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 4, 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 August 4, 2022, Akebia Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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.

Item 7.01. Regulation FD Disclosure.

On August 4, 2022, the Company issued the press release furnished as Exhibit 99.2 to this Report and incorporated herein by reference.

The information in this Report (including Item 2.02, Item 7.01, Exhibit 99.1 and Exhibit 99.2) 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 4, 2022, issued by Akebia Therapeutics, Inc.
99.2	Press Release, dated August 4, 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: August 4, 2022

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

Exhibit 99.1

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

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

- Reported net Auryxia® (ferric citrate) product revenue of $43.7M, a 32.4% increase over Q2 2021
- Increased 2022 net Auryxia product revenue guidance to $170 - $175M
- Regained full rights to vadadustat in the U.S., Europe and other markets
- Delivered a decrease in operating expenses supporting its three strategic pillars
- Shared initial findings from investigator-sponsored study evaluating vadadustat for the prevention and treatment of acute respiratory distress syndrome (ARDS) in patients with COVID-19 and hypoxemia

CAMBRIDGE, Mass.—August 4, 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 second quarter ended June 30, 2022 and provided business highlights.

“In May we outlined the pillars of our refined strategic focus in the wake of the unexpected Complete Response Letter (CRL) for vadadustat from the FDA to focus on driving Auryxia revenue while managing our overall spending, supporting the regulatory path for vadadustat, and thoughtfully investing in our pipeline,” said John P. Butler, Chief Executive Officer of Akebia. “Today we are reporting 32.4% revenue growth for Auryxia versus the second quarter of 2021 and are increasing our revenue guidance for 2022. Since the beginning of the second quarter, we have regained the rights to vadadustat from Otsuka in the U.S., Europe, and other territories, completed our end of review conference with the FDA, and today we shared data for vadadustat in ARDS that we believe supports further development of the drug for this indication. The progress we’ve made in alignment with our refined focus is a testament to the resilience and tenacity of the Akebia team. We look forward to continuing our progress.”

The company had several important business updates since the beginning of the second quarter 2022:

- In April, Akebia completed a reduction in force, reducing the employee base by 42% of full-time employees, and further reducing open headcount for a 47% overall reduction.
- In June, Akebia and Otsuka Pharmaceuticals Co. Ltd (Otsuka) agreed to terminate their U.S. and international collaboration agreements. As a result, Akebia has regained the rights for vadadustat from Otsuka in the U.S., Europe, China, Russia, Canada, Australia, the Middle East, and certain other territories. Vadadustat is under review by the European Medicines Agency (EMA) for the treatment of anemia associated with chronic kidney disease (CKD) in adults.
- In July, Akebia completed an end of review conference with the U.S. Food & Drug Administration (FDA), the first step in the process to determine the path for a potential U.S. approval for vadadustat as a treatment of anemia due to CKD in patients on dialysis. The company received a CRL from the FDA for vadadustat in March 2022.

- In July, Akebia repaid $25 million on its $100 million debt facility with Pharmakon. In exchange for the early payment, Pharmakon agreed to amend and waive certain provisions, as described in the Form 8-K filed by the company at the time. The repayment results in savings of approximately 34% of the company's cash interest on the loan for the remainder of the term.
- Today, in a separate press release, Akebia announced initial findings from an investigator-sponsored clinical study with the University of Texas Health Sciences Center, Houston (UTHealth Houston) evaluating vadadustat, Akebia's investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for the prevention and treatment of ARDS in clinical trial subjects with COVID-19 and hypoxemia (O_2 saturation ≤94%).

"We clearly outlined our objective to manage the company with existing cash resources and ongoing cash from operations and we are pleased to have made significant progress both in terms of net product revenue growth and cost reduction measures," said David A. Spellman, Chief Financial Officer of Akebia. "Auryxia is delivering on a growth trajectory driven by an increase in net price per pill due to an improved payor mix and improved commercial contract terms. Further, our expenses have already begun to decrease significantly as a result of our refined strategy."

Financial Results

- **Revenues:** Total revenue was $126.8 million for the second quarter of 2022 compared to $52.9 million for the second quarter of 2021.
  - Net product revenue was $43.7 million for the second quarter of 2022 compared with $33.0 million for the second quarter of 2021, a 32.4% increase; and, compared with $41.4 million for the first quarter of 2022, a 5.4% increase.
  - Akebia is increasing its net product revenue guidance for Auryxia to $170 - $175 million for fiscal year 2022, raising both the top and bottom end of the guidance range by $5 million. The guidance assumes, among other things, continued stabilization of the phosphate binder market and continued improvement of net realized price per tablet. The company's gross margin continues to expand due to a reduction in supply chain costs and cost management activities.
  - License, collaboration and other revenue was $83.1 million for the second quarter of 2022 compared to $20.0 million for the second quarter of 2021. This increase 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, the company 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.
- **COGS:** Cost of goods sold was $18.6 million for the second quarter of 2022 compared to $52.5 million in the second quarter of 2021.The decrease compared to the prior year period was primarily due to a $30.3 million non-cash charge in 2021 related to an increase to the liability for excess purchase commitments during the second quarter of 2021.

