Akebia Therapeutics Reports Third Quarter 2026 Financial Results and Business Highlights

November 5, 2026

Patients on Vafseo® (vadadustat) increased to approximately 11,500 at the end of Q3 2026 representing an increase of approximately 140% from the end of Q3 2025

Q3 2026 Vafseo® (vadadustat) net product revenues of $14.8 million, impacted by customer inventory reduction and market dynamics as Vafseo's TDAPA expiration approaches

Positive VOICE data demonstrating statistically significant evidence of improved safety outcomes for patients treated with vadadustat versus an ESA presented by U.S. Renal Care at ASN Kidney Week

Reported Positive VOCAL topline data showing vadadustat met primary endpoint of non-inferiority to ESA in maintaining hemoglobin

First patient dosed in Phase 2 open-label basket trial evaluating ebribafusp alfa in multiple rare kidney diseases; initial data expected in 2027

Strong financial position with approximately $159.3 million in cash and cash equivalents at quarter end

Akebia to host conference call at 8:00 a.m. EST on November 5, 2026

WALTHAM, Mass., Nov. 05, 2026 (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 third quarter ended September 30, 2026 and shared recent business highlights related to the commercial launch of Vafseo® (vadadustat) and its advancing kidney disease pipeline, including ebribafusp alfa and praliciguat.

“Our strategic commercial priority remains making Vafseo standard of care for the treatment of anemia for patients on dialysis, and we are focused on continuing to increase the number of patients on therapy,” said John P. Butler, Chief Executive Officer of Akebia. “Our efforts are energized by the exciting presentation of the positive VOICE trial data by Dr. Block of U.S. Renal Care at ASN Kidney Week last month, in which the findings demonstrated improved safety outcomes for dialysis patients treated with vadadustat three times weekly, an investigational regimen that most dialysis providers have chosen to adopt, compared with those treated with erythropoiesis-stimulating agents (ESA) for CKD anemia. We believe this compelling data has the potential to drive Vafseo to be standard of care. We continue to work to strengthen our market position as we enter 2027 when we believe Vafseo access will expand beyond the Transitional Drug Add-on Payment Adjustment (TDAPA)-only patients to nearly all clinically eligible patients. We will continue to work tirelessly to ensure this innovative product reaches patients, and Vafseo realizes its long-term potential.”

Third Quarter and Recent Business Highlights:

- Vafseo net product revenues were $14.8 million in Q3. Approximately 11,500 patients were active on Vafseo at the end of Q3 2026, representing an approximate 8.1% increase from the end of Q2 2026 and an increase of approximately 140**%** over Q3 2025. Total number of prescribers increased to approximately 1,300, representing an increase of over 7% versus Q2 2026.
- In November, Akebia announced topline results of VOCAL, an open-label trial Akebia conducted to evaluate the efficacy and safety of three times weekly (TIW) dosing of vadadustat compared to standard of care ESA in patients with anemia due to CKD receiving in-center hemodialysis. VOCAL met the primary endpoint of non-inferiority to ESA based on change in hemoglobin.
- In October at ASN Kidney Week, Dr. Geoffrey A. Block of U.S. Renal Care delivered a late-breaking presentation of the results of the VOICE trial evaluating the safety of TIW dosing of vadadustat compared with an ESA in patients receiving in-center hemodialysis. The data demonstrated a statistically significant improved safety outcome in patients treated with vadadustat versus ESA on the hierarchical composite endpoint of all-cause mortality and hospitalization, driven by a significant reduction in hospitalization rate. At ASN Kidney Week, Akebia presented additional posters reviewing clinical and economic outcomes associated with Vafseo.
- In September, Akebia announced it had dosed the first patient in a Phase 2 open-label basket trial of ebribafusp alfa, which Akebia believes has the potential to be a next-generation complement inhibitor. The trial is designed to evaluate the safety, efficacy, and pharmacokinetics of ebribafusp alfa and is expected to enroll up to 30 patients with C3 glomerulopathy, lupus nephritis or IgA nephropathy. Akebia expects to report initial data from this trial in 2027.
- At ASN Kidney Week, Akebia also presented three posters on its rare kidney disease pipeline, including a poster highlighting preclinical research of praliciguat in focal segmental glomerulosclerosis (FSGS), the Phase 2 trial evaluating praliciguat in FSGS, and the Phase 2 basket trial of ebribafusp alfa in complement-mediated kidney diseases.

“The third quarter brought a meaningful milestone for our rare kidney disease pipeline as we dosed the first patient in our Phase 2 basket trial evaluating ebribafusp. We believe advancing our pipeline assets has the potential to further drive long-term value for shareholders and patients. We are pursuing our commercial and research and development efforts with a disciplined approach to investment and a strong cash position,” Mr. Butler said.

