Akebia Therapeutics Announces Third Quarter 2018 Financial Results

November 8, 2018

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 8, 2018-- 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 third quarter ended September 30, 2018.

“In the third quarter, we continued to drive our vadadustat Phase 3 development program, while working diligently to close our proposed merger transaction with Keryx Biopharmaceuticals by the end of 2018. The combination is expected to create a fully-integrated kidney disease therapeutics company, with a strengthened financial profile, positioned to deliver substantial long-term value to shareholders,” said John P. Butler, President and Chief Executive Officer of Akebia Therapeutics. “In addition, we look forward to the Phase 3 clinical trial readouts in Japan from our collaboration partner, Mitsubishi Tanabe Pharma Corporation, expected next year. This will be the first time Phase 3 data has been reported for our product candidate, vadadustat, which is an important milestone.”

Third Quarter 2018 and Recent Corporate Highlights

Merger Integration Planning:

- Following the definitive merger agreement with Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX) announced June 28, 2018, Akebia has been actively engaged in integration planning and expects to close the transaction by the end of 2018;
- The combination offers potential operating and product portfolio synergies and the opportunity to create significant value and accelerate the growth potential beyond what either company would achieve separately;
- The combined company will have an expanded and highly complementary nephrology portfolio, with Auryxia® (ferric citrate), a U.S. Food and Drug Administration (FDA)-approved product in two indications with significant growth opportunity, and vadadustat, an investigational late-stage hypoxia-inducible factor prolyl hydroxylase inhibitor, which has the potential to provide a new oral standard of care to patients with anemia due to chronic kidney disease (CKD);
- The combined company will have an established renal development, manufacturing and commercial organization, positioning it as a partner of choice for the renal community and for companies developing renal products; and
- The combined company plans to leverage its leadership’s extensive expertise in the commercial renal market with the goal of maximizing sales of Auryxia while driving launch momentum for vadadustat in the United States, subject to FDA approval.

Clinical Development:

- Akebia continued to enroll subjects in its Phase 3 INNO$_2$VATE program, with top-line results expected in the first quarter of 2020, subject to the accrual of major adverse cardiovascular events (MACE). U.S. enrollment in the Phase 3 INNO$_2$VATE Conversion study completed last quarter, as announced in Akebia’s second quarter 2018 earnings press release;
- Akebia continued to enroll subjects in its Phase 3 PRO$_2$TECT program, with top-line results anticipated in mid-2020, subject to the accrual of MACE; and
- Akebia received a recommendation from the Independent Data Monitoring Committee, which held another meeting in the quarter, for Akebia’s global Phase 3 PRO $_2$TECT and INNO$_2$VATE programs to continue without modification.

Other Business:

- This past quarter, Akebia appointed Cynthia Smith to its Board of Directors. With more than 20 years of broad leadership experience within the healthcare industry, including serving as a Chief Commercial Officer, Cynthia brings expertise that is particularly relevant to Akebia as it prepares for the commercialization of vadadustat, subject to regulatory approval, and works to maximize the value of Auryxia, subject to the consummation of Akebia’s merger with Keryx Biopharmaceuticals.

Financial Results

Akebia reported a net loss of $26.0 million, or ($0.46) per share, for the third quarter of 2018 as compared to a net loss for the third quarter of 2017 of

$23.1 million or ($0.49) per share.

Collaboration revenue was $53.2 million for the third quarter of 2018 compared to $41.3 million for the third quarter of 2017. Collaboration revenue recognized in the third quarter of 2018 related primarily to revenue recognized under both the U.S. collaboration agreement with Otsuka Pharmaceutical Co. Ltd., or Otsuka, and the collaboration agreement with Otsuka related to Europe, China and certain other regions, or the Otsuka International Agreement. Collaboration revenue recognized in the third quarter of 2017 also related to the Otsuka U.S. Agreement and the Otsuka International Agreement, which were consummated in December 2016 and April 2017, respectively.

