Akebia Therapeutics, Inc.
Form 10-Q
November 09, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2015

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 x 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 x No ¨

Indicate by check mark whether registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨ Accelerated filer ¨

Non-accelerated filer x Smaller reporting company ¨

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

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 November 5, 2015
Common Stock, $0.00001 par value	30,631,737

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) commencement of a Phase 3 development program of vadadustat (formerly AKB-6548) in non-dialysis patients with anemia related to chronic kidney disease (CKD), (2) commencement of a Phase 3 development program in dialysis patients with anemia related to CKD, (3) submission of an NDA for vadadustat, (4) filing an Investigational New Drug application with the U.S. Food and Drug Administration for AKB-6899 and (5) completion of preclinical proof-of-concept studies of AKB-6899 in ophthalmology;
- our development plans with respect to vadadustat and AKB-6899;
- the timing or likelihood of regulatory filings and approvals, including any required post-marketing testing or any labeling and 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, 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, even if new information becomes available in the future.

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 uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. 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.

NOTE REGARDING STOCK SPLIT

Unless otherwise indicated, all information in these condensed consolidated financial statements gives retrospective effect to the 1.75-for-1 stock split of the Company's common stock (the Stock Split) that was effected on March 6, 2014, as well as any other stock-splits in historical periods.

Akebia Therapeutics, Inc.

Table of Contents

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except share and per share data)

	September 30, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$66,712	$32,780
Available for sale securities	90,754	76,138
Accounts receivable	14	48
Prepaid expenses and other current assets	1,324	1,514
Total current assets	158,804	110,480
Property and equipment, net	479	210
Other assets	305	305
Total assets	$159,588	$110,995
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$5,273	$2,021
Accrued expenses	8,893	4,864
Total current liabilities	14,166	6,885
Other liabilities	10	32
Total liabilities	14,176	6,917
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock $0.00001 par value, 25,000,000 shares authorized at September 30, 2015 and December 31, 2014; 0 shares issued and outstanding at September 30, 2015 and December 31, 2014	—	—
Common stock: $0.00001 par value; 175,000,000 shares authorized at September 30, 2015 and December 31, 2014; 30,218,094 and 20,370,624 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	—	—
Additional paid-in capital	287,113	204,969
Treasury stock, at cost, 8,463 shares	(162)	(162)
Accumulated other comprehensive loss	(7)	(56)
Accumulated deficit	(141,532)	(100,673)

Total stockholders' equity	145,412	104,078
Total liabilities and stockholders' equity	$159,588	$110,995

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		Nine months ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Operating expenses:				
Research and development	$15,790	$6,648	$30,477	$18,330
General and administrative	3,888	2,936	10,986	9,003
Total operating expenses	19,678	9,584	41,463	27,333
Operating loss	(19,678)	(9,584)	(41,463)	(27,333)
Other income (expense):				
Interest income (expense), net	139	56	350	125
Reimbursements from Aerpio	64	180	254	544
Net loss	$(19,475)	$(9,348)	$(40,859)	$(26,664)
Reconciliation of net loss to net loss applicable to common stockholders:				
Net loss	$(19,475)	$(9,348)	$(40,859)	$(26,664)
Accretion on preferred stock	—	—	—	(86,899)
Net loss applicable to common stockholders	$(19,475)	$(9,348)	$(40,859)	$(113,563)
Net loss per share applicable to common stockholders—basic and diluted	$(0.68)	$(0.47)	$(1.62)	$(8.16)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	28,784,231	19,691,167	25,175,077	13,920,651
Comprehensive loss:				
Net loss	$(19,475)	$(9,348)	$(40,859)	$(26,664)
Other comprehensive loss - unrealized loss on securities	20	(43)	(7)	(52)
Comprehensive loss	$(19,455)	$(9,391)	$(40,866)	$(26,716)

See accompanying notes to unaudited condensed consolidated financial statements.

5

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

	Nine months ended September 30, 2015	September 30, 2014
Operating activities:		
Net loss	$(40,859)	$(26,664)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	85	33
Amortization of premium/discount on investments	418	124
Stock-based compensation expense	3,386	5,125
Changes in operating assets and liabilities:		
Accounts receivable	34	78
Prepaid expenses and other current assets	190	(688)
Accounts payable and accrued expenses	7,276	3,683
Other liabilities	(25)	29
Net cash used in operating activities	(29,495)	(18,280)
Investing activities:		
Purchase of equipment	(342)	(208)
Proceeds from maturities of available for sale securities	49,547	6,990
Purchases of available for sale securities	(64,531)	(64,497)
Net cash used in investing activities	(15,326)	(57,715)
Financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	78,579	104,293
Proceeds from employee stock purchase plan	109	—
Proceeds from the exercise of stock options	70	—
Repurchase of treasury stock	—	(79)
Payments received on promissory notes issued in exchange for shares of common stock	—	237
Payments on capital lease obligations	(5)	(3)
Net cash provided by financing activities	78,753	104,448
Increase in cash and cash equivalents	33,932	28,453
Cash and cash equivalents at beginning of period	32,780	21,215
Cash and cash equivalents at end of period	$66,712	$49,668
Non-cash financing activities:		
Accretion of preferred stock to redemption value	$—	$86,899
Unpaid initial public offering issuance costs	$—	$15,000
Assets acquired under capital lease	$12	$12

See accompanying notes to unaudited condensed consolidated financial statements

Akebia Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

September 30, 2015

1. Nature of Organization and Operations

Akebia Therapeutics, Inc. (Akebia, or the Company) is a biopharmaceutical company focused on delivering innovative therapies to patients with kidney disease through the biology of hypoxia-inducible factor, or HIF. HIF is the primary regulator of the production of red blood cells in the body and a potentially novel mechanism of treating anemia. The Company's lead product candidate, vadadustat, formerly known as AKB-6548, is being developed as a once-daily oral therapy and has successfully completed Phase 2 development demonstrating that vadadustat can safely and predictably raise hemoglobin levels in patients with anemia related to chronic kidney disease.

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, nor is there any assurance of any future product revenue. The Company's product candidates are subject to long development cycles and there is no assurance the Company will be able to successfully develop, obtain regulatory approval for or market its product candidates.

The Company is subject to a number of risks including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, 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 the ability to protect its proprietary technology. If the Company does not successfully commercialize any of its products, it will be unable to generate product revenue or achieve profitability.

