Akebia Therapeutics, Inc.
Form 10-Q
November 10, 2014

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, 2014

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 October 31, 2014
Common Stock, $0.00001 par value	20,340,805

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 (the "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) data from our recently completed Phase 2b study of AKB-6548 in non-dialysis patients with anemia related to chronic kidney disease (CKD), (2) commencement of a Phase 3 development program of AKB-6548, (3) submission of an NDA for AKB-6548 and (4) data from our Phase 2 clinical study of AKB-6548 in CKD patients undergoing dialysis;
- our plans to commercialize AKB-6548, if it is approved;
- our development plans with respect to AKB-6899;
- the timing or likelihood of regulatory filings and approvals, including any required post-marketing testing or any labeling and other restrictions;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the rate and degree of market acceptance and clinical utility of our products;
- our competitive position;
- our intellectual property position;
- developments and projections relating to our competitors and our industry;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our estimates regarding expense, 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 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.

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

AKEBIA THERAPEUTICS, INC.

Condensed Balance Sheets

(unaudited)

(in thousands, except share and per share data)

	September 30, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$49,668	$21,215
Available for sale securities	68,670	11,341
Accounts receivable	57	135
Prepaid expenses and other current assets	1,445	740
Total current assets	119,840	33,431
Property and equipment, net	205	30
Deferred offering costs	—	1,079
Other assets	125	125
Total assets	$120,170	$34,665
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$3,032	$714
Accrued expenses	3,490	3,188
Total current liabilities	6,522	3,902
Other liabilities	34	8
Total liabilities	$6,556	$3,910
Redeemable convertible preferred stock; $0.00001 par value; 0 and 5,500,636 shares authorized at September 30, 2014 and December 31, 2013, respectively:		
Series A redeemable convertible preferred stock; 0 and 734,538 shares issued and outstanding at September 30, 2014 and December 31, 2013; (Aggregate liquidation preference of $39,367 at December 31, 2013)	—	39,367
Series B redeemable convertible preferred stock; 0 and 1,287,525 shares issued and outstanding at September 30, 2014 and December 31, 2013; (Aggregate liquidation preference of $21,031 at December 31, 2013)	—	21,257
Series C redeemable convertible preferred stock; 0 and 3,302,885 shares issued and	—	97,203

outstanding at September 30, 2014 and December 31, 2013; (Aggregate liquidation preference of $97,203 at December 31, 2013)		
Total redeemable convertible preferred stock	$—	$157,827
Stockholders' equity (deficit):		
Preferred stock $0.00001 par value, 25,000,000 and 0 shares authorized; 0 shares outstanding at September 30, 2014 and December 31, 2013, respectively	—	—
Common stock: $0.00001 par value; 175,000,000 and 14,700,000 authorized at September 30, 2014 and December 31, 2013, respectively; 20,300,243 and 1,383,345 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	—	—
Additional paid-in capital	204,048	—
Treasury Stock, at cost, 2,553 shares	(79)	—
Accumulated other comprehensive loss	(52)	—
Accumulated deficit	(90,303)	(127,072)
Total stockholders' equity (deficit)	113,614	(127,072)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$120,170	$34,665

See accompanying notes to unaudited financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

	Three months ended		Nine months ended	
	September 30, 2014	September 30, 2013	September 30, 2014	September 30, 2013
Operating expenses:				
Research and development	$6,648	$3,240	$18,330	$7,591
General and administrative	2,936	794	9,003	2,141
Total operating expenses	9,584	4,034	27,333	9,732
Operating loss	(9,584)	(4,034)	(27,333)	(9,732)
Other income (expense):				
Interest income (expense), net	56	28	125	(723)
Extinguishment of debt and other liabilities	—	—	—	2,420
Reimbursements from Aerpio	180	238	544	816
Net loss	$(9,348)	$(3,768)	$(26,664)	$(7,219)
Reconciliation of net loss to net loss applicable to common stockholders:				
Net loss	$(9,348)	$(3,768)	$(26,664)	$(7,219)
Accretion on preferred stock	-	(2,748)	(86,899)	(52,862)
Net loss applicable to common stockholders	$(9,348)	$(6,516)	$(113,563)	$(60,081)
Net loss per share applicable to common stockholders—basic and diluted	$(0.47)	$(11.92)	$(8.16)	$(117.94)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	19,691,167	546,714	13,920,651	509,425
Comprehensive loss:				
Net loss	$(9,348)	$(3,768)	$(26,664)	$(7,219)
Other comprehensive loss:				
Unrealized loss on securities	(43)	—	(52)	—
Comprehensive loss	$(9,391)	$(3,768)	$(26,716)	$(7,219)

See accompanying notes to unaudited financial statements.