Research and development expenses were $70.6 million for the third quarter of 2018 compared to $58.7 million for the third quarter of 2017. The increase was primarily attributable to external costs related to the global PRO_2TECT and $INNO_2$VATE Phase 3 programs. Research and development expenses were further increased by headcount and compensation-related costs.

General and administrative expenses were $10.4 million for the third quarter of 2018 compared to $6.7 million for the third quarter of 2017. The increase was primarily attributable to an increase in legal and other professional fees related to our proposed merger with Keryx Biopharmaceuticals, and an increase in costs to support the company's research and development programs, including headcount and compensation-related costs.

Akebia ended the third quarter of 2018 with cash, cash equivalents and available for sale securities of $390.1 million. The company also generally receives cost-share funding from its collaboration agreements with Otsuka on a prepaid quarterly basis. Akebia expects its existing cash resources, including the prepaid quarterly committed cost-share funding from its collaborators, to fund its current operating plan through the first quarter of 2020.

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. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

Forward-Looking Statements

Statements in this press release regarding Akebia's strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, including but not limited to statements regarding the expected benefits of the pending merger with Keryx, including but not limited to expected synergies, value creation, growth potential, and the combined company's portfolio; the closing of the pending merger with Keryx, including the timing thereof; the competitive position of the combined company following completion of the merger with Keryx, including but not limited to being a partner of choice for the renal community and for companies developing renal products; plans and goals for the combined company following completion of the merger with Keryx; the potential for vadadustat to provide a new oral standard of care to patients with anemia due to CKD; the rate and timing of enrollment of our clinical trials; the anticipated timing of the availability and presentation of clinical trial data and results; the benefits, including the potential effect on commercial position, of the designs of our studies; the potential characterization and differentiation information we believe will result from the designs of our studies; potential and anticipated payments from our collaborators, including the timing thereof; expectations regarding financial position, including the period of time our cash resources and committed funding from our collaborators will fund our current operating plan. The terms "anticipate," "create," "expect," "goal," "look forward," "may," "opportunity," "plan," "position," "potential," "target," "will," and similar references 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 that Akebia or Keryx may be unable to obtain stockholder approval as required for the pending merger; conditions to the closing of the pending merger may not be satisfied; the pending merger may involve unexpected costs, liabilities or delays; the effect of the announcement of the pending merger on the ability of Akebia or Keryx to retain and hire key personnel and maintain relationships with customers, suppliers and others with whom Akebia or Keryx does business, or on Akebia's or Keryx's operating results and business generally; Akebia's or Keryx's respective businesses may suffer as a result of uncertainty surrounding the pending merger and disruption of management's attention due to the pending merger; the outcome of any legal proceedings related to the pending merger; Akebia or Keryx may be adversely affected by other economic, business, and/or competitive factors, including the receipt by Keryx of notice letters on October 31, 2018, and November 6, 2018, regarding abbreviated new drug applications submitted to the FDA requesting approval to market, sell and use a generic version of the Auryxia; the occurrence of any event, change or other circumstances that could give rise to the termination of the merger agreement; risks that the pending merger disrupts current plans and operations and the potential difficulties in employee retention as a result of the pending merger; the risk that Akebia or Keryx may be unable to obtain governmental and regulatory approvals required for the transaction, or that required governmental and regulatory approvals may delay the transaction or result in the imposition of conditions that could reduce the anticipated benefits from the proposed transaction or cause the parties to abandon the proposed transaction; the impact of legislative, regulatory, competitive and technological changes, including the recent changes to reimbursement coverage for Auryxia that could have a material adverse effect on Auryxia sales and profitability; risks that the anticipated benefits of the pending merger or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected; other risks to the consummation of the merger, including the risk that the merger will not be consummated within the expected time period or at all; rate of enrollment in clinical studies of vadadustat; the rate of major adverse cardiovascular events in PRO_2TECT and $INNO_2$VATE; the risk that clinical trials may not be successful; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; manufacturing risks; the quality and manner of the data that will result from clinical studies of vadadustat; the actual funding required to develop and commercialize 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; the risk that clinical studies are discontinued or delayed for any reason, including for safety, tolerability, enrollment, manufacturing or economic reasons; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the timing and content of decisions made by regulatory authorities; the timing of any additional studies initiated for vadadustat; the actual time it takes to initiate and complete preclinical and clinical studies; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; the scope, timing, and outcome of any ongoing legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia and its partners; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for vadadustat and 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 quarterly period ended September 30, 2018, and other filings that Akebia may make with the U.S. Securities and Exchange Commission (the "SEC") in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

