
**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): **August 5, 2026**

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

Delaware
(State or other jurisdiction
of incorporation)

001-36352
(Commission
File Number)

20-8756903
(IRS Employer
Identification No.)

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

02142
(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 August 5, 2026, Akebia Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the second quarter ended June 30, 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 August 5, 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: August 5, 2026

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

Akebia Therapeutics Reports Second Quarter 2026 Financial Results and Business Highlights

Q2 2026 Vafseo® (vadadustat) net product revenues grew to \$21.3 million; more than 10,500 patients now on therapy

Advancement of rare kidney disease pipeline continues with initiation of Phase 2 open-label basket trial evaluating ebribafusp for treatment of IgA nephropathy, lupus nephritis and C3 glomerulopathy; initial data expected in 2027

Interim analysis of VOICE trial demonstrated overwhelming statistical evidence of improved safety outcomes for patients treated with Vafseo versus an ESA

Akebia to host conference call at 4:30 p.m. EDT on August 5, 2026

CAMBRIDGE, Mass.—August 5, 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 second quarter ended June 30, 2026 and shared recent business highlights related to the commercial launch of Vafseo® (vadadustat) and its advancing rare kidney disease pipeline.

“We’re pleased with Vafseo’s continued sequential revenue growth this quarter, as well as the recently announced positive VOICE trial results for the primary endpoint, which marks an important step in our ultimate goal of making Vafseo standard of care for the treatment of anemia in patients on dialysis,” said John P. Butler, Chief Executive Officer of Akebia. “We also continue to make strong progress advancing our rare kidney disease pipeline with the initiation of our Phase 2 basket trial evaluating ebribafusp for the treatment of three rare glomerular kidney diseases, with initial data expected in 2027. Further, enrollment continues in our Phase 2 trial of praliciguat in FSGS.”

Second Quarter and Recent Business Highlights:

- Vafseo net product revenues grew to \$21.3 million in Q2, representing a 34% increase over Q1 of this year. More than 10,500 patients were active on Vafseo in Q2, representing a 41% increase from the end of Q1 2026. Total number of prescribers increased to approximately 1,200, representing an increase of approximately 17% versus Q1 2026.
- In August, Akebia announced that it initiated a Phase 2 open-label basket trial of ebribafusp (previously known as AKB-097 and ADX-097), a next-generation complement inhibitor. The trial of ebribafusp in patients with IgA nephropathy, lupus nephritis or C3 glomerulopathy is expected to enroll up to 30 patients dosed subcutaneously once weekly. As part of this study, Akebia will measure urine protein creatinine ratio (UPCR), kidney function measured by estimated glomerular filtration rate (eGFR), and ebribafusp pharmacokinetics. In addition, the trial will measure blood and urine complement biomarkers to determine if ebribafusp reduces complement activity in kidneys while avoiding complement system inhibition in the blood. The Phase 2 basket trial is open-label, and Akebia expects to report initial data in 2027.
- In June, U.S. Renal Care (USRC) and Akebia announced that a planned interim analysis of the VOICE trial (n=2,116) met its predefined stopping criteria. The data showed a statistically significant improved safety outcome in patients treated with Vafseo dosed three times per week (TIW) versus erythropoiesis stimulating agents (ESA) on the hierarchical composite endpoint of all-cause mortality and hospitalization (win odds 1.16; 95% CI 1.06, 1.28; p=0.0016), driven by a significant reduction in hospitalizations. The trial results replicated the safety outcomes from the post-hoc win statistics analysis of the Phase 3 INNO₂VATE clinical trial. USRC expects to submit the data for presentation at an upcoming medical meeting.

- In June, Akebia announced it had strengthened its Vafseo intellectual property portfolio with a new Orange Book–listed patent (U.S. Patent No. 12,569,474, expiring June 2034) and eligibility for a five-year patent term extension on a composition of matter patent, which would extend that patent's term to mid-2032. Akebia's Vafseo portfolio now includes 14 Orange Book–listed patents, with expiration dates out to 2036.
- In May, Akebia announced the publication of a post-hoc win odds statistics analysis of all-cause mortality and hospitalization from its global Phase 3 INNO₂VATE program in the Journal of the American Society of Nephrology, which demonstrated a statistically significant improvement relative to the 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.
- In April, Akebia appointed Philip J. Vickers, Ph.D. to its Board of Directors. Dr. Vickers is the President and Chief Executive Officer and a member of the Board of Directors of Solu Therapeutics. He brings deep expertise spanning research and development, translational science and corporate strategy across a broad range of therapeutic areas to the Board.