- **R&D Expenses:** Research and development expenses were $26.0 million for the second quarter of 2022 compared to $37.2 million for the second quarter of 2021. The decrease compared to the prior year period was primarily due to decreased headcount related costs related to the reduction in force and decreased consulting costs.
- **SG&A Expenses:** Selling, general and administrative expenses were $32.8 million for the second quarter of 2022 compared to $41.7 million for the second quarter of 2021. The decrease compared to the same period in the prior year was primarily due to decreased headcount related costs as a result of the reduction in force and lower marketing expenses.
- **Restructuring:** In connection with its previously announced workforce reductions, Akebia incurred $14.5 million in restructuring charges in the second quarter of 2022, primarily related to one-time termination benefits and contractual termination benefits including severance, non-cash stock-based compensation expense, healthcare and related benefits.
- **Net Income:** Net income was $29.3 million for the second quarter of 2022 compared to a $83.0 million net loss for the second quarter of 2021.
- **Cash Position:** Cash and cash equivalents as of June 30, 2022, were $143.9 million, which does not include the $55.0 million cash payment Akebia received from Otsuka in July 2022 and does not reflect Akebia's approximately $25.0 million prepayment made to Pharmakon in July 2022. 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 certain contractual arrangements, including with certain supply partners, and the reduction of certain infrastructure costs. The outcome of these assumptions, such as the potential amendment of certain contractual arrangements with supply partners, are outside of Akebia's control. In addition, future decisions by the FDA or foreign 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.

"A focus on our three strategic pillars have guided us to the point where we believe our existing cash resources and revenues from Auryxia will be sufficient to fund our company's current operating plan for the next several years," said David A. Spellman, Chief Financial Officer of Akebia. "With key inflection points such as a potential European approval and partnering for vadadustat, we look forward to rebuilding in a measured way."

Conference Call

Akebia will host a conference call on Thursday, August 4, 2022, at 4:30 p.m. Eastern Time to discuss its second quarter financial results and provide business updates. To listen to the conference call on August 4th, please dial (833) 630-1955 (domestic) or (412) 317-1836 (international) and ask to join into the Akebia Therapeutics call. The call will also be webcast LIVE and can be accessed via the Investors section of Akebia's website at http://ir.akebia.com.

A replay of the conference call will be available two hours after the completion of the call through August 10, 2022. To access the replay, dial (877) 344-7529 (domestic) or (412) 317-0088 (international) and reference replay access code 3608580. An online archive of the conference call can be accessed via the Investors section of Akebia's website at http://ir.akebia.com.

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 Akebia's response to the receipt of 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 as a treatment of ARDS due to COVID-19 and other causes; 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 the next several years. 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 infrastructure costs;

decisions made by health authorities, such as the FDA and the European Medicines Agency, with respect to regulatory filings, including the New Drug Application 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 June 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 Contact
Mercedes Carrasco
mcarrasco@akebia.com

AKEBIA THERAPEUTICS, INC.
Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended		Six Months Ended	
	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Revenues:				
Product revenue, net	$ 43,703	$ 32,959	$ 85,151	$ 63,367
License, collaboration and other revenue	83,056	19,954	103,307	41,850
Total revenues	126,759	52,913	188,458	105,217
Cost of goods sold:				
Product	9,589	43,484	31,923	69,079
Amortization of intangibles	9,011	9,011	18,021	18,021
Total cost of goods sold	18,600	52,495	49,944	87,100
Operating expenses:				
Research and development	26,027	37,214	69,860	77,825
Selling, general and administrative	32,807	41,651	77,134	82,979
License expense	892	894	1,580	1,590
Restructuring	14,531	—	14,531	—
Total operating expenses	74,257	79,759	163,105	162,394
Operating income (loss)	33,902	(79,341)	(24,591)	(144,277)
Other expense, net	(4,626)	(3,697)	(8,554)	(8,341)
Net income (loss)	$ 29,276	$ (83,038)	$ (33,145)	$ (152,618)
Net income (loss) per share - basic	$ 0.16	$ (0.51)	$ (0.18)	$ (0.97)
Weighted-average number of common shares - basic	183,597,766	161,329,990	181,609,452	157,596,143
Net income (loss) per share - diluted	$ 0.15	$ (0.51)	$ (0.18)	$ (0.97)
Weighted-average number of common shares - diluted	190,375,317	161,329,990	181,609,452	157,596,143