On March 25, 2014, the Company completed its initial public offering, or IPO, whereby the Company sold 6,762,000 shares of common stock, including 879,647 shares of common stock pursuant to the full exercise of an over-allotment option granted to the underwriters in connection with the offering, at a price of $17.00 per share. The shares began trading on the NASDAQ Global Market on March 20, 2014. The aggregate net proceeds received by the Company from the offering were $104.4 million, net of underwriting discounts and commissions and estimated offering expenses payable by the Company. Upon the closing of the IPO, all outstanding shares of convertible redeemable preferred stock converted into 12,115,183 shares of common stock. Additionally, the Company is now authorized to issue up to 175,000,000 shares of common stock and 25,000,000 shares of undesignated preferred stock.

In April 2015, the Company completed a follow-on public offering whereby the Company sold 8,363,636 shares of common stock, including 1,090,909 share 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 $8.25 per share. The aggregate net proceeds received by the Company from the offering were approximately $64.6 million, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

In August 2015, the Company entered into a Sales Agreement with Cantor Fitzgerald & Co. to periodically sell up to $50 million of shares of the Company's common stock in "at-the-market" (ATM) offerings. During the third quarter of 2015, the Company sold 1,311,562 shares of common stock pursuant to the Sales Agreement. The aggregate net proceeds received by the Company were approximately $14.2 million, net of commissions.

The Company believes that it can continue as a going concern as its cash resources of approximately $157.5 million at September 30, 2015 will be sufficient to allow the Company to fund its current operating plan through at least the next twelve months. There can be no assurance, however, that the current operating plan will be achieved in the timeframe 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.

Unless otherwise indicated, all information in these condensed consolidated financial statements gives retrospective effect to the 1.75-for-1 stock split of the Company's common stock (the Stock Split) that was effected on March 6, 2014 (see Note 6), as well as any other stock-splits in historical periods.

The Company was incorporated on February 27, 2007 under the laws of the State of Delaware.

2. Summary of Significant Accounting Policies

Conversion of Redeemable Preferred Stock

Upon the closing of the Company's IPO on March 25, 2014, all outstanding shares of convertible redeemable preferred stock converted into 12,115,183 shares of common stock. The Company's preferred stock was redeemable at the greater of fair value or the original issuance price. The Company recorded $86.9 million of accretion on the preferred stock in the period from January 1, 2014 through the date of the closing of its IPO which represents the difference in the carrying value at December 31, 2013 and the fair value of the preferred stock just prior to conversion into common stock.

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 United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2014, and the notes thereto, which are included in the Company's Annual Report on Form 10-K (File No. 001-3652), which was filed with the Securities and Exchange Commission ("SEC") on March 4, 2015.

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.

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.

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 condensed consolidated 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: percent complete for clinical accruals, stock-based compensation expense, fair value of common stock and preferred stock and the Company's other equity instruments (in periods prior to the IPO), accrued expenses, prepaid expenses and income taxes.

Prior to the IPO, the Company utilized significant estimates and assumptions in determining the fair value of its common stock. The Company granted stock options at exercise prices not less than the fair market value of its common stock as determined by the Board of Directors contemporaneously at the date such grants were made, with input from management. Prior to the Company's IPO in March 2014, the fair value of common stock at the grant date was adjusted in connection with the Company's retrospective fair value assessment for financial reporting purposes. Accordingly, the Board of Directors determined the estimated fair value of the Company's common stock based on a number of objective and subjective factors, including external market conditions affecting the biotechnology industry sector and the prices at which the Company sold shares of preferred stock, the superior rights and preferences of securities senior to the Company's common stock at the time and the likelihood of achieving a liquidity event, such as an IPO or sale of the Company.

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 September 30, 2015, 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 September 30, 2015. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, 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 (expense), net" within the Condensed Consolidated Statements of Operations and Comprehensive Loss. We also include 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.

Research and Development

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses consist of (i) employee-related expenses, including salaries, benefits, travel and stock-based compensation expense; (ii) external research and development expenses incurred under arrangements with third parties, such as contract research organizations, investigational sites and consultants; (iii) the cost of acquiring, developing and manufacturing clinical study materials; (iv) facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities; and (v) costs associated with preclinical and clinical activities and regulatory operations.

The Company enters into consulting, research and other agreements with consulting firms, researchers, universities and others for the provision of goods and services. Under such agreements, the Company may pay for services on an hourly, monthly, quarterly, project or other basis. Such arrangements are generally cancellable upon reasonable notice and payment of costs incurred. Costs are considered incurred based on an evaluation of the progress to completion of specific tasks under each contract using information and data provided to us by the Company's clinical sites and vendors. These costs consist of direct and indirect costs associated with specific projects, as well as fees paid to various entities that perform certain research on behalf of the Company.

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 ASC 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 condensed consolidated financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the condensed consolidated 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 September 30, 2015 and December 31, 2014, 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 FASB 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 FASB 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 and shares of common stock. The Company estimates the fair value of options granted using the Black-Scholes option pricing model. The Company uses the value of its common stock 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 a public market for the trading of the Company's common stock and a lack of company-specific historical and implied volatility data, 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. The Company is in the product development stage with no 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 either service- or performance-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. Compensation expense related to awards to employees with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Consistent with the guidance in ASC 505-50, compensation expense related to awards to non-employees with performance-based vesting conditions is recognized based on the then-current fair value at each financial reporting date prior to the measurement date over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable.

The Company is also required to estimate forfeitures at the time of grant, and revise those estimates in the subsequent periods if actual forfeitures differ from its estimates. The Company uses historical data to estimate pre-vesting forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from the Company's estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the condensed consolidated financial statements is based on awards that are ultimately expected to vest.

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. FASB ASC Topic 820, Fair Value Measurements and Disclosures (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments, and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

- Level 1 – Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

- Level 2 – Valuations based on quoted prices for similar assets or liabilities in markets that are not active, or for which all significant inputs are observable, either directly or indirectly.
- Level 3 – Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Items measured at fair value on a recurring basis include short-term investments (see Note 5). The carrying amounts of accounts receivable, 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, investments and accounts receivable are the only financial instruments that potentially subject the Company to concentrations of credit risk. At September 30, 2015 and December 31, 2014, all of the Company's cash was deposited in accounts at two principal financial institutions. 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 attributable to common stockholders 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, 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 September 30, 2015 and December 31, 2014.

	Useful Life

		September 30, 2015	December 31, 2014
		(in thousands)	
Computer equipment and software	3	$237	$ 99
Furniture and fixtures	5	243	117
Equipment	7	46	6
Leasehold improvements	Shorter of the useful life or remaining lease term (3 years)	64	27
Office equipment under capital lease	3	24	12
		614	261
Less accumulated depreciation		(135)	(51)
Net property and equipment		$479	$ 210

Depreciation expense, including expense associated with assets under capital leases, was approximately $35,000 and $13,000 for the three months ended September 30, 2015 and 2014, respectively and $85,000 and $33,000 for the nine months ended September 30, 2015 and 2014, respectively.

