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): **May 7, 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 2.02. Results of Operations and Financial Condition.

On May 7, 2026, Akebia Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2026 and recent business highlights. A copy of the Company's press release containing this information is furnished as Exhibit 99.1 to this Current Report on Form 8-K ("Report") and is incorporated herein by reference.

The information in this Report (including Item 2.02 and 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, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated May 7, 2026, issued by Akebia Therapeutics, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: May 7, 2026

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

Exhibit 99.1

Akebia Therapeutics Reports First Quarter 2026 Financial Results and Commercial and Pipeline Highlights

Q1 2026 Vafseo® (vadadustat) net product revenues grew to $15.8 million; Q1 2026 total net product revenues of $52.0 million

Number of patients treated with Vafseo increased 60% in Q1 2026 compared to Q4 2025

Akebia hosted virtual R&D Day highlighting robust kidney disease pipeline, outlining clinical trial plans and timing of expected data catalysts

Patient enrollment continues to progress in praliciguat Phase 2 clinical trial in focal segmental glomerulosclerosis (FSGS)

Akebia to host conference call on May 7, 2026, at 8:00 a.m. EST

CAMBRIDGE, Mass.—May 7, 2026—Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today reported financial results for the first quarter ended March 31, 2026 and shared recent business highlights related to the commercial launch of Vafseo® (vadadustat), now in its second year, as well as its advancing pipeline.

“The number of patients on Vafseo increased through the start of the year, and we are further encouraged by trends suggesting continued growth as we leverage improved patient access and adherence as dialysis organizations implement observed dosing protocols,” said John P. Butler, Chief Executive Officer of Akebia. “Increasing the breadth and depth of Vafseo prescribing, complemented by our efforts to generate data that will potentially demonstrate its additional clinical benefits, is critical to achieving our goal to make Vafseo standard of care for patients on dialysis. Separately, I’m pleased with the progress made to advance our clinical pipeline of kidney disease programs, now with two clinical programs enrolling, including a Phase 2 clinical trial of praliciguat in FSGS. We remain on track with plans to initiate a Phase 2 open-label rare kidney disease basket study in the second half of 2026, evaluating AKB-097 in IgA nephropathy, lupus nephritis and C3 glomerulopathy. These efforts were recently highlighted as part of our virtual R&D Day, where key medical experts reinforced the potential of our expanding pipeline.”

Vafseo Q1 2026 Commercial Results:

- Vafseo net product revenues grew to $15.8 million in Q1. Inventory weeks on hand was relatively flat versus Q4 2025.
- Total number of prescribers increased to approximately 1,025 in Q1, representing an increase of approximately 28% over the number of prescribers in Q4 2025.
- Total number of patients on Vafseo increased approximately 60% at the end of Q1 compared to the end of Q4 2025. The number of new patient starts in Q1 was the highest in any quarter since the initial quarter of launch. The majority of new patients began in March.
- Approximately 20% of patients and 30% of prescribers in Q1 2026 were from dialysis organizations other than U.S. Renal Care, representing improved diversification in the patient and prescriber base in Q1.
- First refill adherence rates through the end of March were approximately 86% for patients treated under an observed dosing protocol where we have historically received patient level

data. In Q1, approximately two thirds of all patients were treated under an observed dosing protocol.

Akebia continues to build a body of evidence to potentially demonstrate additional clinical benefits of Vafseo.

