

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

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2015

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 001-36352

AKEBIA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

20-8756903
(I.R.S. Employer
Identification No.)

245 First Street, Suite 1100, Cambridge, MA
(Address of Principal Executive Offices)

02142
(Zip Code)

(617) 871-2098

(Registrant's Telephone Number, Including Area Code)

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether 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 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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at November 5, 2015
Common Stock, \$0.00001 par value	30,631,737

NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the projected timing of (1) commencement of a Phase 3 development program of vadadustat (formerly AKB-6548) in non-dialysis patients with anemia related to chronic kidney disease (CKD), (2) commencement of a Phase 3 development program in dialysis patients with anemia related to CKD, (3) submission of an NDA for vadadustat, (4) filing an Investigational New Drug application with the U.S. Food and Drug Administration for AKB-6899 and (5) completion of preclinical proof-of-concept studies of AKB-6899 in ophthalmology;
- our development plans with respect to vadadustat and AKB-6899;
- the timing or likelihood of regulatory filings and approvals, including any required post-marketing testing or any labeling and other restrictions;
- our plans to commercialize vadadustat, if it is approved;
- the implementation of our business model and strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our competitive position;
- our intellectual property position;
- developments and projections relating to our competitors and our industry;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
 - other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

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

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

NOTE REGARDING STOCK SPLIT

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

Akebia Therapeutics, Inc.

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PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands, except share and per share data)

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

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

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except share and per share data)

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

See accompanying notes to unaudited condensed consolidated financial statements.

AKEBIA THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(in thousands)

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

See accompanying notes to unaudited condensed consolidated financial statements

Akebia Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements

(Unaudited)

September 30, 2015

1. Nature of Organization and Operations

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

The Company's operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing its technology, identifying potential product candidates and undertaking preclinical and clinical studies. The Company has not generated any product revenue to date, nor is there any assurance of any future product revenue. The Company's product candidates are subject to long development cycles and there is no assurance the Company will be able to successfully develop, obtain regulatory approval for or market its product candidates.

The Company is subject to a number of risks including, but not limited to, the need to obtain adequate additional funding, possible failure of preclinical testing or clinical trials, the need to obtain marketing approval for its product candidates, the development of new technological innovations by competitors, the need to successfully commercialize and gain market acceptance of any of the Company's products that are approved and the ability to protect its proprietary technology. If the Company does not successfully commercialize any of its products, it will be unable to generate product revenue or achieve profitability.

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

In April 2015, the Company completed a follow-on public offering whereby the Company sold 8,363,636 shares of common stock, including 1,090,909 share of common stock pursuant to the full exercise of an over-allotment granted to the underwriters in connection with the offering, at a price of \$8.25 per share. The aggregate net proceeds received by the Company from the offering were approximately \$64.6 million, net of underwriting discounts and commissions and estimated offering expenses payable by the Company.

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

The Company believes that it can continue as a going concern as its cash resources of approximately \$157.5 million at September 30, 2015 will be sufficient to allow the Company to fund its current operating plan through at least the next twelve months. There can be no assurance, however, that the current operating plan will be achieved in the timeframe anticipated by the Company, or that its cash resources will fund the Company's operating plan for the period anticipated by the Company or that additional funding will be available on terms acceptable to the Company, or at all.

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

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

2. Summary of Significant Accounting Policies

Conversion of Redeemable Preferred Stock

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

Basis of Presentation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Akebia Therapeutics Securities Corporation and Akebia Europe Limited. All intercompany balances and transactions have been eliminated in consolidation. These condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

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

Recent Accounting Pronouncements

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

Segment Information

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these condensed consolidated financial statements. Management must apply significant judgment in this process. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to

be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes, and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: percent complete for clinical accruals, stock-based compensation expense, fair value of common stock and preferred stock and the Company's other equity instruments (in periods prior to the IPO), accrued expenses, prepaid expenses and income taxes.

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

Cash and Cash Equivalents

Cash and cash equivalents consist of all cash on hand, deposits and funds invested in available for sale securities with original maturities of three months or less at the time of purchase. At September 30, 2015, the Company's cash is primarily in money market funds. The Company may maintain balances with its banks in excess of federally insured limits.

