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): November 3, 2022

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 Global 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 3, 2022, Akebia Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 3, 2022, 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: November 3, 2022

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

Akebia Therapeutics Reports Third Quarter 2022 Financial Results and Recent Business Highlights

Akebia to host conference call on November 3 at 4:30 p.m. ET

- Filed Formal Dispute Resolution Request related to the CRL for vadadustat
- Reported Auryxia® (ferric citrate) quarterly net product revenue of $42.2, an increase of 14.9% over Q3 2021
- Affirmed 2022 Auryxia net product revenue guidance of $170 - $175M
- Managed operating expenses in support of three strategic pillars

CAMBRIDGE, Mass.—November 3, 2022—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, 2022 and provided business highlights.

“Our team continues to execute a strategy aligned with our three strategic pillars, drive Auryxia revenue while managing costs, support the regulatory processes for vadadustat globally, and thoughtfully invest in our pipeline,” said John P. Butler, Chief Executive Officer of Akebia. “Our team is leading the regulatory review of vadadustat in Europe and select ACCESS markets. Between those review processes and the submission of a request for formal dispute resolution with the FDA regarding the Complete Response Letter for vadadustat in the U.S., we anticipate the fourth quarter could bring some clarity and a timeframe for our ability to potentially obtain approval for vadadustat in various markets.”

In October 2022, Akebia submitted a Formal Dispute Resolution Request (FDRR) with the U.S. Food & Drug Administration (FDA) regarding the Complete Response Letter (CRL) received in March 2022 for vadadustat, which was under review as a treatment for anemia due to chronic kidney disease (CKD). The FDRR focuses on the favorable balance of the benefits and risks of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis in light of safety concerns expressed by the FDA in the CRL related to the rate of adjudicated thromboembolic events driven by vascular access thrombosis for vadadustat compared to the active comparator and the risk of drug-induced liver injury. Based on the typical FDRR process, Akebia expects to receive a response to its submission by the end of 2022.

“We act in the interest of patients impacted by kidney disease and believe in the favorable balance of the benefits and risks of vadadustat as a treatment for anemia due to chronic kidney disease,” said John P. Butler, Chief Executive Officer of Akebia. “To that end, we are continuing to pursue a path that could potentially lead to an approval of vadadustat for dialysis dependent patients in the U.S.”

The company had additional important business updates since the beginning of the third quarter of 2022:

- Akebia assumed responsibility from Otsuka Pharmaceuticals Co. Ltd. (Otsuka) for the marketing authorization application (MAA) for vadadustat that Otsuka submitted to the European Medicines Agency (EMA). Based on the current review timeline, Akebia expects a decision on the MAA from EMA in the first quarter of 2023.
- Akebia continued to strengthen its balance sheet position by retiring $33 million of its $100 million debt facility with Pharmakon, inclusive of the first quarterly principal repayment.
- In August 2022, Akebia released initial findings from an investigator-sponsored clinical study with the University of Texas Health Sciences Center, Houston (UTHealth) evaluating vadadustat for the prevention and treatment of acute respiratory distress syndrome (ARDS). Akebia has since further collaborated with UTHealth to begin outlining potential next steps associated with an ARDS development program.

“Managing operating expenses is critical as we look for opportunities to add value to the company,” said David A. Spellman, Chief Financial Officer of Akebia. “By focusing on operating expenses and winding down certain projects, we’re pleased to report a reduction in spend quarter over quarter in 2022. Auryxia net product revenue increased in the third quarter of 2022 from the third quarter of 2021. There was a slight decline from the second quarter of 2022 partially due to the drawdown of inventory at certain customers during the third quarter of 2022. In addition, since the start of COVID, the phosphate binder market has contracted 15%. While the phosphate binder market has continued to decline, the work we’ve done to increase net price per pill puts us in a position to affirm our 2022 net product revenue guidance for Auryxia of $170 - $175 million.”

