



August 11, 2014

Akebia Announces Second Quarter 2014 Financial Results

-Company Remains on Track to Report Phase 2b Data for AKB-6548 in Fourth Quarter-

-Strengthens Management Team and Board-

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Akebia Therapeutics, Inc. (NASDAQ:AKBA), 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, today announced financial results for the second quarter ended June 30, 2014.

"Over the past few months, we have advanced our efforts to deliver a novel, best-in-class therapy that harnesses the power of HIF biology for the treatment of anemia secondary to chronic kidney disease, a significant and growing patient population that remains severely under-treated," stated John P. Butler, President and Chief Executive Officer of Akebia. "We completed enrollment in the Phase 2b trial of AKB-6548, strengthened our board with two key additions, and expanded our management team to help drive growth and advance our programs. We look forward to reporting top-line clinical trial results from the Phase 2b study in the fourth quarter of this year."

Second Quarter and Recent Corporate Highlights

- In April, completed enrollment in the Phase 2b clinical study of AKB-6548 for the treatment of anemia associated with chronic kidney disease (CKD) in patients who are not dependent on dialysis
- Expanded the senior management team, adding Brad Maroni, M.D., as Senior Vice President and Chief Medical Officer, Mark De Rosch, Ph.D., as Vice President of Regulatory Affairs and Tamara Dillon as Vice President of Human Resources
- Strengthened the Board of Directors with the addition of Michael D. Clayman, M.D., Chief Executive Officer of Flexion Therapeutics, Inc., and Maxine Gowen, Ph.D., President and Chief Executive Officer of Trevena, Inc.
- Presented previously reported results from the Phase 2a study of AKB-6548 at the 2014 European Renal Association-European Dialysis and Transplant Association 51st Congress in Amsterdam

Second Quarter 2014 Financial Results

Akebia reported a net loss and a net loss applicable to common stockholders of \$7.6 million, or (\$0.39) per share, for the second quarter of 2014. Net loss applicable to common stockholders for the second quarter of 2013, which includes accretion on preferred stock of \$49.3 million, was \$52.1 million or (\$103.19) per share. In connection with the closing of the Company's initial public offering on March 25, 2014, all of the Company's outstanding shares of preferred stock were converted into shares of common stock.

Research and development expenses were \$5.5 million for the second quarter of 2014 compared to \$2.5 million for the second quarter of 2013. The increase of \$3.0 million in research and development expenses is primarily attributable to increased clinical trial and other costs related to AKB-6548, increased headcount related costs as well as increased stock-based compensation expense of \$1.0 million.

General and administrative expenses were \$2.3 million for the second quarter of 2014 compared to \$0.7 million for the second quarter of 2013. The increase of \$1.6 million in general and administrative expenses is primarily related to an increase in headcount and insurance related costs, increased professional fees as well as increased stock-based compensation expense of \$0.5 million.

The increased stock-based compensation expense in both research and development expenses and general and administrative expenses is primarily a result of an increase in the value of the Company's common stock due to the Company's initial public offering.

The Company's cash used in operations during the second quarter of 2014 was \$6.7 million, an increase of \$4.7 million from \$2.0 million for the same period of 2013. The Company ended the second quarter of 2014 with cash, cash equivalents and investments of \$124.2 million and expects its existing cash resources to support operations through the first half of 2016.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a biopharmaceutical company headquartered in Cambridge, Massachusetts, focused on harnessing the potential of hypoxia-inducible factor (HIF) biology to develop and commercialize novel, proprietary therapeutics to treat kidney disease. Akebia's lead clinical program, AKB-6548, is a once-daily, oral therapy currently in Phase 2b clinical development for the treatment of anemia related to chronic kidney disease, a serious medical condition that leads to increased morbidity and mortality if left untreated. For more information on Akebia, please visit www.akebia.com.

Forward-Looking Statements

This press release includes forward-looking statements. Such forward-looking statements include those about Akebia's strategy, future plans and prospects, including statements regarding the potential indications and benefits of AKB-6548, the expected timing of the announcement of data from the Phase 2b study, the growth of the chronic kidney disease patient population and the projected use of Akebia's existing cash resources. The words "anticipate," "appear," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the ability of Akebia to successfully complete the clinical development of AKB-6548 or any other product candidate; the funding required to develop Akebia's product candidates and operate the Company, and the actual expenses associated therewith; the content of decisions made by the FDA and other regulatory authorities; the actual time it takes to complete the Phase 2b study and analyze the data; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; the introduction or adoption of therapeutic interventions that slow the progression of chronic kidney disease; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for AKB-6548 or any other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, and other filings that Akebia may make with the Securities and Exchange Commission in the future. Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

AKEBIA THERAPEUTICS, INC. Condensed Statement of Operations (in thousands except share and per share data) (unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2014	June 30, 2013	June 30, 2014	June 30, 2013
Revenue	\$ —	\$ —	\$ —	\$ —
Operating expenses:				
Research and development	5,525	2,453	11,683	4,351
General and administrative	2,315	668	6,066	1,347
Total operating expenses	7,840	3,121	17,749	5,698
Operating loss	(7,840)	(3,121)	(17,749)	(5,698)
Other income (expense), net	222	291	434	2,247
Net loss and comprehensive loss	<u>\$ (7,618)</u>	<u>\$ (2,830)</u>	<u>\$ (17,315)</u>	<u>\$ (3,451)</u>

Reconciliation of net loss to net loss applicable to common stockholders:

Net loss	\$ (7,618)	\$ (2,830)	\$ (17,315)	\$ (3,451)
Accretion on preferred stock	—	(49,265)	(86,900)	(50,113)
Loss on extinguishment of preferred stock	—	—	—	—

Net loss applicable to common stockholders	\$ <u>(7,618)</u>	\$ <u>(52,095)</u>	\$ <u>(104,215)</u>	\$ <u>(53,564)</u>
Net loss per share applicable to common stockholders— basic and diluted	\$ <u>(0.39)</u>	\$ <u>(103.19)</u>	\$ <u>(9.48)</u>	\$ <u>(109.21)</u>
Weighted-average number of common shares used in net loss per share applicable to common stockholders'—basic and diluted	<u>19,652,056</u>	<u>504,868</u>	<u>10,987,692</u>	<u>490,472</u>

AKEBIA THERAPEUTICS, INC.
Selected Balance Sheet Data
(in thousands)
(unaudited)

	<u>June 30, 2014</u>	<u>December 31, 2013</u>
Cash, cash equivalents and short-term investments	\$ 124,246	\$ 32,556
Working capital	121,281	29,529
Total assets	126,358	34,665
Total stockholders' equity (deficit)	121,552	(127,072)

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