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): **June 30, 2026**

AKEBIA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36352**	**20-8756903**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

245 First Street Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	**(Zip Code)**

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

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	**AKBA**	**The Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On June 30, 2026, Akebia Therapeutics, Inc. (the "Company") and U.S. Renal Care ("USRC) issued a press release announcing the results of a planned interim analysis of the Vafseo Outcomes In Center Experience ("VOICE") trial and that it met the predefined stopping criteria by establishing non-inferiority and superiority of the primary composite endpoint and the decision by USRC Kidney Research to stop the trial on this basis. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by a specific reference in such filing.

Item 8.01 Other Events.

On June 30, 2026, the Company and USRC announced the results of a planned interim analysis of the VOICE trial and that it met the predefined stopping criteria by establishing non-inferiority and superiority of the primary composite endpoint and the decision by USRC Kidney Research to stop the trial on this basis. The primary investigator made the decision to stop the trial after a recommendation from the Independent Data Monitoring Committee and Trial Steering Committee, based on an interim analysis of data from the trial as of the June 1, 2026 data cutoff date meeting the prespecified stopping criteria.

The VOICE trial enrolled 2,116 patients and was designed as a randomized, open-label, active controlled, non-inferiority trial sponsored by USRC to measure the safety of Vafseo® (vadadustat) administered three times weekly ("TIW") versus standard-of-care erythropoiesis stimulating agent ("ESA"). The primary endpoint is a hierarchical composite endpoint of all-cause mortality and all-cause hospitalization, analyzed by the win-odds method. Vafseo is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor approved for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least three months.

Results of the planned interim analysis as of June 1, 2026, the data cutoff date, demonstrated that the trial met the predefined stopping criteria with a win odds of 1.16 (95% confidence interval ("CI") 1.06, 1.28, p=0.0016), establishing non-inferiority and superiority of the primary composite endpoint. The results further demonstrated a statistically significant decrease in hospitalizations with Vafseo versus ESA (1.11 versus 1.23 hospitalizations per patient year, incidence rate ratio of 0.90 (95% CI, 0.824, 0.988). There was no statistically significant difference between mortality rates with Vafseo versus ESA (8.77% versus 8.78% per 100 patient years, incidence rate ratio of 1.00 (95% CI 0.718, 1.391).

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release, dated June 30, 2026, issued by Akebia Therapeutics, Inc. and U.S. Renal Care
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

IGNATURE

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.

Date: June 30, 2026

By: /s/ John P. Butler

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

Exhibit 99.1

U.S. Renal Care and Akebia Announce Interim Analysis of VOICE Trial Demonstrated Overwhelming Statistical Evidence of Improved Safety Outcomes for Patients Treated with Vafseo versus an ESA

Vafseo® demonstrated a clinically meaningful safety outcome benefit in U.S. patients with anemia due to CKD on dialysis utilizing TIW dosing regimen

Primary Investigator to stop trial on recommendation from Independent Data Monitoring Committee and Trial Steering Committee

Interim analysis on primary endpoint replicated safety outcomes reported in the recently published win odds analysis of the INNO$_2$VATE clinical trial program

Akebia and USRC expect to submit data for presentation at an upcoming scientific meeting

CAMBRIDGE, Mass. — June 30, 2026 — Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, and U.S. Renal Care (USRC), the nation's largest privately held and fastest-growing kidney care provider, are pleased to announce today the decision by USRC Kidney Research to stop the Vafseo Outcomes In Center Experience (VOICE) trial following a planned interim analysis. The Primary Investigator made the decision to stop the study after a recommendation from the Independent Data Monitoring Committee and Trial Steering Committee based on the prespecified stopping criteria and supported by findings of significantly improved safety outcomes in patients treated with Vafseo® (vadadustat) dosed three times weekly (TIW) versus an erythropoiesis-stimulating agent (ESA).

