March 6, 2017

Akebia Announces Fourth Quarter and Full-Year 2016 Financial Results

-- Company to Host Conference Call at 4:30 p.m. Eastern Time --

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, 2016.

"Over the last year, we continued to advance our global Phase 3 development program for vadadustat," said John P. Butler, President and Chief Executive Officer of Akebia. "In addition, we established two major collaborations that provide capital to fund the Phase 3 trials. These collaborations position vadadustat for a strong market introduction upon approval by the regulatory authorities."

Mr. Butler added, "We recently expanded our HIF portfolio through a research and license agreement with Johnson & Johnson for an extensive library of well-characterized HIF compounds and associated intellectual property. This significantly accelerates our research efforts and will enhance our understanding of vadadustat and the potential of the HIF pathway as we develop treatments for patients with renal anemia and other serious diseases. Our core focus is on completing our global Phase 3 program for vadadustat, while supporting Akebia's continued growth and value creation."

2016 Full-Year and Recent Corporate Highlights

- Initiated the global Phase 3 INNO$_2$VATE program to evaluate vadadustat in dialysis-dependent patients with anemia associated with chronic kidney disease (CKD);
- Entered into a collaboration with Otsuka Pharmaceutical Co., Ltd in which the companies equally share the costs of developing and commercializing vadadustat in the U.S. and the profits from sales of vadadustat after approval by the U.S. Food and Drug Administration. This includes $265 million or more in committed capital and up to $765 million in potential development and commercial milestone payments from Otsuka;
- Signed an exclusive agreement with Janssen Pharmaceutica, NV, a Johnson & Johnson company, to license HIF product candidates and access an extensive library of HIF compounds that may have applications across multiple therapeutic areas. The lead compound, a differentiated, oral, non-absorbed preclinical compound for the treatment of inflammatory bowel disease, is poised for IND submission in 12-18 months;
- Prevailed in two patent disputes in which the European Patent Office confirmed that none of FibroGen, Inc.'s patent claims met the requirements for patentability and, as a result, revoked the patents; and
- Published positive Phase 2b study results in non-dialysis dependent chronic kidney disease patients in *Kidney International*. Additional data was presented at several scientific meetings further demonstrating the potential of vadadustat including encouraging results in dialysis-dependent chronic kidney disease patients, and a drug-drug interaction study suggesting that vadadustat should have no impact on the metabolism of any of the major statins, which are commonly prescribed medications for CKD patients.

Financial Results

The company reported a net loss of ($37.9) million, or ($0.99) per share, for the fourth quarter of 2016 as compared to a net loss for the fourth quarter of 2015 of ($19.9) million or ($0.66) per share.

The company reported a net loss for the full year of 2016 of ($135.7) million, or ($3.60) per share as compared to a net loss for the full year of 2015 of ($60.7) million or ($2.29) per share.

Collaboration revenue was $1.5 million for the fourth quarter of 2016, which related to our agreement with Otsuka. Collaboration revenue in connection with our agreement with Mitsubishi Tanabe Pharma Corporation is expected to commence in the second half of 2017.

Research and development expenses were $33.4 million for the fourth quarter of 2016 compared to $14.2 million for the

fourth quarter of 2015. Research and development expenses were $115.8 million for the full year of 2016 compared to $43.0 million for the full year of 2015. The increase in both periods is primarily attributable to external costs related to the global PRO$_2$TECT Phase 3 program, as well as initiation costs of the global INNO$_2$VATE Phase 3 program. Research and development expenses in both periods were further increased by headcount and compensation-related costs.

General and administrative expenses were $6.1 million for the fourth quarter of 2016 compared to $5.8 million for the fourth quarter of 2015. General and administrative expenses were $22.2 million for the full year of 2015 compared to $18.5 million for the full year of 2015. The increase in general and administrative expenses for both periods is primarily due to an increase in costs to support the company's Phase 3 program, including costs related to headcount and compensation, and associated facility-related costs.

The company ended 2016 with cash, cash equivalents and available for sale securities of $260.3 million. The company expects cash resources, together with the timing of amounts expected to be received from collaborators, including a $33.8 million payment from Otsuka received in March of 2017, to fund the current operating plan into mid-2018.

In other news today, Akebia announced that on February 28, 2017, the company granted two newly-hired employees options to purchase an aggregate of 5,500 shares of the company's common stock with a per share exercise price of $10.02, the closing price on the grant date. These options will vest as to 25% of the total number of shares subject to the option on the first anniversary of the grant date. The remaining 75% of shares will vest ratably on the first day of each calendar quarter over the next three years. The stock options were inducements material to these new employees entering into employment with the company, and issued in reliance on NASDAQ Listing Rule 5635(c)(4).

Conference Call and Webcast

Akebia management will host a conference call to discuss the financial results for the year ended December 31, 2016 and recent corporate highlights beginning at 4:30 p.m. Eastern Time today, Monday, March 6, 2017. A live audio webcast of the presentation will be available on the company's website at http://ir.akebia.com/events.cfm. An archived presentation will be available for 90 days.

To access the conference call, follow these instructions:

Dial: (877) 458-0977 (U.S.); (484) 653-6724 (international)
Conference ID: 77605143

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 associated with chronic kidney disease and the INNO$_2$VATE studies for dialysis-dependent patients, is currently ongoing. 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 research and development plan for the portfolio of HIF compounds licensed from Janssen, anticipated collaboration revenue, and the timing of the potential filing of an IND for AKB-5169. 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 funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the actual costs incurred in the Phase 3 studies of vadadustat and the availability of financing to cover such costs; early termination of Akebia's collaboration or license agreements; the timing and content of decisions made by the FDA and other regulatory authorities; the actual time it takes to initiate and complete research and development; 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-K for fiscal year ended December 31, 2016, 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		Twelve Months Ended	
	December 31, 2016	December 31, 2015	December 31, 2016	December 31, 2015
Collaboration revenue	$ 1,535	—	$ 1,535	$ —
Operating expenses:				
Research and development	33,435	14,244	115,785	43,016
General and administrative	6,144	5,806	22,210	18,497
Total operating expenses	39,579	20,050	137,995	61,513
Operating loss	(38,044)	(20,050)	(136,460)	(61,513)
Other income, net	182	193	713	797
Net loss	$ (37,862)	$ (19,857)	$ (135,747)	$ (60,716)
Net loss per share applicable to common stockholders—basic and diluted	$ (0.99)	$ (0.66)	$ (3.60)	$ (2.29)
Weighted-average number of common shares used in net loss per share applicable to common stockholders—basic and diluted	38,277,100	30,309,251	37,716,949	26,469,170

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

	December 31, 2016	December 31, 2015
Cash, cash equivalents and available for sale securities	$ 260,343	$ 138,454
Working capital	182,053	129,149
Total assets	300,216	142,940
Total stockholders' equity	68,120	130,998

View source version on businesswire.com: http://www.businesswire.com/news/home/20170306005419/en/

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