- In February, Akebia presented an economic analysis on cost of hospitalizations for patients treated with vadadustat vs darbepoetin alfa at the Annual Dialysis Conference. As reported in a poster titled, “Cost comparison analysis of hospitalizations for vadadustat versus darbepoetin alfa based on the INNO2VATE trials,” of the patients treated with vadadustat versus darbepoetin alfa, 7.7% had fewer hospitalization events annually; 16.0% had fewer hospitalization days; and, based on Medicare cost data, 14.8% had lower annual hospitalization costs per patient.
- The Journal of the American Society of Nephrology, a leading, peer-reviewed journal in nephrology, published post-hoc win statistics analysis of all-cause mortality and hospitalization from Akebia’s global Phase 3 INNO2VATE program. As reported in the Research Letter titled, “Comparing Vadadustat and Darbepoetin in Maintenance Dialysis with CKD-Related Anemia,” vadadustat demonstrated statistically significant better outcomes relative to the erythropoiesis-stimulating agent (ESA), darbepoetin alfa, on a hierarchical composite endpoint of all-cause mortality and hospitalization in patients with anemia due to chronic kidney disease receiving dialysis.
- Akebia expects topline data from VOCAL, a Phase 3b trial evaluating three times weekly (TIW) dosing of Vafseo versus ESAs, in Q4 2026 and topline data from VOICE, a large Phase IV trial of over 2,100 patients evaluating Vafseo TIW against standard-of-care ESAs using a hierarchical composite endpoint of all-cause mortality and all-cause hospitalization, in early 2027.

Progress on Kidney Disease Pipeline:

- In January, Akebia announced the dosing of the first patient in a Phase 2 clinical trial of praliciguat, an oral, once-daily soluble guanylate cyclase (sGC) stimulator being evaluated for the treatment of biopsy-confirmed FSGS, a rare kidney disease. Akebia expects to enroll up to approximately 60 patients in this trial.
- In April 2026, Akebia held a virtual R&D Day highlighting its robust kidney disease pipeline. The event featured scientific experts, James A. Tumlin, MD (NephroNet), V. Michael Holers, MD (University of Colorado, Anschutz), and Jonathan Barratt, MD. PhD, FRCP (University of Leicester). A replay of the event is available here.
    - Among highlights, Akebia confirmed plans to initiate a Phase 2 open-label basket study to evaluate AKB-097 in IgA nephropathy, lupus nephritis and C3 glomerulopathy. Akebia expects to initiate the study in the second half of 2026 with initial data expected in 2027.
- In April 2026, Akebia initiated a Phase 1 study of AKB-9090 in up to 70 healthy volunteers with topline data expected in early 2027. The initial target indication for AKB-9090 is the prevention of cardiac surgery-associated acute kidney injury.

Financial Results

- **Revenues:** Total revenues were $53.5 million in the first quarter of 2026 compared to $57.3 million in the first quarter of 2025. This decrease was driven by lower Auryxia® (ferric citrate) revenues which were partially offset by higher Vafseo revenues.
    - Vafseo net product revenues were $15.8 million in the first quarter of 2026 compared to $12.0 million in the first quarter of 2025.
    - Auryxia net product revenues were $36.2 million in the first quarter of 2026 as compared to $43.8 million in the first quarter of 2025. We continue to expect generic

competition for Auryxia to expand this year and therefore expect Auryxia revenues to decrease in 2026 as compared to 2025 Auryxia revenues.

- License, collaboration and other revenues were $1.6 million in the first quarter of 2026 compared to $1.5 million in the first quarter of 2025.

- **Cost of Goods Sold:** Cost of goods sold was $12.3 million in the first quarter of 2026 compared to $7.6 million in the first quarter of 2025. This increase was primarily due to an increase in inventory write-downs including as a result of excess, obsolescence and scrap during the first quarter of 2026. Of note, Vafseo-related COGS in both periods was derived from pre-launch inventory, which does not include the full cost of manufacturing as a portion of those inventory-related expenses were recorded as research and development expenses in the period incurred prior to Vafseo's approval in the U.S.
- **Research & Development Expenses:** Research and development expenses were $14.8 million in the first quarter of 2026 compared to $9.8 million in the first quarter of 2025. The increase in expenses was driven by increased clinical trial activities related to praliciguat and AKB-9090 as well as higher headcount-related costs.
- **SG&A Expenses:** Selling, general and administrative expenses were $30.4 million in the first quarter of 2026 compared to $25.7 million in the first quarter of 2025. This increase was driven by higher headcount-related costs.
- **Net Income (Loss):** Net loss was $9.1 million in the first quarter of 2026 compared to net income of $6.1 million in the first quarter of 2025. The change to a net loss in the first quarter of 2026 resulted from lower revenues and higher expenses during the quarter as compared to the first quarter of 2025.
- **Cash Position:** Cash and cash equivalents as of March 31, 2026 were approximately $162.6 million as compared to $184.8 million as of December 31, 2025. Akebia expects its existing cash resources and cash from operations will be sufficient to fund its current operating plan for at least two years.

