March 4, 2015

Akebia Announces Fourth Quarter and Full-Year 2014 Financial Results

-Company Remains on Track to Launch Phase 3 Program for AKB-6548 in 2015-

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Akebia Therapeutics, Inc. (NASDAQ:AKBA), a biopharmaceutical company focused on delivering innovative therapies to patients with kidney disease through the biology of hypoxia inducible factor (HIF), today announced financial results for the fourth quarter and full year ended December 31, 2014.

"2014 was a transformative year for Akebia, beginning with the completion of our initial public offering in March, followed by the expansion of our leadership team and Board of Directors and, most importantly, the advancement of our clinical development programs for AKB-6548 in renal-anemia, bringing this potential therapy one step closer to patients," stated John P. Butler, President and Chief Executive Officer of Akebia. "In the fourth quarter, we reported positive top-line results from our Phase 2b clinical study in non-dialysis patients with anemia related to chronic kidney disease (CKD), confirming that our once-daily, oral therapy has the potential to safely and predictably increase and maintain hemoglobin levels in this very ill patient population. We look forward to presenting the study results at the World Congress of Nephrology in mid-March, and remain on track to launch our Phase 3 program in the non-dialysis setting this year. We have also reported significant progress with our Phase 2 study in CKD patients undergoing dialysis, with faster-than-expected enrollment in our first two cohorts. This speaks to investigator and patient interest in this new potential therapeutic option. We expect to report data from this study in the third quarter, consistent with our original timeline."

2014 Corporate Highlights

- Announced positive top-line results from its Phase 2b study of AKB-6548 in non-dialysis patients with anemia related to CKD
- Completed enrollment ahead of schedule in the original two cohorts of its Phase 2 study of AKB-6548 in patients with anemia related to CKD who are undergoing dialysis, and added an additional cohort designed to evaluate the safety, efficacy and tolerability of AKB-6548 dosed three times per week, administered in conjunction with a patient's hemodialysis schedule
- Presented data from the AKB-6548 development program at the American Society of Nephrology 2014 Annual Meeting and the 2014 European Renal Association-European Dialysis and Transplant Association (ERA-EDTA) 51st Congress
- Strengthened corporate leadership with the addition of 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
- Added Ronald C. Renaud Jr., Michael Clayman, M.D., Maxine Gowen, Ph.D., and Michael Wyzga to the Board of Directors
- Completed an initial public offering and fully exercised underwriters' option to purchase additional shares with net proceeds of the offering totaling $104.4 million

Financial Results

Akebia reported a net loss and a net loss applicable to common stockholders of $10.4 million, or ($0.52) per share, for the fourth quarter of 2014. Net loss applicable to common stockholders for the fourth quarter of 2013, which includes accretion on preferred stock of $3.0 million, was $9.0 million or ($13.92) per share.

Akebia reported a net loss applicable to common stockholders for the full year of 2014 of $123.9 million, or ($8.04) per share, which includes accretion on preferred stock of $86.9 million. Net loss applicable to common stockholders for the full year of 2013, which includes accretion on preferred stock of $55.9 million, was $69.1 million or ($126.94) 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 and accordingly the accretion on the preferred stock ceased as of such date.

Research and development expenses were $7.1 million for the fourth quarter of 2014 compared to $3.2 million for the fourth

quarter of 2013. Research and development expenses were $25.4 million for the full year of 2014 compared to $10.8 million for the full year of 2013. The increase in both periods is primarily attributable to costs related to AKB-6548 including Phase 2b study costs due to the ongoing enrollment through April 2014, the initiation and conduct of Phase 2 clinical development for the treatment of anemia in patients undergoing dialysis, Phase 3 program costs and manufacturing costs.

Research and development expenses in both periods were further increased by stock-based compensation, wage and personnel-related costs due to increased headcount and drug development costs for AKB-6899.

General and administrative expenses were $3.5 million for the fourth quarter of 2014 compared to $3.0 million for the fourth quarter of 2013. General and administrative expenses were $12.5 million for the full year of 2014 compared to $5.2 million for the full year of 2013. The increase in general and administrative expenses for both periods is primarily related to increased headcount, professional fees, facility related costs and commercial planning costs, as well as increased stock-based compensation expense.

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 and the expense associated with both the restricted stock grants made in December 2013 and grants made to employees hired during 2014.

The Company's cash used in operations during the fourth quarter of 2014 was $9.2 million, an increase of $4.3 million from $4.9 million for the same period of 2013. The Company's cash used in operations during the full year of 2014 was $27.5 million, an increase of $16.2 million from $11.3 million for the same period of 2013. The Company ended 2014 with cash, cash equivalents and available for sale securities of $108.9 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 delivering innovative therapies to patients with kidney disease through HIF biology. Akebia's lead clinical program, AKB-6548, is a once-daily, oral therapy, which has completed a Phase 2b study in non-dialysis patients with anemia related to CKD and is in Phase 2 development for the treatment of anemia in patients undergoing dialysis, serious medical conditions that lead to increased morbidity and mortality if left untreated. We routinely post information that may be important to investors in the "Investors" section of our website at www.akebia.com. We encourage investors and potential investors to consult our website regularly for important information about us.

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 presentation of data from the Phase 2b study in non-dialysis patients at the World Congress of Nephrology, the commencement of the Phase 3 clinical study in non-dialysis patients with renal-anemia, and the development plan for the Phase 2 study in dialysis patients with renal-anemia including the timing of the announcement of study results. 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; the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the timing and content of decisions made by the FDA and other regulatory authorities; the rate of enrollment in the Phase 2 study; the actual time it takes to complete the Phase 2 study and analyze the data; the actual time it takes to prepare for and initiate the Phase 3 clinical study; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for AKB-6548. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-K for the fiscal year ended December 31, 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.

Tables Follow:

AKEBIA THERAPEUTICS, INC.
Consolidated Statements of Operations

(in thousands except share and per share data)
(unaudited)

	Three months ended December 31,		Year ended December 31,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	$ 7,068	$ 3,190	$ 25,398	$ 10,781
General and administrative	3,539	3,011	12,542	5,152
Total operating expenses	10,607	6,201	37,940	15,933
Operating loss	(10,607)	(6,201)	(37,940)	(15,933)
Other income, net	237	253	906	2,766
Net loss and comprehensive loss	$ (10,370)	$ (5,948)	$ (37,034)	$ (13,167)
Reconciliation of net loss to net loss applicable to common stockholders:				
Net loss	$ (10,370)	$ (5,948)	$ (37,034)	$ (13,167)
Accretion on preferred stock	—	(3,024)	(86,899)	(55,886)
Net loss applicable to common stockholders	$ (10,370)	$ (8,972)	$ (123,933)	$ (69,053)
Net loss per share applicable to common stockholders—basic and diluted	$ (0.52)	$ (13.92)	$ (8.04)	$ (126.94)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	19,815,141	644,597	15,406,386	544,002

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

	December 31, 2014	December 31, 2013
Cash, cash equivalents and available for sale securities	$ 108,918	$ 32,556
Working capital	103,595	29,529
Total assets	110,995	34,665
Total stockholders' equity (deficit)	104,078	(127,072)

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Source: Akebia Therapeutics, Inc.