volatility by using a blend of our stock price history for the length of time we have market data for our stock and the historical volatility of similar public companies for the expected term of each grant. We are a company in the product development stage with no product revenue and the representative group of companies has certain similar characteristics. We believe the group selected has sufficient similar economic and industry characteristics, and includes companies that are most representative of our company. We use the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as we do not expect substantially different exercise or post-vesting termination behavior among our employee population. For options granted to non-employees, we utilize the contractual term of the arrangement as the basis for the expected term

assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as we have never paid dividends and have no current plans to pay any dividends on our common stock, similar to our peer group. We estimate grant date fair value of restricted stock awards with corresponding promissory notes using the Black-Scholes option pricing model. The grant date fair value of restricted stock awards and awards of common stock has been based on the estimated value of our common stock at the date of grant.

Our stock-based awards are subject to service-based vesting conditions. Compensation expense related to awards to employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is generally the vesting term. Consistent with the guidance in ASC 505-50, compensation expense related to awards to non-employees with service-based vesting conditions is recognized on a straight-line basis based on the then-current fair value at each financial reporting date prior to the measurement date over the associated service period of the award, which is generally the vesting term.

The Company adopted ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, effective in the first quarter of the year ended December 31, 2017. Prior to adoption, share-based compensation expense was recognized on a straight line basis, net of estimated forfeitures, such that expense was recognized only for share-based awards that are expected to vest. A forfeiture rate was estimated annually and revised, if necessary, in subsequent periods if actual forfeitures differed from initial estimates. Upon adoption, the Company will no longer apply a forfeiture rate and instead will account for forfeitures as they occur.

Stock-based compensation expense totaled approximately $2.5 million and $1.2 million for the three months ended June 30, 2017 and 2016, respectively, and approximately $7.9 and $2.5 million for the six months ended June 30, 2017 and 2016, respectively.

We expect the impact of our stock-based compensation expense for stock options and restricted stock granted to employees and non-employees to grow in future periods due to the potential increases in the fair value of our common stock and the increase in the number of grants as a result of an increase in headcount.

Emerging Growth Company Status

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

Results of Operations

Comparison of the Three Months Ended June 30, 2017 and 2016

	Three months ended		Increase
	June 30, 2017	June 30, 2016	(Decrease)
	(In Thousands)		
Collaboration revenue	$28,520	$—	$28,520
Operating expenses:			
Research and development	43,751	30,877	12,874
General and administrative	6,905	5,311	1,594
Total operating expenses	50,656	36,188	14,468
Loss from operations	(22,136)	(36,188)	(14,052)
Other income, net	618	409	209
Net loss	$(21,518)	$(35,779)	$(14,261)

Collaboration Revenue. Collaboration revenue was $28.5 million for the three months ended June 30, 2017 and related entirely to our agreements with Otsuka. We did not recognize any collaboration revenue in the three month period ended June 30, 2016 as the Otsuka agreements were not consummated in that time period, and all revenue recognition criteria for the MTPC Agreement, as required under ASC 605, had not been satisfied, which the Company expects will be in the second half of 2017.

Research and Development Expenses. Research and development expenses were $43.8 million for the three months ended June 30, 2017, compared to $30.9 million for the three months ended June 30, 2016, an increase of $12.9

million. The increase was primarily due to the following:

	(in millions)
PRO$_2$TECT and INNO$_2$VATE Phase 3 program	$ 7.4
FO$_2$RWARD Phase 2 study	1.7
TRILO$_2$GY Phase 3 study	1.2
Regulatory activities and other clinical and non-clinical	0.3
Manufacture of drug substance	(0.7)
Total increase related to the continued development of vadadustat	9.9
Headcount, consulting and facilities	2.9
Other	0.1
Total net increase	$ 12.9

The increase in the costs related to the development of vadadustat is primarily attributable to external costs related to the PRO_2TECT and $INNO_2VATE$ Phase 3 program as well as the FO_2RWARD and $TRILO_2GY$ studies. The increase in headcount, consulting and facility related costs relates to additional resources required in support of our expanding research and development programs, as well as rent associated with our leasing of additional office and lab space. We expect our research and development expenses to increase in future periods in support of the Phase 3 programs and other studies and our pipeline development.