3. Available for sale securities

Available for sale securities at September 30, 2015 and December 31, 2014 consist of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
September 30, 2015				
Cash and cash equivalents:				
Cash and money market account	$66,712	$ —	$ —	$66,712
Total cash and cash equivalents	$66,712	$ —	$ —	$66,712
Available for sale securities:				
Certificates of deposit	$20,170	—	—	$20,170
U.S. Government debt securities	48,531	15	(6)	48,540
Corporate debt securities	22,060	5	(21)	22,044
Total available for sale securities	$90,761	$ 20	$ (27)	$90,754
Total cash, cash equivalents, and available for sale securities	$157,473	$ 20	$ (27)	$157,466

The estimated fair value of the Company's available for sale securities balance at September 30, 2015, by contractual maturity, is as follows:

Due in one year or less	$39,783
Due after one year	50,971
Total available for sale securities	$90,754

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
	(in thousands)			
December 31, 2014				
Cash and cash equivalents:				
Cash and money market account	$32,780	$ —	$ —	$32,780
Total cash and cash equivalents	$32,780	$ —	$ —	$32,780
Available for sale securities:				
Certificates of deposit	$13,429	—	—	$13,429
U.S. Government debt securities	38,412	1	(28)	38,385
Commercial paper	2,499	—	—	2,499
Corporate debt securities	21,854	3	(32)	21,825

Total available for sale securities	$76,194	$ 4	$ (60)	$76,138
Total cash, cash equivalents, and available for sale securities	$108,974	$ 4	$ (60)	$108,918

4. Fair Value of Financial Instruments

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

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

Assets measured or disclosed at fair value on a recurring basis as of September 30, 2015 are summarized below:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash and cash equivalents	$66,712	$—	$ —	$66,712
Certificates of deposit	—	20,170	—	20,170
U.S. Government debt securities	—	48,540	—	48,540
Corporate debt securities	—	22,044	—	22,044
	$66,712	$90,754	$ —	$157,466

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

Assets measured or disclosed at fair value on a recurring basis as of December 31, 2014 are summarized below:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Cash and cash equivalents	$32,780	$—	$ —	$32,780
Certificates of deposit	—	13,429	—	13,429
U.S. Government debt securities	—	38,385	—	38,385
Commercial paper	—	2,499	—	2,499
Corporate debt securities	—	21,825	—	21,825
	$32,780	$76,138	$ —	$108,918

The Company had no assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) at September 30, 2015 and December 31, 2014.

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.

5. Accrued Expenses

Accrued expenses are as follows:

	September 30, 2015	December 31, 2014
	(in thousands)	
Professional fees	$5,785	$ 2,460
Accrued bonus	1,240	1,286
Accrued vacation	258	177
Accrued severance	29	179
Accrued payroll	582	213
Other	999	549
Total accrued expenses	$8,893	$ 4,864

In August 2014, the Company entered into a separation agreement with an employee. The Company records the expense and liability associated with the separation agreement ratably over the period from August 5, 2014 through December 31, 2015 because the severance payments are subject to continued service and forfeiture until December 31, 2015. During the third quarter of 2015, the Company recorded severance expense in the amount of approximately $73,000, which was recorded to research and development expense. During the first nine months of 2015, approximately $287,000 was paid out of the severance accrual. Payments under this separation agreement will be paid out through December 2015.

6. Stockholders' Equity

As of September 30, 2015, the authorized capital stock of the Company included 175,000,000 shares of common stock, par value $0.00001 per share and 25,000,000 shares of undesignated preferred stock, par value $0.00001 per share.

On March 6, 2014, the Company effected a 1.75-for-1 stock split of its outstanding common stock. Unless otherwise indicated, all share data and per share amounts in these condensed consolidated financial statements have been retroactively adjusted to reflect the stock split, as well as any stock splits that occurred in periods prior to March 6, 2014.

Reserved for Future Issuance

As of September 30, 2015 and December 31, 2014 based on the authorized shares for each series, the Company has reserved the following shares of common stock for future issuance:

	September 30, 2015	December 31, 2014
Options to purchase common stock	2,251,908	1,526,346
Shares available for future issuance	1,342,719	1,549,154
Total	3,594,627	3,075,500

7. Income Taxes

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. There were no significant income tax provisions or benefits for the three and nine months ended September 30, 2015 and 2014. 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.

8. Commitments and Contingencies

In December 2013, the Company entered into a three-year lease for 6,837 square feet of office space in Cambridge, Massachusetts. The lease has monthly lease payments of approximately $31,000 for the first twelve months, with annual rent escalation thereafter, and provides a rent abatement of approximately $31,000 for the first full calendar month of the lease term. The lease term commenced and rental payments began in January 2014. The Company recorded a deferred lease obligation in 2014 which represents the cumulative difference between actual facility lease payments and lease expense recognized ratably over the lease period, which is included in other liabilities. In accordance with the lease, the Company entered into a cash-collateralized irrevocable standby letter of credit in the amount of $125,345, naming the landlord as beneficiary.

In December 2014, the Company entered into a First Amendment to Lease, or the Amendment, for additional office space contiguous to its current office space in Cambridge, Massachusetts. The Amendment includes leasing an additional 8,530 square feet of office space, or the Expansion Space, with an occupancy date of March 13, 2015. The Amendment provides for additional monthly lease payments of approximately $45,000 for the 8,530 square feet for the first twelve months and provides for annual rent escalations thereafter. The monthly rent on the existing 6,837 square feet will remain at approximately $32,000 through December 31, 2016, the expiration of the lease. The Amendment includes a Landlord's contribution for leasehold improvements in the amount of approximately $100,000 which will be accounted for as a deferred lease incentive and reduction in monthly rent expense over the term of the lease. The Company recorded an additional deferred lease obligation for the Expansion Space which represents the cumulative difference between actual facility lease payments and lease expense recognized ratably over the lease period. The Company has an existing cash-collateralized irrevocable standby letter of credit of $125,345, naming the landlord as beneficiary. In connection with the Amendment, the Company paid an additional cash security deposit to the landlord of $179,130. These amounts are included in other assets.

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

At September 30, 2015, the Company's future minimum payments required under these leases are as follows:

	Operating Lease	Capital Lease	Total
	(in thousands)		
2015	$230	$ 2	$232
2016	936	8	944
2017	—	5	5
2018	—	1	1
Total	$1,166	16	$1,182
Less amount representing interest		—	
Present value of minimum lease payments at September 30, 2015		$ 16	

The Company recorded approximately $0.2 million and $0.1 million in rent expense for the three months ended September 30, 2015 and 2014, respectively, and approximately $0.6 million and $0.3 million in rent expense for the nine months ended September 30, 2015 and 2014, respectively.

