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

August 7, 2025

Continued Vafseo® (vadadustat) growth with Q2 2025 net product revenues increasing to $13.3 million; Total Q2 2025 net product revenues increased to $60.5 million

DaVita physicians are expected to begin treating patients with Vafseo in August 2025 as part of an operational pilot at 100+ DaVita dialysis clinics

Patient enrollment completed in VOICE, a collaborative clinical trial of Vafseo conducted by USRC

Akebia to host Conference Call at 8:00 a.m. ET on Thursday, August 7, 2025

CAMBRIDGE, Mass., Aug. 07, 2025 (GLOBE NEWSWIRE) -- 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, 2025 and recent business highlights.

"Vafseo® (vadadustat) U.S. product launch momentum builds as we continued to add new prescribers, increase volume with existing writers, and importantly, progress efforts to further expand patient access to the therapy," said John P. Butler, Chief Executive Officer of Akebia. "We are working to increase utilization at mid-sized dialysis organizations, and we expect by September, both Dialysis Clinics, Inc. (DCI) and Innovative Renal Care (IRC), the fourth and fifth largest dialysis organizations, will have operationalized protocols to simplify and expand Vafseo prescribing. Additionally, we are pleased that DaVita has begun ordering Vafseo to support an operational pilot in Q3, which we expect to lead to the opportunity for broad prescribing before year end. I am also excited about the progress we have made executing on our post-marketing development strategy, which is critical to our ultimate goal of making Vafseo the standard of care for the treatment of anemia in patients with chronic kidney disease (CKD)."

Vafseo U.S. Commercial Updates:

- Vafseo net product revenue in Q2 2025 totaled $13.3 million. Prescription demand grew by approximately 55% over Q1 2025 and customer inventory weeks on hand remained approximately flat.
- During the quarter, more than 725 prescribers wrote a prescription for Vafseo and prescribers, on average, wrote more than 13 prescriptions.
- More than 80% of prescriptions in Q2 were refill prescriptions. The average dose of refills increased by approximately 25%.
- By the end of Q3, we expect dialysis organizations will have operationalized protocols enabling Vafseo prescribing access to more than 75,000 patients, an increase from about 40,000 patients at the end of Q2.
- DaVita, a leading dialysis organization serving more than 200,000 patients, is expected to enable prescribing Vafseo to patients in an operational pilot this month. In July, DaVita placed an order to begin to supply the pilot across more than 100 clinics. The purpose of this pilot study is to ensure that prescribers can write Vafseo and efficiently deliver the drug to dialysis patients.

Additional Key Business Updates:

- U.S. Renal Care (USRC) completed enrollment in VOICE, a collaborative clinical trial of Vafseo designed to measure non-inferiority of Vafseo versus standard-of-care erythropoietin stimulating agents (ESAs) using hierarchical endpoints of all-cause mortality and all-cause hospitalization. USRC enrolled 2,116 patients and top line data are expected in early 2027.
- Akebia initiated the VOCAL trial to evaluate the efficacy and safety of three times per week (TIW) dosing of vadadustat compared to standard of care ESAs in patients with anemia of CKD receiving in-center hemodialysis. The trial is expected to enroll approximately 350 patients across 18 DaVita hemodialysis clinics. The trial will include a sub-study of approximately 28 patients to study the impact of Vafseo on red blood cell phenotypes (e.g., deformability, resistance to oxidative stress, metabolomics) compared to ESA treatment.
- Akebia is working towards its goal to initiate VALOR, a Phase 3 clinical trial to study the use of vadadustat for treating anemia in late-stage CKD patients who are not on dialysis by the end of this year. The company has requested a Type-C meeting with the U.S. Food and Drug Administration.
- Auryxia® (ferric citrate) net product revenue in Q2 2025 totaled $47.2 million. 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.

