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): **August 25, 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 August 25, 2023, Akebia Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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 August 25, 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: August 25, 2023

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

Exhibit 99.1

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

Akebia to host conference call on August 25, 2023 at 9:00 a.m. ET

- Expects to resubmit NDA for vadadustat as a treatment for anemia due to CKD in adult patients on dialysis in Q3 2023
- Reports Auryxia® (ferric citrate) net product revenue of $42.2 million for Q2 2023 and reaffirms 2023 net product revenue guidance of $175.0-$180.0 million

CAMBRIDGE, Mass.—August 25, 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 second quarter ended June 30, 2023 and reviewed recent business highlights. Akebia intends to file an amendment to 2022 Annual Report on Form 10-K to revise previously filed financial statements.

In July, Akebia completed an End of Dispute Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss Akebia's anticipated resubmission of its New Drug Application (NDA) for vadadustat as a treatment for anemia due to chronic kidney disease (CKD) in adult patients on dialysis and received the FDA's Meeting Minutes in August. Akebia plans to resubmit its NDA for vadadustat by the end of this quarter with a potential PDUFA date projected in March 2024.

Akebia reported Auryxia® (ferric citrate) net product revenue of $42.2 million for the second quarter of 2023. Akebia also reaffirmed previously issued 2023 Auryxia net product revenue guidance of $175.0 - $180.0 million.

"Through 2023 we have worked to best position Akebia to deliver a new potential oral treatment option for anemia due to CKD to dialysis patients around the globe," said John P. Butler, Chief Executive Officer of Akebia. "This past quarter alone we made remarkable progress by gaining approval for vadadustat in 33 additional countries, securing Medice as our partner to bring Vafseo to patients in Europe in 2024 and clarifying the path to resubmission of the vadadustat NDA in the U.S. These impactful milestones mark significant progress toward our purpose to better the lives of people impacted by kidney disease."

Akebia reported additional business highlights in the second quarter:

- The European Commission, United Kingdom Medicines and Healthcare products Regulatory Agency and Swiss Agency for Therapeutic Products approved Vafseo for the treatment of symptomatic anemia associated with chronic kidney disease in adults on chronic maintenance dialysis. Akebia expects a regulatory opinion on vadadustat in Australia this year. With these additional approvals, vadadustat is now approved in 34 countries.

- In May, Akebia entered into an exclusive license agreement with MEDICE Arzneimittel Pütter GmbH&Co.KG (Medice), granting Medice the rights to market and sell Vafseo in the European Economic Area, the United Kingdom, Switzerland and Australia. Under the terms of the agreement, Akebia recognized an upfront payment of $10.0 million, and is eligible for commercial milestone payments up to an aggregate of $100.0 million and tiered royalty payments ranging from 10% to 30% of Medice's net sales.

- Akebia strengthened its management team, announcing that Ellen Snow joined as Senior Vice President, Chief Financial Officer and Treasurer. Most recently serving in a leadership role within a commercial pharmaceutical organization, Ms. Snow brings more than 25 years of accounting and financial management expertise to the role, critical as Akebia moves toward a launch of vadadustat in the U.S. next year, if approved.

- In June, Akebia reported positive topline results from IMPACT, a Phase 4 collaborative study investigating the impact of Auryxia, when used as the primary phosphate-lowering therapy, on the utilization of erythropoiesis-stimulating agent and intravenous iron as well as on laboratory parameters indicative of phosphate and anemia management compared to the standard of care in adult patients with CKD on dialysis.

