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 9, 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 March 9, 2023, Akebia Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter and fiscal year ended December 31, 2022 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 9, 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: March 9, 2023

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

Akebia Therapeutics Reports Fourth Quarter and Full-Year 2022 Financial Results and Recent Business Highlights

Akebia to host conference call on March 9 at 8:30 a.m. ET

- Receives positive CHMP opinion for Vafseo™ (vadadustat); anticipates potential Marketing Authorization in Europe in May 2023
- Reports Auryxia® (ferric citrate) net product revenue of $177.1M for 2022, an increase of approximately 24.5% over 2021
- Sets 2023 Auryxia net product revenue guidance at $175-$180M

CAMBRIDGE, Mass.—March 9, 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 fourth quarter and full-year ended December 31, 2022 and provided business highlights.

"We ended our year delivering on our strategic focus, which included a commitment to maximize Auryxia revenue, support vadadustat globally and thoughtfully invest in our pipeline," said John P. Butler, Chief Executive Officer of Akebia. "We believe the work our team executed through the fourth quarter and more broadly in 2022 has put us in a strong position as we prepare for several meaningful upcoming milestones. Building on our positive CHMP opinion for vadadustat in Europe, we anticipate potential Marketing Authorization of Vafseo by the European Commission in May 2023, and we are active in our process to select a partner in Europe to deliver Vafseo to patients with chronic kidney disease (CKD) on dialysis, if approved."

Last month, Akebia announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the European Commission (EC) to approve Vafseo™ (vadadustat), for the treatment of symptomatic anaemia associated with CKD in adults on chronic maintenance dialysis. If approved, an EC Marketing Authorization of Vafseo would be applicable to all 27 European Union member states plus Iceland, Norway and Liechtenstein. Akebia is seeking a partner to commercialize vadadustat in Europe.

Additionally, Akebia had an important year with several key milestones in 2022 and into early 2023:

- Achieved Auryxia revenue of $177.1 million representing 24.5% growth versus 2021;
- Implemented multiple initiatives to reduce costs and create a clear path to positive cash flows from operations supported by Auryxia revenues;
- Restructured and simplified the Auryxia supply chain, saving significant anticipated cash over a five-year period;
- Signed a European license agreement with Averoa SAS for the development and commercialization of Auryxia in Europe;

- Regained the rights from Otsuka Pharmaceutical Co. Ltd. for vadadustat in the U.S., Europe, China, Russia, Canada, Australia, the Middle East, and certain other territories;
- Assumed responsibility for vadadustat regulatory filings in EMA and ACCESS Consortium countries: U.K., Switzerland and Australia;
- Submitted a Formal Dispute Resolution Request (FDRR) to the U.S. Food and Drug Administration (FDA), disputing the Complete Response Letter (CRL) for vadadustat received in March 2022; and,
- Released data from an investigator-sponsored clinical study with the University of Texas Health Sciences Center, Houston (UT Health), evaluating vadadustat for the prevention and treatment of COVID-19 related acute respiratory distress syndrome (ARDS).

Pipeline Progress Expected in 2023

- Obtain potential Marketing Authorization for Vafseo expected in Europe in May 2023;
- Receive regulatory decision for vadadustat for U.K., Switzerland and Australia;
- Receive decision on appeal process related to CRL for vadadustat;
- Present data from the IMPACT investigator-sponsored study evaluating the effect of Auryxia as a phosphate binder on utilization of IV iron and erythropoiesis-stimulating agents on dialysis patients;
- Present data from the FOCUS study on three times weekly dosing for vadadustat in dialysis patients;
- Initiate UT Health study of vadadustat for the prevention and treatment of ARDS in a broader population beyond patients with COVID-19;
- Assess potential regulatory path for vadadustat in other acute treatment indications; and,
- Advance preclinical development of multiple novel hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitor compounds for potential indications of serious unmet need.

“Auryxia revenue continues to fund our business, and we entered 2023 with a robust operating plan, including funding for several compelling pipeline opportunities,” said David A. Spellman, Chief Financial Officer of Akebia. “Regarding revenue, we reported nearly 25% net product revenue growth for Auryxia over 2021, which exceeded guidance. The fourth quarter of 2022 included an inventory build of approximately $3M year over year. We have set 2023 net product revenue guidance at $175-180 million as we remain cautious about a phosphate binder market recovery; the market continues to contract modestly due to COVID-19 and dialysis staffing issues. We will continue to be mindful of non-essential spend and work to reduce costs overall.”

Financial Results

- **Revenues:** Total revenue was $55.2 million in the fourth quarter of 2022 compared to $59.6 million for the fourth quarter of 2021, and $292.6 million for the full-year 2022 compared to $213.6 million for full-year 2021.
    - Net product revenue was $49.7 million in the fourth quarter of 2022 compared to $42.1 million in the fourth quarter of 2021, an 18.1% increase. Net product revenue was $177.1 million for the full-year 2022 compared to $142.2 million for the full-year 2021, an increase of approximately 24.5%. The increase compared to the fourth quarter and full-year of 2021 is primarily due to pricing and improved payer mix, and a 2022 year-end inventory build by a customer that exceeded 2021. Total units sold decreased year over year.