The Company contracts with various organizations to conduct research and development activities with remaining contract costs to the Company of approximately $19.6 million and $4.3 million at September 30, 2015 and December 31, 2014, respectively. The scope of the services under the 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.

In September 2015, a purported securities class action lawsuit was filed against the Company, including its Chief Executive Officer, its Chief Financial Officer, and members of its Board of Directors, in the Business Litigation Section of the Suffolk County Superior Court of Massachusetts. The complaint is brought on behalf of an alleged class of those who purchased common stock of the Company pursuant or traceable to our initial public offering, and purports to allege claims arising under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended (the "Securities Act"). The complaint generally alleges that the defendants violated the federal securities laws by, among other things, making material misstatements or omissions concerning the Phase 2b clinical study of vadadustat. The complaint seeks, among other relief, unspecified compensatory damages, rescission of certain stock purchases, attorneys' fees, and costs. In October 2015, we removed the case to the United States District Court for the District of Massachusetts, and the plaintiff filed a motion to remand the case back to the Business Litigation Section of the Suffolk County Superior Court of Massachusetts. The plaintiff's motion to remand is currently pending. The Company believes such claims are without merit, and will engage in a vigorous defense of such litigation.

The Company is not able to predict the outcome of the lawsuit described above or estimate the amount or range of any possible loss the Company might incur if the Company does not prevail in the final, non-appealable determination of this lawsuit. Therefore, we have not accrued any amounts in connection with this lawsuit.

9. Stock-Based Compensation

On February 28, 2014, the Company's Board of Directors adopted its 2014 Incentive Plan (2014 Plan) and its 2014 Employee Stock Purchase Plan (ESPP), which were subsequently approved by its stockholders and became effective upon the closing of the Company's IPO on March 25, 2014. The 2014 Plan replaces the 2008 Equity Incentive Plan (2008 Plan).

The 2014 Plan allows for the granting of stock options, stock appreciation rights, or SARs, restricted stock, unrestricted stock, RSUs, performance awards and other awards convertible into or otherwise based on shares of our common stock. Dividend equivalents may also be provided in connection with an award under the 2014 Plan. The Company's employees, officers, directors and consultants and advisors are eligible to receive awards under the 2014 Plan. The Company initially reserved 1,785,000 shares of its common stock for the issuance of awards under the 2014 Plan. The 2014 Plan provides that the number of shares reserved and available for issuance under the 2014 Plan will automatically increase annually on January 1st of each calendar year, by an amount equal to three percent (3%) of the number of shares of stock outstanding on a fully diluted basis as of the close of business on the immediately preceding December 31st. 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). Subject to adjustment, no more than 1,131,937 shares of our common stock may be delivered in satisfaction of incentive stock options awarded under the 2014 Plan. Any options or awards outstanding under the 2008 Plan at the time of adoption of the 2014 Plan remain outstanding and effective.

The ESPP authorizes the initial issuance of up to a total of 262,500 shares of the Company's common stock to participating employees. The first offering period under the ESPP opened on January 2, 2015.

As of September 30, 2015, the total number of common shares that may be issued under all equity award plans is 3,594,627 and 1,342,719 shares remain available for future grants.

In August 2014, the Company entered into both a separation agreement with an employee and a consulting agreement for continued services to the Company upon the separation date of December 31, 2014. As a result of the change in employment status to a consultant effective January 1, 2015, the Company recorded approximately $0.3 million of stock compensation expense during the first nine months of 2015.

During the first nine months of 2015, the Company granted 913,050 stock options to employees, 35,000 stock options to directors and 27,875 RSUs to employees.

Stock Options

On March 6, 2015, the Company issued 479,750 stock options to employees. Options granted by the Company vest over periods of between 12 and 48 months. 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 (as defined) or grant date, subject to the employee's continuous service with the Company. Options generally expire ten years after the date of grant.

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. The liquidity event occurred upon the closing of the Company's IPO on March 25, 2014. Accordingly, the Company recognized $0.1 million of compensation expense on March 25, 2014 related to the restricted stock awards with a requisite service period that was complete upon grant. Compensation expense related to the remainder of the restricted stock awards is being recognized over the associated requisite service period commencing on March 25, 2014. The Company recorded approximately $61,000 of stock-based compensation expense related to restricted stock during the third quarter of 2015 and approximately $0.6 million of stock-based compensation during the first nine months of 2015.

Restricted Stock Units

On March 6, 2015, the Company issued 27,875 RSUs to employees. The RSUs vest 100% on the three year anniversary. Total stock-compensation expense to be recognized over the life of the RSUs is $0.3 million and will be recognized on a straight-line basis over the vesting period. The Company recorded approximately $13,000 of stock-based compensation expense related to the RSUs during the third quarter of 2015 and approximately $44,000 of stock-based compensation during the first nine months of 2015.

Compensation Expense Summary

The Company has recognized the following compensation cost related to share-based awards:

	Three months ended		Nine months ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
	(in thousands)		(in thousands)	
Research and development	$468	$ 583	$1,431	$ 2,490
General and administrative	694	652	1,955	2,635
Total	$1,162	$ 1,235	$3,386	$ 5,125

Compensation expense by type of award:

	Three months ended		Nine months ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
	(in thousands)		(in thousands)	
Stock options	$1,065	$ 554	$2,673	$ 1,330
Restricted stock	61	681	604	3,795
Restricted stock units	13	—	44	—
Employee stock purchase plan	23	—	65	—
Total	$1,162	$ 1,235	$3,386	$ 5,125

Included in the compensation expense for the nine months ended September 30, 2014, is approximately $1.0 million related to the modification of awards in connection with an employee separation agreement in the first quarter of 2014.

10. Net Loss per Share

The following table presents the calculation of basic and diluted net loss per share applicable to common stockholders:

	Three months ended		Nine months ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
	(in thousands, except share and per share data)		(in thousands, except share and per share data)	
Numerator:				
Net loss	$(19,475)	$(9,348)	$(40,859)	$(26,664)
Accretion on preferred stock	—	—	—	(86,899)
Net loss applicable to common stockholders	$(19,475)	$(9,348)	$(40,859)	$(113,563)
Denominator:				
Weighted-average number of common shares – basic and diluted	28,784,231	19,691,167	25,175,077	13,920,651
Net loss per share applicable to common stockholders – basic and diluted	$(0.68)	$(0.47)	$(1.62)	$(8.16)

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		Nine months ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Outstanding stock options	2,251,908	1,596,538	2,251,908	1,596,538
Unvested restricted stock	265,402	563,810	265,402	563,810
Unvested restricted stock units	24,425	—	24,425	—
Total	2,541,735	2,160,348	2,541,735	2,160,348

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, contributions in the amount of approximately $71,000 and $0 were made during the three months ended September 30, 2015 and 2014, respectively.

