# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

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# FORM 8-K

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**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 8, 2023**

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# AKEBIA THERAPEUTICS, INC.
**(Exact name of registrant as specified in its charter)**

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| **Delaware** | **001-36352** | **20-8756903** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| **245 First Street**<br>**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)**

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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 8, 2023, Akebia Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2023 and recent business highlights. A copy of the press release 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 8, 2023, 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 8, 2023

By: /s/ John P. Butler

Name: John P. Butler
Title: President and Chief Executive Officer

**Exhibit 99.1**

**Akebia Therapeutics Reports Third Quarter 2023 Financial Results and Recent Business Highlights**

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

- Vadadustat NDA assigned a PDUFA date of March 27, 2024
- Vadadustat approved in 36 countries, including Australia and Taiwan
- Akebia strengthens cash position modifying Pharmakon loan
- Auryxia® (ferric citrate) quarterly net product revenue of $40.1 million

CAMBRIDGE, Mass.—November 8, 2023—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, 2023 and reviewed recent business highlights.

In September, Akebia completed its resubmission to its New Drug Application for vadadustat to the U.S. Food and Drug Administration (FDA) as a treatment for anemia due to chronic kidney disease (CKD) in adult patients on dialysis. FDA subsequently accepted the resubmission and assigned a user fee goal date ("PDUFA date") of March 27, 2024. The resubmission includes post-marketing safety data from tens of thousands of patients in Japan where vadadustat is approved and has been in the market for more than three years.

“Akebia is extremely well-positioned following the acceptance of our vadadustat NDA resubmission, with a March 27, 2024 PDUFA date,” said John P. Butler, Chief Executive Officer of Akebia. "We are preparing for a commercial launch if vadadustat is approved and stand ready with a commercial team in place and product supply on the shelf. We also added Australia and Taiwan to the list of countries where vadadustat is approved for CKD patients on dialysis. Additionally, we have strengthened our financial position by deferring our Pharmakon principal payments until October 2024.”

Auryxia® (ferric citrate) net product revenue for the third quarter was $40.1 million and management reaffirms previously issued 2023 net product revenue guidance of $170.0 - $175.0 million for Auryxia.

**Third Quarter 2023 and Recent Business Highlights**

- Australia’s Therapeutic Goods Administration granted approval for Vafseo® (vadadustat) for the treatment of anemia associated with CKD in adults on chronic maintenance dialysis. Vadadustat was also authorized for use in Taiwan during this time, marking approval in 36 countries.
- Akebia supported five posters presented at the American Society of Nephrology Kidney Week 2023, which took place on November 2-5, 2023. Notably, one poster presented data on a potential alternative dosing regimen for vadadustat.
- Akebia modified the terms of its loan agreement with Pharmakon Advisors, LP to extend the maturity of the loan from November 2024 until March 2025, and to defer its principal payments until October 31, 2024.

**Third Quarter Financial Results**

**Total Revenues:** Total revenues were $42.0 million for the third quarter of 2023, compared to $48.7 million for the third quarter of 2022. The decrease is primarily due to a decrease in license, collaboration and other revenue.

**Net Product Revenues:** Net product revenues were $40.1 million for the third quarter of 2023, compared to $42.0 million for the third quarter of 2022. The decrease was primarily due to a reduction in volume and the impact of shifting payor mix, partially caused by contracting dynamics and a decline in the phosphate binder market. The decline was partially offset by price increases in January 2023 and July 2023.

**License, Collaboration and Other Revenues:** License, collaboration and other revenues were $1.9 million for the third quarter of 2023, compared to $6.7 million for the third quarter of 2022. The decrease is primarily due to the transfer and assignment of a supply agreement to Akebia's collaboration partner.

**Cost of Goods Sold (COGS):** COGS was $18.0 million for the third quarter of 2023, compared to $38.3 million for the third quarter of 2022. COGS reflects the costs of Auryxia, including non-cash intangible amortization charge of $9.0 million per quarter through the fourth quarter of 2024 and third-party royalties. The decrease was primarily due to a reduction in a non-cash charge related to the prior liability for excess purchase commitments, a decrease in inventory write-downs and lower volume of sales resulting in reduced product costs.

**Research and Development (R&D) Expenses:** R&D expenses were $13.3 million for the third quarter of 2023, compared to $28.0 million for the third quarter of 2022. The decrease was primarily due to a reduction in spending for vadadustat development, including clinical trial costs, and curtailment of outsourced contract services.

