

Akebia Therapeutics, Inc.
Form 10-Q
May 12, 2014
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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 March 31, 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)

Massachusetts
(State or Other Jurisdiction of

20-8756903
(I.R.S. Employer

Incorporation or Organization)

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 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 April 30, 2014

Common Stock, \$0.00001 par value

20,262,293

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NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that 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, 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 timing of data from our pending Phase 2b trial of AKB-6548, the timing of commencement of our Phase 3 development program of AKB-6548 and the timing of our submission of an NDA for AKB-6548;

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 grown 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.

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Table of Contents**PART I FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS.****AKEBIA THERAPEUTICS, INC.****(A Development Stage Company)****Balance Sheets****(unaudited)**

	March 31, 2014	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	\$ 126,319,457	\$ 21,215,228
Investments	5,831,843	11,341,241
Accounts receivable	119,395	135,339
Prepaid expenses and other current assets	1,468,165	739,235
Total current assets	133,738,860	33,431,043
Equipment, net	164,204	30,366
Deferred offering costs		1,078,138
Other assets	125,345	125,345
Total assets	\$ 134,028,409	\$ 34,664,892
Liabilities, redeemable convertible preferred stock and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	\$ 2,077,302	\$ 714,137
Accrued expenses	4,042,007	3,183,761
Current portion of capital lease obligation	3,911	3,912
Total current liabilities	6,123,220	3,901,810
Capital lease obligation, net of current portion	7,364	8,004
Other liabilities	30,434	
Total liabilities	\$ 6,161,018	\$ 3,909,814
Redeemable convertible preferred stock; \$0.00001 par value; 0 and 5,500,636 shares authorized at March 31, 2014 and December 31, 2013, respectively:		
Series A redeemable convertible preferred stock; 0 and 734,538 shares issued and outstanding at March 31, 2014 and December 31, 2013; (Aggregate liquidation preference of \$39,367,094 at December 31, 2013)		39,367,094

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Series B redeemable convertible preferred stock; 0 and 1,287,525 shares issued and outstanding at March 31, 2014 and December 31, 2013; (Aggregate liquidation preference of \$21,031,365 at December 31, 2013)		21,257,044
Series C redeemable convertible preferred stock; 0 and 3,302,885 shares issued and outstanding at March 31, 2014 and December 31, 2013; (Aggregate liquidation preference of \$97,202,997 at December 31, 2013)		97,202,997
Total redeemable convertible preferred stock		157,827,135
Stockholders' equity (deficit):		
Common stock; \$0.00001 par value; 175,000,000 and 14,700,000 authorized at March 31, 2014 and December 31, 2013, respectively; 20,262,693 and 1,383,345 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively	202	14
Additional paid-in capital	201,203,384	
Deficit accumulated during the development stage	(73,336,195)	(127,072,071)
Total stockholders' equity (deficit)	127,867,391	(127,072,057)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 134,028,409	\$ 34,664,892

See accompanying notes to unaudited financial statements.

Table of Contents**AKEBIA THERAPEUTICS, INC.****Statements of Operations and Comprehensive Loss****(A Development Stage Company)****(Unaudited)**

	Three months ended		February 27, 2007
	March 31,	March 31, 2013	(inception) through
	2014		March 2014
	\$	\$	\$
Revenue			
Operating expenses:			
Research and development	6,157,928	1,897,795	57,905,773
General and administrative	3,751,319	678,923	19,020,256
Total operating expenses	9,909,247	2,576,718	76,926,029
Operating loss	(9,909,247)	(2,576,718)	(76,926,029)
Other income (expense):			
Grant income			1,481,408
Interest income (expense), net	19,025	(754,114)	(4,897,573)
Extinguishment of debt and other liabilities		2,419,766	3,735,499
Reimbursements from Aerpio	193,112	290,152	3,214,203
Gain on cancellation of preferred stock future tranche rights			653,465
Net loss and comprehensive loss	\$ (9,697,110)	\$ (620,914)	\$ (72,739,027)
Reconciliation of net loss to net loss applicable to common stockholders:			
Net loss	\$ (9,697,110)	\$ (620,914)	\$ (72,739,027)
Accretion on preferred stock	(86,899,555)	(848,125)	(153,637,754)
Loss on extinguishment of preferred stock			(597,174)
Net loss applicable to common stockholders	\$ (96,596,665)	\$ (1,469,039)	\$ (226,973,955)
Net loss per share applicable to common stockholders basic and diluted	\$ (43.37)	\$ (3.09)	\$ (669.68)
Weighted-average number of common shares used in net loss per share applicable to common stockholders basic and diluted	2,227,058	475,915	338,930

See accompanying notes to unaudited financial statements.