Additional Information and Where to Find It

In connection with the proposed merger, Akebia has filed with the SEC a Registration Statement on Form S-4, which, as amended, includes a final prospectus with respect to the shares of Akebia's common stock to be issued in the proposed merger and a definitive joint proxy statement of Keryx and Akebia with respect to the proposed merger. The Registration Statement was declared effective by the SEC on October 30, 2018 and the definitive joint proxy statement was mailed or otherwise made available to Keryx's and Akebia's respective stockholders on October 31, 2018. BEFORE MAKING ANY VOTING DECISION, KERYX'S AND AKEBIA'S RESPECTIVE STOCKHOLDERS ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS IN ITS ENTIRETY AND ANY OTHER DOCUMENTS FILED BY EACH OF AKEBIA AND KERYX WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION AND THE PARTIES TO THE PROPOSED TRANSACTION. Investors and stockholders can obtain a free copy of the joint proxy statement/prospectus and other documents containing important information about Akebia and Keryx, once such documents are filed with the SEC, through the website maintained by the SEC at www.sec.gov. Akebia and Keryx make available free of charge at www.akebia.com and www.keryx.com, respectively (in the "Investors" section), copies of materials they file with, or furnish to, the SEC.

Participants in the Merger Solicitation

Akebia, Keryx and their respective directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of Akebia and Keryx in connection with the proposed merger. Information regarding the interests of such individuals in the proposed merger, by security holdings or otherwise, is included in the joint proxy statement/prospectus relating to the proposed merger that has been filed with the SEC. In addition, security holders may obtain information regarding the names, affiliations and interests of Akebia's directors and officers in Akebia's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on March 12, 2018, and its definitive proxy statement for the 2018 annual meeting of stockholders, which was filed with the SEC on April 30, 2018, and information regarding the names, affiliations and interests of Keryx's directors and officers in Keryx's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on February 21, 2018, and the Amendment No. 1 on Form 10-K/A, which was filed with the SEC on April 30, 2018, and its definitive proxy statement for the 2018 annual meeting of stockholders, which was filed with the SEC on May 31, 2018. To the extent the holdings of Akebia securities by Akebia's directors and executive officers or the holdings of Keryx securities by Keryx's directors and executive officers have changed since the amounts set forth in the joint proxy statement/prospectus, such changes have been or will be reflected on Statements of Change in Ownership on Form 4 filed with the SEC. These documents (when available) may be obtained free of charge from the SEC's website at www.sec.gov, Akebia's website at www.akebia.com and Keryx's website at www.keryx.com.

This document does not constitute a solicitation of proxy, an offer to purchase or a solicitation of an offer to sell any securities.

Tables Follow

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

	Three Months Ended		Nine Months Ended	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Collaboration revenue	$ 53,169	$ 41,283	$ 147,892	$ 90,668
Operating expenses:				
Research and development	70,634	58,711	203,955	162,511
General and administrative	10,378	6,748	31,940	19,441
Total operating expenses	81,012	65,459	235,895	181,952
Operating loss	(27,843)	(24,176)	(88,003)	(91,284)
Other income, net	1,796	1,042	4,469	2,090
Net loss	$ (26,047)	$ (23,134)	$ (83,534)	$ (89,194)
Net loss per share - basic and diluted	$ (0.46)	$ (0.49)	$ (1.54)	$ (2.11)
Weighted-average number of common shares - basic and diluted	57,027,598	46,938,618	54,207,973	42,202,560

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

	September 30, 2018	December 31, 2017
Cash, cash equivalents and available for sale securities	$ 390,144	$ 317,792
Working capital	220,127	217,250
Total assets	403,826	364,247

Total stockholders' equity	142,541	122,574

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