12. Subsequent Event

During the period October 1, 2015 through November 5, 2015, the Company sold an additional 372,058 shares pursuant to the Sales Agreement with Cantor Fitzgerald & Co. The aggregate net proceeds received by the Company were approximately $3.9 million, net of commissions.

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, 2014, 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 4, 2015, 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 ot 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.

Product Overview

We are a biopharmaceutical company focused on the development of novel proprietary therapeutics based on hypoxia inducible factor, or HIF, biology and the commercialization of these products for patients with kidney disease. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body and a potentially novel mechanism for treating anemia.

Our Product Candidates

Vadadustat (formerly known as AKB-6548)

Our lead product candidate, vadadustat, is being developed as a once-daily, oral therapy. Vadadustat works by a differentiated mechanism of action that we believe has the potential to be safer than that of injectable recombinant protein erythropoiesis stimulating agents, or rESAs. This novel mechanism of action is referred to as HIF prolyl-hydroxylase, or HIF-PH, inhibition. Instead of binding directly to the erythropoietin, or EPO, receptors on cells in the bone marrow, vadadustat leads to activation of critical pathways for hemoglobin and RBC production. This approach mimics the physiological adjustment made by the body when exposed to reduced oxygen levels at higher altitudes.

Anemia is a serious medical condition in which blood is deficient in RBCs and hemoglobin, both of which are critical in delivering oxygen to tissue. Anemia generally exists when hemoglobin, a protein in RBCs that carries oxygen, is less than 13 g/dL in men or 12 g/dL in women. Untreated anemia is associated with chronic fatigue, increased risk of progression of multiple diseases and death. Anemia is common in patients with chronic kidney disease (CKD), cancer, heart failure, inflammatory diseases and other critical illnesses, as well as in the elderly.

We have successfully completed Phase 2 development of vadadustat, an oral therapy for the treatment of anemia related to CKD in both non-dialysis and dialysis patients. Positive results from our Phase 2b study in non-dialysis patients demonstrated that vadadustat raised hemoglobin levels with no safety signal observed. We have obtained agreement with United States and European regulatory authorities regarding the design of our Phase 3 vadadustat program, PRO_2TECT^{TM}, in non-dialysis patients with anemia related to CKD, and plan to initiate by year end. If the results from the PRO_2TECT^{TM} Phase 3 program support the results observed across our previous clinical studies with a combined total of 29,000 days of patient exposure, we anticipate submitting a New Drug Application, or NDA, for vadadustat in the United States by 2019.

We have also completed a Phase 2 study of vadadustat for the treatment of anemia in patients undergoing dialysis, the second indication we plan to pursue. We expect to initiate this Phase 3 vadadustat program, $INNO_2VATE^{TM}$, in dialysis-dependent patients in 2016.

We own worldwide rights to vadadustat. If approved by regulatory authorities, we plan to commercialize vadadustat in the United States ourselves and intend to seek one or more collaborators to commercialize the product candidate in additional markets.

AKB-6899

Our preclinical candidate, AKB-6899, is a small molecule HIF-PH inhibitor with potential therapeutic benefit in oncology and ophthalmology. AKB-6899 has demonstrated the ability in vitro to reduce VEGF levels in the presence of hypoxia. In several preclinical mouse models, AKB-6899 has been active in reducing tumor growth and development of metastases. Therefore, Investigational New Drug, or IND, enabling studies are being performed with the goal of opening an IND with the FDA in 2015.

Operating Overview

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 our IPO, our follow-on public offering, our at-the-market offerings and the private placements of preferred stock, common stock and convertible notes.

We have never been profitable and have incurred net losses in each year since inception. Our net losses were $40.9 million and $26.7 million for the nine months ended September 30, 2015 and 2014, 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:

- Prepare for and initiate a global Phase 3 development program of vadadustat for the treatment of anemia secondary to CKD;
- 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;
- continue preclinical and clinical development of AKB-6899;
- initiate additional preclinical, clinical or other studies for additional indications for AKB-6548, AKB 6899 and other product candidates that we may develop or acquire;
- seek to discover and develop additional product candidates;
- acquire or in-license other commercial products, product candidates and technologies;
- make royalty, milestone or other payments under any future 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. 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.

On March 6, 2014, we effected a 1.75-for-1 stock split of our outstanding common stock. Our historical share and per share information have been retroactively adjusted to give effect to this stock split. Shares of common stock underlying outstanding stock options and other equity instruments were proportionately increased and the respective exercise prices, if applicable, were proportionately reduced in accordance with the terms of the agreements governing such securities. Shares of common stock reserved for issuance upon the conversion of our Series A Redeemable Convertible Preferred Stock, Series B Redeemable Convertible Preferred Stock and Series C Redeemable Convertible Preferred Stock were proportionately increased, and the respective conversion prices were proportionately reduced.

On March 25, 2014, we completed our IPO whereby we sold 6,762,000 shares of common stock, including 879,647 shares of common stock pursuant to the full exercise of an over-allotment option granted to the underwriters, at a price of $17.00 per share. The shares began trading on the NASDAQ Global Market on March 20, 2014. The aggregate net proceeds received by us from the offering were approximately $104.4 million, net of underwriting discounts and commissions and estimated offering expenses. Upon the closing of the IPO, all of our outstanding shares of convertible redeemable preferred stock converted into 12,115,183 shares of common stock. Additionally, we are now authorized to issue 175,000,000 shares of common stock and 25,000,000 shares of preferred stock.

On April 22, 2015, we completed a follow-on public offering whereby we sold 8,363,636 shares of common stock, including 1,090,909 share 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 $8.25 per share. The aggregate net proceeds received by us from the offering were approximately $64.6 million, net of underwriting discounts and commissions and estimated offering expenses.

In August 2015, we entered into a Sales Agreement with Cantor Fitzgerald & Co. to periodically sell up to $50 million of shares of our common stock in ATM offerings. During the third quarter of 2015, the Company sold 1,311,562 shares of common stock pursuant to the Sales Agreement. The aggregate net proceeds received by the Company were approximately $14.2 million, net of commissions.

Financial Overview

Revenue

To date, we have not generated any revenue from the sales of products or other means. 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.