Table of Contents**AKEBIA THERAPEUTICS, INC.****(A Development Stage Company)****Statements of Cash Flows****(Unaudited)**

	Three months ended		February 27,
	March 31,	March 31,	2007
	2014	2013	(inception)
			through
			March 31,
			2014
Operating activities:			
Net loss	\$ (9,697,110)	\$ (620,914)	\$ (72,739,027)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on extinguishment of debt and other liabilities		(2,419,766)	(3,735,499)
Depreciation expense	8,118		99,539
Amortization of debt issuance costs		751,880	81,248
Amortization of debt discount and interest expense			5,159,034
Gain on cancellation of preferred stock future tranche rights			(653,465)
Issuance of 2007 Series X preferred stock for licensing agreement			31,800
Stock-based compensation expense	2,444,864	56,392	4,754,116
Changes in operating assets and liabilities:			
Accounts receivable	15,944	(13,828)	(119,395)
Prepaid expenses and other current assets	(719,534)	264,212	(1,429,607)
Other assets			(125,345)
Accounts payable and accrued expenses	1,909,614	452,445	5,526,503
Deferred rent	30,434		30,434
Net cash used in operating activities	(6,007,670)	(1,529,579)	(63,119,664)
Investing activities:			
Purchases of property and equipment	(141,956)		(414,747)
Proceeds from maturities of short-term investments	5,500,000		18,677,943
Proceeds from sale of short-term investments			800,234
Purchases of short-term investments			(25,383,162)
Net cash (used in) provided by investing activities	5,358,044		(6,319,732)
Financing activities:			

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Proceeds from issuance of preferred stock			83,033,938
Preferred stock issuance costs		(17,348)	(1,682,007)
Debt issuance costs			(76,857)
Initial public offering issuance costs	(9,199,504)		(9,420,672)
Proceeds from issuance of 2012 Series X preferred stock		2,500,007	5,000,001
Proceeds from issuance of common stock	114,954,000		114,959,376
Proceeds from issuance of convertible debt			3,945,715
Payments on capital lease obligations	(641)		(641)
Net cash provided by financing activities	105,753,855	2,482,659	195,758,853
Increase (decrease) in cash and cash equivalents	105,104,229	953,080	126,319,457
Cash and cash equivalents at beginning of period	21,215,228	1,641,038	
Cash and cash equivalents at end of period	\$ 126,319,457	\$ 2,594,118	\$ 126,319,457
Non-cash financing activities:			
Issuance of Series A preferred stock in settlement of convertible notes	\$	\$	\$ 5,383,000
Accretion of preferred stock to redemption value	\$	\$ 848,125	\$ 153,637,754
Reclassification of 2012 Series X preferred stock from debt to preferred stock	\$	\$	\$ 2,486,251
Conversion of 2012 Series X preferred stock into Series C preferred stock	\$	\$	\$ 4,944,155
Unpaid initial public offering issuance costs	\$ 1,168,768	\$	\$ 1,168,768
Assets acquired under capital lease	\$	\$	\$ 11,916
Loss on extinguishment of 2007 Series X preferred stock	\$	\$	\$ 597,174
Book value of assets transferred in distribution of subsidiary	\$	\$	\$ 193,114
Book value of liabilities transferred in distribution of subsidiary	\$	\$	\$ (575,964)
Exchange of convertible debt	\$	\$	\$ 304,054

See accompanying notes to unaudited financial statements.

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Akebia Therapeutics, Inc.

Notes to Financial Statements

(Unaudited)

March 31, 2014

1. Nature of Organization and Operations

Akebia Therapeutics, Inc. (Akebia, or the Company) is a biopharmaceutical company focused on the development of novel proprietary therapeutics based on hypoxia inducible factor (HIF) biology and the commercialization of these products for patients with kidney disease. HIF is the primary regulator of the production of red blood cells 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 2a proof of concept study demonstrating that AKB-6548 can safely and predictably raise hemoglobin levels in patients with anemia secondary to chronic kidney disease (CKD) not requiring dialysis. AKB-6548 is currently being studied in a Phase 2b trial in patients with anemia secondary to CKD, who are not dependent on dialysis, with data expected in the fourth quarter of 2014.

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. Accordingly, the Company is considered to be in the development stage as defined by U.S. generally accepted accounting principles (U.S. GAAP).

The Company is subject to a number of risks similar to other life science companies in the development stage, 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, competitors developing new technological innovations, the need to successfully commercialize and gain market acceptance of any of the Company's products that are approved and protection of proprietary technology. If the Company does not successfully commercialize any of its products, it will be unable to generate product revenue or achieve profitability. As of March 31, 2014, the Company had a deficit accumulated during the development stage of approximately \$73.3 million.

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.

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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