- License, collaboration, and other revenue was $5.5 million for the fourth quarter of 2022 compared to $17.5 million for the fourth quarter of 2021, and $115.5 million for the full-year 2022 compared with $71.4 million for the full-year 2021. The increase for the full-year 2022 reflects a nonrefundable and non-creditable payment of $55.0 million that Otsuka paid to Akebia in July 2022 under the terms of a termination and settlement agreement between the companies. In addition, Akebia recognized $15.5 million related to previously deferred revenue as of the date of termination and $9.6 million of non-cash consideration related to Otsuka's obligations to complete certain agreed upon clinical activities. Additionally, Akebia recognized $19.1 million in collaboration revenue in 2022 from the cost sharing arrangement with Otsuka prior to the termination, compared to $53.0 million for the full-year 2021.
- Auryxia revenue guidance for 2023 of $175—$180 million assumes, among other things, an increase in realized net price per pill, partially offset by a reduction in total units sold and inventories returning to normal levels.

- **COGS:** Cost of goods sold was a benefit of $3.1 million for the fourth quarter of 2022 compared to a cost of $50.4 million for the fourth quarter of 2021. Cost of goods sold was $84.8 million for the full-year 2022, compared with $153.4 million for the full-year 2021. The decrease in both periods compared to the same periods in 2021 was primarily due to a non-cash reduction of our excess purchase commitment liability driven by the reduction in purchase commitments with the restructuring of our supply chain. The decrease was partially offset by contract termination fees and inventory reserves associated with Auryxia drug substance that will not be forward processed.
- **R&D Expenses:** Research and development expenses were $31.9 million for the fourth quarter of 2022 compared to $29.6 million for the fourth quarter of 2021, and $129.1 million for the full-year 2022 compared to $147.9 million for the full-year 2021. The increase for the fourth quarter of 2022 compared to the fourth quarter of 2021 was largely due to a one-time credit of $8.6 million representing a reimbursement from Vifor Pharma following the sale of the Priority Review Voucher that occurred in 2021. The decrease for the full-year 2022 compared to the full-year 2021 was primarily due to decreased headcount related costs as a result of the April 2022 reduction in force, decreased consulting costs, and decreased outsourced contract services.
- **SG&A Expenses:** Selling, general and administrative expenses were $30.6 million for the fourth quarter of 2022 compared to $44.8 million for the fourth quarter of 2021, and $138.7 million for the full-year 2022 compared to $174.2 million for the full-year 2021. The decrease in both periods compared to the same periods in 2021 was primarily due to decreased headcount related costs as a result of both the April 2022 and November 2022 reductions in force, decreased one-time legal costs, and lower marketing expenses following receipt of the CRL for vadadustat.

- **Net Loss:** Net loss was $7.6 million for the fourth quarter of 2022 compared to $70.7 million for the fourth quarter of 2021, and $92.6 million for the full-year 2022 compared to $282.8 million for the full-year 2021. The decrease in net loss for the full-year 2022 compared to the prior year was due primarily to higher revenues, lower cost of goods sold and lower operating expenses, partially offset by restructuring expenses in 2022.
- **Cash Position:** Cash and cash equivalents as of December 31, 2022 were $90.5 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 operating plan assumed certain contractual changes and cost avoidance measures would be executed over the course of 2022, which has now occurred. 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 the anticipated loss of exclusivity in March 2025.

Conference Call

Akebia will host a conference call on Thursday, March 9 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: https://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 currently under review by the European Medicines Agency for the treatment of anemia due to CKD in adults. In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

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 FDRR 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 U.K., Switzerland and Australia; Akebia's expectations on the timing of a decision from the European Commission and, if approved, Akebia's plans with respect to commercializing and identifying a partner for vadadustat in Europe; Akebia's expectations with respect to certain development activities and the timing of those activities, including the initiation of a trial to study vadadustat for the treatment of ARDS; 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 and the European Medicines Agency, with respect to regulatory filings, including the New Drug Application and the FDRR 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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®, Auryxia® (ferric citrate), and Vafseo™ (vadadustat) 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)
(unaudited)

	Three Months Ended		Twelve Months Ended	
	December 31, 2022	December 31, 2021	December 31, 2022	December 31, 2021
Revenues:				
Product revenue, net	$ 49,677	$ 42,096	$ 177,067	$ 142,216
License, collaboration and other revenue	5,503	17,509	115,535	71,362
Total revenues	55,180	59,605	292,602	213,578
Cost of goods sold:				
Product	(12,104)	41,340	48,754	117,352
Amortization of intangibles	9,010	9,010	36,042	36,042
Total cost of goods sold	(3,094)	50,350	84,796	153,394
Operating expenses:				
Research and development	31,904	29,556	129,114	147,852
Selling, general and administrative	30,647	44,825	138,699	174,161
License expense	852	1,029	3,175	3,489
Restructuring	1,221	—	15,933	—
Total operating expenses	64,624	75,410	286,921	325,502
Operating loss	(6,350)	(66,155)	(79,115)	(265,318)
Other income (expense), net	(1,202)	(4,523)	(12,541)	(17,522)
Loss on extinguishment of debt	—	—	(906)	—
Net loss before income taxes	(7,552)	(70,678)	(92,562)	(282,840)
Benefit from income taxes	—	—	—	—
Net loss	$ (7,552)	$ (70,678)	$ (92,562)	$ (282,840)
Net loss per share—basic and diluted	$ (0.04)	$ (0.40)	$ (0.51)	$ (1.70)
Weighted-average number of common shares—basic and diluted	183,991,111	175,605,992	182,782,680	165,949,695

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents and available for sale securities	$ 90,466	$ 149,800
Working capital	60,193	15,517
Total assets	351,830	525,550
Total stockholders' equity	9,342	76,456