Financial Results

- **Revenues:** Total revenues were $36.9 million in the third quarter of 2026 compared to $58.8 million in the third quarter of 2025. This decrease was due to a decrease in Auryxia® (ferric citrate) revenues.
  - Vafseo net product revenues were $14.8 million in the third quarter of 2026 compared to $14.3 million in the third quarter of 2025. Despite an 8.1% increase in Vafseo patients in Q3 2026 as compared to Q2 2026, Q3 2026 revenues were lower than in Q2 2026 primarily driven by an inventory reduction at our largest customer.
  - Auryxia net product revenues were $20.0 million in the third quarter of 2026 compared to $42.5 million in the third 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 $2.1 million in the third quarter of 2026 compared to $2.0 million in the third quarter of 2025.
- **Cost of Goods Sold (COGS):** Cost of goods sold was $6.4 million in the third quarter of 2026 compared to $9.4 million in the third 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 $16.2 million in the third quarter of 2026 compared to $14.9 million in the third quarter of 2025. The increase in expenses was driven by increased clinical trial activities related to our mid-stage pipeline assets, which include praliciguat and ebribafusp alfa.
- **SG&A Expenses:** Selling, general and administrative expenses were $23.5 million in the third quarter of 2026 compared to $29.1 million in the third quarter of 2025. This decrease was driven by lower marketing costs and decreased headcount-related costs.
- **Net Income (Loss):** Net loss was $14.4 million in the third quarter of 2026 compared to net income of $0.5 million in the third quarter of 2025. The change to a net loss in the third quarter of 2026 resulted from lower revenues, which were partially offset by lower operating expenses, which included a $1.3 million restructuring charge during the quarter.
- **Cash Position:** Cash and cash equivalents as of September 30, 2026 were approximately $159.3 million as compared to $155.5 million as of June 30, 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 Thursday, November 5 at 8:00 a.m. EST to discuss third quarter 2026 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 Waltham, 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. A pregnancy exposure registry is available to monitor outcomes in women exposed to VAFSEO 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 the data and results from the VOICE trial, including that the data demonstrated statistically significant evidence of improved safety outcomes for patients treated with vadadustat versus an ESA and the potential for such data to drive Vafseo to become standard of care; Akebia's goal of making Vafseo standard of care for the treatment of anemia in patients on dialysis and increasing the number of patients on therapy; Akebia's goals and expectations regarding the Phase 2 open-label basket trial evaluating ebribafusp alfa, including the timing of reporting initial data, the expected number of patients to be enrolled and the timing thereof; Akebia's belief that ebribafusp alfa has the potential to be a next-generation complement inhibitor; Akebia's plans and expectations regarding the progress of its rare kidney disease pipeline; Akebia's expectations regarding Auryxia revenues continuing to decrease due to generic competition and pricing pressure; 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; Akebia's beliefs regarding the expansion of access to Vafseo in 2027 beyond TDAPA-only patients to nearly all clinically eligible patients; and Akebia's plans to refinance its senior secured term loan facility.

The terms "intend," "believe," "designed," "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 topline results do not necessarily predict final results and remain subject to final verification that may result in the final data being materially different from the initial data previously published; preclinical, clinical or retrospective data, analyses or results may not be replicated in, or predictive of, results of future preclinical or clinical data, analyses or results or that such analyses 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; Akebia's ability to refinance its senior secured term loan facility on acceptable terms or at all; 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.
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AKEBIA THERAPEUTICS, INC.
Unaudited Condensed Consolidated Statements of Operations

(in thousands, except per share data)	Three Months Ended September 30, 2026	2025
Revenues		
Product revenue, net	$ 34,827	$ 56,789
License, collaboration and other revenue	2,076	1,977
Total revenues	36,903	58,766
Cost of goods sold		
Cost of product and other revenue	6,362	9,383
Total cost of goods sold	6,362	9,383
Operating expenses		
Research and development	16,183	14,944
Selling, general and administrative	23,531	29,094
License	946	896
Restructuring	1,343	—
Total operating expenses	42,003	44,934
Income (loss) from operations	**(11,462)**	**4,449**
Other expense, net	(3,148)	(4,758)
Change in fair value of warrant liability	431	1,464
Income (loss) before income taxes	**(14,179)**	**1,155**
Income tax expense	(175)	(615)
Net income (loss)	$ (14,354)	$ 540
Net income (loss) per share - basic	$ (0.05)	$ 0.00
Net income (loss) per share - diluted	$ (0.05)	$ 0.00
Weighted-average number of common shares - basic	276,862,564	264,786,432
Weighted-average number of common shares - diluted	276,862,564	274,372,722

Unaudited Selected Balance Sheet Data

(in thousands)	September 30, 2026	December 31, 2025
Cash and cash equivalents	$ 159,254	$ 184,844
Working capital	$ 58,436	$ 90,017
Total assets	$ 342,127	$ 376,565
Total stockholders' equity	$ 20,369	$ 32,610

Source: Akebia Therapeutics, Inc.