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AKEBIA THERAPEUTICS, INC.

Condensed Statements of Cash Flows

(Unaudited)

(in thousands)

See accompanying notes to unaudited financial statements.

	Nine months ended September 30,	
	2014	2013
Operating activities:		
Net loss	$(26,664)	$(7,219)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on extinguishment of debt and other liabilities	—	(2,420)
Depreciation expense	33	—
Amortization of debt issuance costs	—	4
Amortization of premium/discount on investments	124	752
Stock-based compensation expense	5,125	438
Changes in operating assets and liabilities:		
Accounts receivable	78	(80)
Prepaid expenses and other current assets	(688)	(28)
Accounts payable and accrued expenses	3,683	2,129
Other liabilities	29	—
Net cash used in operating activities	(18,280)	(6,424)
Investing activities:		
Purchase of equipment	(208)	(6)
Proceeds from maturities of available for sale securities	6,990	—
Purchases of available for sale securities	(64,497)	(13,154)
Net cash used in investing activities	(57,715)	(13,160)
Financing activities:		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	42,546
Repurchase of treasury stock	(79)	—
Proceeds from issuance of common stock, net of issuance costs	104,293	—
Proceeds from receipt of payment on promissory notes issued in exchange for shares of common stock	237	—
Payments on capital lease obligations	(3)	—
Net cash provided by financing activities	104,448	42,546
Increase in cash and cash equivalents	28,453	22,962
Cash and cash equivalents at beginning of period	21,215	1,641
Cash and cash equivalents at end of period	$49,668	$24,603
Non-cash financing activities:		
Accretion of preferred stock to redemption value	$86,899	$52,862
Unpaid initial public offering issuance costs	$15,000	$—
Reclassification of 2012 Series X preferred stock from debt to preferred stock	$—	$2,486
Conversion of 2012 Series X preferred stock into Series C preferred stock	$—	$4,944

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Akebia Therapeutics, Inc.

Notes to Financial Statements

(Unaudited)

September 30, 2014

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 (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, AKB-6548, is being developed as a once-daily, oral therapy that has successfully completed a Phase 2b study demonstrating that AKB-6548 can safely and predictably raise hemoglobin levels in non-dialysis patients with anemia related to chronic kidney disease (CKD).

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.

Unless otherwise indicated, all information in these 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 7), 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

Initial Public Offering

On March 25, 2014, the Company completed its initial public offering (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 $104,364,560, 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 175,000,000 shares of common stock and 25,000,000 shares of undesignated preferred stock.

Our preferred stock is redeemable at the greater of fair value or the original issuance price. We recorded $86,899,555 of accretion on the preferred stock in the period from January 1, 2014 through the date of the closing of our 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 financial statements are unaudited and have been prepared by the Company in accordance with U.S. GAAP and are stated in U.S. Dollars. Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These interim financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods ended September 30, 2014 and 2013.

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 financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2013, and the notes thereto, which are included in the Company's prospectus that forms a part of the Company's

Registration Statement on Form S-1 (File No. 333-193969 and 333-194695), which was filed with the Securities and Exchange Commission (SEC) on March 21, 2014.

Recent Accounting Pronouncements

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

In June 2014, the FASB issued ASU No. 2014-10, which eliminates the concept of a development stage entity, or DSE, in its entirety from GAAP. Under existing guidance, DSEs are required to report incremental information, including inception-to-date financial information, in their financial statements. A DSE is an entity devoting substantially all of its efforts to establishing a new business and for which either planned principal operations have not yet commenced or have commenced but there has been no significant revenues generated from that business. Entities classified as DSEs will no longer be subject to these incremental reporting requirements after adopting ASU No. 02014-10. ASU No. 2014-10 is effective for fiscal years beginning after December 15, 2014, with early adoption permitted. Retrospective application is required for the elimination of incremental DSE disclosure. Prior to the issuance of ASU No. 2014-10, the Company had met the definition of a DSE since its inception. The Company elected to adopt this ASU early and, therefore, it has eliminated the incremental disclosures previously required of DSEs, starting with the Quarterly Report on Form 10-Q for the quarter ended June 30, 2014 (File No. 001-36352), which was filed with the SEC on August 11, 2014.

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 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: 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. For periods prior to 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. Prior

to the Company's IPO, 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.

