UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported):
October 6, 2015

AKEBIA THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-36352**	**20-8756903**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

245 First Street, Suite 1100, Cambridge, Massachusetts 02142
(Address of Principal Executive Offices) (Zip Code)

(617) 871-2098
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 7.01 Regulation FD Disclosure.

On October 6, 2015, the Company issued a press release announcing that the company has reached agreement with the United States Food and Drug Administration and the European Medicines Agency regarding key elements of the global Phase 3 program for its lead product, vadadustat (formerly AKB-6548), for patients with anemia related to non-dialysis dependent chronic kidney disease. A copy of the press release is attached to this report as Exhibit 99.1.

The information contained in this Item shall not be deemed "filed" for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated October 6, 2015.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AKEBIA THERAPEUTICS, INC.

/s/ John P. Butler

Name: John P. Butler
Title: President and Chief Executive Officer

Date: October 6, 2015

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Akebia Therapeutics, Inc. dated October 6, 2015.

Exhibit 99.1

Akebia Therapeutics, Inc.
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Akebia Reaches Agreement with FDA and EMA on Vadadustat Global Phase 3 Program

Plans to Initiate Phase 3 PRO$_2$TECT™ Clinical Program by Year-End

Cambridge, Mass. – October 6, 2015 – 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 the successful completion of the End-of-Phase 2 Meeting process with the United States Food and Drug Administration (FDA) and the Scientific Advice Process with the European Medicines Agency (EMA) for its lead product, vadadustat (formerly AKB-6548), for patients with anemia related to non-dialysis dependent chronic kidney disease (NDD-CKD). The company has reached agreement with both the FDA and EMA regarding key elements of the Phase 3 program, known as the PRO$_2$TECT™ program, and expects to launch the program later this year.

The PRO$_2$TECT™ program includes two separate studies and will collectively enroll approximately 3,100 NDD-CKD patients across 500 sites globally. The correction study will address anemia patients not currently being treated with recombinant erythropoiesis stimulating agents (rESAs). The conversion study includes patients currently receiving rESA who will be converted to either vadadustat or the active control with the goal of maintaining their baseline hemoglobin levels. Both studies will include a 1:1 randomization, and an open label, active-control, non-inferiority design. Primary endpoints include an efficacy assessment of the hemoglobin response and an assessment of cardiovascular safety measured by major adverse cardiac events.

“Akebia’s Phase 3 program is designed to provide the medical community and regulators with a clear understanding of vadadustat’s potential benefit and safety advantages over rESAs, the current standard of care worldwide and, with a positive outcome, to establish vadadustat as the best-in-class treatment option for patients with renal anemia,” stated John P. Butler, President and Chief Executive Officer of Akebia. “We are pleased that the regulators are in agreement regarding the importance of an active-control trial as this design is the most clinically relevant and commercially valuable, and will allow us the quickest path to full enrollment. We are now moving rapidly to launch these studies and advance our goal of bringing forward new treatment options for patients suffering from renal anemia.”

“This Phase 3 program builds on the positive data from our Phase 2 program in NDD-CKD patients which demonstrated that once- daily vadadustat can control and maintain hemoglobin levels in a clinically relevant range while minimizing fluctuations in hemoglobin levels that are associated with increased cardiovascular safety risks,” stated Brad Maroni, M.D., Chief Medical Officer at Akebia. “These two Phase 3 event-driven studies are designed to establish the safety and efficacy of vadadustat in the setting of contemporary clinical practice patterns, and support regulatory approvals globally.”

In addition, Akebia discussed with the FDA and EMA a parallel Phase 3 program, known as the INNO$_2$VATE™ program, for vadadustat in patients with anemia related to chronic kidney disease who are undergoing dialysis (DD-CKD). Akebia expects to formalize its Phase 3 program in DD-CKD patients after presenting the results from its recently completed Phase 2 study to both regulatory agencies.

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About Vadadustat (Formerly AKB-6548)

Vadadustat is an oral therapy currently in development for the treatment of anemia related to chronic kidney disease (CKD). Vadadustat is designed to stabilize HIF, a transcription factor that regulates the expression of genes involved with red blood cell (RBC) production in response to changes in oxygen levels, by inhibiting the hypoxia-inducible factor prolyl hydroxylase (HIF-PH) enzyme. Vadadustat exploits the same mechanism of action used by the body to naturally adapt to lower oxygen availability associated with a moderate increase in altitude. At higher altitudes, the body responds to lower oxygen availability with increased production of HIF, which coordinates the interdependent processes of iron mobilization and erythropoietin (EPO) production to increase RBC production and, ultimately, improve oxygen delivery.

As a HIF stabilizer with best-in-class potential, vadadustat raises hemoglobin levels predictably and sustainably, with a dosing regimen that allows for a gradual and controlled titration. Vadadustat has been shown to improve iron mobilization, potentially eliminating the need for intravenous iron administration and reducing the overall need for iron supplementation.

About Anemia Related to CKD

Approximately 30 million people in the United States have CKD, with an estimated 1.8 million of these patients suffering from anemia. Anemia results from the body's inability to coordinate RBC production in response to lower oxygen levels due to the progressive loss of kidney function, which occurs in patients with CKD. Left untreated, anemia significantly accelerates patients' overall deterioration of health with increased morbidity and mortality. Renal anemia is currently treated with injectable rESAs, which are associated with inconsistent hemoglobin responses and well-documented safety risks.

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. The company has completed Phase 2 development of its lead product candidate, vadadustat, an oral therapy for the treatment of anemia related to CKD in both non-dialysis and dialysis patients.

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, dosing and benefits of vadadustat, the development plan for vadadustat, the design and potential benefits of the Phase 3 program in NDD-CKD patients, and the timing for finalizing the Phase 3 program in DD-CKD patients and initiating the Phase 3 program in NDD-CKD patients. 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 vadadustat; the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the cost of the Phase 3 program and the availability of financing to cover such cost; the timing and content of decisions made by the FDA, EMA and other regulatory authorities; the actual time it takes to prepare for and initiate the Phase 3 program, including initiating sites and enrolling patients; the success of competitors in developing

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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. 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, 2015, 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.

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