August 8, 2017

Akebia Announces Second Quarter 2017 Financial Results

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 second quarter ended June 30, 2017.

"Akebia continues to maximize the potential of vadadustat through value-enhancing deals and executing on our clinical development program," said John P. Butler, President and Chief Executive Officer of Akebia. "Our agreement with Vifor Pharma establishes vadadustat as its exclusive HIF product for distribution to Fresenius Medical Care, the largest kidney dialysis provider in the U.S., following FDA approval. In addition, we initiated our Phase 2 FO_2RWARD study in patients with renal anemia who are hyporesponsive to erythropoiesis-stimulating agents, and plan to start our Phase 3 TRILO$_2$GY trial in the second half of the year to confirm previous positive results of vadadustat administered on a three-times-weekly basis. Topline data from both of these studies are expected by the end of 2018, followed by results from our global Phase 3 program for vadadustat."

Mr. Butler added, "Substantial financial commitments from our collaborators, together with our existing cash, position Akebia well in advance of multiple value-creating events anticipated over the next 12-18 months, including filing an IND for AKB-5169, our HIF product candidate for inflammatory bowel disease, in the first half of next year."

Second Quarter 2017 and Recent Corporate Highlights

- Entered into an exclusive license agreement with Vifor Pharma to sell vadadustat as its only HIF product for distribution to Fresenius Medical Care in the U.S., a kidney dialysis provider serving approximately 40% of dialysis patients, following approval of vadadustat by the U.S. Food and Drug Administration (FDA). The profit-sharing arrangement is based on inclusion of vadadustat in a bundled reimbursement model, which will generate a $20 million payment to Akebia from Vifor Pharma. Separately, Vifor Pharma made a $50 million equity investment in Akebia;
- Dosed the first patient in the randomized, open-label Phase 2 FO_2RWARD study of vadadustat in dialysis-dependent chronic kidney disease patients who are hyporesponsive to erythropoiesis-stimulating agents (ESAs). Akebia expects to report data from FO_2RWARD by the end of 2018;
- Prevailed in two additional European Patent disputes in which the Opposition Division of the European Patent Office revoked another FibroGen, Inc. HIF-related patent in Europe, and another of their patents was significantly narrowed to cover only an indication for which Akebia is not intending to develop vadadustat;
- Appointed Rita Jain, M.D. as Senior Vice President and Chief Medical Officer to lead the global development program for vadadustat and the clinical development of Akebia's growing HIF pipeline;
- Raised approximately $67 million through an underwritten public offering of common stock and full exercise of the underwriters' option to purchase additional shares; and
- Otsuka Pharmaceutical Co. Ltd. waived its option, in advance of its expiration, to convert its U.S. arrangement with Akebia from a profit share to a right to receive royalties.

Financial Results

Akebia reported a net loss of ($21.5) million, or ($0.53) per share, for the second quarter of 2017 as compared to a net loss for the second quarter of 2016 of ($35.8) million or ($0.95) per share.

Collaboration revenue was $28.5 million for the second quarter of 2017, which related to the Company's agreements with Otsuka. Collaboration revenue in connection with Akebia's agreement with Mitsubishi Tanabe Pharma Corporation is expected to commence in the second half of 2017.

Research and development expenses were $43.8 million for the second quarter of 2017 compared to $30.9 million for the second quarter of 2016. The increase is primarily attributable to external costs related to the global PRO$_2$TECT and

INNO$_2$VATE Phase 3 programs, as well as the FO$_2$RWARD and TRILO$_2$GY studies. Research and development expenses were further increased by headcount and compensation-related costs.

General and administrative expenses were $6.9 million for the second quarter of 2017 compared to $5.3 million for the second quarter of 2016. The increase is primarily attributable to an increase in costs to support the Company's research and development programs, including headcount and compensation-related costs and associated facility costs.

Akebia ended the second quarter of 2017 with cash, cash equivalents and marketable securities of $321.2 million, which included a $50.0 million equity investment from Vifor Pharma. In July 2017, the Company raised approximately $67.0 million from a follow-on offering. The Company's collaborators have committed up to $373.0 million or more in license and cost-share funding, which Akebia continues to receive on a quarterly prepaid basis. Akebia expects existing cash resources, including net proceeds from the July 2017 follow-on offering and the timing of committed research and development funding from its collaborators to fund the Company's current operating plan into the second quarter of 2019. Thereafter, committed research and development funding will continue to be received from Otsuka on a prepaid, quarterly basis.

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 hypoxia-inducible factor biology. Akebia's lead product candidate, vadadustat, is an oral, investigational therapy in development for the treatment of anemia related to chronic kidney disease in both non-dialysis and dialysis patients. Akebia's global Phase 3 program for vadadustat, which includes the PRO$_2$TECT studies for non-dialysis patients with anemia secondary to chronic kidney disease and the INNO$_2$VATE studies for dialysis-dependent patients, is currently ongoing. In addition, the Company has initiated the Phase 2 FO$_2$RWARD study of vadadustat in dialysis-dependent chronic kidney disease patients who are hyporesponsive to erythropoiesis-stimulating agents (ESAs), and expects to commence the Phase 3 TRILO$_2$GY study to further evaluate a three-times-weekly dosing regimen for vadadustat. For more information, please visit our website at 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 commercialization of vadadustat if approved by regulatory authorities, the potential indications and benefits of vadadustat and Akebia's other product candidates, the expected timing of clinical studies, the timing of the potential submission of an IND for AKB-5169, anticipated financial contributions from Otsuka and Mitsubishi Tanabe Pharma Corporation under Akebia's collaboration agreements, and the expected timing and 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 actual funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the actual costs incurred in the clinical studies of vadadustat and the availability of financing to cover such costs; early termination of Akebia's collaboration or license agreements; Akebia's ability to satisfy its obligations under its collaboration or license agreements; the timing and content of decisions made by the FDA and other regulatory authorities; the timing of any additional studies initiated by Akebia or its collaborators for vadadustat; the rate of enrollment in clinical studies of vadadustat; the actual time it takes to initiate and complete research and clinical studies; 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 vadadustat and its other product candidates. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Annual Report on Form 10-Q for quarter ended June 30, 2017, 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
Consolidated Statements of Operations
(in thousands except share and per share data)
(unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2017	June 30, 2016	June 30, 2017	June 30, 2016

Collaboration revenue	$ 28,520	$ —	$ 49,385	$ —
Operating expenses:				
Research and development	43,751	30,877	103,800	51,112
General and administrative	6,905	5,311	12,693	11,122
Total operating expenses	50,656	36,188	116,493	62,234
Operating loss	(22,136)	(36,188)	(67,108)	(62,234)
Other income, net	618	409	1,048	657
Net loss	$ (21,518)	$ (35,779)	$ (66,060)	$ (61,577)
Net loss per share - basic and diluted	$ (0.53)	$ (0.95)	$ (1.66)	$ (1.65)
Weighted-average number of common shares - basic and diluted	40,819,957	37,811,056	39,795,282	37,342,324

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

	June 30, 2017	December 31, 2016
Cash, cash equivalents and available for sale securities	$ 321,215	$ 260,343
Working capital	150,798	182,053
Total assets	336,822	300,216
Total stockholders' equity	56,998	68,120

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