Financial Results

- **Revenues:** Total revenues increased to $62.5 million in the second quarter of 2025 compared to $43.6 million in the second 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 $13.3 million in the second quarter of 2025.
    - Auryxia net product revenues were $47.2 million in the second quarter of 2025 as compared to $41.2 million in the second quarter of 2024.
    - License, collaboration and other revenues were $2.0 million in the second quarter of 2025 as compared to $2.4 million in the second quarter of 2024.
- **Cost of Goods Sold:** Cost of goods sold was $9.9 million in the second quarter of 2025 as compared to $17.0 million in the second 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 $11.0 million in the second quarter of 2025 as compared to $7.6 million in the second quarter of 2024. The increase was primarily driven by increased clinical trial activities related to Vafseo as well as our other programs.
- **Selling, General & Administrative Expenses:** Selling, general and administrative expenses were $26.6 million in the second quarter of 2025 as compared to $26.9 million in the second quarter of 2024.
- **Net Income (Loss):** Net income was $0.2 million in the second quarter of 2025 compared to a net loss of $8.6 million in the second quarter of 2024. The increase in net income was driven by the increase in net product revenues, which was partially offset by $7.0 million in non-cash expense related to the change in fair value of our warrant liability, as well as $5.4 million in non-cash interest expense related to the settlement royalty liability in connection with the Vifor Termination and Settlement Agreement that Akebia signed in July 2024.
- **Cash Position:** Cash and cash equivalents as of June 30, 2025 were approximately $137.3 million. Akebia believes it is financed to achieve profitability based on its current operating plan, which includes pursuing label expansion for Vafseo and advancing other existing programs.

Conference Call

Akebia will host a conference call on Thursday, August 7 at 8:00 a.m. Eastern Time to discuss second 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 plans and expectations with respect to the U.S. launch of Vafseo, including to further expand patient access and to increase utilization at mid-size dialysis organizations; Akebia's expectations that DCI and IRC will have operationalized protocols to simplify and expand Vafseo prescribing by September; Akebia's expectations with respect to the DaVita pilot, including the timing and size of the pilot and the opportunity for the pilot to enable broad prescribing of Vafseo and timing thereof; Akebia's statements about the progress and focus of its post-marketing development strategy, including its goal to make Vafseo the standard of care for the treatment of anemia in patients with CKD; Akebia's expectations that dialysis organizations will have operational protocols enabling Vafseo prescribing access and the number of patients and timing thereof; Akebia's expectations regarding the VOICE trial, including the timing of top line data; Akebia's expectations regarding the VOCAL trial, including the potential benefits of Vafseo for the treatment of anemia in CKD patients receiving in-center hemodialysis, potential benefits of Vafseo when dosed three times per week and the expected patient enrollment; Akebia's plans and expectations with respect to a Phase 3 clinical trial (VALOR) to study the use of vadadustat for treating anemia in late-stage CKD patients who are not on dialysis, including the timing thereof; and Akebia's expectations that it is financed to achieve profitability based on its current operating plan, which includes pursuing label expansion for Vafseo and advancing other 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 March 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 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.

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AKEBIA THERAPEUTICS, INC.
Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended June 30,	
(in thousands, except per share data)	**2025**	**2024**
Revenues		
Product revenue, net	$ 60,461	$ 41,209
License, collaboration and other revenue	2,011	2,439
Total revenues	62,472	43,648
Cost of goods sold		

Cost of product and other revenue	9,919	8,036
Amortization of intangible asset	—	9,011
Total cost of goods sold	9,919	17,047
Operating expenses		
Research and development	11,013	7,647
Selling, general and administrative	26,555	26,917
License	896	762
Total operating expenses	38,464	35,326
Income (loss) from operations	**14,089**	**(8,725)**
Other expense, net	(6,862)	(2,188)
Change in fair value of warrant liability	(6,980)	2,331
Net income (loss)	**$ 247**	**$ (8,582)**
Net income (loss) per share - basic	$ 0.00	$ (0.04)
Net income (loss) per share - diluted	$ 0.00	$ (0.04)
Weighted-average number of common shares - basic	262,565,500	209,705,397
Weighted-average number of common shares - diluted	271,104,020	209,705,397

Unaudited Selected Balance Sheet Data

(in thousands)	**June 30, 2025**	**December 31, 2024**
Cash and cash equivalents	$ 137,308	$ 51,870
Working capital	$ 115,940	$ 32,917
Total assets	$ 345,595	$ 220,670
Total stockholders' equity (deficit)	$ 29,224	$ (49,185)

Source: Akebia Therapeutics, Inc.