Akebia Therapeutics Reports Second Quarter 2024 Financial Results and Recent Business Highlights

August 8, 2024

- *Vafseo® (vadadustat) Tablets market availability on track for January 2025*
- *TDAPA application submission and WAC pricing announcement for Vafseo complete*
- *Second quarter 2024 Auryxia® (ferric citrate) net product revenues of $41.2 million*

Akebia to host conference call at 8:00 a.m. ET on August 8

CAMBRIDGE, Mass., Aug. 8, 2024 /PRNewswire/ -- 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, 2024, and recent business highlights. During the quarter, Akebia made significant progress across multiple initiatives related to the commercial launch of Vafseo® (vadadustat) Tablets recently approved by the U.S. Food and Drug Administration (FDA) for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months.

"Since receiving FDA approval in late March, our key priority has been to execute on our launch strategy developed with a goal for Vafseo to become the standard of care in the treatment of anemia for dialysis patients," said John P. Butler, Chief Executive Officer of Akebia. "Our team is actively engaged with prescribers, and I'm extremely encouraged by the positive reception we've seen across the kidney community for a new choice in anemia management. Equally important, our commercial team is now in active discussions with dialysis organizations covering the vast majority of patients to contract both Auryxia® (ferric citrate) and Vafseo, giving our team a unique opportunity to contract across the portfolio."

Vafseo Global Launch Activities

- In June, Akebia submitted its Transitional Drug Add-on Payment Adjustment (TDAPA) application. Akebia expects to have Healthcare Common Procedure Coding System (HCPCS) codes assigned in October 2024 and TDAPA designation by January 1, 2025.
- Akebia set the Vafseo wholesale acquisition cost (WAC) at $1,278 for a 30-day supply at the labeled starting dose, or approximately $15,500 per year. All Vafseo sales in dialysis will be under contracts that include an off-invoice discount as well as volume-based tier discounts off the WAC price.
- Akebia partner MEDICE Arzneimittel Pütter GmbH&Co.KG (Medice) launched Vafseo in Germany and Austria in June and in the Netherlands in August.
- In July, Akebia regained full rights to sell Vafseo in the U.S. and is now able to contract directly with all dialysis organizations following the execution of a royalty-based termination agreement with CSL Vifor to simplify operational execution and improve economics.

Corporate Updates

In June, Erik Ostrowski joined Akebia as Senior Vice President, Chief Financial Officer and Chief Business Officer. Mr. Ostrowski brings over 20 years of finance and biotech operating experience, with a background in investment banking, including as a director of healthcare investment banking at Leerink Partners. He brings an impressive track record of corporate development leadership and strategic transaction execution.

Akebia reported second quarter 2024 Auryxia net product revenues of $41.2 million. Akebia expects Auryxia full year 2024 net product revenues to be in line with 2023 Auryxia net product revenue levels. Akebia's commercial organization is heavily engaged in efforts to contract Auryxia through dialysis organizations in 2025, as phosphate binders are expected to be added to the Centers for Medicare & Medicaid Services bundled payment for dialysis care in January 2025.

Financial Results

- **Revenues:** Total revenues were $43.6 million in the second quarter of 2024 compared to $56.4 million in the second quarter of 2023. The decrease was driven by a reduction in license, collaboration and other revenue, which included a one-time $10 million upfront payment related to our Medice license agreement in the second quarter of 2023.
    - Net product revenues were $41.2 million in the second quarter of 2024 compared to $42.2 million in the second quarter of 2023.
    - License, collaboration and other revenues were $2.4 million in the second quarter of 2024 compared to $14.1

million in the second quarter of 2023.

- **Cost of Goods Sold:** Cost of goods sold (COGS) was $17.0 million in the second quarter of 2024 compared to $17.3 million in the second quarter of 2023. Akebia continues to carry a non-cash intangible amortization charge of $9.0 million per quarter in COGS through the fourth quarter of 2024.
- **Research & Development Expenses:** Research and development expenses were $7.6 million in the second quarter of 2024 compared to $20.2 million in the second quarter of 2023. The decrease was largely due to the completion of activities related to certain clinical trials, a reduction in consulting expenses and lower headcount related costs.
- **Selling, General & Administrative Expenses:** Selling, general and administrative expenses were $26.9 million for the second quarter of 2024 compared to $27.0 million in the second quarter of 2023.
- **Net Loss:** Net loss was $8.6 million in the second quarter of 2024 compared to $11.2 million in the second quarter of 2023.
- **Cash Position:** Cash and cash equivalents as of June 30, 2024 were $39.5 million. Akebia expects its existing cash resources and cash from operations will be sufficient to fund its current operating plan, including the U.S. Vafseo launch, for at least two years.