"The VOICE trial was rigorously and pragmatically designed to test the hypothesis that there are clinically important areas of differentiation between Vafseo and ESAs," said Geoffrey A. Block, M.D., FASN, Associate Chief Medical Officer and Senior Vice President, Clinical Research & Medical Affairs for USRC. "Importantly, based on the interim data, we observed that Vafseo resulted in a statistically significant and clinically meaningful reduction in the primary composite endpoint of all-cause mortality and hospitalization, with the result driven by a reduction in hospitalization. We are eager to share data that we believe shows substantial clinical benefit with clinicians and dialysis industry colleagues, and expect to submit the VOICE trial results to an upcoming scientific meeting. We are indebted to the thousands of patient volunteers who have participated in this trial, to our team of dedicated Investigators, to the extraordinary work of the USRC Kidney Research team, and to the dedicated staff at all of our participating facilities who bring innovation directly to patient care."

The VOICE trial enrolled 2,116 patients and was designed as a randomized, open-label, active controlled, non-inferiority trial sponsored by USRC to measure the safety of Vafseo administered TIW versus standard-of-care ESA using a hierarchical composite endpoint of mortality and hospitalization rates. Results of the planned interim analysis as of June 1, 2026, the data cutoff date, demonstrated that the trial met the predefined stopping criteria with a win odds of 1.16 (95% confidence interval (CI) 1.06, 1.28, p=0.0016), establishing non-inferiority and superiority of the primary composite endpoint. The results further demonstrated a statistically significant decrease in hospitalizations with Vafseo versus ESA (1.11 versus 1.23 hospitalizations per patient year, incidence rate ratio of 0.90 (95% CI, 0.824, 0.988). There was no statistically significant difference between mortality rates with Vafseo versus ESA (8.77% versus 8.78% per 100 patient-years, incidence rate ratio of 1.00 (95% CI 0.718, 1.391).

“It was striking to see results in the VOICE trial, where we used vadadustat three times weekly during hemodialysis, that were nearly identical to those reported in a post-hoc analysis of the phase 3 INNO$_2$VATE program, where vadadustat was dosed daily at home,” said Glenn M. Chertow, M.D., M.P.H., Professor of Medicine, Stanford University School of Medicine and member of the Executive Steering Committee for the VOICE trial. “The data analyzed in the VOICE trial confirms the observation that vadadustat, when compared to standard-of-care erythropoiesis stimulating agents, reduces the composite endpoint of death or hospitalization in patients receiving dialysis with CKD-related anemia.”

"Anemia is far more than a lab value – it can take away a person's energy, independence, ability to work, and quality of life," said Edward V. Hickey, III, President of the American Association of Kidney Patients (AAKP), Chair of AAKP's Veterans Health Initiative, and a chronic kidney disease patient. "Every advancement in kidney care should ultimately be measured by its ability to help patients live healthier, fuller lives. AAKP views kidney disease as both a healthcare issue and a workforce issue because the burden of this disease extends well beyond the clinic. When patients have access to innovations that can improve outcomes, support transplant readiness, and reduce hospitalizations, they have a greater opportunity to remain active in their families, workplaces, and communities. AAKP is proud to have represented the patient voice on the VOICE Trial Steering Committee, and we remain committed to advancing patient-centered innovation that expands care choices for people living with kidney disease."

In March 2024, Vafseo was approved by the U.S. Food and Drug Administration for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least three months, and it has been available in the U.S. since January 2025. Vafseo is approved for once-daily administration. There are no other oral hypoxia-inducible factor prolyl hydroxylase inhibitors (HIF-PHI) to treat anemia in the market or in development in the U.S.

About the VOICE Trial

The Vafseo Outcomes In-Center Experience (VOICE) trial, a collaborative trial between U.S. Renal Care and Akebia Therapeutics, is an investigator-initiated, multi-center, randomized, open-label, active-controlled, non-inferiority trial of the safety of vadadustat administered three times per week for the treatment of anemia in in-center hemodialysis patients with end stage kidney disease. The primary endpoint is a composite hierarchical endpoint of all-cause mortality and all-cause hospitalization, analyzed by the win odds method. The secondary endpoints are all-cause hospitalization and all-cause mortality. Please refer to NCT06520826 on www.clinicaltrials.gov for more information about the VOICE trial.