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

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$143,893	$ 149,800
Working capital	70,483	15,517
Total assets	521,804	525,550
Total stockholders' equity	62,300	76,456

Akebia Therapeutics Announces Initial Findings from Investigator-Sponsored Clinical Study Evaluating Vadadustat for the Prevention and Treatment of Acute Respiratory Distress Syndrome (ARDS) in Subjects with COVID-19 and Hypoxemia (VSTAT)

CAMBRIDGE, Mass.—August 4, 2022— Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced initial findings from an investigator-sponsored study evaluating vadadustat, Akebia's investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), for the prevention and treatment of ARDS in clinical trial subjects with COVID-19 and hypoxemia (O2 saturation ≤94%). The VSTAT trial (Vadadustat for the Prevention and Treatment of ARDS in Hospitalized Patients with Coronavirus Disease 2019) was a phase 2, randomized, double-blind, placebo-controlled trial, conducted by The University of Texas Health Science Center at Houston (UTHealth) in Houston, Texas and partially funded by Akebia.

The trial enrolled 449 adult subjects at five hospitals who were randomized 1:1 to vadadustat 900 mg or placebo once per day orally for up to 14 days while hospitalized. The VSTAT trial measured the proportion of subjects with either 6 (non-invasive ventilation or high flow oxygen devices), 7 (invasive mechanical ventilation or extracorporeal membrane oxygenation), or 8 (death) on the National Institute of Allergy and Infectious Disease Ordinal Scale (NIAID-OS) at Day 7 and Day 14 (primary). While a smaller proportion of subjects in the vadadustat group had a score of 6, 7, or 8 on the NIAID-OS than in the placebo group at Day 14, the trial failed to meet its primary superiority threshold of >95% probability. Those receiving vadadustat; however, did demonstrate 94% probability for conferring benefit on the NIAID-OS at Day 14.

At Day 14, the proportions of subjects who had a 6, 7 or 8 on the NIAID-OS were 13.3% (9.6%, 17.7%; 2.5, 97.5 percentiles from Bayesian simulations) for vadadustat versus 16.9% (12.6%, 22.0%) for placebo with a relative risk of 0.79 and 94% probability that vadadustat was superior to placebo. In a pre-specified analysis at Day 7, the proportions of subjects who had a 6, 7 or 8 on the NIAID-OS were 25.4% (20.7%, 30.5%) for vadadustat versus 29.7% (24.5%, 35.3%) for placebo with a relative risk of 0.86 and 97% probability that vadadustat was superior to placebo.

The incidence of treatment emergent adverse events was 78.6% in the vadadustat group and 76.2% in the placebo group. The most common treatment emergent adverse events reported in vadadustat/placebo subjects were alanine aminotransferase increase (34.4%/28.7%), COVID-19 pneumonia (19.5%/27.4%), anemia (14.0%/17.0%), aspartate aminotransferase increase (14.0%/14.8%), hyponatremia (10.7%/15.7%), septic shock (11.6%/10.8%), hyperkalemia (10.2%/10.8%), and hypermagnesemia (7.0%/13.9%). The incidence of serious treatment emergent adverse events was 27.9% in the vadadustat group and 32.7% in the placebo group. The most common serious treatment emergent adverse events reported in vadadustat/placebo subjects were COVID-19 pneumonia (19.5%/27.4%) and septic shock (11.6%/10.8%).

"While the trial missed its prespecified primary endpoint at Day14, we are extremely encouraged by the data and believe they support further developing vadadustat as a treatment for ARDS due to COVID-19 or other causes," said John P. Butler, Chief Executive Officer of Akebia. "I want to thank UTHealth for delivering a well-executed clinical trial during this difficult period. We also want to thank the patients who participated in the trial. We will now work to review the full data set more thoroughly, consult with experts in the field and ultimately consult FDA on a potential path forward."

Akebia is working with UTHealth Houston on publication of the full trial results and determining next steps in developing vadadustat as a potential treatment for ARDS due to COVID-19 or other causes.

About Akebia Therapeutics

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vadadustat, if approved; the risks associated with potential generic entrants; the timing and content of decisions made by regulatory authorities; the competitive landscape; the scope, timing, and outcome of any legal, regulatory and administrative proceedings; the actual time it takes to initiate and complete preclinical and clinical studies; changes in the economic and financial conditions of the businesses of Akebia and its partners; and Akebia's and its partners' ability to obtain, maintain and enforce patent and other intellectual property protection. 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, 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.

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