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): **February 26, 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 February 26, 2026, Akebia Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2025 and recent business highlights related to the commercial launch of Vafseo® (vadadustat) as well as its pipeline. 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 February 26 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: February 26, 2026

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

Exhibit 99.1

Akebia Therapeutics Reports Fourth Quarter and Full Year 2025 Financial Results and Commercial and Pipeline Highlights

Q4 2025 net product revenues of $54.3 million; 2025 full-year net product revenues of $227.3 million, representing a 49% increase over 2024 full-year net product revenues

Expect significant Vafseo® (vadadustat) revenue growth in 2026 through expanded access to therapy at dialysis organizations, new patient starts, and improved adherence rates

Pipeline advancement continues with enrollment underway for praliciguat Phase 2 clinical trial in focal segmental glomerulosclerosis (FSGS) and AKB-097 Phase 2 rare kidney disease basket trial planned to begin in 2H 2026

Akebia to Host Conference Call at 8:00 a.m. EST on February 26, 2026

CAMBRIDGE, Mass.—February 26, 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 fourth quarter and full year ended December 31, 2025 and recent business highlights related to the commercial launch of Vafseo® (vadadustat) as well as its robust pipeline.

“Vafseo commercial trends are showing marked improvement in early 2026, built on the solid foundation we created for the brand in its first year of launch,” said John P. Butler, Chief Executive Officer of Akebia. “Patient access to Vafseo therapy now stands at 290,000 patients, and early data points to improved patient adherence rates, which we believe are enhanced as a result of dialysis organizations deciding to implement observed dosing protocols. These dynamics, along with the building evidence of clinical differentiation, are expected to drive significant Vafseo revenue growth in 2026 and beyond as we work toward our goal to make Vafseo standard of care for treating anemia due to CKD in patients on dialysis. Separately, we are advancing our pipeline in rare kidney disease and actively enrolling patients into the Phase 2 trial of praliciguat in FSGS. We expect to initiate an open-label rare kidney disease basket study with our tissue-targeted complement inhibitor, AKB-097, in the second half of 2026 with initial data expected in 2027. Through these efforts, we remain steadfast in working to better the lives of people impacted by kidney disease.”

Vafseo Q4 2025 Commercial Updates

- Total number of prescribers increased to approximately 800 in Q4, representing an increase of 10% over the number of prescribers in Q3.
- Broadened customer base as approximately 25% of new patients in Q4 originated from dialysis organizations other than U.S. Renal Care (USRC), an increase from less than 10% in Q3.
- Patient demand was approximately $11 million. This approximately $1 million decline in demand versus Q3 was driven by fewer patient starts, which Akebia believes was a result of providers at select dialysis organizations anticipating the initiation of new in-center observed dosing protocols.
- Within centers that adopted an in-center observed dosing protocol in Q4, first refill adherence rates improved to 91% in Q4 from 75% in the first 9 months of 2025 with daily dosing.

2025 Vafseo Post Marketing Clinical Development Achievements

- In November at the American Society of Nephrology Kidney Week 2025, Dr. Glenn M. Chertow presented a post-hoc analysis of data from the INNO2VATE trials comparing dialysis patients taking vadadustat or darbepoetin alfa for CKD-related anemia. The data demonstrated

statistically significant favorable outcomes in the hierarchical composite endpoint of all-cause mortality and hospitalization in patients treated with vadadustat compared to patients in the erythropoietin stimulating agent (ESA) control group.

- In July, enrolled the first patient in VOCAL, a Phase IIIb trial evaluating three times weekly (TIW) dosing of Vafseo versus ESAs, which is expected to report topline data in Q4 2026. The VOCAL trial of approximately 350 total patients also contains a sub-study of Vafseo's impact on red blood cell characteristics.
- In June, USRC completed enrollment in 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. VOICE topline results are expected in early 2027.