Financial Results

- **Revenues:** Total revenues were \$49.1 million in the second quarter of 2026 compared to \$62.5 million in the second quarter of 2025. This decrease was due to a decrease in Auryxia® (ferric citrate) revenues which was partially offset by higher Vafseo revenues.
 - Vafseo net product revenues were \$21.3 million in the second quarter of 2026 compared to \$13.3 million in the second quarter of 2025.
 - Auryxia net product revenues were \$25.5 million in the second quarter of 2026 compared to \$47.2 million in the second quarter of 2025. We continue to expect Auryxia revenues to decrease in 2026 as compared to 2025 due to generic competition and pricing pressure.
 - License, collaboration and other revenues were \$2.4 million in the second quarter of 2026 compared to \$2.0 million in the second quarter of 2025.
- **Cost of Goods Sold (COGS):** Cost of goods sold was \$10.4 million in the second quarter of 2026 compared to \$9.9 million in the second quarter of 2025. 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 \$14.1 million in the second quarter of 2026 compared to \$11.0 million in the second quarter of 2025. The increase in expenses was driven by increased clinical trial activities related to our mid-stage pipeline assets, which include praliguat and ebribafusp, as well as higher headcount-related costs.
- **SG&A Expenses:** Selling, general and administrative expenses were \$28.2 million in the second quarter of 2026 compared to \$26.6 million in the second quarter of 2025. This increase was driven by higher commercialization-related activities.
- **Net Income (Loss):** Net loss was \$8.9 million in the second quarter of 2026 compared to net income of \$0.2 million in the second quarter of 2025. The change to a net loss in the second quarter of 2026 resulted from lower revenues and higher expenses during the quarter, including a \$1.9 million restructuring expense related to the reorganization of our commercial organization aimed at increasing the efficiency and effectiveness of our commercial efforts.
- **Cash Position:** Cash and cash equivalents as of June 30, 2026 were approximately \$155.5 million as compared to \$162.6 million as of March 31, 2026. We believe our existing cash resources and the cash we expect to generate from product, royalty, supply and license revenues, along with

our plan to refinance our senior secured term loan facility, will enable us to fund our current operating plan for at least two years.

Conference Call

Akebia will host a conference call on Wednesday, August 5, 2026 at 4:30 p.m. EDT to discuss second quarter 2026 earnings. To access the call, please dial (646) 307-1963 or toll-free (800) 715-9871 and enter passcode: 4727037. 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.

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**

SAFSEO has not been studied and is not recommended in patients with active malignancies. Malignancies were observed in 2.2% of SAFSEO 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 $\geq 10\%$) were hypertension and diarrhea.

DRUG INTERACTIONS

- Iron supplements and iron-containing phosphate binders:** Administer SAFSEO at least 1 hour before products containing iron.
- Non-iron-containing phosphate binders:** Administer SAFSEO 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 SAFSEO 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: statements regarding: Akebia's plans, strategies and prospects for its business; Akebia's beliefs regarding Vafseo's continued revenue growth; Akebia's beliefs regarding the data and results from the VOICE trial, including that the data demonstrated overwhelming statistical evidence of improved safety outcomes for patients treated with Vafseo versus an ESA; Akebia's goal of making Vafseo standard of care for the treatment of anemia in patients on dialysis; Akebia's plans and expectations regarding the Phase 2 open-label basket trial evaluating ebrifabusp, including the timing of reporting initial data, the expected number of patients to be enrolled and the timing thereof; Akebia's beliefs and expectations regarding the progress of its rare kidney disease pipeline, including its Phase 2 trial of praliguat in FSGS; Akebia and USRC's plans and expectations regarding submitting data from the VOICE trial for presentation at an upcoming medical meeting; Akebia's expectations and beliefs about the strength of its Vafseo (vadadustat) intellectual property portfolio and expectations regarding its ability to maintain its intellectual property protection through the respective expiration dates; Akebia's expectations regarding Auryxia revenues continuing to decrease due to generic competition and pricing pressure; Akebia's goals and expectations regarding its commercial reorganization aimed at increasing the efficiency and effectiveness of its commercial efforts; Akebia's beliefs and expectations regarding the cash it expects to generate from product, royalty, supply and license revenues and the sufficiency of, and the period in which Akebia expects to have, cash to fund its current operating plan; and Akebia's plans to refinance its senior secured term loan facility.

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 Akebia's products and product candidates; 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®, Auryxia® and Vafseo® are registered trademarks of Akebia Therapeutics, Inc. and its affiliates.

Akebia Therapeutics Contact

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AKEBIA THERAPEUTICS, INC.
Unaudited Condensed Consolidated Statements of Operations

(in thousands, except per share data)	Three Months Ended June 30,	
	2026	2025
Revenues		
Product revenue, net	\$ 46,765	\$ 60,461
License, collaboration and other revenue	2,363	2,011
Total revenues	49,128	62,472
Cost of goods sold		
Cost of product and other revenue	10,424	9,919
Total cost of goods sold	10,424	9,919
Operating expenses		
Research and development	14,059	11,013
Selling, general and administrative	28,171	26,555
License	855	896
Restructuring	1,945	—
Total operating expenses	45,030	38,464
Income (loss) from operations	(6,326)	14,089
Other expense, net	(3,078)	(6,862)
Change in fair value of warrant liability	566	(6,980)
Income (loss) before income taxes	(8,838)	247
Income tax expense	(70)	—
Net income (loss)	\$ (8,908)	\$ 247
Net income (loss) per share - basic	\$(0.03)	\$0.00
Net income (loss) per share - diluted	\$(0.03)	\$0.00
Weighted-average number of common shares - basic	269,602,747	262,565,500
Weighted-average number of common shares - diluted	269,602,747	271,104,020

Unaudited Selected Balance Sheet Data

(in thousands)	June 30, 2026		December 31, 2025	
Cash and cash equivalents	\$	155,548	\$	184,844
Working capital	\$	68,688	\$	90,017
Total assets	\$	349,658	\$	376,565
Total stockholders' equity	\$	25,018	\$	32,610