Q2 2023 Financial Results

- **Revenues:** Total revenue was $56.4 million for the second quarter of 2023 compared to $126.4 million for the second quarter of 2022.
    - Net product revenue was $42.2 million for the second quarter of 2023 compared to $43.3 million for the second quarter of 2022, an 2.5% decrease, and compared with $34.7 million for the first quarter of 2023, a 21.6% increase. The decrease compared to the second quarter of 2022 is primarily due to the impact of shifting payor mix and a volume decrease partially caused by contracting dynamics and a decline in the phosphate binder market. The increase compared to the first quarter of 2023 was due to timing of purchases of Auryxia made by certain customers and expected cyclical demand growth from the first quarter to the second quarter. Akebia has affirmed its 2023 Auryxia net product revenue guidance of $175.0 - $180.0 million.
    - License, collaboration and other revenue was $14.1 million for the second quarter of 2023 compared to $83.1 million for the second quarter of 2022. The decrease is primarily related to the non-recurring impact on the second quarter of 2022 of the termination and settlement agreement between Otsuka and Akebia. Specifically, license, collaboration and other revenue in the second quarter of 2022 included a nonrefundable and non-creditable termination and settlement payment of $55.0 million that Otsuka paid to Akebia in July 2022. In addition, Akebia recognized $15.5 million related to previously deferred revenue and $9.6 million of non-cash consideration related to Otsuka’s obligations to complete certain agreed upon clinical activities in the second quarter of 2022. This decrease was partially offset by a $10.0 million upfront payment as part of license agreement entered into with Medice in the second quarter of 2023.

- **COGS:** Cost of goods sold was $17.3 million for the second quarter of 2023 compared to $18.6 million for the second quarter of 2022. The decrease was primarily due to lower write-downs of inventory as a result of excess, obsolescence, scrap or other reasons charged to costs of goods sold in the second quarter of 2023. Akebia continues to incur a non-cash amortization expense related to the intangible asset of $9.0 million per quarter through the fourth quarter of 2024.

- **R&D Expenses:** Research and development expenses were $20.2 million for the second quarter of 2023 compared to $26.0 million for the second quarter of 2022. The decrease was primarily due to a reduction in spending on vadadustat development, including decreased clinical trial costs. In addition, Akebia decreased the overall R&D headcount related costs as a result of the April 2022 reduction in force and decreased outsourced contract services.

- **SG&A Expenses:** Selling, general and administrative expenses were $27.0 million for the second quarter of 2023 compared to $32.2 million for the second quarter of 2022. The

decrease was primarily due to decreased headcount related costs as a result of the April and November 2022 reductions in force. In addition, Akebia decreased Auryxia marketing, promotional expenses and professional service costs.

- **Net Loss:** Net loss was $11.2 million for the second quarter of 2023 compared to net income of $29.4 million for the second quarter of 2022. The net loss is primarily a result of lower license, collaboration and other revenue due to the second quarter of 2022 benefiting from the $55.0 million termination fee from Otsuka noted above. In the second quarter of 2023 Akebia continued to implement further cost saving initiatives and operate more efficiently with significantly lower headcount as a result of the reductions in force that occurred in April and November 2022.

- **Cash Position:** Cash and cash equivalents as of June 30, 2023, were approximately $53.6 million. Akebia expects to fund its current operating plan with existing cash resources and cash from operations for at least the next twelve months.

Revisions to Prior Period Financial Results

Through the course of preparing its financial statements for the quarter ended June 30, 2023, Akebia identified certain accounting errors related to the recording and reporting of accrued product returns for Auryxia (Product Return Reserves Errors) and, as a result, identified a material weakness in its internal controls over financial reporting as of December 31, 2022 and through June 30, 2023. The amendment to Akebia's 2022 annual report that the company intends to file will reflect revisions to its financial statements for the fiscal years ended December 31, 2022, 2021 and 2020 to correct the Product Return Reserves Errors, which primarily impact the balance sheet in those years and to correct certain other adjustments in those periods.

The Product Return Reserves Errors resulted in an under accrual of liabilities of $8.2 million, $7.9 million and $6.0 million for the years ended December 31, 2022, 2021 and 2020, respectively. In addition, accounts receivable was understated by $1.1 million, $0.7 million and $0.7 million, for the years ended December 31, 2022, 2021 and 2020, respectively, and goodwill was understated by $2.6 million for the years ended December 31, 2022, 2021 and 2020. Additional immaterial adjustments have been made to the prior year financial statements. Included at the end of this release are tables identifying the impacts of the revision on the Company's unaudited condensed consolidated financial statements as of and for the three and six months ended June 30, 2022 and the three months ended March 31, 2023 and 2022, respectively.

