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

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): May 8, 2023

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

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

245 First Street **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)

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 May 8, 2023, Akebia Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2023 and commenting on certain business updates. A copy of the Company's press release containing this information 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 May 8, 2023, issued by Akebia Therapeutics, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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: May 8, 2023

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

Akebia Therapeutics Reports First Quarter 2023 Financial Results and Recent Business Highlights

Akebia to host conference call on May 8 at 8:30 a.m. ET

- Announced vadadustat is now approved in 32 countries following European Commission marketing authorization
- Expects a response to Formal Dispute Resolution from FDA within next 30 days
- Released positive top-line results from vadadustat alternative dosing study
- Reports Auryxia® (ferric citrate) net product revenue of $34.8M for Q1 2023
- Affirms 2023 Auryxia net product revenue guidance at $175-$180M

CAMBRIDGE, Mass.—May 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 first quarter ended March 31, 2023 and provided business highlights.

“Approval of Vafseo™ (vadadustat) by the European Commission is a significant milestone for us and for dialysis patients in Europe with anemia due to chronic kidney disease,” said John P. Butler, Chief Executive Officer of Akebia. “This is an important step as we continue to deliver on our commitment to better the lives of people with kidney disease. Now we are working to complete a partnership to launch Vafseo in Europe, and we are eager to conclude our appeal process with the FDA.”

In April, the European Commission granted marketing authorization for Vafseo (vadadustat), for the treatment of symptomatic anemia associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis. Akebia plans to select a partner to commercialize Vafseo in Europe. Vadadustat is now approved in 32 countries. Akebia also expects a regulatory opinion on vadadustat in the United Kingdom, Switzerland and Australia over the course of this year.

In the U.S., Akebia has continued to engage with the Office of New Drugs on its Formal Dispute Resolution regarding vadadustat. Dr. Stein, the deciding authority on the appeal, indicated he has completed his internal discussions, and the company expects a response within the next 30 days.

Akebia also recently reported positive top-line results from FO_2CUS, a study evaluating the efficacy and safety of vadadustat in hemodialysis patients who were converted from a long-acting erythropoiesis-stimulating agent (ESA) to three times weekly oral vadadustat dosing for the maintenance treatment of anemia. The data demonstrated that vadadustat met the primary and secondary efficacy endpoints and was non-inferior to an ESA in the treatment of anemia due to chronic kidney disease in patients on hemodialysis when used three times a week at the time of dialysis and with a comparable safety profile to the current standard of care.

“Our team has been diligent in efforts to manage spend and sustain a reduction in operating costs,” said David A. Spellman, Chief Financial Officer of Akebia. “Auryxia revenue was impacted by a $5 million reduction in the volume of channel inventory from year end. We believe quarterly fluctuations in our revenue will continue, which do not impact revenue guidance of $175-$180 million. Our team is delivering operating expense savings, with an almost 50% reduction versus the first quarter of 2022, and almost 30% reduction from the fourth quarter of 2022. We continue to execute strategic decisions to enable us to operate with cash on hand and Auryxia revenue for at least the next twelve months.”

Financial Results

- **Revenues:** Total revenue was $40.1 million in the first quarter of 2023 compared to $61.7 million for the first quarter of 2022.
    - Net product revenue was $34.8 million in the first quarter of 2023 compared to $41.4 million in the first quarter of 2022, a 15.9% decrease; and compared with $49.7 million in the fourth quarter of 2022, a 30.0% decrease. The decrease compared to the first quarter of 2022 was primarily due to a reduction in inventory of Auryxia by certain customers, as well as a decline in volume, partially offset by higher net price per tablet. The decrease compared to the fourth quarter of 2022 is primarily due to the previously discussed year-end inventory build up by a customer at the end of 2022, which has now been reduced significantly.
    - License, collaboration, and other revenue was $5.3 million for the first quarter of 2023 compared to $20.3 million for the first quarter of 2022. The decrease was primarily related to a reduction in revenue from the termination of the U.S. and international collaboration agreements between Akebia and Otsuka in the second quarter of 2022.
- **COGS:** Cost of goods sold was $19.5 million for the first quarter of 2023 compared to $31.3 million for the first quarter of 2022. The decrease was primarily due to lower excess and obsolescence reserves associated with Auryxia, lower manufacturing costs associated with the supply of Vafseo to Mitsubishi Tanabe Pharma Corporation for commercial sale in Japan, and lower freight costs as a result of a lower volume of shipments. The company continues to carry a non-cash intangible amortization charge of $9.0 million per quarter through the fourth quarter of 2024.
- **R&D Expenses:** Research and development expenses were $19.7 million for the first quarter of 2023 compared to $43.8 million for the first quarter of 2022. The decrease was primarily due to decreased headcount related costs as a result of the April 2022 reduction in force, decreased outsourced contract services, decreased clinical trial costs, and development expenses related to vadadustat.
- **SG&A Expenses:** Selling, general and administrative expenses were $25.2 million for the first quarter of 2023 compared to $44.3 million for the first quarter of 2022. The decrease was primarily due to decreased headcount related costs as a result of the 2022 reductions in force and lower marketing expenses following receipt of the complete response letter for vadadustat from the U.S. Food and Drug Administration (FDA).