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, 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 scope, design (including the use of an active comparator), size, rate of progress, results and costs of initiating and 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 or, 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, timing and outcome of our efforts to obtain marketing approval for vadadustat in the United States, Europe and in other jurisdictions;
- the scope, progress, results and costs of additional preclinical, clinical, or other studies for additional indications for vadadustat, AKB-6899 and other product candidates that we may develop or acquire;
- the timing of, and the costs involved in, obtaining regulatory approvals for AKB-6899 if clinical studies are successful;
- 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;
- the cost of having our product candidates manufactured for clinical trials;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing and prosecuting patent applications and maintaining, defending and enforcing our intellectual property rights, including litigation costs, and the outcome of such litigation; and
- 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 September 30, 2015, we have incurred $107.6 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 AKB-6899. Our current and planned research and development activities include the following:

We plan to initiate a Phase 3 development program for vadadustat in 2015 for anemia secondary to CKD in patients not on dialysis.

We plan to initiate a Phase 3 development program for vadadustat in 2016 for anemia secondary to CKD in patients on dialysis.

We intend to submit an IND for AKB-6899 in the fourth quarter of 2015.

Our direct research and development expenses consist principally of external costs, such as startup fees paid to investigators, consultants, central laboratories and CROs in connection with our clinical studies, and costs related to

acquiring and manufacturing clinical study materials.

We currently have two 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 expense include facility-related costs, fees for directors, accounting and legal services fees, recruiting fees and expenses associated with obtaining and maintaining patents. We obtain from, and provide to, Aerpio services under the terms of administrative services agreements between the two companies.

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 condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our condensed consolidated financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued 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 condensed 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 condensed consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our condensed consolidated financial statements, we are required to estimate our accrued 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 accrued expenses as of each balance sheet date in our condensed 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 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 these contracts 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 and shares of common stock. We account for our stock-based compensation awards in accordance with 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 FASB 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. Since the consummation of our IPO, stock option, common stock and restricted stock values are determined based on the quoted market price of our common stock.

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 a public market for the trading of our common stock and a lack of company-specific historical and implied volatility data, 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. We are a company in the product development stage with no 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. Post IPO, the grant date fair value of restricted stock award grants without a promissory note 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 either service or performance-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. Compensation expense related to awards to employees with performance-based vesting conditions is recognized based on the grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Consistent with the guidance in ASC 505-50, compensation expense related to awards to non-employees with performance-based vesting conditions is recognized based on the then-current fair value at each financial reporting date prior to the measurement

date over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable.

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. We use historical data to estimate pre-vesting forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the condensed consolidated financial statements is based on awards that are ultimately expected to vest.

In June 2011, certain of our employees purchased shares of our restricted stock in exchange for promissory notes. Although these notes were 50% recourse to the employees, we have accounted for the promissory notes as nonrecourse in their entirety since the promissory notes are not aligned with a corresponding percentage of the underlying shares. Accordingly, we have accounted for the combination of the promissory note and restricted stock as a grant of an option, as the substance is similar to the grant of an option. The exercise price of this stock option is the principal and interest due on the promissory note. The fair value of the stock option is recognized over the requisite service period (not the term of the promissory note) through a charge to compensation cost. The maturity date of the promissory notes reflects the legal term of the stock option for purposes of valuing the award. The outstanding principal and interest on the promissory notes was paid in full during the third quarter of 2014.

Stock-based compensation expense totaled approximately $1.2 million for the three months ended September 30, 2015 and 2014, and approximately $3.4 million and $5.1 million for the nine months ended September 30, 2015 and 2014, 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 September 30, 2015 and 2014

	Three months ended		Increase
	September 30, 2015	September 30, 2014	(Decrease)
	(In Thousands)		
Operating expenses:			
Research and development	$15,790	$ 6,648	$ 9,142
General and administrative	3,888	2,936	952
Total operating expenses	(19,678)	(9,584)	10,094
Loss from operations	(19,678)	(9,584)	10,094
Other income (expense), net	203	236	(33)
Net loss	$(19,475)	$ (9,348)	$ 10,127

Research and Development Expenses. Research and development expenses were $15.8 million for the three months ended September 30, 2015, compared to $6.6 million for the three months ended September 30, 2014, an increase of $9.1 million. The increase was primarily due to the following:

	(in millions)
Completion of Phase 2 study for the treatment of anemia in patients undergoing dialysis	$ (0.7)
Completion of Phase 2b study in non-dialysis patients with anemia related to CKD	(1.1)
Preparation of the Phase 3 study in non-dialysis patients with anemia related to CKD	7.2
Regulatory activities	0.4
Other clinical and non- clinical	1.0
Total increase related to the continued development of AKB-6548	6.8
Drug development for AKB-6899	0.4

Manufacture of drug substance and drug product	0.2
Headcount and consulting	1.1
Stock compensation	(0.1)
Other	0.7
Total net increase	$ 9.1

General and Administrative Expenses. General and administrative expenses were $3.9 million for the three months ended September 30, 2015, compared to $2.9 million for the three months ended September 30, 2014. The increase of $1.0 million was primarily due to the following expense increases: $0.6 million of wage and personnel-related costs due to increased headcount, $0.2 million of stock-based compensation, $0.1 million in commercial planning costs and $0.3 million related to facilities.

Other Income, Net. Other income, net, was $0.2 million for the three months ended September 30, 2015 and September 30, 2014. Other income, net for the three months ended September 30, 2015 is primarily related to $0.1 million of interest income and $0.1 million related to reimbursements from Aerpio for employee-related costs. Other income, net for the three months ended September 30, 2014, is primarily related to reimbursements from Aerpio for employee-related costs. Under the terms of the administrative

services agreements entered into upon disposition of Aerpio in 2011, we and Aerpio obtain from, and provide to, each other certain services.

Comparison of the Nine Months Ended September 30, 2015 and 2014

	Nine months ended		Increase
	September 30, 2015	September 30, 2014	(Decrease)
	(In Thousands)		
Operating expenses:			
Research and development	$30,477	$18,330	$12,147
General and administrative	10,986	9,003	1,983
Total operating expenses	41,463	27,333	14,130
Loss from operations	(41,463)	(27,333)	14,130
Other income, net	604	669	(65)
Net loss	$(40,859)	$(26,664)	$14,195

Research and Development Expenses. Research and development expenses were $30.5 million for the nine months ended September 30, 2015, compared to $18.3 million for the nine months ended September 30, 2014, an increase of $12.1 million. The increase was primarily due to the following:

	(in millions)
Phase 2 study for the treatment of anemia in patients undergoing dialysis	$ 0.5
Completion of Phase 2b study in non-dialysis patients with anemia related to CKD	(3.8)
Preparation of the Phase 3 study in non-dialysis patients with anemia related to CKD	7.7
Regulatory activities	0.9
Other clinical and non- clinical	1.2
Total increase related to the continued development of AKB-6548	6.5
Drug development for AKB-6899	2.1
Headcount and consulting	2.9
Patent costs	0.5
Stock compensation	(1.1)
Other	1.2
Total net increase	$ 12.1

General and Administrative Expenses. General and administrative expenses were $11.0 million for the nine months ended September 30, 2015, compared to $9.0 million for the nine months ended September 30, 2014. The increase of $2.0 million was primarily due to the following expense increases: $1.7 million of wage and personnel-related costs due to increased headcount, $0.7 million in commercial planning costs and $0.7 million related to insurance and facilities partially offset by the following expense decreases: $0.7 million of stock-based compensation and $0.3 million of public company related costs.