About U.S. Renal Care

U.S. Renal Care is the largest privately held and fastest-growing dialysis provider in the nation. We partner with nephrologists to care for more than 37,000 people living with kidney disease across 32 states, offering in-center and home dialysis options that support each patient’s unique lifestyle and care needs. U.S. Renal Care leads the dialysis industry with the highest percentage of CMS 4- and 5-star rated centers for patient experience and quality of care. U.S. Renal Care’s Kidney Research team designs and conducts clinical trials, spanning across academic collaboration, investigator-initiated research, industry-sponsored research, and federally-funded research. Since 2000, U.S. Renal Care has grown through clinical excellence, innovation and a shared commitment to improving the lives of people with kidney disease. Visit USRenalCare.com to learn more.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease. Akebia was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

About Vafseo® (vadadustat) tablets

Vafseo® (vadadustat) tablets is a once-daily oral hypoxia-inducible factor prolyl hydroxylase inhibitor that activates the physiologic response to hypoxia to stimulate endogenous production of erythropoietin, increasing hemoglobin and red blood cell production to manage anemia. Vafseo is approved for use in 37 countries.

INDICATION

VAFSEO is indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months.

Limitations of Use

- VAFSEO has not been shown to improve quality of life, fatigue, or patient well-being.
- VAFSEO is not indicated for use:
    - As a substitute for red blood cell transfusions in patients who require immediate correction of anemia.
    - In patients with anemia due to CKD not on dialysis.

IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) tablets

WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, and THROMBOSIS OF VASCULAR ACCESS.

VAFSEO increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE). Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels.

No trial has identified a hemoglobin target level, dose of VAFSEO, or dosing strategy that does not increase these risks.

Use the lowest dose of VAFSEO sufficient to reduce the need for red blood cell transfusions.

CONTRAINDICATIONS

- Known hypersensitivity to VAFSEO or any of its components
- Uncontrolled hypertension

WARNINGS AND PRECAUTIONS

- **Increased Risk of Death, Myocardial Infarction (MI), Stroke, Venous Thromboembolism, and Thrombosis of Vascular Access**
  A rise in hemoglobin (Hb) levels greater than 1 g/dL over 2 weeks can increase these risks. Avoid in patients with a history of MI, cerebrovascular event, or acute coronary syndrome within the 3 months prior to starting VAFSEO. Targeting a Hb level of greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events. Use the lowest effective dose to reduce the need for red blood cell (RBC) transfusions. Adhere to dosing and Hb monitoring recommendations to avoid excessive erythropoiesis.
- **Hepatotoxicity**
  Hepatocellular injury attributed to VAFSEO was reported in less than 1% of patients, including one severe case with jaundice. Elevated serum ALT, AST, and bilirubin levels were observed in 1.8%, 1.8%, and 0.3% of CKD patients treated with VAFSEO, respectively. Measure ALT, AST, and bilirubin before treatment and monthly for the first 6 months, then as clinically indicated. Discontinue VAFSEO if ALT or AST is persistently elevated or accompanied by elevated bilirubin. Not recommended in patients with cirrhosis or active, acute liver disease.
- **Hypertension**
  Worsening of hypertension was reported in 14% of VAFSEO and 17% of darbepoetin alfa patients. Serious worsening of hypertension was reported in 2.7% of VAFSEO and 3% of darbepoetin alfa patients. Cases of hypertensive crisis, including hypertensive encephalopathy and seizures, have also been reported in patients receiving VAFSEO. Monitor blood pressure. Adjust anti-hypertensive therapy as needed.
- **Seizures**
  Seizures occurred in 1.6% of VAFSEO and 1.6% of darbepoetin alfa patients. Monitor for new-onset seizures, premonitory symptoms, or change in seizure frequency.
- **Gastrointestinal (GI) Erosion**
  Gastric or esophageal erosions occurred in 6.4% of VAFSEO and 5.3% of darbepoetin alfa patients. Serious GI erosions, including GI bleeding and the need for RBC transfusions, were reported in 3.4% of VAFSEO and 3.3% of darbepoetin alfa patients. Consider this risk in patients at increased risk of GI erosion. Advise patients about signs of erosions and GI bleeding and urge them to seek prompt medical care if present.
- **Serious Adverse Reactions in Patients with Anemia Due to CKD and Not on Dialysis**
  The safety of VAFSEO has not been established for the treatment of anemia due to CKD in adults not on dialysis and its use is not recommended in this setting. In large clinical trials in adults with anemia of CKD who were not on dialysis, an increased risk of mortality, stroke, MI, serious acute kidney injury, serious hepatic injury, and serious GI erosions was observed in patients treated with VAFSEO compared to darbepoetin alfa.
- **Malignancy**
  VAFSEO has not been studied and is not recommended in patients with active malignancies. Malignancies were observed in 2.2% of VAFSEO and 3.0% of darbepoetin alfa patients. No evidence of increased carcinogenicity was observed in animal studies.