Conference Call

Akebia will host a conference call on Thursday, August 8 at 8:00 a.m. Eastern Time to discuss second quarter 2024 earnings. To access the call, please dial (800) 715-9871 (USA & Canada - Toll-Free) and enter Conference ID: 4155557.

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.

IMPORTANT U.S. SAFETY INFORMATION FOR AURYXIA (ferric citrate)

CONTRAINDICATION

AURYXIA (ferric citrate) is contraindicated in patients with iron overload syndromes, e.g., hemochromatosis.

WARNINGS AND PRECAUTIONS

- **Iron Overload:** Increases in serum ferritin and transferrin saturation (TSAT) were observed in clinical trials with AURYXIA in patients with chronic kidney disease (CKD) on dialysis treated for hyperphosphatemia, which may lead to excessive elevations in iron stores. Assess iron parameters prior to initiating AURYXIA and monitor while on therapy. Patients receiving concomitant intravenous (IV) iron may require a reduction in dose or discontinuation of IV iron therapy.
- **Risk of Overdosage in Children Due to Accidental Ingestion:** Accidental ingestion and resulting overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Advise patients of the risks to children and to keep AURYXIA out of the reach of children.

ADVERSE REACTIONS

Most common adverse reactions with AURYXIA were:

- **Hyperphosphatemia in CKD on Dialysis:** Diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%).
- **Iron Deficiency Anemia in CKD Not on Dialysis:** Discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%).

SPECIFIC POPULATIONS

- **Pregnancy and Lactation:** There are no available data on AURYXIA use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. However, an overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Data from rat studies have shown the transfer of iron into milk, hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman.

To report suspected adverse reactions, contact Akebia Therapeutics at 1-844-445-3799.

Please click to see the full Prescribing Information for AURYXIA.

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 global launch activities of Vafseo (vadadustat) Tablets, including Akebia's ability to execute on its launch strategy and achieve its goal for Vafseo to become the standard of care in the treatment of anemia for dialysis patients; Akebia's ability to contract with dialysis organizations covering the vast majority of patients to contract both Auryxia and Vafseo; Akebia's expectations for timing to have HCPCS codes and TDAPA designation; expectations that Vafseo sales in dialysis will be under contracts that include an off-invoice discount as well as volume-based tier discounts off the WAC price; that the execution of a royalty-based termination agreement with CSL Vifor will simplify operational execution and improve economics; Akebia's expectations for Auryxia full year 2024 net product revenues to be in line with 2023 net product revenue levels and assumptions related thereto; Akebia's efforts to contract Auryxia through dialysis organizations in 2025 and its expectations that phosphate binders will be added to the Centers for Medicare & Medicaid Services bundled payment for dialysis care in January 2025; and Akebia's expectations that its existing cash resources and cash from operations will be sufficient to fund its current operating plan, including the U.S. Vafseo launch, for at least two years.

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: whether Vafseo will be commercially available when expected; 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 potential generic entrants; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to implement cost avoidance measures and reduce operating expenses; decisions made by health authorities, such as the FDA, with respect to regulatory filings; the potential therapeutic benefits, safety profile, and effectiveness of Vafseo; the results of preclinical and clinical research; the direct or indirect impact of the COVID-19 pandemic on the markets and communities in which Akebia and its partners, collaborators, vendors and customers operate; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; and early termination of any of Akebia's collaborations. 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, 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 June 30,	
(in thousands, except per share data)	**2024**	**2023**

Revenues		
Product revenue, net	$ 41,209	$ 42,244
License, collaboration and other revenue	2,439	14,132
Total revenues	43,648	56,376
Cost of goods sold		
Cost of product and other revenue	8,036	8,273
Amortization of intangible asset	9,011	9,011
Total cost of goods sold	17,047	17,284
Operating expenses		
Research and development	7,647	20,197
Selling, general and administrative	26,917	27,036
License	762	949
Restructuring	—	(94)
Total operating expenses	35,326	48,088
Loss from operations	**(8,725)**	**(8,996)**
Other expense, net	(2,188)	(1,652)
Change in fair value of warrant liability	2,331	—
Loss on termination of lease	—	(524)
Net loss	**$ (8,582)**	**$ (11,172)**
Net loss per share - basic and diluted	$(0.04)	$(0.06)
Weighted-average number of common shares - basic and diluted	209,705,397	186,817,431

Unaudited Selected Balance Sheet Data

(in thousands)	**June 30, 2024**	**December 31, 2023**
Cash and cash equivalents	$ 39,499	$ 42,925
Working capital	$ 4,797	$ 18,279
Total assets	$ 220,196	$ 241,703
Total stockholders' (deficit) equity	$ (33,754)	$ (30,584)

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