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.

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

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			