Other Income, Net. Other income, net, was $0.6 million for the nine months ended September 30, 2015, compared to $0.7 million for the nine months ended September 30, 2014. Other income, net for the nine months ended September

30, 2015 is primarily related to $0.3 million of interest income and $0.3 million related to reimbursements from Aerpio for employee-related costs. Other income net for the nine months ended September 30, 2014 is primarily related to reimbursements from Aerpio for employee-related costs. Under the terms of the administrative services agreements entered into upon disposition of Aerpio in 2011, we and Aerpio obtain from, and provide to, each other certain services.

Liquidity and Capital Resources

We have incurred losses and cumulative negative cash flows from operations since our inception in February 2007, and as of September 30, 2015, we had an accumulated deficit of $141.5 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 from the sale of common stock and preferred stock. As of September 30, 2015, we had cash and cash equivalents and available for sale securities of approximately $157.5 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 and stated at fair value, are also available as a source of liquidity.

Cash Flows

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

	Nine months ended	
	September 30, 2015	September 30, 2014
	(In Thousands)	
Net cash provided by (used in):		
Operating activities	$(29,495)	$(18,280)
Investing activities	(15,326)	(57,715)
Financing activities	78,753	104,448
Net increase (decrease) in cash and cash equivalents	$33,932	$28,453

Operating Activities. The net cash used in operating activities was $29.5 million for the nine months ended September 30, 2015 and consisted primarily of a net loss of $40.9 million adjusted for non-cash items, including stock-based compensation expense of $3.4 million and amortization of premium/discount on investments of $0.4 million and a net increase in operating assets and liabilities of $7.5 million. The significant items in the change in operating assets and liabilities include an increase in accounts payable and accrued expenses of approximately $7.3 million and a decrease in prepaid expenses and other current assets of $0.2 million. The increase in accounts payable and accrued expenses is primarily driven by accrued clinical and non-clinical study costs associated with vadadustat and AKB-6899. The decrease in prepaid expenses and other current assets is primarily related to prepaid clinical and non-clinical study costs associated with vadadustat and AKB-6899.

The net cash used in operating activities was $18.3 million for the nine months ended September 30, 2014 and consisted primarily of a net loss of $26.7 million adjusted for non-cash items, including stock-based compensation expense of $5.1 million and a net increase in operating assets and liabilities of $3.1 million. The significant items in the change in operating assets and liabilities include increases in accounts payable and accrued expense of $3.7 million, offset by an increase in prepaid expenses, other current assets and other assets of $0.6 million. The increase in accounts payable and accrued expenses is driven by clinical, non-clinical and TQT study costs associated with vadadustat as well as wage and personnel-related costs due to increased headcount. The increase in prepaid expenses, other current assets and other assets is primarily related to directors and officers insurance.

Investing Activities. Net cash used in investing activities for the nine months ended September 30, 2015 was $15.3 million and was comprised primarily of purchases of available for sale securities of $64.5 million and purchases of equipment of $0.3 million, offset by proceeds from the maturities of available for sale securities of $49.5 million.

Net cash used in investing activities for the nine months ended September 30, 2014 was $57.7 million and was comprised primarily of purchases of available for sale securities of $64.5 million and purchases of equipment of $0.2 million, offset by proceeds from the maturities of available for sale securities of $7.0 million.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2015 was $78.8 million and consisted primarily of net proceeds from the issuance of common stock in connection with our follow-on public offering and sales of common stock pursuant to our ATM facility.

Net cash provided by financing activities for the nine months ended September 30, 2014 was $104.4 million and consisted primarily of $104.3 million of net proceeds from the issuance of common stock in connection with our IPO and $0.2 million of proceeds from the receipt of payment on promissory notes issued in exchange for shares of common stock.

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 also, we anticipate that we will need substantial additional funding in connection with our continuing operations.

Our existing cash and cash equivalents and available for sale securities, together with the proceeds we expect to receive from our ATM offerings, are sufficient to fund our projected operating requirements into the fourth quarter of 2016. However, we may require additional capital for the further development of our existing product candidates and may also need to raise additional funds sooner to pursue other development activities related to additional product candidates. If and until we can generate a sufficient amount of revenue from our products, we expect to finance future cash needs through public or private equity or debt offerings. There can be no assurance that additional funds will 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 4, 2015.

Off-Balance Sheet Arrangements

As of September 30, 2015 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 September 30, 2015 and December 31, 2014, we had cash and cash equivalents and available for sale securities of $157.5 million and $108.9 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 September 30, 2015, 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. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2015, 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

Item 1. Legal Proceedings

Shareholder Litigation

In September 2015, a purported securities class action lawsuit was filed against the Company, including its Chief Executive Officer, its Chief Financial Officer, and members of its Board of Directors, in the Business Litigation Section of the Suffolk County Superior Court of Massachusetts. The complaint is brought on behalf of an alleged class of those who purchased common stock of the Company pursuant or traceable to our initial public offering, and purports to allege claims arising under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, as amended (the "Securities Act"). The complaint generally alleges that the defendants violated the federal securities laws by, among other things, making material misstatements or omissions concerning the Phase 2b clinical study of vadadustat. The complaint seeks, among other relief, unspecified compensatory damages, rescission of certain stock purchases, attorneys' fees, and costs. In October 2015, we removed the case to the United States District Court for the District of Massachusetts, and the plaintiff filed a motion to remand the case back to the Business Litigation Section of the Suffolk County Superior Court of Massachusetts. The plaintiff's motion to remand is currently pending. The Company believes such claims are without merit, and will engage in a vigorous defense of such litigation.

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.

As explained in more detail below, we have had some 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, the European Opposition Division issued a non-binding preliminary opinion that none of FibroGen's '823 patent claims meet the requirements for patentability. 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 JPO issued a preliminary decision finding all of the challenged claims to be invalid. 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 in Europe and Japan in the '823 and '131 patents. In the event FibroGen were to obtain such patents in the United States, we may decide to challenge them like we have done in Europe and Japan. On May 13, May 20, and July 6, 2015, we also filed oppositions to FibroGen's European Patent Nos. 2322155, 1633333, and 2322153 respectively, requesting the patents be revoked in their entirety.

