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):
September 8, 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 September 8, 2015, the Company issued a press release announcing results from its Phase 2 study of vadadustat (formerly AKB-6548) in dialysis patients with anemia related to chronic kidney disease. A copy of the press release is attached to this report as Exhibit 99.1. A copy of the presentation materials for the Akebia conference call and webcast on September 8, 2015 is attached to this report as Exhibit 99.2.

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 September 8, 2015
99.2	Presentation Materials of Akebia Therapeutics, Inc. dated September 8, 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: September 8, 2015

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Akebia Therapeutics, Inc. dated September 8, 2015
99.2	Presentation Materials of Akebia Therapeutics, Inc. dated September 8, 2015

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

-Treatment with Vadadustat Successfully Maintained Mean Hemoglobin Levels Following Conversion from rESA Therapy-

-Vadadustat Demonstrated a Favorable Safety Profile with Once Daily and Three Times per Week Dosing-

-Conference Call at 5:00 PM Eastern Time Today-

CAMBRIDGE, MA, September 8, 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 positive top-line results from its Phase 2 study of vadadustat (formerly AKB-6548) in dialysis patients with anemia related to chronic kidney disease (CKD). The study achieved its primary objective, indicating that vadadustat maintained stable hemoglobin (HGB) levels throughout the 16-week treatment period following conversion from recombinant erythropoiesis-stimulating agent (rESA) therapy. Vadadustat demonstrated a favorable safety profile with no drug-related serious adverse events and no deaths. The results highlight the potential of vadadustat, dosed either once daily or three times per week, to safely and predictably manage and sustain HGB levels in CKD patients undergoing dialysis.

The open-label, multi-center, 94 patient study was designed to evaluate the ability of vadadustat to maintain hemoglobin levels in patients undergoing hemodialysis who were previously being treated with rESAs. Patients were assigned to one of three dose cohorts: once daily vadadustat at a starting dose of 300mg, once daily vadadustat at a starting dose of 450mg, or vadadustat three times per week in conjunction with the patient's hemodialysis schedule at a starting dose of 450mg. The study achieved its primary endpoints of maintaining stable hemoglobin levels over 16 weeks of treatment in all three cohorts of patients converting from rESAs to vadadustat.

Mean Hemoglobin Levels (g/dL)*	***Baseline***	***Week 7/8***	***Week 15/16***
300mg Daily Dose	10.4	10.4	10.3
450mg Daily Dose	10.6	10.3	10.5
450mg Three Times per Week Dose	10.5	10.2	10.4

** Modified intent-to-treat (MITT) population, n=94*

Vadadustat was well tolerated among patients in all three dose cohorts. Treatment-emergent adverse events (TEAEs) with vadadustat were balanced across the cohorts. Serious adverse events (SAEs) were reported in 13 subjects (13.8%), well within the expected range for this patient population. There were no drug-related SAEs and no deaths reported in the study.

"This study was a clear success, demonstrating the potential of vadadustat to effectively and safely treat anemia in dialysis patients switching from injectable rESA therapy," said Brad Maroni, M.D., Chief Medical Officer at Akebia. "We are impressed with the consistency in hemoglobin levels across the duration of the study, which highlights the ability of vadadustat to control and maintain hemoglobin levels in this patient population. Furthermore, the results indicate that daily and three times per week dosing regimens are both viable options for patients on dialysis."

John P. Butler, President and Chief Executive Officer of Akebia, stated "These results further confirm vadadustat as a potential best-in-class anemia treatment for CKD patients, and reinforce our confidence in this product candidate as we advance toward our Phase 3 program. Adding these results to the 12 other clinical studies we have completed, we are

confident in the potential for vadadustat to treat anemia in a broad array of patients with CKD. We are pleased to have successfully completed this stage of our drug development and look forward to initiating Phase 3 studies."

Complete efficacy and safety data from this Phase 2 study will be presented at an upcoming medical meeting.

About the Phase 2 Study Design of Vadadustat in Dialysis Patients with Anemia Related to CKD

The Phase 2 multi-center, open-label study evaluated 94 patients over 16 weeks of treatment, at 20 dialysis centers in the United States, including an assessment of HGB response to the starting dose of vadadustat during the first 8 weeks, followed by an assessment of HGB response to algorithm-guided dose adjustments of vadadustat during the subsequent 8 weeks of treatment. The study enrolled three cohorts, each consisting of approximately 30 CKD patients with anemia undergoing dialysis who were switched from injectable rESA therapy to vadadustat. Patients in the first two cohorts received once daily doses of vadadustat, while patients in the third cohort received vadadustat three times per week in conjunction with their hemodialysis schedule.

