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

May 8, 2025

Strong initial quarter of Vafseo® (vadadustat) U.S. product launch, with Vafseo net product revenues of $12.0 million in Q1 2025

Total Q1 2025 net product revenues of $55.8 million

Bolstered balance sheet and expanded institutional investor ownership through $50 million underwritten public offering of common stock; cash and cash equivalents of $113.4 million as of the end of the quarter

Akebia to Host Conference Call at 8:00 a.m. ET on May 8, 2025

CAMBRIDGE, Mass., May 08, 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 first quarter ended March 31, 2025 and recent business highlights.

"We are tremendously encouraged by the early progress of the Vafseo® (vadadustat) launch, having generated $12.0 million in net product revenues in the first quarter. We believe the early success reflects the excitement among physicians of having an alternative treatment for anemia available for their dialysis patients," said John P. Butler, Chief Executive Officer of Akebia. "We believe the introduction of Vafseo is one of the strongest drug launches into the dialysis market in many years, certainly since the adoption of transitional drug add-on payment adjustment (TDAPA) reimbursement, and we continue to believe that Vafseo could be a new standard of care for the treatment of anemia due to chronic kidney disease (CKD). Initial usage as expected is in the small and mid-sized dialysis providers and we look forward to continuing to drive adoption across all dialysis providers, large and small."

Vafseo U.S. Commercial Updates:

- Vafseo net product revenue in Q1 2025 totaled $12.0 million.
- Through the end of March, more than 640 prescribers wrote a prescription for Vafseo and each prescriber, on average, had written nearly 12 prescriptions. About 1/3 of all prescriptions written were refills and refill data demonstrate an increase in average dose per patient.
- Through the end of April, the top five dialysis organizations placed Vafseo orders, though most revenue continues to be driven by mid-sized dialysis organizations.
- Akebia estimates that it has at least 12 months of Vafseo inventory on hand in the U.S. free of potential incremental tariff payments based on its current operating plan.

Additional Key Business Highlights:

- In March, completed an underwritten public offering of 25 million shares priced at $2.00 per share, raising gross proceeds of $50 million.
- U.S. Renal Care continues enrollment in VOICE, a collaborative clinical trial of Vafseo designed to assess mortality and hospitalization in patients treated with Vafseo compared to current standard of care. Enrollment is now at 75% of the planned trial enrollment of approximately 2,200 patients.
- Plan to initiate 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. Expect the VALOR clinical trial to begin in the second half of 2025.
- In January, Vafseo was recommended for symptomatic anemia in adults undergoing dialysis for CKD by the United Kingdom (U.K.) National Institute for Health and Care Excellence (NICE), a distinction especially relevant for practitioners and commissioners making care choices for patients in the U.K. and of interest globally. Akebia's partner Medice launched Vafseo in the U.K.
- Auryxia® (ferric citrate) net product revenue in Q1 2025 totaled $43.8 million. In January 2025, phosphate binders, including Auryxia, were added to the bundled payment for dialysis services and qualified for TDAPA, providing an additional payment for each service in which Auryxia is used. Loss of Auryxia market 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.

- In April, the Committee for Medicinal Products for Human Use of the European Medicines Agency adopted a positive opinion recommending the European Commission to approve XOANACYL® (Ferric Citrate as Coordination Complex) for the treatment of concomitant elevated serum phosphorous and iron deficiency in adult patients with CKD.