General and Administrative Expenses. General and administrative expenses were $6.9 million for the three months ended June 30, 2017, compared to $5.3 million for the three months ended June 30, 2016. The increase of $1.6 million was primarily due to an increase in costs to support our research and development programs, including headcount and compensation-related costs, and associated facility-related costs. We expect our general and administrative expenses to increase in future periods to support our continued research and development and potential commercialization of our product candidates.

Other Income, Net. Other income, net, was $0.6 million for the three months ended June 30, 2017 and $0.4 million for the three months ended June 30, 2016. Other income, net for the three months ended June 30, 2017 and 2016 is primarily comprised of interest income.

Results of Operations

Comparison of the Six Months Ended June 30, 2017 and 2016

	Six Months Ended		Increase
	June 30, 2017	June 30, 2016	(Decrease)
	(In Thousands)		
Collaboration revenue	$49,385	$—	$ 49,385
Operating expenses:			
Research and development	$103,800	$51,112	$ 52,688
General and administrative	12,693	11,122	1,571
Total operating expenses	116,493	62,234	54,259
Loss from operations	(67,108)	(62,234)	$ 4,874
Other income, net	1,048	657	391
Net loss	$(66,060)	$(61,577)	$ 4,483

Collaboration Revenue. Collaboration revenue was $49.4 million for the six months ended June 30, 2017 under our agreement with Otsuka. We did not recognize any collaboration revenue in the six month period ended June 30, 2016 as the Otsuka agreements were not consummated in that time period, and all revenue recognition criteria for the MTPC Agreement, as required under ASC 605, had not been satisfied, which the Company expects will be in the second half of 2017.

Research and Development Expenses. Research and development expenses were $103.8 million for the six months ended June 30, 2017, compared to $51.1 million for the six months ended June 30, 2016, an increase of $52.7 million. The increase was primarily due to the following:

	(in millions)
PRO$_2$TECT and INNO$_2$VATE Phase 3 program	$ 39.9
FO$_2$RWARD Phase 2 study	1.7
Regulatory and other clinical and non-clinical activities	1.6
TRILO$_2$GY Phase 3 study	1.2
Manufacture of drug substance	(1.2)
Total increase related to the continued development of vadadustat	43.2
Headcount, consulting and facilities	4.8
Fair value of warrant issued in connection with Janssen Agreement	3.4
License fee in connection with Janssen Agreement	1.0
Other	0.3
Total net increase	$ 52.7

The increase in the costs related to the development of vadadustat is primarily attributable to external costs related to the PRO$_2$TECT and INNO$_2$VATE Phase 3 program as well as the FO$_2$RWARD and TRILO$_2$GY studies. The increase in headcount, consulting and

facility related costs relates to additional resources required in support of our expanding research and development programs, as well as rent associated with our leasing of additional office and lab space. We expect our research and development expenses to increase in future periods in support of the Phase 3 programs and other studies and our pipeline development.

General and Administrative Expenses. General and administrative expenses were $12.7 million for the six months ended June 30, 2017, compared to $11.1 million for the six months ended June 30, 2016. The increase of $1.6 million was primarily due to an increase in costs to support our research and development programs, including headcount and compensation-related costs, and associated facility-related costs partially offset by lower commercial planning costs and patent related costs. We expect our general and administrative expenses to increase in future periods to support our continued research and development and potential commercialization of our product candidates.

Other Income, Net. Other income, net, was $1.0 million for the six months ended June 30, 2017 and $0.7 million for the six months ended June 30, 2016. Other income, net for the six months ended June 30, 2017 and 2016 is primarily comprised of interest income.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception in February 2007, and as of June 30, 2017, we had an accumulated deficit of $363.2 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

We have funded our operations principally through sales of our common stock and payments received from our collaboration partners. As of June 30, 2017, we had cash and cash equivalents and available for sale securities of approximately $321.2 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Accordingly, available for sale securities, consisting principally of corporate and government debt securities stated at fair value, are also available as a source of liquidity.