Conference Call and Webcast

Date:	September 8, 2015
Time:	5:00 PM ET
Telephone Access:	Domestic callers: dial 877-458-0977 International callers: dial 484-653-6724 Please reference the Akebia conference call Passcode: 3379-3912
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.

About Vadadustat (Formerly AKB-6548)

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 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, plans for presenting a more detailed analysis of the data from the Phase 2 study, and the initiation of the Phase 3 program. 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 our Phase 3 studies and the availability of financing to cover such cost; the timing and content of decisions made by the FDA and other regulatory authorities; the acceptance of Akebia's abstract for presentation at a medical meeting; the actual time it takes to prepare for and initiate Phase 3 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. 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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Exhibit 99.2

AkebiaTherapeutics

September 8, 2015

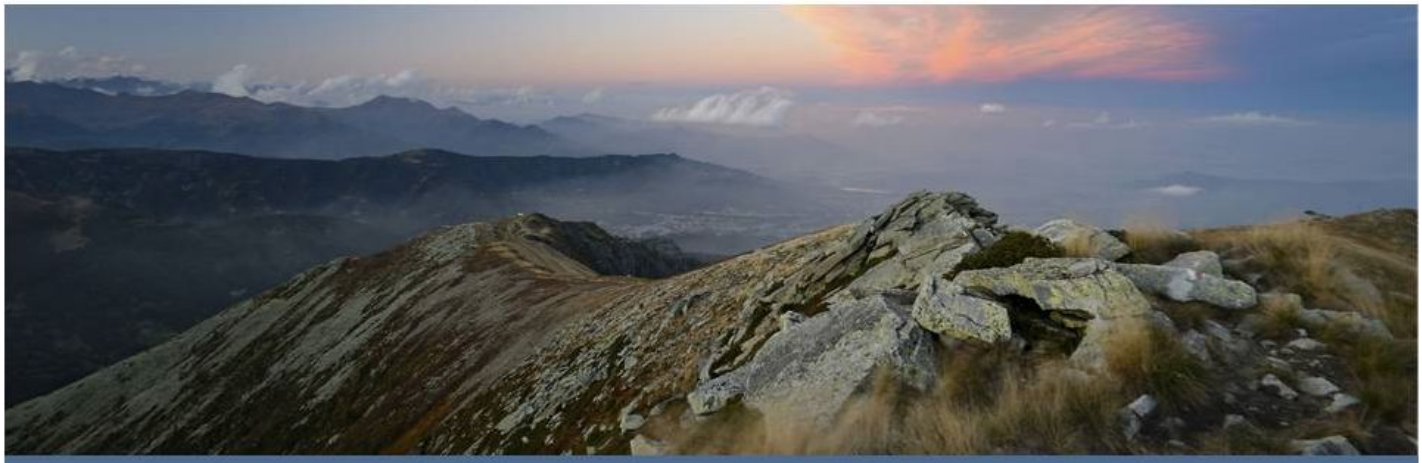
Forward-Looking Statements

This presentation 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, plans for presenting a more detailed analysis of the data from the Phase 2 study, and the initiation of the Phase 3 program. 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 our Phase 3 studies and the availability of financing to cover such cost; the timing and content of decisions made by the FDA and other regulatory authorities; the acceptance of Akebia's abstract for presentation at a medical meeting; the actual time it takes to prepare for and initiate Phase 3 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. 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 presentation.