Financial Results

- **Revenues:** Total revenues were $57.3 million in the first quarter of 2025 as compared to $32.6 million in the first quarter of 2024, driven by initial sales of Vafseo in the U.S. and an increase in sales of Auryxia.
  - Vafseo net product revenues were $12.0 million in the first quarter of 2025. Vafseo was launched into the U.S. market in the first quarter of 2025.
  - Auryxia net product revenues were $43.8 million in the first quarter of 2025 as compared to $31.0 million in the first quarter of 2024.
  - License, collaboration and other revenues were $1.5 million in the first quarter of 2025 as compared to $1.6 million in the first quarter of 2024.
- **Cost of Goods Sold:** Cost of goods sold was $7.6 million in the first quarter of 2025 as compared to $11.6 million in the first quarter of 2024. A key driver of this decrease was the fact that 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 is derived from pre-launch inventory which does not include the full cost of manufacturing, as a portion of those inventory-related costs were recorded as R&D expenses in the period incurred prior to Vafseo's approval in the U.S. Also, during the first quarter of 2024, Akebia realized a $3.7 million benefit due to its ability to sell Auryxia inventory previously written down as excess inventory.
- **Research & Development Expenses:** Research and development expenses were $9.8 million in the first quarter of 2025 as compared to $9.7 million in the first quarter of 2024.
- **Selling, General & Administrative Expenses:** Selling, general and administrative expenses were $25.7 million in the first quarter of 2025 as compared to $25.4 million in the first quarter of 2024.
- **Net Income (Loss):** Net income was $6.1 million in the first quarter of 2025 compared to a net loss of $18.0 million in the first quarter of 2024. Net income in the first quarter of 2025 was driven by the increase in net product revenues, including the introduction of Vafseo sales in the U.S., which was partially offset by $5.4 million in interest expense related to the settlement royalty liability in connection with the July 2024 Vifor Termination and Settlement Agreement.
- **Cash Position:** Cash and cash equivalents as of March 31, 2025 were approximately $113.4 million compared to $51.9 million at December 31, 2024, which includes $46.5 million in net proceeds raised from an underwritten public offering of common stock completed in March. Akebia believes 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.

Conference Call

Akebia will host a conference call on Thursday, May 8 at 8:00 a.m. Eastern Time to discuss first 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 commercial launch of Vafseo, including that its early success reflects excitement among physicians of having an alternative treatment for anemia available for dialysis patients; Akebia’s statements about the strength of the Vafseo launch; Akebia’s beliefs and plans to establish Vafseo as the new standard of care for the treatment of anemia due to CKD; Akebia’s expectations as to usage and its plans to drive adoption across all dialysis providers; Akebia’s estimates about the amount of Vafseo inventory on hand in the U.S. that is free of potential incremental tariff payments based on its current operating plan; 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 and the timing thereof; Akebia’s expectations regarding the VOICE trial; 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 commercial availability of Vafseo; 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; decisions made by health authorities, such as the FDA, with respect to regulatory filings and other interactions; the potential therapeutic benefits, safety profile, and effectiveness of Vafseo; the results of preclinical and clinical research; 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 Annual Report on Form 10-K for the year ended December 31, 2024, 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 March 31,

(in thousands, except per share data)	2025	2024
Revenues		
Product revenue, net	$ 55,791	$ 31,009
License, collaboration and other revenue	1,545	1,598
Total revenues	57,336	32,607
Cost of goods sold		
Cost of product and other revenue	7,625	2,594
Amortization of intangible asset	—	9,011
Total cost of goods sold	7,625	11,605
Operating expenses		
Research and development	9,754	9,731
Selling, general and administrative	25,742	25,438
License	701	711
Restructuring	—	58
Total operating expenses	36,197	35,938
Income (loss) from operations	**13,514**	**(14,936)**
Other expense, net	(7,557)	(2,403)
Change in fair value of warrant liability	155	(129)
Loss on extinguishment of debt	—	(517)
Net income (loss)	**$ 6,112**	**$ (17,985)**
Net income (loss) per share - basic	$ 0.03	$ (0.09)
Net income (loss) per share - diluted	$ 0.03	$ (0.09)
Weighted-average number of common shares - basic	235,497,720	204,955,151
Weighted-average number of common shares - diluted	241,602,853	204,955,151

Unaudited Selected Balance Sheet Data

(in thousands)	March 31, 2025	December 31, 2024
Cash and cash equivalents	$ 113,374	$ 51,870
Working capital	$ 112,555	$ 32,917
Total assets	$ 310,185	$ 220,670
Total stockholders' equity (deficit)	$ 24,581	$ (49,185)

Source: Akebia Therapeutics, Inc.