Conference Call

Akebia will host a conference call on Friday, August 25 at 9:00 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 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 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 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 will be available via SwissMedic 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 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 expectations regarding the filing of an amendment to its Annual Report on Form 10-K for the year ended December 31, 2022; Akebia's expectations and plans with respect to the resubmission of its NDA for vadadustat, including the timing thereof; Akebia's expectations regarding the timing for a decision by the FDA on its NDA for vadadustat once resubmitted; Akebia's expectations on the timing for certain regulatory decisions for vadadustat by regulatory authorities in Australia; Akebia's plans and expectations with respect to commercializing Vafseo in Europe, including the timing thereof; 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 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," "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 resubmission of the NDA for vadadustat; 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 March 31, 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
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AKEBIA THERAPEUTICS, INC.

Unaudited Consolidated Statements of Operations

(in thousands, except per share data)

	Three Months Ended June 30,	
	2023	**2022**
Revenues		
Product revenue, net	$ 42,244	$ 43,309
License, collaboration and other revenue	14,132	83,056
Total revenues	56,376	126,365
Cost of goods sold		
Product	8,273	9,589
Amortization of intangible asset	9,011	9,011
Total cost of goods sold	17,284	18,600
Operating expenses		
Research and development	20,197	26,027
Selling, general and administrative	27,036	32,240
License expense	949	892
Restructuring	(94)	14,531
Total operating expenses	48,088	73,690
Operating (loss) income	(8,996)	34,075
Other expense, net	(1,652)	(4,626)
Loss on lease termination	(524)	—
Net (loss) income	$ (11,172)	$ 29,449
Net (loss) income per share – basic	$ (0.06)	$ 0.16
Weighted-average number of common shares - basic	186,817	183,598
Net (loss) income per share – diluted	$ (0.06)	$ 0.15
Weighted-average number of common shares - diluted	186,817	190,375

Unaudited Selected Balance Sheet Data

(in thousands)

	June 30, 2023	**December 31, 2022**
Cash and cash equivalents	$ 53,572	$ 90,466
Working capital	26,263	55,646
Total assets	253,712	356,054
Total stockholders’ equity	(26,807)	5,230

The following tables reflect the impact of the revision on the Company's condensed consolidated financial statements as of and for the three and six months ended June 30, 2022. Only the individual lines previously reported that are impacted by the Product Return Reserve Errors as well as the correction of other immaterial misstatements to the financial statements are shown below (*dollars in thousands, except per share amount*):

	June 30, 2022		
Unaudited Condensed Consolidated Balance Sheet	**As Previously Reported**	**Adjustment**	**As Revised**
Inventories	$ 36,272	$ 3,954	$ 40,226
Accounts receivable, net	81,869	133	82,002
Total current assets	304,163	4,087	308,250
Goodwill	55,053	3,991	59,044
Total assets	521,804	8,078	529,882
Accrued expenses and other current liabilities	91,284	3,721	95,005
Total current liabilities	233,680	3,721	237,401
Other non-current liabilities	66,889	7,721	74,610
Total liabilities	459,504	11,442	470,946
Accumulated deficit	(1,493,496)	(3,363)	(1,496,859)
Total liabilities and stockholders' equity	$ 521,804	$ 8,078	$ 529,882

	Three Months Ended June 30, 2022		
Unaudited Condensed Consolidated Statement of Operations and Comprehensive Income	**As Previously Reported**	**Adjustment**	**As Revised**
Product revenue, net	$ 43,703	$ (394)	$ 43,309
Selling, general and administrative	32,807	(567)	32,240
Operating income	33,902	173	34,075
Net income and comprehensive income	$ 29,276	$ 173	$ 29,449
Earnings per share - basic	$ 0.16	$ —	$ 0.16
Earnings per share – diluted	$ 0.15	$ —	$ 0.15