Rare Kidney Disease and Early-Stage Pipeline Progress

- Initiated 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, and dosed the first patient in December 2025. Akebia expects to enroll approximately 60 patients in this trial.
- In November 2025, Akebia acquired a humanized anti-C3d monoclonal antibody fusion protein from Q32 Bio Inc. which is designed to act as a complement inhibitor through a tissue-targeted mechanism. A Phase 2 open-label rare kidney disease basket study is expected to start in the second half of 2026 evaluating AKB-097 in IgA nephropathy, lupus nephritis and C3 glomerulopathy. The study will evaluate safety, tolerability, pharmacokinetics, pharmacodynamics, and effects on disease-relevant biomarkers, including proteinuria and measures of kidney function. Initial data is expected in 2027.
- Akebia plans to initiate a Phase 1 study of AKB-9090 in healthy volunteers. The study is expected to begin in the first half of 2026 with topline data expected by the end of the year. The initial target indication for AKB-9090 is the treatment of acute kidney injury associated with cardiac surgery.

Financial Results

- **Revenues:** Total revenues were $57.6 million in the fourth quarter of 2025 compared to $46.5 million in the fourth quarter of 2024, and $236.2 million for the full-year 2025 compared to $160.2 million for the full-year 2024. These increases were driven by sales of Vafseo, which was launched in the U.S. in January 2025, and an increase in Auryxia® (ferric citrate) sales volumes.
    - Vafseo net product revenues were $6.2 million in the fourth quarter of 2025 and $45.8 million for the full-year 2025.
    - Auryxia net product revenues were $48.1 million in the fourth quarter of 2025 compared to $44.4 million in the fourth quarter of 2024, and $181.5 million for the full-year 2025 compared to $152.2 million for the full-year 2024. We expect generic competition for Auryxia to expand this year beyond the current authorized generic competition and therefore expect Auryxia revenues to decrease in 2026 as compared to 2025 Auryxia revenues.
    - License, collaboration and other revenues were $3.3 million in the fourth quarter of 2025 compared to $2.1 million in the fourth quarter of 2024, and $8.9 million for the full-year 2025 compared to $8.0 million for the full-year 2024.
- **COGS:** Cost of goods sold was $12.5 million in the fourth quarter of 2025 compared to $20.4 million in the fourth quarter of 2024, and $39.5 million for the full-year 2025 compared to $63.2 million for the full-year 2024. COGS in both periods was driven by higher Auryxia sales volumes

in 2025, and was impacted by the elimination in 2025 of a quarterly $9.0 million non-cash intangible amortization charge that Akebia incurred through the fourth quarter of 2024. In addition, COGS for the full-year 2024 included a $12.3 million benefit due to our ability to sell inventory previously written-down as excess inventory. 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.

- **R&D Expenses:** Research and development expenses were $26.6 million in the fourth quarter of 2025 compared to $11.8 million in the fourth quarter of 2024, and $62.4 million for the full-year 2025 compared to $37.7 million for the full-year 2024. The increase in expenses in both periods was driven by increased clinical trial activities related to Vafseo and our other product candidates, higher headcount related costs, as well as by a $12.8 million charge incurred during the fourth quarter of 2025 related to acquired in-process R&D costs associated with the acquisition of AKB-097 from Q32 Bio Inc.
- **SG&A Expenses:** Selling, general and administrative expenses were $26.1 million in the fourth quarter of 2025 compared to $27.7 million in the fourth quarter of 2024, and $107.5 million for the full-year 2025 compared to $106.5 million for the full-year 2024.
- **Net Loss:** Net loss was $12.2 million in the fourth quarter of 2025 compared to a net loss of $22.8 million in the fourth quarter of 2024. Net loss was $5.3 million for the full-year 2025 compared to $69.4 million for the full-year 2024. The decrease in net loss in both periods was driven by the increase in net product revenues, which was partially offset by higher expenses.
- **Cash Position:** Cash and cash equivalents as of December 31, 2025, were approximately $184.8 million compared to $51.9 million as of December 31, 2024. 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, February 26, 2026 at 8:00 a.m. EST to discuss fourth quarter and full year 2025 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.