The Company utilized various valuation methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock in periods prior to March 2014. The methodologies included a probability analysis including both a potential public trading scenario and potential sale scenario. In both scenarios, value is estimated using the guideline public company method. The sale scenario includes an adjustment for a market participant acquisition premium. Value is allocated among the preferred and common shares according to the rights associated with each type of security. Valuation methodologies include estimates and assumptions that require the Company's judgment. These estimates include assumptions regarding future performance, including the successful completion of a public offering. Significant changes to the key assumptions used in the valuations could result in different fair values of common stock at each valuation date.

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, 2014, 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, with temporary unrealized gains and losses, reported in accumulated other comprehensive income, a component of stockholders' equity (deficit). 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 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 commercial 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.

Organizational Costs

All organizational costs and start-up costs are expensed as incurred.

Income Taxes

Income taxes are recorded in accordance with FASB Topic 740, Income Taxes (ASC 740), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred

tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of September 30, 2014 and December 31, 2013, 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 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. 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. Prior to the IPO, 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 a very early stage of product development 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 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, 2014 and December 31, 2013, 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 and unvested restricted stock 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, 2014 and December 31, 2013.

	Useful Life	September 30, 2014	December 31, 2013
Computer equipment and software	3	$ 82,916	$ 19,732
Furniture and fixtures	5	117,657	—
Equipment	7	6,195	—
Leasehold improvements	Shorter of the useful life or remaining lease term (3 years)	20,777	—
Office equipment under capital lease	3	11,916	11,916
		239,461	31,648
Less accumulated depreciation		(34,567)	(1,282)
Net property and equipment		$ 204,894	$ 30,366

Depreciation expense, including expense associated with assets under capital leases, was $13,193 and $26 for the three months ended September 30, 2014 and 2013, respectively and $33,285 and $26 for the nine months ended September 30, 2014 and 2013, respectively.

3. Distribution of Aerpio Therapeutics, Inc.

On December 22, 2011, the Company assigned certain assets and liabilities to a wholly-owned subsidiary, Aerpio Therapeutics, Inc. (Aerpio), which has since operated as an independent, stand-alone company and is no longer a wholly-owned subsidiary. The assigned assets and liabilities included all of the Company's fixed assets, the Company's Tie2 activator program, AKB-9778, for diabetic macular edema, the HIF-1 stabilizer program, AKB-4924, for inflammatory bowel disease and contracts, intellectual property, current assets and current liabilities associated with these programs. The Aerpio shares were then distributed to the Company's shareholders as a distribution on the basis of one share of Aerpio Series A Preferred Stock for every 35 shares of Akebia Series A Preferred Stock owned, one share of Aerpio Series A Preferred Stock for every 100 shares of Akebia Series B Preferred Stock owned, and one share of Aerpio Common Stock for every 175 shares of Akebia Common Stock owned.

Under the terms of administrative services agreements, the Company and Aerpio obtain from and provide to each other certain services beginning in 2012, and as outlined below. These agreements are cancellable upon mutual agreement or a sale of either company.

Below is a summary of the activities included in the statements of operations and comprehensive loss:

	Three Months Ended September 30,	Nine Months Ended September 30,

Activity	Financial Statement Caption	2014	2013	2014	2013
Reimbursement from Aerpio for Akebia employee costs	Reimbursements from Aerpio	$180,132	$238,107	$544,471	$815,704
Facility-related charges from Aerpio	General and administrative Operating expenses	$10,914	$2,601	$58,250	$186,518

Below is a summary of the receivables and payables included in the balance sheets related to Aerpio:

Activity	Financial Statement Caption	September 30, 2014	December 31, 2013
Amounts receivable from Aerpio	Accounts receivables	$ 57,245	$ 135,339
Amounts payable to Aerpio	Accounts payable	$ 7,656	$ 62,735

4. Available for sale securities

Available for sale securities at September 30, 2014 and December 31, 2013 consist of the following:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2014				
Cash and cash equivalents:				
Cash and money market account	$ 49,667,984	—	—	$ 49,667,984
Total cash and cash equivalents	$ 49,667,984	$ —	$ —	$ 49,667,984
Available for sale securities:				
Certificates of deposit	$ 10,014,977	—	—	$ 10,014,977
U.S. Government debt securities	31,741,636	3,299	(25,976)	31,718,959
Commercial paper	4,997,360	—	—	4,997,360
Corporate debt securities	21,967,553	—	(28,580)	21,938,973
Total available for sale securities	$ 68,721,526	$ 3,299	$ (54,556)	$ 68,670,269
Total cash, cash equivalents, and available for sale securities	$ 118,389,510	$ 3,299	$ (54,556)	$ 118,338,253

The estimated fair value of the Company's available for sale securities balance at September 30, 2014, by contractual maturity, is as follows:

Due in one year or less	$ 27,333,292
Due after one year	41,336,977
Total available for sale securities	$ 68,670,269

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2013				
Cash and cash equivalents:				
Cash and money market account	$ 21,215,228	$ —	$ —	$ 21,215,228
Total cash and cash equivalents	$ 21,215,228	$ —	$ —	$ 21,215,228
Available for sale securities:				
Certificates of deposit	$ 1,330,132	$ —	$ —	$ 1,330,132
U.S. Government debt securities	7,506,951	2,418	—	7,509,369
Corporate debt securities	2,501,686	54	—	2,501,740
Total available for sale securities	$ 11,338,769	$ 2,472	$ —	$ 11,341,241
Total cash, cash equivalents, and available for sale securities	$ 32,553,997	$ 2,472	$ —	$ 32,556,469

5. Fair Value of Financial Instruments

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

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

Assets measured or disclosed at fair value on a recurring basis as of September 30, 2014 are summarized below:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$49,667,984	$—	$ —	$49,667,984
Certificates of deposit	—	10,014,977	—	$10,014,977
U.S. Government debt securities	—	31,718,959	—	$31,718,959
Commercial paper	—	4,997,360	—	$4,997,360
Corporate debt securities	—	21,938,973	—	$21,938,973
	$49,667,984	$68,670,269	$ —	$118,338,253

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, 2013 are summarized below:

	Fair Value Measurements Using			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash and cash equivalents	$21,215,228	$—	$ —	$21,215,228
Certificates of deposit	—	1,330,132	—	1,330,132
U.S. Government debt securities	—	7,509,369	—	7,509,369
Corporate debt securities	—	2,501,740	—	2,501,740
	$21,215,228	$11,341,241	$ —	$32,556,469

The Company had no assets or liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3) at September 30, 2014 and December 31, 2013.

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

6. Accrued Expenses

Accrued expenses are as follows:

	September 30, 2014	December 31, 2013

Professional fees	$ 1,887,471	$ 2,452,067
Accrued bonus	626,342	439,435
Accrued vacation	179,219	109,921
Accrued severance	180,214	—
Accrued payroll	313,641	—
Other	303,400	186,338
Total accrued expenses	$ 3,490,287	$ 3,187,761

In February 2014, the Company entered into a separation agreement with an employee primarily as a result of the transition to the Company's Cambridge, Massachusetts location. During the first quarter of 2014, the Company recorded severance expense in the amount of $323,685, which was recorded to general and administrative expense. During the first nine months of 2014, approximately $189,000 was paid out of the severance accrual. At September 30, 2014, $133,532 remained in accrued expenses in relation to the unpaid severance costs, which will be paid out through February 2015.

In August 2014, the Company entered into a separation agreement with an employee, which became effective on August 13, 2014. The Company will record 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 2014, the Company recorded severance expense in the amount of $46,682, which was recorded to research and development expense and will be paid out beginning January 2015 through December 2015.

7. Stockholders' Equity

As of September 30, 2014, 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 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.

As of December 31, 2013, the authorized capital stock of the Company included 5,500,636 shares of preferred stock, par value $0.00001 per share, of which: (i) 734,538 shares were designated as Series A redeemable convertible preferred stock (Series A Redeemable Convertible Preferred Stock), (ii) 1,287,525 shares were designated as Series B redeemable convertible preferred stock (Series B Redeemable Convertible Preferred Stock), (iii) 3,428,572 shares were designated as Series C redeemable convertible preferred stock (Series C Redeemable Convertible Preferred Stock) and (iv) 50,001 shares were designated as Series X convertible preferred stock (Series X Convertible Preferred Stock). There is no outstanding Series X Convertible Preferred Stock as of December 31, 2013. The Series A Redeemable Convertible Preferred Stock, the Series B Redeemable Convertible Preferred Stock and the Series C Redeemable Convertible Preferred Stock are collectively referred to as the Redeemable Convertible Preferred Stock.

Upon the closing of the IPO on March 25, 2014, all of the outstanding shares of the Company's redeemable convertible preferred stock were converted into 12,115,183 shares of its common stock. As of September 30, 2014, the Company does not have any redeemable convertible preferred stock issued or outstanding.

Reserved for Future Issuance

As of September 30, 2014 and December 31, 2013 based on the authorized shares for each series, the Company has reserved the following shares of common stock for future issuance:

	September 30, 2014	December 31, 2013
Conversion of Series A Redeemable Convertible Preferred Stock	—	3,672,673
Conversion of Series B Redeemable Convertible Preferred Stock	—	2,253,157
Conversion of Series C Redeemable Convertible Preferred Stock	—	6,296,451
Options to purchase common stock	1,596,538	1,251,398
Shares available for future issuance	1,555,254	155,108
Total	3,151,792	13,628,787

8. 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, 2014 and 2013. 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.