	Six Months Ended June 30, 2022		
Unaudited Condensed Consolidated Statement of Operations and Comprehensive Income	**As Previously Reported**	**Adjustment**	**As Revised**
Product revenue, net	$ 85,151	$ (470)	$ 84,681
Cost of goods sold, product	31,923	771	32,694
Selling, general and administrative	77,134	(328)	76,806
Operating loss	(24,591)	(913)	(25,504)
Net loss and comprehensive loss	$ (33,145)	$ (913)	$ (34,058)
Net loss per share - basic and diluted	$ (0.18)	$ (0.01)	$ (0.19)

The following tables reflect the impact of the revision on the Company's condensed consolidated financial statements as of and for the three months ended March 31, 2023 and 2022. Only the individual lines previously reported that are impacted by the Product Return Reserve Errors as well as the correction

of other immaterial misstatements to the financial statements are shown below (*dollars in thousands, except per share amount*):

Unaudited Condensed Consolidated Balance Sheet	March 31, 2023		
	As Previously Reported	Adjustment	As Revised
Inventories	$ 20,604	$ (194)	$ 20,410
Accounts receivable, net	17,781	950	18,731
Prepaid expenses and other current assets	25,381	(678)	24,703
Total current assets	120,719	79	120,798
Goodwill	55,053	3,991	59,044
Total assets	276,858	4,070	280,928
Accrued expenses and other current liabilities	46,367	4,712	51,079
Total current liabilities	82,944	4,712	87,656
Other non-current liabilities	12,643	4,129	16,772
Total liabilities	291,210	8,841	300,051
Accumulated deficit	(1,579,130)	(4,772)	(1,583,902)
Total liabilities and stockholders' equity	$ 276,858	$ 4,070	$ 280,928

Unaudited Condensed Consolidated Statement of Operations and Comprehensive Income	Three Months Ended March 31, 2023		
	As Previously Reported	Adjustment	As Revised
Product revenue, net	$ 34,828	$ (122)	$ 34,706
Cost of goods sold, product	10,473	705	11,178
Selling, general and administrative	25,221	(168)	25,053
Operating loss	(24,938)	(659)	(25,597)
Net loss and comprehensive loss	$ (26,217)	$ (659)	$ (26,876)
Earnings per share - basic and diluted	$ (0.14)	$ (0.01)	$ (0.15)

Unaudited Condensed Consolidated Balance Sheet	March 31, 2022		
	As Previously Reported	Adjustment	As Revised
Inventories	$ 39,422	$ 1,676	$ 41,098
Accounts receivable, net	64,582	776	65,358
Total current assets	302,687	2,452	305,139
Goodwill	55,053	3,991	59,044
Total assets	535,356	6,443	541,799
Accrued expenses and other current liabilities	109,660	4,583	114,243
Total current liabilities	253,914	4,583	258,497
Other non-current liabilities	77,743	5,398	83,141
Total liabilities	509,240	9,981	519,221
Accumulated deficit	(1,522,772)	(3,537)	(1,526,309)
Total liabilities and stockholders' equity	$ 535,356	$ 6,443	$ 541,799

Unaudited Condensed Consolidated Statement of Operations and Comprehensive Income	Three Months Ended March 31, 2022		
	As Previously Reported	Adjustment	As Revised
Product revenue, net	$ 41,448	$ (76)	$ 41,372
Cost of goods sold, product	22,333	772	23,105
Selling, general and administrative	44,327	239	44,566
Operating loss	(58,493)	(1,088)	(59,581)
Net loss and comprehensive loss	$ (62,421)	$ (1,088)	$ (63,509)
Earnings per share - basic and diluted	$ (0.35)	$ —	$ (0.35)