Cash Flows

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

	Six Months Ended	
	June 30, 2017	June 30, 2016
	(In Thousands)	
Net cash provided by (used in):		
Operating activities	$14,836	$(9,521)
Investing activities	(123,993)	(55,168)
Financing activities	47,212	61,088
Net increase in cash and cash equivalents	$(61,945)	$(3,601)

Operating Activities. The net cash provided by operating activities was $14.8 million for the six months ended June 30, 2017 and consisted primarily of a net loss of $66.1 million adjusted for non-cash items, including stock-based

compensation expense of $7.9 million, amortization of premium/discount on investments of $0.4 million, depreciation and amortization of $0.3 million and a net increase in operating assets and liabilities of $72.3 million. The significant items in the change in operating assets and liabilities include an increase in deferred revenue of $40.6 million, a decrease in unbilled receivable of approximately $33.8 million related to unbilled payments from Otsuka received in the first quarter of 2017, an increase in accounts payable and accrued expenses of approximately $6.6 million and an increase of $0.4 million in deferred rent partially offset by an increase of approximately $9.0 million in prepaid expenses and other current assets. The net increase in accounts payable and accrued expenses is primarily driven by clinical and non-clinical study costs associated with vadadustat.

The net cash used in operating activities was $9.5 million for the six ended June 30, 2016 and consisted primarily of a net loss of $61.6 million adjusted for non-cash items, including stock-based compensation expense of $2.5 million and amortization of premium/discount on investments of $0.3 million and a net increase in operating assets and liabilities of $49.2 million. The significant items in the change in operating assets and liabilities include an increase in deferred revenue of $40.0 million attributable to payments made to us pursuant to our collaboration with Mitsubishi Tanabe and an increase in accounts payable, accrued expenses and other liabilities of approximately $10.5 million partially offset by a decrease of approximately $1.3 million in prepaid expenses and other current assets. The net increase in operating assets and liabilities is primarily driven by clinical and non-clinical study costs associated with vadadustat and AKB-6899.

Investing Activities. Net cash used in investing activities for the six months ended June 30, 2017 was $124.0 million and was comprised primarily of purchases of available for sale securities of $177.5 million and purchases of equipment of $0.6 million, offset by proceeds from the maturities of available for sale securities of $54.1 million.

Net cash used in investing activities for the six months ended June 30, 2016 was $55.2 million and was comprised primarily of purchases of available for sale securities of $118.7 million and purchases of equipment of $1.4 million, offset by proceeds from the maturities of available for sale securities of $64.9 million.

Financing Activities. Net cash provided by financing activities for the six months ended June 30, 2017 was $47.2 million and consisted primarily of net proceeds from the public issuance of common stock pursuant to our ATM facility, proceeds from the exercise of stock options and proceeds from the sale of stock under our employee stock purchase plan.

Net cash provided by financing activities for the six months ended June 30, 2016 was $61.1 million and consisted primarily of net proceeds from the public issuance of common stock, proceeds from the exercise of stock options and proceeds from the sale of stock under our employee stock purchase plan.

Operating Capital Requirements

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

We ended the second quarter of 2017 with cash, cash equivalents and available for sale securities of $321.2 million. The Company completed a follow-on offering in July raising approximately $62.6 million in net proceeds. Our collaborators have committed up to $373.0 million or more in license payments and cost-share funding, which the Company continues to receive on a quarterly prepaid basis. The Company expects its existing cash resources, including net proceeds from the July 2017 follow-on offering and the timing of committed research and development funding from its collaborators, to fund the Company’s current operating plan into the second of 2019. Thereafter committed research and development funding will continue to be received from Otsuka on a prepaid, quarterly basis.