Financial Results

- **Revenues:** Total revenue was $49.0 million in the third quarter of 2022 compared to $48.8 million for the third quarter of 2021.
  - Net product revenue was $42.2 million in the third quarter of 2022 compared to $36.8 million in the third quarter of 2021, a 14.9% increase; and compared with $43.7 million in the second quarter of 2022, a 3.3% decrease. The increase compared to the third quarter of 2021 is primarily due to pricing and improved payer mix. The decrease compared to the second quarter of 2022 was due to a reduction in inventory drawdowns of Auryxia by certain customers.
  - License, collaboration and other revenue was $6.7 million in the third quarter of 2022 compared to $12.0 million in the third quarter of 2021. 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 $37.9 million in the third quarter of 2022 compared to $15.9 million in the third quarter of 2021. The increase compared to the prior year period was primarily due to a $13.2 million non-cash charge related to an increase in the liability for excess purchase commitments during the third quarter of 2022 and a $6.0 million non-cash benefit related to a decrease in the liability for excess purchase commitments in the third quarter of 2021 which did not reoccur.

- **R&D Expenses:** Research and development expenses were $27.4 million in the third quarter of 2022 compared to $40.5 million in the third quarter of 2021. The decrease compared to the prior year period was primarily due to decreased headcount related costs due to the previously announced reduction in force and decreased clinical trial costs.
- **SG&A Expenses:** Selling, general and administrative expenses were $30.9 million in the third quarter of 2022 compared to $46.4 million in the third quarter of 2021. The decrease compared to the prior year period was primarily due to decreased headcount related costs as a result of the reduction in force, lower one-time legal costs, and lower marketing expenses.
- **Net Loss:** Net loss was $51.9 million in the third quarter of 2022 compared to $59.5 million in the third quarter of 2021.
- **Cash Position:** Cash and cash equivalents as of September 30, 2022 were $144.8 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 includes assumptions pertaining to cost avoidance measures and the reduction of overhead costs resulting from the planned amendment of contractual arrangements with certain supply partners, and the reduction of operating expenses. The outcome of these assumptions, such as the potential amendment of contractual arrangements with certain supply partners, are outside of Akebia's control. In addition, future decisions by the FDA or other regulatory agencies related to the potential regulatory approval of vadadustat or our ability to generate additional value from vadadustat through partnerships or other transactions may potentially further extend our cash runway, but such future decisions or transactions are not contemplated in our operating plan.

Conference Call

Akebia will host a conference call on November 3 at 4:30 p.m. ET to discuss its financial results and recent company highlights. Access to the call will be provided via a new process. 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. The Company 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 Formal Dispute Resolution Request, or FDRR, that Akebia submitted with the FDA to appeal the Complete Response Letter that it received in March 2022; Akebia's future plans with respect to its strategic growth and operating plans; Akebia's revenue guidance for Auryxia in 2022 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, 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 overhead costs, including its ability to execute planned amendments to certain contractual arrangements 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; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; 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® and Auryxia® (ferric citrate) 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		Nine Months Ended	
	September 30, 2022	September 30, 2021	September 30, 2022	September 30, 2021
Revenues:				
Product revenue, net	$ 42,239	$ 36,753	$ 127,390	$ 100,120
License, collaboration and other revenue	6,725	12,003	110,032	53,853
Total revenues	48,964	48,756	237,422	153,973
Cost of goods sold:				
Product	28,936	6,933	60,859	76,012
Amortization of intangibles	9,011	9,011	27,032	27,032
Total cost of goods sold	37,947	15,944	87,891	103,044
Operating expenses:				
Research and development	27,350	40,471	97,210	118,296
Selling, general and administrative	30,918	46,357	108,052	129,336
License expense	743	870	2,323	2,460
Restructuring	180	—	14,711	—
Total operating expenses	59,191	87,698	222,296	250,092
Operating (loss)	(48,174)	(54,886)	(72,765)	(199,163)
Other expense, net	(2,785)	(4,658)	(11,339)	(12,999)
Loss on extinguishment of debt	(906)	—	(906)	—
Net (loss)	$ (51,865)	$ (59,544)	$ (85,010)	$ (212,162)
Net (loss) per share - basic	$ (0.28)	$ (0.34)	$ (0.47)	$ (1.30)
Weighted-average number of common shares - basic	183,882,446	173,782,151	182,375,443	163,050,769

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

	September 30, 2022	December 31, 2021
Cash and cash equivalents	$ 144,761	$ 149,800
Working capital	49,547	15,517
Total assets	435,894	525,550
Total stockholders’ equity	13,853	76,456