In June 2013, the European Patent Office granted the '823 patent, to FibroGen. The '823 patent claims, among other things, the use of a heterocyclic carboxamide compound selected from the group consisting of pyridine carboxamides, quinoline carboxamides, isoquinoline carboxamides, cinnoline carboxamides, and beta-carboline carboxamides that inhibits HIF-PH enzyme activity in the manufacture of a medicament for increasing endogenous EPO in the prevention, pretreatment or treatment of anemia. On December 5, 2013, we filed an opposition to the '823 patent requesting that the '823 patent be revoked in its entirety. On July 7, 2015, the European Opposition Division scheduled oral proceedings for March 1, 2016 (later rescheduled to March 8, 2016) and also issued a non-binding preliminary opinion that none of the '823 patent's claims met the requirements for patentability. While, for the reasons set forth in our opposition, we believe the '823 patent should be revoked in its entirety, the ultimate outcome of the opposition remains uncertain. If the European Patent Office decides not to revoke the '823 patent in its entirety, or only certain claims of the '823 patent, and any surviving claims are determined to encompass our intended use of our lead product candidate, we may not be able to commercialize our lead product candidate in the European Union for its intended use, which could materially adversely affect our business, operating results and financial condition.

In August 2011, the Japanese Patent Office granted the '131 patent, to FibroGen. The '131 patent claims, among other things, the use of certain heterocyclic carboxamides selected from the group consisting of pyridine carboxamides, quinoline carboxamides, and isoquinoline carboxamides to treat anemia, wherein the heterocyclic carboxamides also suppress HIF prolyl hydroxylase. On June 2,

2014, we filed an invalidity proceeding in the Japanese Patent Office challenging the validity of the ’131 patent and requesting that certain claims be revoked in their entirety. An oral hearing before the Japanese Patent Office was held on February 9, 2015, and on May 11, 2015 the Japanese Patent Office issued a preliminary decision finding all of the challenged claims to be invalid. While, for the reasons set forth in our Request For Trial and subsequent briefing filed in that proceeding, we believe the ’131 patent should be revoked in its entirety, the ultimate outcome of the invalidity proceeding remains uncertain. If the Japanese Patent Office decides not to revoke the ’131 patent in its entirety, or only certain claims of the ’131 patent, and any surviving claims are determined to encompass our intended use of our lead product candidate, we may not be able to commercialize our lead product candidate in Japan for its intended use, which could materially adversely affect our business, operating results and financial condition.

In August 2014, the European Patent Office granted European Patent Nos. 2322153, 2322155, and 1633333, or the ’153 patent, the ’155 patent, and the ’333 patent, respectively, to FibroGen. 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 EPO, and microcytosis in microcytic anemia. On May 13, May 20, and July 6, 2015, we filed oppositions to the ’155 patent, the ’333 patent, and the ’153 patent, respectively, requesting that the patents be revoked in their entireties. While, for the reasons set forth in our oppositions, we believe that the ’153 patent, the ’155 patent, and the ’333 patent should be revoked in their entireties, the ultimate outcomes of the oppositions remains uncertain. If the European Patent Office decides not to revoke the ’153 patent, the ’155 patent, or the ’333 patent in their entireties, or only certain claims of those patents, and any surviving claims are determined to encompass our intended use of our lead product candidate, we may not be able to commercialize our lead product candidate in the European Union for its intended use, which could materially adversely affect our business, operating results and financial condition.

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 $40.9 million for the nine months ended September 30, 2015, and $26.7 million for the nine months ended September 30, 2014. As of September 30, 2015, we had an accumulated deficit of $141.5 million. To date, we have not commercialized any products or generated any revenue from the sale of products, and we do not expect to generate any product revenue in the foreseeable future. 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 initial public offering, or IPO completed in March 2014, our follow-on offering completed in April 2015, our at-the-market offerings and private placements of our preferred stock. 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, strategic collaborations or grants. Our lead product candidate, vadadustat, recently completed Phase 2 development, and our other product candidate, AKB-6899, is in preclinical development. Therefore, we expect that it will be several years, if ever, before we have a product candidate ready for commercialization. Even if we obtain regulatory approval to market vadadustat, our future revenue will depend upon the size of any markets in which vadadustat has received 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:

- prepare for and initiate a Phase 3 development program of vadadustat for the treatment of anemia secondary to CKD;
- seek regulatory approvals for our product candidates that successfully complete clinical studies;
- have our product candidates manufactured for clinical trials and for commercial sale;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;

- initiate additional preclinical, clinical or other studies for additional indications for vadadustat, AKB 6899 and other product candidates that we may develop or acquire;
- seek to discover and develop additional product candidates;
- acquire or in-license other commercial products, product candidates and technologies;
- make royalty, milestone or other payments under any future in-license agreements;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel; and
- continue to create additional infrastructure to support our operations as a public company.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, if at all, we will be able to achieve profitability. If we are required by the United States Food and Drug Administration, or FDA, the European Medicines Agency, or EMA, or other regulatory authorities to perform studies in addition to, different from or larger than those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

To become and remain profitable, we must succeed in developing and commercializing our product candidates, which must generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering or acquiring additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could cause our stockholders to lose all or part of their investment.

We will require substantial additional financing. A failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

As of September 30, 2015, our cash and cash equivalents and available for sale securities were $157.5 million. We believe that we will continue to expend substantial resources for the foreseeable future developing vadadustat, AKB-6899 and any other product candidates that we may develop or acquire. These expenditures will include costs associated with research and development, potentially obtaining regulatory approvals and having our products manufactured, as well as marketing and selling products approved for sale, if any. For example, we anticipate significant costs associated with our Phase 3 clinical studies of vadadustat for the treatment of anemia secondary to CKD. In addition, other unanticipated costs may arise as a result of our decision to include certain elements in our Phase 3 programs. Because the outcome of our current and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amount of funding necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

- 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 scope, design (including the use of an active comparator), size, rate of progress, results and costs of initiating and 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 or, 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, timing and outcome of our efforts to obtain marketing approval for vadadustat in the United States, Europe and in other jurisdictions;
the scope, progress, results and costs of additional preclinical, clinical, or other studies for additional indications for vadadustat, AKB-6899 and other product candidates that we may develop or acquire;
the timing of, and the costs involved in, obtaining regulatory approvals for AKB-6899 if clinical studies are successful;
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;
the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
the cost of having our product candidates manufactured for clinical trials and in preparation for commercialization;