9. 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 has 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. The Company did not have rent expense associated with this lease in 2013.

The Company leases office equipment under a three year capital lease with payments commencing in February 2014.

At September 30, 2014, the Company's future minimum payments required under these leases are as follows:

	Operating Lease	Capital Lease	Total
2014	$94,009	$1,050	$95,059
2015	382,872	4,200	387,072
2016	389,709	4,200	$393,909
2017	—	350	350
Total	$866,590	9,800	$876,390
Less amount representing interest		(467)	
Present value of minimum lease payments at September 30, 2014		$9,333	

The Company contracts with various organizations to conduct research and development activities with remaining contract costs to the Company of approximately $6,628,384 and $4,477,081 at September 30, 2014 and December 31, 2013, 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.

10. Stock-Based Compensation

On February 28, 2014, the Company's Board of Directors adopted its 2014 Incentive Plan (2014 Plan), which was 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, stock units, 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 1,980,890 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. As of September 30, 2014, the total number of common shares that may be issued under all equity award plans is 3,151,792 and approximately 1,555,254 shares remain available for future grants.

During the first nine months of 2014, the Company granted 398,189 stock options to employees, 77,525 stock options to a director and 56,000 shares of restricted stock to a former employee.

Stock Options

The options granted to directors and non-employees vest over periods of between 12 and 48 months. For employees with less than one year's worth of service, options vest in installments of (i) 25% at the one year anniversary and (ii) in either 36 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 granted to other employees vest in 48 equal monthly installments 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 awards of restricted stock contain 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,

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 IPO on March 25, 2014.

Compensation Expense Summary

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	$582,900	$24,222	$2,489,049	$63,684
General and administrative	651,856	306,037	2,634,515	374,368
Total	$1,234,756	$330,259	$5,123,564	$438,052

Compensation expense by type of award:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Stock options	$554,031	$17,542	$1,329,715	$38,167
Restricted stock	680,725	312,717	3,793,849	399,885
Total	$1,234,756	$330,259	$5,123,564	$438,052

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.

11. Employee Retirement Plan

During 2008, the Company established a retirement plan (the Plan) authorized by Section 401(k) of the Internal Revenue Code. In accordance with the Plan, all employees who have attained the age of 21 are eligible to participate in the Plan as of the first Entry Date, as defined, following their date of employment. Each employee can contribute a percentage of compensation up to a maximum of the statutory limits per year. Company contributions are discretionary, and no contributions were made during the nine months ended September 30, 2014 or 2013.

12. 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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Numerator:				
Net loss	$(9,348,391)	$(3,767,890)	$(26,663,829)	$(7,219,236)
Accretion on preferred stock	—	(2,748,232)	(86,899,555)	(52,861,367)
Net loss applicable to common stockholders	$(9,348,391)	$(6,516,122)	$(113,563,384)	$(60,080,603)
Denominator:				
Weighted-average number of common shares – basic and diluted	19,691,167	546,714	13,920,651	509,425
Net loss per share applicable to common stockholders – basic and diluted	$(0.47)	$(11.92)	$(8.16)	$(117.94)

The amounts 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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Preferred stock	—	11,882,768	—	11,882,768
Outstanding stock options	1,596,538	1,229,594	1,596,538	1,229,594
Unvested restricted stock	563,810	110,521	563,810	110,521
Total	2,160,348	13,222,883	2,160,348	13,222,883

13. Accumulated Other Comprehensive Loss

The following table summarizes the changes in the accumulated balances for each component of accumulated other comprehensive loss, net of tax:

	Unrealized Loss on Investments	Total
Balance at December 31, 2013	$ —	$—
Other comprehensive loss before reclassifications	(51,257)	(51,257)
Net current-period other comprehensive loss	(51,257)	(51,257)
Balance at September 30, 2014	$ (51,257)	$(51,257)

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 audited financial information and the notes thereto included in the prospectus that was filed with the SEC on March 21, 2014.

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 (the 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.

Overview

We are 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, or RBCs, in the body and potentially a novel mechanism of treating anemia. Our lead product candidate, AKB-6548, is being developed as a once-daily, oral therapy that has successfully completed a Phase 2b study demonstrating that AKB-6548 can safely and predictably raise hemoglobin levels in non-dialysis patients with anemia related to chronic kidney disease, or CKD.