Akebia at a Glance

Akebia is a biopharmaceutical company focused on delivering innovative therapies to patients with kidney disease through the biology of hypoxia inducible factor (HIF)

- Experienced Management Team with extensive knowledge in HIF biology combined with renal expertise
- Lead program: vadadustat (AKB-6548) is a once-daily, oral therapy with best-in-class potential for the treatment of renal anemia
- Completed Phase 2 vadadustat studies in both non-dialysis and dialysis patients
- Additional HIF-PH inhibitor compounds in pipeline
- Public (NASDAQ:AKBA), headquartered in Cambridge, MA



Top-Line Results of Phase 2 Vadadustat Study in Dialysis Patients Anemia Related to Chronic Kidney Disease

Vadadustat (AKB-6548) dialysis efficacy study

Patient Criteria

- n= 90
- Age: 18 –79 years old
- CKD Stage 5 undergoing chronic hemodialysis for ≥ 3 months and dialysis 3x per week
- Mean HGB: ≥ 9.0 and ≤ 12.0 g/dL
- Receives epoetin alfa regularly

Open Label 16 Weeks of Treatment

1st analysis: change in HGB at Week 8

2nd analysis: subsequent change in HGB with dose adjustment starting at Week 8

- Vadadustat 300 mg QD
- Vadadustat 450 mg QD
- Vadadustat 450 mg TIW

Endpoints

Primary endpoint

1. Compare the change in HGB from baseline for three different doses of Vadadustat

Secondary endpoint

1. Safety of Vadadustat in ESRD subjects on dialysis
2. Effect of dialysis on the PK of Vadadustat

(1) First eight weeks include Weeks 1 – 8.
(2) Second eight weeks include Weeks 9 – 16.

Demographics

	300 mg QD N=30	450 mg QD N=33	450 mg TIW N=31	All Subjects N=94
Sex-female	13 (43.3%)	15 (45.5%)	12 (38.7%)	40 (42.6%)
Race				
White/Caucasian	24 (80.0%)	21 (63.6%)	19 (61.3%)	64 (68.1%)
Black or African American	6 (20.0%)	9 (27.3%)	9 (29.0%)	24 (25.5%)
Other	0 (0.0%)	3 (9.1%)	3 (9.7%)	6 (6.4%)
Mean Age (years)	55.5	59.4	57.8	57.6
Mean Weight (kg)	82.7	82.1	84.2	83.0
Mean BMI (kg/m^2)	29.8	29.6	29.2	29.5
Mean time on dialysis (years)	4.92	4.93	3.87	4.58
Mean Hemoglobin (g/dL)	10.4	10.6	10.5	10.5
Mean Ferritin (ng/mL)	763	782	808	784
Etiology of CKD				
Diabetes	16 (53.3%)	23 (69.7%)	21 (67.7%)	60 (63.8%)
Hypertension & Large Vessel Disease	15 (50.0%)	17 (51.5%)	21 (67.7%)	53 (56.4%)
Other	7 (23.3%)	4 (12.1%)	1 (3.2%)	12 (12.8%)

Mean HGB Average Results at Study Stages

MITTPopulation

Mean Hemoglobin levels (g/dL)	Baseline	Week 7/8	Week 15/16
300mg Daily Dose	10.4	10.4	10.3
450mg Daily Dose	10.6	10.3	10.5
450mg Three Times-per-Week Dose	10.5	10.2	10.4

PPPopulation

Mean Hemoglobin levels (g/dL)	Baseline	Week 7/8	Week 15/16
300mg Daily Dose	10.3	10.4	10.3
450mg Daily Dose	10.6	10.4	10.6
450mg Three Times-per-Week Dose	10.5	10.5	10.5

Summary of adverse events (AEs) and serious AEs (SAEs)
ITT Population

	300 mg QD N=30	450 mg QD N=33	450 mg TIW N=31	All Subjects N=94
Number ofAEs	110	95	89	294
Subjects with ≥ 1 AE	26 (86.7%)	26 (78.8%)	26 (83.9%)	78 (83.0%)
Subjects with ≥ 1 SAE	2 (6.7%)	6 (18.2%)	5 (16.1%)	13 (13.8%)
Subjects with SAE Reported as Related	0	0	0	0
Deaths	0	0	0	0

Dialysis Phase 2 Study Top Line Summary

Vadadustat maintained stable HGB levels across the 3 dosing cohorts following conversion from rESA

- Daily and three times-a-week regimens are viable dosing options in dialysis subjects
- Hemoglobin level was maintained within the desired range while minimizing excursions ≥13.0 g/dL
- Improvements in iron mobilization consistent with previous studies

Vadadustat was generally well-tolerated across the 3 dose cohorts

- No apparent differences in the type or frequency of AEs across the 3 dosing groups
- Observed SAEs were consistent with events described in dialysis population
- There were no SAEs reported as related to study drug, no strokes, and no deaths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September 8, 2015