ADVERSE REACTIONS

- The most common adverse reactions (occurring at ≥ 10%) were hypertension and diarrhea.

DRUG INTERACTIONS

- **Iron supplements and iron-containing phosphate binders:** Administer VAFSEO at least 1 hour before products containing iron.
- **Non-iron-containing phosphate binders**: Administer VAFSEO at least 1 hour before or 2 hours after non-iron-containing phosphate binders.
- **BCRP substrates**: Monitor for signs of substrate adverse reactions and consider dose reduction.
- **Statins**: Monitor for statin-related adverse reactions. Limit the daily dose of simvastatin to 20 mg and rosuvastatin to 5 mg.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm. A pregnancy exposure registry is available to monitor outcomes in women exposed to VAFSEO during pregnancy. Report pregnancies to 1-844-445-3799.
- Lactation: Breastfeeding not recommended until two days after the final dose.
- Hepatic Impairment**:** Not recommended in patients with cirrhosis or active, acute liver disease.

Please note that this information is not comprehensive. Please click here for the Full Prescribing Information, including BOXED WARNING and Medication Guide.

Forward-Looking Statements

Statements in this press release regarding Akebia Therapeutics, Inc.'s ("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, and include, but are not limited to: Akebia and USRC's plans and expectations regarding submitting data from the VOICE trial to an upcoming scientific meeting; statements made by Geoffrey A. Block in this press release, including beliefs regarding the rigorous and pragmatic design of the VOICE trial, the hypothesis of clinically important areas of differentiation between Vafseo and ESAs and the extent to which data from the VOICE trial tests such hypothesis, and beliefs that the data from the VOICE trial shows substantial clinical benefit; statements made by Glenn M. Chertow in this press release, including his opinions regarding the results of the VOICE trial and his beliefs and observations regarding vadadustat's ability to reduce the composite endpoint of death or hospitalization in patients receiving dialysis with CKD-related anemia; and statements made by Edward V. Hickey III in this press release.

The terms "intend," "believe," "plan," "goal," "potential," "anticipate," "estimate," "target," "predict," "expect," "future," "may," "will," "could," "continue," derivatives of these words, and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to, risks associated with: the potential therapeutic benefits, safety profile, and effectiveness of Vafseo; risks and uncertainties related to Akebia's ongoing and

planned research and development activities, including initiating, conducting or completing preclinical studies and clinical trials and the timing of such preclinical studies and clinical trials; the results of Akebia's preclinical studies and clinical trials, including that initial, preliminary, interim or retrospective data, analysis or results may not be replicated in, or predictive of, final analyses or results of future preclinical or clinical data, analyses or results or that such analysis or results may not support further development of such product candidates; Akebia's ability to initiate and enroll patients in its clinical trials; decisions made by health authorities, such as the FDA, with respect to regulatory filings and other interactions; the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to Akebia's commercial products, including estimates regarding the potential market opportunity; the competitive landscape for Akebia's commercial products, including generic entrants and the timing thereof; Akebia's ability to obtain and maintain patent protection on its products and product candidates, and to successfully defend these patents against third-party challenges; Akebia's ability to attract and retain qualified personnel; Akebia's ability to achieve and maintain profitability and to maintain operating expenses consistent with its operating plan; Akebia's revenue and that its financial results from prior periods may not be indicative of future results; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; early termination of any of Akebia's collaborations; and changes in the geopolitical environment and uncertainty surrounding U.S. trade policy on tariffs. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's most recent Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC), and other filings that Akebia may make with the SEC in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

Akebia Therapeutics Contact

Mercedes Carrasco
mcarrasco@akebia.com