Conference Call

Akebia will host a conference call on Thursday, May 7 at 8:00 a.m. EDT to discuss first quarter 2026 earnings. To access the call, please register by clicking on this Registration Link, and you will be provided with dial in details. To avoid delays and ensure timely connection, we encourage dialing into the conference call 15 minutes ahead of the scheduled start time.

A live webcast of the conference call will be available via the "Investors" section of Akebia's website at: https://ir.akebia.com/. An online archive of the webcast can be accessed via the Investors section of Akebia's website at https://ir.akebia.com approximately two hours after the event.

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.

Exhibit 99.1

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.

Exhibit 99.1

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 presentation 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, statements regarding: Akebia's plans, strategies and prospects for its business; Akebia's beliefs regarding the continued growth of the number of patients on Vafseo and ability to leverage improved patient access and adherence; Akebia's plans with respect to its U.S. commercial launch of Vafseo®, including the potential U.S. market opportunity and plans to increase the breadth and depth of Vafseo prescribing; Akebia's plans for Vafseo to become standard of care for treatment of anemia due to CKD in dialysis, including its ability to continue to build on the body of evidence demonstrating Vafseo's value potential, and progress towards that goal; Akebia's expectations and beliefs about demand for Vafseo, including the number of patients with access to Vafseo and the focus of dialysis organizations; Akebia's plans and expectations with respect to the VOCAL and VOICE trials, including the timing of top-line data; Akebia's expectations with respect to the potential of its expanding pipeline; Akebia's plans and expectations with respect to praliciguat and the Phase 2 trial, including the number of patients to be enrolled in the trial; Akebia's plans and expectations with respect to AKB-097, including the timing of initiation of, and initial data from, an open label Phase 2 basket study and the indications to be evaluated; Akebia's plans and expectations with respect to AKB-9090, including the timing of initiation of, and top-line data from, a Phase 1 trial and the indication to be evaluated; the sufficiency of, and the period in which Akebia expects to have, cash to fund its current operating plan.

The terms "intend," "believe," "plan," "goal," "potential," "anticipate, "estimate," "expect," "future," "will," "continue," "could", 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 and Akebia's development candidates; the results of preclinical and clinical research; 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; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to achieve and maintain profitability and to maintain operating expenses consistent with its operating plan; 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 Report on Form 10-K for the year ended December 31, 2025, and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this presentation, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this presentation.

Akebia Therapeutics Contact

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AKEBIA THERAPEUTICS, INC.
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
(in thousands, except per share data)	**2026**	**2025**
Revenues		
Product revenue, net	$ 51,992	$ 55,791
License, collaboration and other revenue	1,552	1,545
Total revenues	53,544	57,336
Cost of goods sold		
Cost of product and other revenue	12,290	7,625
Total cost of goods sold	12,290	7,625
Operating expenses		
Research and development	14,807	9,754
Selling, general and administrative	30,436	25,742
License	707	701
Total operating expenses	45,950	36,197
Income (loss) from operations	**(4,696)**	**13,514**
Other expense, net	(4,688)	(7,557)
Change in fair value of warrant liability	456	155
Income (loss) before income taxes	**(8,928)**	**6,112**
Income tax expense	(126)	—
Net income (loss)	$ (9,054)	$ 6,112
Net income (loss) per share - basic	$(0.03)	$0.03
Net income (loss) per share - diluted	$(0.03)	$0.03
Weighted-average number of common shares - basic	267,046,755	235,497,720
Weighted-average number of common shares - diluted	267,046,755	241,602,853

Exhibit 99.1

Unaudited Selected Balance Sheet Data

(in thousands)	March 31, 2026	December 31, 2025
Cash and cash equivalents	$ 162,644	$ 184,844
Working capital	$ 69,597	$ 90,017
Total assets	$ 362,520	$ 376,565
Total stockholders' equity	$ 27,375	$ 32,610