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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:		