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): **November 10, 2025**

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 November 10, 2025, Akebia Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the third quarter ended September 30, 2025 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 November 10, 2025, 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: November 10, 2025

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

Exhibit 99.1

Akebia Therapeutics Reports Third Quarter 2025 Financial Results and Recent Business Highlights

Vafseo® (vadadustat) Q3 2025 net product revenues grew to $14.3 million; Q3 2025 total net product revenues were $56.8 million

Operational pilot of Vafseo at DaVita expected to complete in the fourth quarter; Access for 275,000 total patients across customer base expected by year-end

Vadadustat post-hoc data analysis presented at ASN Kidney Week demonstrates composite of all-cause mortality and hospitalization outcomes statistically more favorable for patients receiving vadadustat compared to ESAs

Akebia to host Conference Call at 8:00 a.m. ET on Monday, November 10, 2025

CAMBRIDGE, Mass.—November 10, 2025—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 third quarter ended September 30, 2025 and recent business highlights.

“Through the quarter we’ve continued to make progress against our goal to make Vafseo standard of care for the treatment of anemia for patients on dialysis and capitalize on nephrologists’ strong desire to prescribe Vafseo,” said John P. Butler, Chief Executive Officer of Akebia. “These efforts include generating incremental data, like the data Dr. Glenn Chertow presented last week at ASN Kidney Week, further informing physicians about potential additional benefits of the product, and enabling increased patient access to Vafseo. To that end, we expect to close the year with four times the prescribing access to Vafseo as compared to the end of Q3, which we believe will accelerate broader uptake and growth in 2026.”

Driving Vafseo Toward Our Goal to Become Standard of Care for Patients on Dialysis

- Vafseo® *(vadadustat)* net product revenue in Q3 2025 totaled $14.3 million. The vast majority of Vafseo revenues were derived from US Renal Care (USRC) and since launch more than 85% of all USRC physicians have written a prescription. Total number of prescribers in Q3 was approximately 725 and the average number of prescriptions written per prescriber was approximately 12.7. More than 85% of prescriptions in Q3 were refill prescriptions. The average dose of refills increased by 5% over Q2.
- On August 18, DaVita, Inc. initiated an operational pilot at over 100 dialysis clinics. Akebia expects the pilot to complete in November at which point Vafseo is expected to be widely available to DaVita patients.
- In mid-August, Innovative Renal Care implemented a standardized treatment protocol for Vafseo across its approximately 230 dialysis centers. Seven additional independent and small dialysis providers also operationalized protocols in September, increasing total prescribing access across our customer base by the end of Q3 to 60,000 patients. We continue to expect this number to grow to 275,000 patients by the end of the year.
- At the recent American Society of Nephrology (ASN) 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 more favorable outcomes in the composite of all-cause mortality and hospitalization in patients treated with vadadustat compared to patients in the ESA control group.

- At ASN Kidney Week, Akebia and partners presented posters on trial design for VOICE and VOCAL, clinical trials studying Vafseo three times weekly dosing, being conducted by USRC and by Akebia at DaVita, respectively. The VOICE trial is fully enrolled, and VOCAL enrollment is progressing well.

Regulatory Update

As previously announced, Akebia recently completed a Type C meeting with the U.S. Food and Drug Administration (FDA) and did not achieve alignment on Akebia's proposed path forward for a Phase 3 clinical trial in non-dialysis patients. Akebia does not plan to initiate the VALOR clinical trial and therefore does not expect to pursue a broad label for Vafseo for CKD non-dialysis dependent patients.