Investments

Management determines the appropriate classification of securities at the time of purchase and reevaluates such designation as of each balance sheet date. Currently, the Company classifies all securities as available-for-sale which are included in current assets as they are intended to fund current operations. The Company carries available-for-sale securities at fair value. The Company conducts periodic reviews to identify and evaluate each investment that has an unrealized loss, in accordance with the meaning of other-than-temporary impairment and its application to certain investments. When assessing whether a decline in the fair value of a security is other-than-temporary, the Company considers the fair market value of the security, the duration of the security's decline, and prospects for the underlying business. Based on these considerations, the Company did not identify any other-than-temporary unrealized losses at September 30, 2015. Unrealized losses on available-for-sale securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive loss, a component of stockholders' equity. The amortized cost of debt securities in this category reflects amortization of premiums and accretion of discounts to maturity computed under the effective interest method. The Company includes this amortization in the caption "Interest income (expense), net" within the Condensed Consolidated Statements of Operations and Comprehensive Loss. We also include in net investment income, realized gains and losses and declines in value determined to be other than temporary. The Company bases the cost of securities sold upon the specific identification method, and includes interest and dividends on securities in interest income.

Research and Development

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

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

Patents

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

Income Taxes

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

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. As of September 30, 2015 and December 31, 2014, the Company does not have any significant uncertain tax positions. The Company recognizes interest and penalties related to uncertain tax positions in income tax expense.

Stock-Based Compensation

The Company accounts for its stock-based compensation awards in accordance with FASB ASC Topic 718, Compensation—Stock Compensation (ASC 718). ASC 718 requires all stock-based payments to employees, including grants of employee stock options,

restricted stock, restricted stock units, or RSUs, and modifications to existing stock awards, to be recognized in the statements of operations and comprehensive loss based on their fair values. The Company accounts for stock-based awards to non-employees in accordance with FASB ASC Topic 505-50, Equity-Based Payments to Non-Employees (ASC 505-50), which requires the fair value of the award to be re-measured at fair value until a performance commitment is reached or counterparty performance is complete. The Company's stock-based awards are comprised of stock options, shares of restricted stock and shares of common stock. The Company estimates the fair value of options granted using the Black-Scholes option pricing model. The Company uses the value of its common stock to determine the fair value of restricted stock awards and common stock awards.

The Black-Scholes option pricing model requires the input of certain subjective assumptions, including (a) the expected stock price volatility, (b) the calculation of expected term of the award, (c) the risk-free interest rate and (d) expected dividends. Due to the lack of a public market for the trading of the Company's common stock and a lack of company-specific historical and implied volatility data, the Company has based its estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. The historical volatility is calculated based on a period of time commensurate with the expected term assumption. The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The Company is in the product development stage with no revenue and the representative group of companies has certain similar characteristics to the Company. The Company believes the group selected has sufficient similar economic and industry characteristics, and includes companies that are most representative of the Company. The Company uses the simplified method as prescribed by the SEC Staff Accounting Bulletin No. 107, Share-Based Payment, to calculate the expected term for options granted to employees as it does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. The expected term is applied to the stock option grant group as a whole, as the Company does not expect substantially different exercise or post-vesting termination behavior among its employee population. For options granted to non-employees, the Company utilizes the contractual term of the arrangement as the basis for the expected term assumption. The risk-free interest rate is based on a treasury instrument whose term is consistent with the expected life of the stock options. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock, which is similar to the Company's peer group.

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

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

Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. FASB ASC Topic 820, Fair Value Measurements and Disclosures (ASC 820), establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available.

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

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

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

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

Items measured at fair value on a recurring basis include short-term investments (see Note 5). The carrying amounts of accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to their short-term maturities. The rate implicit within the Company’s capital lease obligation approximates market interest rates.

Concentrations of Credit Risk and Off-Balance Sheet Risk

Cash, investments and accounts receivable are the only financial instruments that potentially subject the Company to concentrations of credit risk. At September 30, 2015 and December 31, 2014, all of the Company’s cash was deposited in accounts at two principal financial institutions. The Company maintains its cash with high quality, accredited financial institutions and, accordingly, such funds are subject to minimal credit risk. The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Net Loss per Share

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the diluted net loss per share calculation, preferred stock, stock options, unvested restricted stock and RSUs are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

Property and Equipment

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

The following is the summary of property and equipment and related accumulated depreciation as of September 30, 2015 and December 31, 2014.

Useful Life

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

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

3. Available for sale securities

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

	Gross Unrealized Amortized (in thousands)	Cost	Gross Unrealized Losses	Fair Value
September 30, 2015				
Cash and cash equivalents:				
Cash and money market account	\$			