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): **March 14, 2024**

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 March 14, 2024, Akebia Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 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 March 14, 2024, 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: March 14, 2024

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

Akebia Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Recent Business Highlights

Potential vadadustat U.S. approval on PDUFA date of March 27, 2024

Strengthened balance sheet with $55.0 million term loan financing and $26.0 million in proceeds from ATM

Reported 2023 Auryxia (ferric citrate) net product revenue of $170.3 million

CAMBRIDGE, Mass.—March 14, 2024—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 fourth quarter and full year ended December 31, 2023 and recent business highlights. Akebia is preparing for a potential launch of vadadustat, which is currently under review by the U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) date of March 27, 2024.

"We are eagerly awaiting the PDUFA date for vadadustat, now within weeks, and we believe the progress we have made over the past 12 months has positioned our team to successfully launch vadadustat in the U.S., if approved," said John P. Butler, Chief Executive Officer of Akebia. "A U.S. approval for vadadustat will be transformational for Akebia and a significant step toward our goal of bettering the lives of people impacted by kidney disease. Our team remains dedicated to delivering an innovative oral therapeutic treatment for anemia due to chronic kidney disease for patients on dialysis."

Fourth Quarter 2023 and Recent Business Highlights:

- Appointed Nicholas Grund as Chief Commercial Officer, who brings years of expertise in customer-facing roles to Akebia. Mr. Grund's operational, commercial and strategic leadership experience across renal and specialty markets will be critical as Akebia prepares for the vadadustat launch in the U.S., if approved.

- Introduced new pipeline programs in acute care settings, potentially for acute kidney injury or acute respiratory distress syndrome (AKB-9090) and retinopathy of prematurity in neonates (AKB-10108).

- Closed a new debt facility with BlackRock that provides access to up to $55.0 million in borrowing capacity and used the proceeds from the first tranche of $37.0 million to pay down principal outstanding under the then loan agreement with Pharmakon Advisors, LP. The BlackRock debt facility, which closed on January 29, 2024, also extends the interest-only period in the event of vadadustat approval in the U.S. on or prior to June 30, 2024 without requiring any principal repayment until December 31, 2026.

- Concluded its offering of common stock under its "at-the-market" (ATM) sales agreement. Akebia raised approximately $26.0 million in gross proceeds.

Akebia reported fourth quarter 2023 Auryxia® (ferric citrate) net product revenues of $53.2 million and full year 2023 revenues of $170.3 million, within Akebia's 2023 Auryxia net product revenue guidance of $170.0 - $175.0 million.

"We are approaching a potential U.S. launch of vadadustat from an extremely strong financial position. We expect Auryxia net product revenue growth in 2024, with a quarterly revenue cadence that is similar to 2023, we executed a term loan with BlackRock and implemented other financial strategies that together we believe will support our business operations for at least two years if vadadustat is approved. As we move forward, we will continue to carefully manage expenses, while investing appropriately for a successful potential launch of vadadustat," Mr. Butler added.

Financial Results

- **Revenues:** Total revenues were $56.2 million for the fourth quarter of 2023 compared to $55.8 million for the fourth quarter of 2022, and $194.6 million for the full-year 2023 compared to $292.5 million for the full-year 2022.
    - Net product revenues were $53.2 million for the fourth quarter of 2023 compared to $50.3 million for the fourth quarter of 2022, and $170.3 million for the full-year 2023 compared to $176.9 million for the full-year 2022.
    - License, collaboration and other revenues were $3.0 million for the fourth quarter of 2023 compared to $5.5 million for the fourth quarter of 2022, and $24.3 million for the full-year 2023 compared to $115.5 million for the full-year 2022.
- **COGS:** Cost of goods sold was $18.7 million for the fourth quarter of 2023 compared to a benefit of $3.4 million for the fourth quarter of 2022, and $74.1 million for the full-year 2023 compared to $85.6 million for the full-year 2022. Akebia continues to record 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 $9.9 million for the fourth quarter of 2023 compared to $32.1 million for the fourth quarter of 2022, and $63.1 million for the full-year 2023 compared to $130.0 million for the full-year 2022.
- **SG&A Expenses:** Selling, general and administrative expenses were $25.4 million for the fourth quarter of 2023 compared to $29.9 million for the fourth quarter of 2022, and $100.2 million for the full-year 2023 compared to $138.6 million for the full-year 2022.
- **Net Income / Loss:** Net income was $0.6 million for the fourth quarter of 2023 compared to a net loss of $6.1 million for the fourth quarter of 2022, and $51.9 million for the full-year 2023 compared to $94.2 million for the full-year 2022.
- **Cash Position:** Cash and cash equivalents as of December 31, 2023, were approximately $42.9 million. Akebia believes its existing cash resources and the cash it expects to