On October 27, 2014, we announced positive top-line results from our Phase 2b study of AKB-6548 in non-dialysis patients with anemia related to CKD, and we expect complete efficacy and safety data to be presented in the first half of 2015. We expect to initiate Phase 3 studies for anemia secondary to CKD in 2015 and would anticipate submitting an NDA for AKB-6548 in the United States by 2018, if the Phase 3 data are favorable. We have also initiated Phase 2 clinical development for AKB-6548 for the treatment of anemia in patients undergoing dialysis, the second indication we will pursue. The results from that study are expected in the third quarter of 2015. We will also enter into discussions with European regulatory authorities in the first quarter of 2015, with the goal of potentially also submitting European marketing application(s). Also in the third quarter of 2014, we completed a thorough QT (TQT) study, demonstrating that AKB-6548 does not have an adverse effect on cardiac repolarization or conduction (i.e., negative TQT study).

Our preclinical candidate, AKB-6899, is a small molecule with minor structural differences from our lead compound AKB-6548. However, AKB-6899 has distinctive biochemical and physiological properties that may be beneficial for

treatment of certain cancers. 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 filing an IND and having it approved by the U.S. Food and Drug Administration (FDA) in 2015.

We own global rights to our HIF-based product candidates, including AKB-6548. If approved by regulatory authorities, we plan to commercialize AKB-6548 in the United States ourselves and intend to seek one or more collaborators to commercialize the product candidate in additional markets.

Since our inception in 2007, we have devoted the largest portion of our resources to our development efforts relating to AKB-6548, including preparing for and conducting clinical studies of AKB-6548, 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 and the private placement of preferred stock, common stock and convertible notes.

In December 2011, we distributed our programs focused on the treatment of diabetic eye disease and inflammatory bowel disease into Aerpio, which has since operated as a stand-alone company. We currently have administrative services agreements with Aerpio under which we obtain from, and provide to, Aerpio certain services including consulting services and use of premises.

We have never been profitable and have incurred net losses in each year since inception. Our net losses were $26.7 million and $7.2 million for the nine months ended September 30, 2014 and 2013, 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 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:

- continue our clinical development for AKB-6548 for the treatment of anemia in patients undergoing dialysis;
- prepare for a potential global Phase 3 development program of AKB-6548 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 for 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 clinical 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 $104,364,560, net of underwriting discounts and commissions and estimated offering expenses. Upon the closing of the IPO, 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.

Financial Operations 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 rate of progress of, results of and cost of completing our Phase 2 clinical development for AKB-6548 for the treatment of anemia in patients undergoing dialysis;
- assuming AKB-6548 advances to Phase 3, the scope, size, rate of progress, results and costs of initiating and completing our Phase 3 development program of AKB-6548;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical studies for AKB-6899 and any other product candidates that we may develop or acquire;
- the cost of having our product candidates manufactured for clinical trials;
- difficulties or delays in enrolling patients in our clinical trials;
- unanticipated changes to laws or regulations applicable to our clinical trials; and
- the timing of, and the costs involved in, obtaining regulatory approvals for AKB-6548 and any other product candidates, if clinical trials are successful.

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 beyond 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, 2014, we have incurred $70.1 million in research and development expenses. We plan to increase our research and development expenses for the foreseeable future as we continue the development

of AKB-6548 and AKB-6899. Our current and planned research and development activities include the following:

- We have completed a Phase 2b study during 2014 to examine the safety and efficacy of AKB-6548 in non-dialysis patients with anemia related to CKD, and we will prepare the data for presentation in 2015 at a scientific meeting.
- We plan to initiate a Phase 3 development program for AKB-6548 in 2015 for anemia secondary to CKD in patients not on dialysis.

- We have begun Phase 2 clinical development for AKB-6548 for the treatment of anemia in patients undergoing dialysis, the second indication we will pursue. The results from that study are expected in the third quarter of 2015.
- We intend to conduct a Phase 2 clinical study of AKB-6548 in idiopathic anemia of aging, or IAA.
- We intend to file an IND and begin Phase 1 studies for AKB-6899.

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 to broadly 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

We obtain from, and provide to, Aerpio services under the terms of administrative services agreements between the two companies. See “Certain Relationships and Related Party Transactions.” General and administrative expenses consist primarily of salaries and related costs for personnel, including stock-based compensation and travel expenses for our employees in executive, operational, finance and human resource functions. Other general and administrative expenses include facility-related costs, fees for directors, accounting and legal services, recruiting fees and expenses associated with obtaining and maintaining patents.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance premiums, and investor relations 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 financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these 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 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 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 financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our 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 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 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. Following 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 a very early stage of product development 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 financial statements is based on awards that are ultimately expected to vest.

