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 27, 2014

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 7.01 Regulation FD Disclosure.

On October 27, 2014, Akebia Therapeutics, Inc. issued a press release announcing results from its Phase 2b study of AKB-6548 in non-dialysis patients with anemia related to 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 of Akebia Therapeutics, Inc. dated October 27, 2014

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: October 27, 2014

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Akebia Therapeutics, Inc. dated October 27, 2014

Akebia Therapeutics, Inc.
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Akebia Announces Positive Top-Line Results from its Phase 2b Study of AKB-6548 in Non-Dialysis Patients with Anemia Related to Chronic Kidney Disease

Study Meets Primary Endpoint

Company Plans to Initiate Global Phase 3 Registration Studies in 2015

Conference Call at 8:30 AM Eastern Time Today

Cambridge, Mass. – Oct. 27, 2014 – 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 positive top-line results from its Phase 2b placebo-controlled trial of AKB-6548 in non-dialysis patients with anemia related to chronic kidney disease (CKD). The study achieved its primary endpoint and AKB-6548 was generally well tolerated, confirming that the once-daily, oral therapy can successfully increase and maintain hemoglobin (HGB) levels.

The 20-week study enrolled 209 patients, who were randomized 2:1 to active treatment or placebo. The results showed that 54.9 percent of patients who received AKB-6548 met the primary endpoint versus 10.3 percent in the placebo group ($p<0.0001$). The primary endpoint was defined as achieving or maintaining a mean HGB $\geq$ 11.0 g/dL or increasing HGB by $\geq$ 1.2 g/dL above the pre-treatment value as measured by the mean HGB value at weeks 19 and 20.

The study also was designed to evaluate the ability of the dose titration algorithm to minimize HGB excursions $\geq$ 13.0 g/dL. Only six patients (4.4 percent) treated with AKB-6548 experienced an excursion above this threshold. This result supports the adaptive dosing approach used in the study, which enabled robust HGB increases while minimizing excursions.

“These Phase 2b results are impressive, demonstrating a sustained effect on hemoglobin throughout the twenty weeks of treatment,” said Brad Maroni, M.D., Senior Vice President and Chief Medical Officer at Akebia. “The challenges associated with current treatment options are well documented. The data underscore the potential of AKB-6548 to effectively raise and maintain hemoglobin levels in a safe, predictable and controlled manner.”

AKB-6548 was generally well tolerated. Treatment-emergent adverse events (TEAEs) with AKB-6548 were consistent with those reported in past studies and were well balanced overall between the active and placebo treatment groups (74.6 percent and 73.6 percent, respectively). There was a higher incidence of serious adverse events (SAEs) reported in the active treatment group versus the placebo group (23.9 percent and 15.3 percent, respectively), the most common being renal-related. Of the 49 SAEs reported in the active treatment group, one was considered probably related to active treatment and two were considered possibly related, including one death. There were two additional deaths in the treatment group, neither of which was considered drug-related.

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Patients at this advanced stage of CKD have many associated comorbidities and are progressing toward end stage renal disease and dialysis. The overall profile of study participants was consistent with that seen in the general population in the later stages of CKD.

“There is a clear need for new treatment options for patients with renal anemia,” said Steve Fishbane, M.D., Chief of Nephrology and Vice President of North Shore-Long Island Jewish Health System, Inc. “These exciting results illustrate the therapeutic potential of AKB-6548 to address this unmet need, and I look forward to Akebia’s initiation of Phase 3 studies.”

“We are extremely pleased with the results of our Phase 2b study. This marks a very important milestone for Akebia and sets a clear path forward for a global Phase 3 program in renal anemia,” said John P. Butler, President and Chief Executive Officer of Akebia. “The strength of these data reinforces the best-in-class potential of AKB-6548 in anemia related to CKD and brings us a significant step closer to achieving our goal of bringing innovative therapies to renal patients who are in need of new treatment options. We look forward to discussing these data with U.S. and European regulatory agencies in preparation for launching Phase 3 registration studies next year.”

Complete efficacy and safety data from this Phase 2b study will be presented at an upcoming medical meeting. Akebia is also evaluating AKB-6548 in a Phase 2 clinical study for the treatment of dialysis patients with anemia related to CKD. Results from that study are expected in the third quarter of 2015.

About AKB-6548 Phase 2b Study Design

The randomized, double-blind, placebo-controlled study evaluated the HGB response to orally administered AKB-6548, compared to baseline and to placebo treated subjects, in non-dialysis subjects with CKD stages 3, 4 and 5 dosed for 20 weeks. Secondary objectives were to evaluate the hematologic pharmacodynamic response, safety, and tolerability of orally administered AKB-6548. The study enrolled 209 non-dialysis patients with CKD stages 3, 4 and 5, who were randomized 2:1 to receive AKB-6548 or placebo. Patients initiated treatment with either 450 mg of AKB-6548 or placebo, administered once daily for 20 weeks. The dose was adjusted in accordance with the patient’s hemoglobin response based on the AKB-6548 dose titration algorithm. Patients were assigned to one of three study groups: recombinant erythropoietin stimulating agents (rESAs) treatment naïve, rESAs previously treated or rESAs actively treated.

Conference Call and Webcast

Date:	October 27, 2014
Time:	8:30 AM ET
Telephone Access:	Domestic callers: dial 877-458-0977 International callers: dial 484-653-6724 Please reference the Akebia conference call Passcode: 26837073
Online Access:	Go to the Investor Relations section of the Akebia website and follow instructions for accessing the live webcast. Please connect to the website at least 15 minutes prior to the start of the conference call to ensure adequate time for any software download that may be necessary.

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About AKB-6548

AKB-6548 is a once-daily, oral therapy currently in development for the treatment of anemia related to CKD. AKB-6548 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. AKB-6548 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, AKB-6548 may raise hemoglobin levels and RBC count predictably and sustainably, with a positive safety profile and a dosing regimen that allows for a gradual and controlled titration. Furthermore, AKB-6548 may improve iron mobilization, potentially eliminating 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. Akebia's lead product candidate, AKB-6548, is a once-daily, oral therapy, which has completed Phase 2b clinical development for the treatment of anemia related to CKD in non-dialysis patients and is also in Phase 2 clinical development for the treatment of anemia in patients undergoing dialysis. For more information on Akebia, please visit 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 indications and benefits of AKB-6548, plans for presenting a more detailed analysis of the data from the Phase 2b study, the development plan for the Phase 3 study including discussions with regulatory authorities, the expected timing of results from

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the Phase 2 study in dialysis patients with anemia related to CKD, and the potential of AKB-6548 to be a “best-in-class” drug. 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 AKB-6548; the funding required to develop Akebia’s product candidates and operate the company, and the actual expenses associated therewith; the acceptance of Akebia’s abstract for presentation at a medical meeting; the timing and content of decisions made by the FDA and other regulatory authorities; the rate of enrollment in the Phase 2 study; the actual time it takes to complete the Phase 2 study and analyze the data; 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 AKB-6548. 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, 2014, 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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