- **Net Loss:** Net loss was $26.2 million for the first quarter of 2023 compared to $62.4 million for the first quarter of 2022. The decrease in net loss was due primarily to lower cost of goods sold and lower operating expenses, partially offset by lower revenues.
- **Cash Position:** Cash and cash equivalents as of March 31, 2023 were approximately $57.0 million. Akebia believes that its cash resources will be sufficient to fund its current operating plan for at least the next twelve months. Akebia's objective is to fund its current operating plan with existing cash resources and cash from operations for at least the next twelve months. Future decisions by the FDA or other regulatory agencies related to the potential regulatory approval of vadadustat, or Akebia's ability to generate additional value from vadadustat through partnerships or other transactions may potentially further extend our cash runway, but are not currently reflected in the operating plan. Akebia also plans to continue to work on initiatives to extend its revenues from Auryxia beyond anticipated loss of exclusivity in March 2025.

Conference Call

Akebia will host a conference call on Monday, May 8 at 8:30 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 then you will be provided with dial in details. To avoid delays, we encourage dialing into the conference call fifteen 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 http://ir.akebia.com. An online archive of the webcast can be accessed via the Investors section of Akebia's website at http://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 an investigational new drug and is not approved by the U.S. Food and Drug Administration (FDA). On March 29, 2022, the FDA issued a complete response letter to Akebia's New Drug Application for vadadustat for the treatment of anemia due to chronic kidney disease (CKD). Vadadustat is approved in Europe 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.

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 see full Prescribing Information

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, including with respect to the Formal Dispute Resolution Request that Akebia submitted with the FDA to appeal the complete response letter that it received in March 2022; Akebia's expectations on the timing for certain regulatory decisions for vadadustat by the FDA and regulatory authorities in the United Kingdom, Switzerland and Australia; Akebia's plans with respect to commercializing and completing a partnership for vadadustat in Europe; Akebia's future plans with respect to its strategic growth and operating plans; Akebia's revenue guidance for Auryxia in 2023 and assumptions related thereto; Akebia's plans with respect to vadadustat as a treatment of anemia due to CKD in patients on dialysis; 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 revenues from Auryxia will be sufficient to fund its current operating plan for at least the next twelve months. The terms "intend," "believe," "plan," "goal," "expect," "potential," "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 New Drug Application and the Formal Dispute Resolution Request for vadadustat; Akebia's ability to partner for vadadustat in Europe in a timely manner, on acceptable terms, or at all; 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 Annual Report on Form 10-K for the year ended December 31, 2022, 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
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AKEBIA THERAPEUTICS, INC.
Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended	
	March 31, 2023	March 31, 2022
Revenues:		
Product revenue, net	$ 34,828	$ 41,448
License, collaboration and other revenue	5,299	20,251
Total revenues	40,127	61,699
Cost of goods sold:		
Product	10,473	22,333
Amortization of intangibles	9,011	9,011
Total cost of goods sold	19,484	31,344
Operating expenses:		
Research and development	19,686	43,833
Selling, general and administrative	25,221	44,327
License expense	568	688
Restructuring	106	—
Total operating expenses	45,581	88,848
Operating loss	(24,938)	(58,493)
Other expense, net	(1,279)	(3,928)
Net loss	$ (26,217)	$ (62,421)
Net loss per share - basic	$ (0.14)	$ (0.35)
Weighted-average number of common shares - basic	184,768,983	179,599,045

AKEBIA THERAPEUTICS, INC.
Selected Balance Sheet Data
(in thousands)
(unaudited)

	March 31, 2023	December 31, 2022
Cash and cash equivalents	$ 56,953	$ 90,466
Working capital	37,775	60,193
Total assets	276,858	351,830
Total stockholders' (deficit) equity	(14,352)	9,342