In September 2011, certain of our employees purchased shares of our restricted stock in exchange for promissory notes. Although these notes are 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 totaled approximately $1.2 million and $330,000 for the three months ended September 30, 2014 and 2013, respectively, and approximately $5.1 million and $438,000 for the nine months ended September 30, 2014 and 2013, 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, 2014 and 2013

	Three Months Ended September 30,		Increase (Decrease)
	2014	2013	
	(In Thousands)		
Expenses:			
Research and development	$6,648	$3,240	$ 3,408
General and administrative	2,936	794	2,142
Total expenses	9,584	4,034	5,550
Loss from operations	(9,584)	(4,034)	5,550
Other income, net	236	266	(30)
Net loss	$(9,348)	$(3,768)	$ (5,580)

Research and Development Expenses. Research and development expenses were $6.6 million for the three months ended September 30, 2014, compared to $3.2 million for the three months ended September 30, 2013, an increase of $3.4 million. The increase was primarily due to an increase in costs related to AKB-6548, including, costs of approximately $1.2 million related to Phase 2 clinical development of AKB-6548, $0.5 million for the manufacture of drug substance and drug product and $0.4 million in other clinical costs. Research and development expenses were further increased by $0.1 million of patent costs, $0.4 million of stock compensation costs, $0.5 million of wage and personnel-related costs due to increased headcount, as well as $0.3 million of drug development costs for AKB-6899.

General and Administrative Expenses. General and administrative expenses were $2.9 million for the three months ended September 30, 2014, compared to $0.8 million for the three months ended September 30, 2013. The increase of $2.1 million was primarily due to the following expense increases: $0.5 million of stock-based compensation, $0.2 million of professional fees, $0.5 million of wage and personnel-related costs due to increased headcount, $0.2 million of insurance related costs, $0.1 million of facility costs and an increase of approximately $0.3 million in commercial planning costs.

Other Income, Net. Other income, net, was $0.2 million for the three months ended September 30, 2014, compared to $0.3 million for the three months ended September 30, 2013. Other income, net for both the three months ended September 30, 2014 and the three months ended September 30, 2013, 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, 2014 and 2013

	Nine Months Ended September 30,		Increase (Decrease)
	2014	2013	
	(In Thousands)		
Expenses:			
Research and development	$18,330	$7,591	$ 10,739
General and administrative	9,003	2,141	6,862
Total expenses	27,333	9,732	17,601
Loss from operations	(27,333)	(9,732)	17,601
Other income, net	669	2,513	(1,844)
Net loss	$(26,664)	$(7,219)	$ (19,445)

Research and Development Expenses. Research and development expenses were $18.3 million for the nine months ended September 30, 2014, compared to $7.6 million for the nine months ended September 30, 2013, an increase of $10.7 million. The increase was primarily due to an increase in costs related to AKB-6548, including, Phase 2b study costs of approximately $1.6 million due to ongoing enrollment through April 2014, $1.6 million related to Phase 2 clinical development of AKB-6548 and $2.7 million related to a thorough QT (TQT) study and other clinical and non-clinical costs as well as costs for manufacturing drug substance and drug product. Research and development expenses were further increased by $0.7 million of patent costs, $1.2 million of wage and personnel-related costs due to increased headcount, $2.3 million of stock-based compensation costs and approximately $0.3 million of drug development costs for AKB-6899.

General and Administrative Expenses. General and administrative expenses were $9.0 million for the nine months ended September 30, 2014, compared to $2.1 million for the nine months ended September 30, 2013. The increase of $6.9 million was primarily due to the following expense increases: $2.4 million of stock-based compensation expense, $0.7 million of professional fees related to the IPO, $1.2 million of wage and personnel-related costs due to increased headcount, $0.4 million of consulting-related costs, $0.4 million of insurance costs, $0.3 million of facility costs, $0.4 million of commercial planning costs, $0.4 million of severance related costs and $0.3 million in other costs including recruiting fees and public company-related fees.