- 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 expectations about Vafseo commercial trends showing marked improvement in early 2026 and the reasons therefor; Akebia's beliefs that improved patient adherence rates are enhanced as a result of dialysis organizations deciding to implement observed dosing protocols; Akebia's expectations about significant Vafseo revenue growth in 2026 and beyond through expanded access to therapy at dialysis organizations, new patient starts, and improved adherence rates, along with the building evidence of clinical differentiation; Akebia's goal to make Vafseo standard of care for treating anemia due to CKD in patients on dialysis; Akebia's plans and expectations with respect to advancing its pipeline in rare kidney disease, including expectations of the number of patients to be enrolled in the Phase 2 trial of praliciguat in FSGS; Akebia's plans and expectations with respect to a Phase 2 open-label rare kidney disease basket study with its tissue-targeted complement inhibitor, AKB-097, including the timing of the study and the timing of initial data; Akebia's beliefs about patient demand for Vafseo and that fewer patients starts in Q4 2025 was the result of providers at select dialysis organizations anticipating the initiation of new in-center observed dosing protocols; Akebia's plans and expectations with respect to the VOCAL and VOICE trials, including the timing of topline data; Akebia's plans and expectations with respect to AKB-9090, including the timing of a Phase 1 study and the timing of topline data, and the initial target indication; Akebia's expectations with respect to generic competition for Auryxia and Auryxia revenues in 2026; and Akebia expectations that its existing cash resources and cash from operations will be sufficient to fund its current operating plan for at least two years and assumptions related thereto.

The terms "intend," "believe," "plan," "goal," "potential," "anticipate, "estimate," "expect," "future," "will," "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 and Akebia's development candidates; Akebia's ability to initiate and enroll patients in its clinical trials; the results of preclinical and clinical research; 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, Auryxia and Vafseo, including estimates regarding the potential market opportunity; the competitive landscape for Auryxia and Vafseo, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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 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
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Exhibit 99.1

AKEBIA THERAPEUTICS, INC.
Consolidated Statements of Operations

(in thousands, except share and per share data)	Quarters Ended December 31, 2025	Quarters Ended December 31, 2024	Years Ended December 31, 2025	Years Ended December 31, 2024
Revenues:				
Product revenue, net	$ 54,290	$ 44,370	$ 227,332	$ 152,180
License, collaboration and other revenue	3,330	2,127	8,864	8,000
Total revenues	57,620	46,497	236,196	160,180
Cost of goods sold:				
Cost of product and other revenue	12,535	11,355	39,462	27,135
Amortization of intangibles	—	9,010	—	36,042
Total cost of goods sold	12,535	20,365	39,462	63,177
Operating expenses:				
Research and development	26,648	11,787	62,359	37,652
Selling, general and administrative	26,089	27,674	107,480	106,545
License expense	901	978	3,396	3,220
Restructuring	—	—	—	58
Total operating expenses	53,638	40,439	173,235	147,475
Operating income (loss)	(8,553)	(14,307)	23,499	(50,472)
Other expense, net	(4,944)	(6,822)	(24,121)	(18,091)
Change in fair value of warrant liability	2,262	(1,675)	(3,099)	(330)
Loss on extinguishment of debt	—	—	—	(517)
Net loss before income taxes	(11,235)	(22,804)	(3,721)	(69,410)
Income tax expense	(1,009)	—	(1,624)	—
Net loss	$ (12,244)	$ (22,804)	$ (5,345)	$ (69,410)
Net loss per share				
Basic and diluted	$(0.05)	$(0.10)	$(0.02)	$(0.33)
Weighted-average number of common shares outstanding:				
Basic and diluted	265,369,385	218,699,008	257,157,782	210,946,658

Selected Balance Sheet Data
(unaudited)

(in thousands)	December 31, 2025	December 31, 2024
Cash and cash equivalents	$ 184,844	$ 51,870
Working capital	$ 90,017	$ 32,917
Total assets	$ 376,565	$ 220,670
Total stockholders' equity (deficit)	$ 32,610	$ (49,185)