We will require additional capital for the further development of our existing product candidates and will need to raise additional funds sooner to pursue development activities related to additional product candidates. If and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity, debt offerings, or strategic transactions. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Furthermore, our development milestones may not be achieved, we may not receive the anticipated funding from our collaboration partners, and we may not secure other sources of financing. Additional funds may not be available to us on acceptable terms or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. If we raise additional funds through the issuance of additional debt or equity securities, it could result in dilution to our existing stockholders or increased fixed payment obligations, and any such securities may have rights senior to those of our common stock. If we incur indebtedness, we could become subject to covenants that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating

restrictions that could adversely impact our ability to conduct our business. Any of these events could significantly harm our business, financial condition and prospects.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors. We have based this estimate on assumptions that may be substantially different than actual results, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements, both near- and long-term, will depend on many factors including, but not limited to, those described under Part II, Item 1A. Risk Factors of this Quarterly Report on Form 10-Q.

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

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations from those described in our Annual Report on Form 10-K that was filed with the SEC on March 6, 2017.

Off-Balance Sheet Arrangements

As of June 30, 2017 we did not have any off-balance sheet arrangements as defined in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. As of June 30, 2017 and December 31, 2016, we had cash and cash equivalents and available-for-sale securities of $321.2 million and $260.3 million, respectively, primarily money market mutual funds consisting of U.S. government debt securities, certificates of deposit and corporate debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in short-term securities. Our investments are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

Item 4. Controls and Procedures

Management’s Evaluation of our Disclosure Controls and Procedures

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

As of June 30, 2017, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

During the second quarter of fiscal 2017, we identified a material weakness in our internal control over financial reporting resulting from inadequate control over expense recognition of certain cash advance payments made to one of our clinical research organizations supporting our global Phase 3 program. Specifically, we did not have adequate controls in place to properly determine the portion of the cash advance payments that should be recorded as an expense in the period and the portion that should be recorded as a prepaid expense. In addition, the amount of revenue recognized pursuant to certain of our collaboration agreements was consequently affected, as such revenue is recognized based on the percentage of expense incurred on the total of the expected cost of the global Phase 3

program. Based upon that discovery, our principal executive officer and principal financial officer have concluded that, as of June 30, 2017, our disclosure controls and procedures were not effective at a level that provides reasonable assurance.

To remediate the material weakness described above, we have initiated compensating controls and are enhancing and revising the design of existing controls and procedures to properly account for certain research and development expenses. The revised and enhanced controls will not be considered effective until they operate for a sufficient period of time and management has concluded, through testing, that these controls are operating as designed.

Changes in Internal Control over Financial Reporting

Except as noted above, during the quarter ended June 30, 2017, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

Opposition Proceeding Against Our ’005 Patent

In July 2011, a third party filed an opposition to our issued European Patent No. 2044005, or the ’005 Patent. During the oral proceedings, which took place on April 10, 2013, the Opposition Division of the European Patent Office maintained the ’005 Patent on the basis of the third auxiliary request filed during the oral proceedings. This decision resulted in the maintenance of a claim

directed to a compound chosen from a group of eight compounds, including vadadustat, as well as claims to compositions and methods for treating various diseases, including, but not limited to, anemia. Both parties have appealed the decision of the Opposition Division and final resolution of the opposition proceedings will likely take a year or more. We cannot be assured of the breadth of the claims that will remain in the ’005 Patent or that the patent will not be revoked in its entirety.

Opposition and Invalidity Proceedings Against FibroGen Inc.