Financial Results

- **Revenues:** Total revenues increased to $58.8 million in the third quarter of 2025 compared to $37.4 million in the third quarter of 2024, driven by sales of Vafseo, which was launched in the U.S. in January 2025, and an increase in Auryxia® sales.
  - Vafseo net product revenues were $14.3 million in the third quarter of 2025.
  - Auryxia net product revenues were $42.5 million in the third quarter of 2025 as compared to $35.6 million in the third quarter of 2024. Though loss of exclusivity occurred on March 20, 2025, to date no Abbreviated New Drug Application has been approved for Auryxia, and there is only one authorized generic for Auryxia sold by Akebia's distributor.
  - License, collaboration and other revenues were $2.0 million in the third quarter of 2025 as compared to $1.8 million in the third quarter of 2024.
- **Cost of Goods Sold:** Cost of goods sold was $9.4 million in the third quarter of 2025 as compared to $14.2 million in the third quarter of 2024. Akebia carried a non-cash intangible amortization charge of $9.0 million per quarter through the fourth quarter of 2024. Of note, Vafseo-related cost of goods sold in the quarter 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 $14.9 million in the third quarter of 2025 as compared to $8.5 million in the third quarter of 2024. The increase was primarily driven by increased clinical trial activities related to Vafseo and higher headcount related costs.
- **Selling, General & Administrative Expenses:** Selling, general and administrative expenses were $29.1 million in the third quarter of 2025 as compared to $26.5 million in the third quarter of 2024. The increase was largely due to higher marketing costs in connection with the Vafseo U.S. launch and increased headcount-related costs.
- **Net Income (Loss):** Net income was $0.5 million in the third quarter of 2025 compared to a net loss of $20.0 million in the third quarter of 2024. The increase in net income was driven by the increase in net product revenues, which was partially offset by higher operating expenses.

- **Cash Position:** Cash and cash equivalents as of September 30, 2025 were approximately $166.4 million. Akebia believes it is financed to achieve profitability based on its current operating plan, which includes advancing its existing programs.

Conference Call

Akebia will host a conference call on Monday, November 10 at 8:00 a.m. Eastern Time to discuss third quarter 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.

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 statements about its progress against its goal to make Vafseo standard of care for the treatment of anemia for patients on dialysis and capitalize on nephrologists’ strong desire to prescribe Vafseo, including generating incremental data, further informing physicians about potential benefits of the product, and enabling increased patient access to Vafseo; Akebia’s expectations and beliefs about prescribing access to Vafseo, including the number of patients and timing of access and that it will accelerate broader uptake and growth in 2026; Akebia’s expectations with respect to the DaVita pilot, including the timing of the pilot and when Vafseo will be widely available to DaVita patients; Akebia’s expectations that post-hoc data analysis from the $INNO_2VATE$ trials demonstrated statistically significant more favorable outcomes in the composite of all-cause mortality and hospitalization in patients treated with vadadustat compared to patients in the ESA control group; Akebia’s expectations about the progress of VOCAL enrollment; Akebia’s expectations that its Type C meeting with the FDA did not achieve alignment on its proposed path forward for a Phase 3 clinical trial in non-dialysis patients; Akebia’s plans and expectations to not initiate the VALOR clinical trial and not pursue a broad label for Vafseo for CKD non-dialysis dependent patients; and Akebia’s expectations that it is financed to achieve profitability based on its current operating plan, which includes advancing its existing programs 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; 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, 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 June 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®, Auryxia® and Vafseo® are registered trademarks of Akebia Therapeutics, Inc. and its affiliates.

Akebia Therapeutics Contact

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Exhibit 99.1

AKEBIA THERAPEUTICS, INC.
Unaudited Condensed Consolidated Statements of Operations

(in thousands, except per share data)	Three Months Ended September 30, 2025	2024
Revenues		
Product revenue, net	$ 56,789	$ 35,592
License, collaboration and other revenue	1,977	1,836
Total revenues	58,766	37,428
Cost of goods sold		
Cost of product and other revenue	9,383	5,150
Amortization of intangible asset	—	9,011
Total cost of goods sold	9,383	14,161
Operating expenses		
Research and development	14,944	8,487
Selling, general and administrative	29,094	26,516
License	896	769
Total operating expenses	44,934	35,772
Income (loss) from operations	**4,449**	**(12,505)**
Other expense, net	(4,758)	(6,678)
Change in fair value of warrant liability	1,464	(856)
Income (loss) before income taxes	**1,155**	**(20,039)**
Income tax expense	(615)	—
Net income (loss)	$ 540	$ (20,039)
Net income (loss) per share - basic	$0.00	$(0.10)
Net income (loss) per share - diluted	$0.00	$(0.10)
Weighted-average number of common shares - basic	264,786,432	210,348,459
Weighted-average number of common shares - diluted	274,372,722	210,348,459

Unaudited Selected Balance Sheet Data

(in thousands)	September 30, 2025	December 31, 2024
Cash and cash equivalents	$ 166,444	$ 51,870
Working capital	$ 124,957	$ 32,917
Total assets	$ 364,152	$ 220,670
Total stockholders' equity (deficit)	$ 41,592	$ (49,185)