**Selling, General and Administrative (SG&A) Expenses:** SG&A expenses were $22.7 million for the third quarter of 2023, compared to $31.9 million for the third quarter of 2022. The decrease was primarily due to a reduction in headcount related costs, the benefits realized from the assignment of the Boston lease in May 2023 and a targeted cutback in Auryxia marketing and promotional expense which were offset by some one-time non-recurring expenses.

**Net Loss:** Net loss was $14.5 million for the third quarter of 2023, compared to net loss of $54.1 million for the third quarter of 2022.

**Cash Position:** Cash, cash equivalents and restricted cash as of September 30, 2023, totaled $48.2 million. Akebia expects its existing cash resources and cash from operations will be sufficient to fund its current operating plan for at least the next twelve months.

**Conference Call Information**

Akebia will host a conference call and webcast on Wednesday, November 8 at 8:00 a.m. ET to discuss its financial results and recent business highlights. 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 Vadadustat**
Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxia-inducible factor, which can lead to increased red blood cell production and improved oxygen delivery to tissues. Vadadustat is not approved by the U.S. Food and Drug Administration. Vadadustat is approved in Europe, Australia and Taiwan for the treatment of symptomatic anemia due to CKD in adult patients on chronic maintenance dialysis. In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

**IMPORTANT SAFETY INFORMATION FOR VAFSEO (vadadustat)**
For safety information, view the European Summary of Product Characteristics (SPC/SmPC) for Vafseo® (vadadustat) at https://ec.europa.eu/health/documents/community-register/2023/20230424158854/anx_158854_en.pdf, https://products.mhra.gov.uk/ and https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/authorisations/swisspar.html and will be available via the Australian Therapeutic Goods Administration website here.

**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: the anticipated scheduled PDUFA date for vadadustat; Akebia's ability to enable a successful commercial launch of vadadustat if approved; Akebia's expectations and beliefs regarding the impact that the amendment with Pharmakon will have on Akebia; Akebia's revenue guidance for Auryxia in 2023 and assumptions related thereto; and Akebia's goals, objectives and expectations with respect to its operating plan, expenses, cash resources and sources of funding for its cash runway, including its belief that its existing cash resources and cash from operations will be sufficient to fund its current operating plan for at least the next twelve months. The terms "intend," "believe," "plan," "goal," "expect," "potential," "anticipate," "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 demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia, including estimates regarding the potential market opportunity; the competitive landscape for Auryxia, 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, including the anticipated FDA decision on the NDA for vadadustat and the potential effects of a negative decision on Akebia's cash runway; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat;

the results of preclinical and clinical research; the direct or indirect impact of the COVID-19 pandemic on regulators and Akebia's business, operations, and 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, 2023, 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 Contact**
Mercedes Carrasco
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**Exhibit 99.1**

**AKEBIA THERAPEUTICS, INC.**

**Unaudited Condensed Consolidated Statements of Operations**

| | Three Months Ended September 30, | |
|---|---|---|
| **(in thousands, except per share data)** | **2023** | **2022** |
| **Revenues** | | |
| Product revenue, net | $ 40,118 | $ 41,989 |
| License, collaboration and other revenue | 1,928 | 6,725 |
| Total revenues | 42,046 | 48,714 |
| **Cost of goods sold** | | |
| Product | 8,998 | 29,270 |
| Amortization of intangible asset | 9,011 | 9,011 |
| Total cost of goods sold | 18,009 | 38,281 |
| Operating expenses | | |
| Research and development | 13,330 | 28,028 |
| Selling, general and administrative | 22,710 | 31,887 |
| License expense | 864 | 743 |
| Restructuring | 169 | 180 |
| Total operating expenses | 37,073 | 60,838 |
| **Loss from operations** | **(13,036)** | **(50,405)** |
| Other expense, net | (1,453) | (2,785) |
| Loss on extinguishment of debt | — | (906) |
| **Net loss** | **$ (14,489)** | **$ (54,096)** |
| Net loss per share - basic and diluted | $(0.08) | $(0.29) |
| Weighted-average number of common shares - basic and diluted | 188,306 | 183,882 |

**Unaudited Selected Balance Sheet Data**

| **(in thousands)** | **September 30, 2023** | **December 31, 2022** |
|---|---|---|
| Cash and cash equivalents | $ 46,529 | $ 90,466 |
| Working capital | $ 29,900 | $ 55,646 |
| Total assets | $ 234,998 | $ 356,054 |
| Total stockholders' (deficit) equity | $ (39,422) | $ 5,230 |