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)
January 4, 2016

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)**	**(I.R.S. Employer Identification No.)**

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

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

Not Applicable
(Former name or former address, if changed since last report)

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:

☐ 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 8.01 Other Events.

On January 4, 2016, Akebia Therapeutics, Inc. issued a press release containing an update on recent significant corporate developments. A copy of this press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Akebia Therapeutics, Inc. dated January 4, 2016.

SIGNATURES

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.

By: /s/ John P. Butler
John P. Butler
President and Chief Executive Officer

Date: January 4, 2016

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Akebia Therapeutics, Inc. dated January 4, 2016

Exhibit 99.1

Akebia Initiates Phase 3 PRO$_2$TECT™ Program

-Achieved All Corporate Objectives for 2015-

CAMBRIDGE, MA, January 4, 2016 – 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 announces several corporate and clinical developments consistent with its objectives for 2015, including dosing the first patient in its global Phase 3 PRO$_2$TECT™ program in December. This program is evaluating vadadustat (formerly AKB-6548) in non-dialysis patients with anemia related to chronic kidney disease (NDD-CKD). In addition, the U.S. Food and Drug Administration (FDA) recently opened Akebia's Investigational New Drug (IND) application, allowing the company to initiate a Phase 1 clinical study of AKB-6899, an orally-available HIF stabilizer, in oncology. The company also made progress with its intellectual property efforts in Japan for vadadustat.

"We achieved all of our clinical and corporate objectives for 2015, positioning Akebia for continued success with the vadadustat anemia program in chronic kidney disease and further building our pipeline of HIF stabilizers," stated John P. Butler, President and Chief Executive Officer of Akebia. "The launch of our global Phase 3 PRO$_2$TECT™ program in non-dialysis patients is a significant milestone in our efforts to establish vadadustat as the best-in-class treatment option for chronic kidney disease patients with anemia. Following positive Phase 2 data for vadadustat in dialysis patients, we are now working with regulators to finalize the design for our INNO$_2$VATE™ global Phase 3 program, which is expected to commence this year."

Mr. Butler added, "We were also very pleased to have announced a collaboration with Mitsubishi Tanabe, one of the largest and most successful pharmaceutical companies in Japan, for the development and commercialization of vadadustat in Japan and certain other Asian countries. Additionally, the FDA opened an IND for our second HIF stabilizing compound, AKB-6899, and we expect to initiate a Phase 1 study in oncology this year. We look forward to continuing to build on this momentum in 2016 and beyond."

PRO$_2$TECT™ Program Update

The PRO$_2$TECT™ Phase 3 program includes two separate studies that will collectively enroll approximately 3,100 NDD-CKD patients across 500 sites globally. The first patient was recently dosed in the PRO$_2$TECT™ correction study, which is enrolling anemic patients not currently being treated with recombinant erythropoiesis stimulating agents (rESAs). The PRO$_2$TECT™ 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 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 cardiovascular safety as measured by major adverse cardiovascular events. The PRO$_2$TECT™ program is designed to support registration in major markets worldwide and to collect the data required to establish a new standard of care for chronic kidney disease (CKD) patients. The company expects to complete enrollment in late 2017.

"The PRO$_2$TECT™ Phase 3 program builds on our robust Phase 2 program in NDD-CKD patients, which found that once-daily vadadustat maintained 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 studies are designed to establish the safety and efficacy of vadadustat in the setting of contemporary clinical practice, and to support regulatory approvals globally."

AKB-6899 Update

The company's second clinical candidate, AKB-6899, is designed as a small molecule HIF stabilizer with potential therapeutic benefit in oncology and ophthalmology. In *in vitro* studies, AKB-6899 reduced VEGF levels in the presence of hypoxia, and therefore has the potential to reduce VEGF in tumor cells specifically. In several preclinical models, AKB-6899 reduced tumor growth and the development of metastases. Therefore, Akebia opened an IND with the FDA at the end of 2015 and expects to commence clinical development of AKB-6899 in 2016.

Intellectual Property Update

Akebia is pleased to provide an update on its challenge to Japanese Patent No. 4804131 (the '131 patent), which is owned by FibroGen. On June 2, 2014, Akebia filed an invalidity proceeding in the Japanese Patent Office (JPO) challenging the validity of the '131 patent, requesting that it be revoked in its entirety. In a preliminary decision dated May 11, 2015, the JPO found all of the challenged claims to be invalid. In response, FibroGen filed a request for correction in which it requested that the '131 patent claims be amended to exclude pyridine carboxamides from their scope. On November 18, 2015, Akebia received the final trial decision from the JPO in which it accepted FibroGen's requested claim amendments. As a result of the JPO's decision and FibroGen's subsequent amendments, the FibroGen '131 patent does not cover vadadustat or any pyridine carboxamide compounds.

About Vadadustat

Vadadustat is an oral therapy currently in development for the treatment of anemia related to 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 HIF prolyl-hydroxylase 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. 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 reducing the 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. Enrollment in the PRO_2TECT^{TM} Phase 3 program in non-dialysis CKD patients commenced in late 2015 and the $INNO_2VATE^{TM}$ Phase 3 program in dialysis-dependent CKD patients is expected to commence in 2016.

Forward-Looking Statements

This press release includes forward-looking statements. Such forward-looking statements include those about Akebia Therapeutics, Inc.'s strategy, future plans and prospects, including statements regarding the potential indications, dosing and benefits of vadadustat, the development plans for vadadustat and AKB-6899, the initiation of the vadadustat Phase 3 program, and the commencement of clinical development for AKB-6899. 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 studies; 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 1 study of AKB-6899 and the Phase 3 studies of vadadustat and the availability of financing to cover such costs; the timing and content of decisions made by the FDA and other regulatory authorities; the actual time it takes to prepare for and initiate 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 AKB-6899. 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 September 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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