Other Income, Net. Other income, net, was $0.7 million for the nine months ended September 30, 2014, compared to $2.5 million for the nine months ended September 30, 2013, a decrease of approximately $1.8 million. Other income, net for the nine months ended September 30, 2014, is primarily related to reimbursements from Aerpio for employee-related costs of approximately $0.5 million and interest income of approximately $0.1 million. Other income, net for the nine months ended September 30, 2013 included $0.8 million in reimbursements from Aerpio for employee-related costs and a $2.4 million gain on the extinguishment of debt, partially offset by net interest expense of $0.8 million. The decrease in reimbursements from Aerpio for employee-related costs is principally the result of reduced time spent by our employees on Aerpio related activities. 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, 2014, we had an accumulated deficit of $90.3 million. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

We have funded our operations principally from the sale of common stock, preferred stock and convertible notes. As of September 30, 2014, we had cash and cash equivalents of approximately $49.7 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 of $68.6 million, 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,	
	2014	2013
	(In Thousands)	
Net cash provided by (used in):		
Operating activities	$(18,280)	$(6,424)
Investing activities	(57,715)	(13,160)
Financing activities	104,448	42,546
Net increase in cash and cash equivalents	$28,453	$22,962

Operating Activities. 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 expenses 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 primarily driven by clinical, non-clinical and TQT study costs associated with AKB-6548 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.

The net cash used in operating activities was $6.4 million for the nine months ended September 30, 2013, and consisted primarily of a net loss of $7.2 million adjusted for non-cash items including gain on extinguishment of debt of $2.4 million, amortization of debt issue costs and premium/discount on available for sale securities of $0.8 million, and stock-based compensation of $0.4 million and a net increase in operating assets and liabilities of $2.0 million.

Investing Activities. 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. The net cash used in investing activities for the nine months ended September 30, 2013 consisted primarily of purchases of available for sale securities.

Financing Activities. 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. Net cash provided by financing activities for the nine months ended September 30, 2013 was $42.6 million and consisted primarily of $40.1 million of net proceeds from the issuance of Series C preferred stock and $2.5 million of net proceeds from the sale of shares of our Series X preferred 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.

We believe that the net proceeds from our IPO and our existing cash and cash equivalents will be sufficient to fund our projected operating requirements through the first half 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. Additional capital may not be available on reasonable terms, if 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:

- the rate of progress of, results of and cost of completing Phase 2 clinical development for AKB-6548 for the treatment of anemia in patients undergoing dialysis;
- other costs for additional clinical studies to support marketing approval;
- our operating costs incurred through our end of Phase 2 meeting with the FDA, and equivalent meetings with the EMA and other regulatory authorities;
- assuming AKB-6548 advances to Phase 3 clinical studies, the scope, size, rate of progress, results and costs of initiating and completing our Phase 3 development program of AKB-6548;
- assuming favorable Phase 3 clinical results, the cost, timing and outcome of our efforts to obtain marketing approval for AKB-6548 in the United States and in other jurisdictions, including to fund the preparation and filing of regulatory submissions for AKB-6548 with the FDA, the EMA and other regulatory authorities and the guidance provided by and decisions made by such regulatory authorities;
- the scope, progress, results and costs of preclinical development, laboratory testing and clinical studies for AKB-6899 and any 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, and the outcome of regulatory review of AKB-6899;
- 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 in preparation for regulatory approval and in preparation for commercialization;
- 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, prosecuting patent applications, maintaining, defending and enforcing our intellectual property rights, including litigation costs, and the outcome of such litigation and decisions by the United States Patent and Trademark Office, or US PTO, and patent offices of other countries;
- the efforts and activities of competitors and potential competitors;
- the costs associated with legal compliance, including addressing changes in policies and laws adopted by the U.S. and governmental authorities of other countries;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the need to implement additional infrastructure and internal systems; and
- the extent to which we acquire or in-license other products or technologies.

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 prospectus that was filed with the SEC on March 21, 2014

Off-Balance Sheet Arrangements

As of September 30, 2014 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, 2014 and December 31, 2013, we had cash and cash equivalents and investments of $118.3 million and $32.6 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, 2014, 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, 2014, 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, 2014, 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.

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Part II. Other

Item 1. Legal Proceedings

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 AKB-6548, 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 number of years. 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.

In June 2013, the European Patent Office granted European Patent No. 1463823, or the ’823 patent, to FibroGen, Inc., or 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. 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 Japanese Patent No. 4804131, or 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 it be revoked in its entirety. While, for the reasons set forth in our Request For Trial 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.

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 $26.7 million for the nine months ended September 30, 2014, and $7.2 million for the nine months ended September 30, 2013. As of September 30, 2014, we had an accumulated deficit of $90.3 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 IPO 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, AKB-6548, has recently completed a Phase 2b study, and our other product candidate 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 AKB-6548, our future revenue will depend upon the size of any markets in which AKB-6548 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 increasing operating losses for the foreseeable future. We anticipate that our expenses will increase significantly if and as we:

- continue our Phase 2 clinical development of AKB-6548 for the treatment of anemia in patients undergoing dialysis and prepare for a Phase 3 development program of AKB-6548 for the treatment of anemia secondary to CKD in patients not on dialysis;
- 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;