generate from product, royalty, supply and license revenues as well as the borrowings and potential future borrowings that are available under the BlackRock debt facility and the working capital liability are sufficient to fund our current operating plan for at least twenty-four months if vadadustat is approved.

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 and Australia for the treatment of symptomatic anemia due to CKD in adult patients on chronic maintenance dialysis and in Taiwan for the treatment of anemia due to CKD in adult patients on 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.

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 financial results for the fourth quarter and full year ended December 31, 2023; the anticipated scheduled PDUFA date for vadadustat and the potential approval of vadadustat; Akebia's ability to enable a successful commercial launch of vadadustat, if approved; statements that a U.S. approval for vadadustat will be transformational for Akebia; Akebia's expectations and beliefs regarding the impact that the BlackRock debt facility will have on Akebia; Akebia's expectations for Auryxia revenue growth in 2024 and assumptions related thereto; Akebia's plans with respect to vadadustat as a treatment of anemia due to chronic kidney disease in patients on dialysis in the U.S.; Akebia's expectations with respect to Akebia's pipeline in acute care settings for acute kidney injury or acute respiratory distress syndrome (AKB-9090) and retinopathy of prematurity in neonates (AKB-10108) and market potential; 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 the cash it expects to generate from product, royalty, supply and license revenues as well as the borrowings and potential future borrowings that are available under the BlackRock debt facility and the working capital liability are sufficient to fund our current operating plan for at least twenty-four months if vadadustat is approved. 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 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 September 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®, Auryxia® and Vafseo® are registered trademarks of Akebia Therapeutics, Inc. and its affiliates.

Akebia Therapeutics Contact
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AKEBIA THERAPEUTICS, INC.

Consolidated Statements of Operations

(in thousands, except share and per share data)	Quarters Ended December 31,		Years Ended December 31,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product revenue, net	$ 53,233	$ 50,280	$ 170,301	$ 176,949
License, collaboration and other revenue	2,963	5,503	24,322	115,535
Total revenues	56,196	55,783	194,623	292,484
Cost of goods sold:				
Cost of product and other revenue	9,656	(12,439)	38,107	49,526
Amortization of intangibles	9,010	9,010	36,042	36,042
Total cost of goods sold	18,666	(3,429)	74,149	85,568
Operating expenses:				
Research and development	9,866	32,098	63,079	129,986
Selling, general and administrative	25,434	29,908	100,233	138,601
License expense	856	852	3,237	3,175
Restructuring	—	1,221	181	15,933
Total operating expenses	36,156	64,079	166,730	287,695
Operating income (loss)	1,374	(4,867)	(46,256)	(80,779)
Other income (expense), net	(761)	(1,201)	(5,145)	(12,541)
Loss on extinguishment of debt	—	—	—	(906)
Loss on lease termination	—	—	(524)	—
Net income (loss)	$ 613	$ (6,068)	$ (51,925)	$ (94,226)
Net income (loss) per share				
Basic and diluted	$—	$(0.03)	$(0.28)	$(0.52)
Weighted-average number of common shares outstanding:				
Basic	189,903,365	183,991,111	187,465,448	182,782,680
Diluted	190,496,470	183,991,111	187,465,448	182,782,680

Selected Balance Sheet Data

(unaudited)

(in thousands)	December 31,	
	2023	**2022**
Cash and cash equivalents	$ 42,925	$ 90,466
Working capital	$ 18,279	$ 55,646
Total assets	$ 241,703	$ 356,054
Total stockholders' (deficit) equity	$ (30,584)	$ 5,230