We have had a number of positive developments in our opposition and invalidity proceedings against FibroGen, Inc., or FibroGen. With regard to the opposition that we filed in Europe against FibroGen’s European Patent No. 1463823, or the ’823 patent, an oral proceeding took place March 8 and 9, 2016. Following the oral proceeding, the European Opposition Division ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. FibroGen has appealed that decision and the appeal process is expected to take 2 to 3 years. Likewise, with regard to the invalidity proceeding that we filed in Japan against certain claims of FibroGen’s Japanese Patent No. 4804131, or the ’131 patent, which is the Japanese counterpart to the ’823 patent, the Japan Patent Office, or JPO, issued a preliminary decision finding all of the challenged claims to be invalid. FibroGen subsequently amended the claims and the JPO accepted the amendments. The resulting FibroGen Japanese ’131 patent does not cover vadadustat or any pyridine carboxamide compounds. To date, FibroGen has been unsuccessful in its attempts to obtain a patent in the United States covering the same claim scope as it obtained initially in Europe and Japan in the ’823 and ’131 patents. In the event FibroGen were to obtain such a patent in the United States, we may decide to challenge the patent like we have done in Europe and Japan.

With regard to the opposition that we filed in Europe against FibroGen’s European Patent No. 163333, or the ’333 patent, an oral proceeding took place December 8 and 9, 2016. Following the oral proceeding, the European Opposition Division ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. FibroGen has appealed that decision.

On May 13, 2015, May 20, 2015 and July 6, 2015, we filed oppositions to FibroGen’s European Patent Nos. 2322153, 2322155, and 163333, or the ’153 patent, the ’155 patent, and the ’333 patent, respectively, requesting the patents be revoked in their entirety. These related patents claim, among other things, various compounds that either stabilize HIF or inhibit a HIF hydroxylase or a HIF prolyl hydroxylase for treating or preventing various conditions, including, inter alia, iron deficiency, microcytosis associated with iron deficiency, anemia of chronic disease, anemia wherein the subject has a transferrin saturation of less than 20%, anemia refractory to treatment with exogenously administered erythropoietin, or EPO, and microcytosis in microcytic anemia. Such method of use patents do not prevent persons from using the compound for other uses, including any previously known use of the compound. In particular, these patents do not claim methods of using any of our product candidates for purposes of inhibiting hypoxia-inducible factor prolyl hydroxylases, or HIF-PHs, for the treatment of anemia secondary to CKD. While we do not believe these patents will prevent us from commercializing vadadustat for the treatment of anemia secondary to CKD, we filed these oppositions to provide us and any future partners with maximum flexibility for developing vadadustat and our pipeline of HIF PH inhibitors. Oppositions to the ’155 patent and to the ’153 patent were also filed by Glaxo Group Limited, or Glaxo, and by Bayer Intellectual Property GmbH, Bayer Pharma Aktiengesellschaft, and Bayer Animal Health GmbH. In oral proceedings held on May 29, 2017, the European Opposition Division ruled that the '155 patent as granted did not meet the requirements for patentability under the European Patent Convention and, therefore, revoked the patent in its entirety. Subsequently, in related oral proceedings held on May 31, 2017 and June 1, 2017 for the '153 patent, FibroGen significantly narrowed the claims to an indication for which vadadustat is not intended to be developed.

Item 1A. Risk Factors

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and

uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. Please reference our "Cautionary Note Regarding Forward-Looking Statements," which identifies certain forward-looking statements contained in this report that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

Risks Related to our Financial Position and Need for Additional Capital

We have incurred significant losses since inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred net losses each year since our inception, including net losses of $66.1 million for the six months ended June 30, 2017, and $61.6 million for the six months ended June 30, 2016. As of June 30, 2017, we had an accumulated deficit of $363.2 million. To date, we have not commercialized any products or generated any revenue from the sale of products. We do not know whether or when we will generate revenue or become profitable.

We have devoted most of our financial resources to research and development, including our clinical and preclinical development activities. To date, we have financed our operations primarily through our public offerings of common stock, private placements of our preferred stock and strategic collaborations. The amount of our future net losses will depend, in part, on the rate of our future expenditures, and our financial position will depend, in part, on our ability to obtain funding through equity or debt financings or strategic collaborations. Even if we obtain regulatory approval to market vadadustat, our future revenue will depend upon the timing of such approval, the size of any markets in which vadadustat receives approval, our ability to achieve sufficient market acceptance, the availability and extent of reimbursement from third-party payors and other factors.

We expect to continue to incur significant expenses and increased operating losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we: