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 5, 2021

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 5, 2021, Akebia Therapeutics, Inc. (the "Company") announced financial results for the quarter ended June 30, 2021 and commented on certain corporate accomplishments and plans. 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 Items 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 5, 2021, 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 5, 2021

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

Exhibit 99.1

Akebia Therapeutics Reports Second Quarter 2021 Financial Results and Highlights Recent Company Milestones

- *Vadadustat New Drug Application (NDA) Accepted for Filing with the U.S. Food and Drug Administration (FDA)*
- *Vadadustat PDUFA Target Action Date of March 29, 2022*
- *Net Product Revenue for Auryxia® (ferric citrate) Increases to $33.0 Million, Up 7.4% from Q2'FY20*
- *Company to Host Conference Call Today at 9:00 a.m. ET*

CAMBRIDGE, Mass.—Aug. 5, 2021— Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose of bettering the lives of people impacted by kidney disease, today reported financial results for the second quarter ended June 30, 2021 and highlighted recent corporate milestones. The Company will host a conference call today, Thursday, August 5, 2021, at 9:00 a.m. Eastern Time.

"The first half of 2021 has been marked by significant milestones that have further strengthened Akebia's position and the potential market opportunity for vadadustat, an investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI), setting the stage for an exciting and catalyst-rich year ahead for us. During the quarter, these achievements included publication of our global Phase 3 results for vadadustat in the *New England Journal of Medicine* and, more recently, FDA acceptance of the vadadustat NDA for filing with a PDUFA target action date of March 29, 2022," stated John P. Butler, Chief Executive Officer of Akebia. "As there are currently no approved HIF-PHIs to treat anemia due to chronic kidney disease (CKD) in the U.S., we believe vadadustat is positioned as a potential first-in-class product with a broader opportunity in the dialysis market than originally anticipated. With vadadustat's PDUFA date set for March, we are highly focused on pre-launch activities to ensure that we are well positioned for a successful U.S. launch in 2022, and are excited to be one step closer to having a novel, oral therapeutic available for people living with this disease, subject to regulatory approval."

Steven K. Burke, M.D., Senior Vice President, Research & Development and Chief Medical Officer of Akebia stated, "We remain confident in the clarity and quality of our data, and continue to be

encouraged by the safety profile of vadadustat demonstrated in our global Phase 3 program for the treatment of anemia due to CKD. As seen in the recent *New England Journal of Medicine* publications of our global Phase 3 results, the data showed no significant safety signals on adverse events, including thromboembolic events, seizures and infections. More specifically, the data showed that these events were very similar for vadadustat as compared to darbepoetin alfa."

Akebia is also working in close collaboration with its partner, Otsuka Pharmaceutical Co. Ltd., to prepare a Marketing Authorization Application for vadadustat for submission to the European Medicines Agency, expected this year.

Recent Business Highlights:

- In late May, the FDA accepted for filing the NDA for vadadustat for the treatment of anemia due to CKD in both adult patients on dialysis and adult patients not on dialysis. The FDA assigned the application a standard review and a Prescription Drug User Fee Act (PDUFA) target action date of March 29, 2022.
- In April, the *New England Journal of Medicine* published the results of Akebia's global Phase 3 program for vadadustat, which consisted of two programs that evaluated the efficacy and safety of vadadustat versus darbepoetin alfa for the treatment of anemia due to CKD in adult patients on dialysis (INNO$_2$VATE) and not on dialysis (PRO$_2$TECT).
- In June, Akebia presented data regarding the hematologic efficacy of vadadustat for anemia in patients with kidney failure on dialysis and not on dialysis from the global Phase 3 program for vadadustat at the European Renal Association - European Dialysis and Transplant Association (ERA-EDTA) Virtual Congress 2021.
- In March, Akebia submitted an NDA to the FDA for vadadustat for the treatment of anemia due to CKD in both adult patients on dialysis and adult patients not on dialysis.

Second Quarter Financial Results

- **Revenues:** Total revenue was $52.9 million for the second quarter of 2021 compared to $90.1 million for the second quarter of 2020. The decrease compared to the same period in 2020 was primarily due to lower collaboration revenue consistent with the Company successfully completing the INNO$_2$VATE and PRO$_2$TECT global Phase 3 clinical programs.

- Collaboration revenue was $20.0 million for the second quarter of 2021 compared to $59.4 million for the second quarter of 2020.
- Net product revenue for Auryxia was $33.0 million for the second quarter of 2021 compared with $30.7 million for the second quarter of 2020, an increase of 7.4 percent.

- **COGS:** Cost of goods sold was $52.5 million for the second quarter of 2021 and included a $30.3 million non-cash charge related to an increase to the liability for excess purchase commitments consistent with the Company's long-term payor contract strategy, which remains focused on contract economics and net product revenue growth. Cost of goods sold was $174.6 million for the second quarter of 2020 and included a non-cash impairment charge of $115.5 million related to the Auryxia intangible asset, $19.9 million in non-cash charges related to the fair-value inventory step-up from the application of purchase accounting, $11.0 million in non-cash charges related to an increase to the liability for excess purchase commitments and $9.9 million primarily related to the write-down of inventory.
- **R&D Expenses:** Research and development expenses were $37.2 million for the second quarter of 2021 compared to $52.8 million for the second quarter of 2020. The decrease compared to the prior year period was primarily due to the completion of the INNO$_2$VATE and PRO$_2$TECT global Phase 3 clinical programs.
- **SG&A Expenses:** Selling, general and administrative expenses were $41.7 million for the second quarter of 2021 compared to $35.5 million for the second quarter of 2020. The increase compared to the prior year period was due primarily to higher marketing expenses.
- **Net Loss:** Net loss was $83.0 million for the second quarter of 2021 compared to $175.8 million for the second quarter of 2020. The improvement in net loss compared to the prior year period was due primarily to the non-recurrence of a $115.5 million non-cash impairment charge in the prior year period, as well as lower operating expenses in the 2021 period, partially offset by lower collaboration revenue in the 2021 period.
- **Cash Position:** Cash, cash equivalents and available-for-sale securities as of June 30, 2021 were $247.0 million. This balance includes net proceeds of $37.3 million from sales of common stock under the Company's at-the-market offering program during the second quarter of 2021.

The Company also received net cash proceeds of $16.1 million from sales of common stock under this program subsequent to quarter end through July 16, 2021. The Company believes that its cash resources will be sufficient to fund its current operating plan through at least the next twelve months. Additionally, the Company believes its cash runway would extend beyond the next twelve months assuming timely regulatory approval of vadadustat and the receipt of associated regulatory milestones.

“We continue to be encouraged by Auryxia’s revenue growth, which we believe is a great illustration of our commercial team’s execution in this ongoing COVID-19 environment,” stated David A. Spellman, Chief Financial Officer of Akebia. “We believe this performance also highlights Auryxia’s favorable product profile and the critical nature of this therapy. While we remain cautious due to COVID-19, we believe the team’s focus and execution on marketing, sales, and payor strategies will continue to drive net product revenue growth.”

Conference Call

Akebia will host a conference call today, Thursday, August 5, 2021, at 9:00 a.m. Eastern Time to discuss its second quarter financial results and recent business highlights. To listen to the conference call, please dial (877) 458-0977 (domestic) or (484) 653-6724 (international) using conference ID number 5529396. The call will also be webcast LIVE and can be accessed via the Investors section of the Company’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 11, 2021. To access the replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and reference conference ID number 5529396. An online archive of the conference call can be accessed via the Investors section of the Company’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 a potential first-in-class oral hypoxia-inducible factor prolyl hydroxylase (HIF-PH) 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. The New Drug Application (NDA) for vadadustat for the treatment of anemia due to chronic kidney disease (CKD) is under review by the U.S. Food and Drug Administration (FDA). Vadadustat is an investigational new drug and is not approved by the FDA or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare (MHLW). In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

About Anemia due to Chronic Kidney Disease (CKD)

Anemia is a condition in which a person lacks enough healthy red blood cells to carry adequate oxygen to the body's tissues. It commonly occurs in people with CKD because their kidneys do not produce enough erythropoietin (EPO), a hormone that helps regulate production of red blood cells. Anemia due to CKD can have a profound impact on a person's quality of life as it can cause fatigue, dizziness, shortness of breath and cognitive dysfunction. Left untreated, anemia leads to deterioration in health and is associated with increased morbidity and mortality in people with CKD.

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'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, including, but not limited to, statements regarding: vadadustat's potential positioning as a first-in-class product for the treatment of anemia due to chronic kidney disease in the U.S.; the market opportunity for vadadustat; the launch of vadadustat, if approved, and the timing thereof; the timing of submission of a Marketing Authorization Application for vadadustat to the European Medicines Agency; the potential impact of COVID-19 on the business, including Auryxia's revenue growth; the potential for product revenue growth due to the Company's marketing,

sales and payor strategies; Auryxia's revenue growth highlighting Auryxia's product profile and nature of the therapy; and the Company's expectations with respect to its cash resources and cash runway. The terms "believe," "confident," "expect," "plan," "potential," "will," and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including, but not limited to: the timing of regulatory filings and approvals; interactions with the FDA, including reviews and inspections, the timing related thereto and the outcome thereof; the potential therapeutic benefits, safety profile and effectiveness of our product candidates, including vadadustat; the direct or indirect impact of the COVID-19 pandemic on our business, operations, and the markets and communities in which the Company and its partners, collaborators, vendors and customers operate; the timing and content of advice given and decisions made by health authorities, including approval and labeling decisions; the potential indications, demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia and vadadustat, if approved, including estimates regarding the potential market opportunity for the Company's product, vadadustat or any other product candidates and the size of eligible patient populations; enrollment in clinical and preclinical studies; manufacturing, supply and quality risks, and any recalls, write-downs, impairments or other related consequences or potential consequences; risks associated with hiring, training, management and retention and key personnel changes and transitional periods; the actual funding required to continue to commercialize Akebia's commercial product, to develop and commercialize vadadustat, and to operate the Company; the risks associated with potential generic entrants for Akebia's commercial product and vadadustat, if approved; early termination of or changes to the terms of agreements that Akebia has with any of its collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the competitive landscape for Akebia's commercial product and vadadustat, if approved; the scope, timing, and outcome of any legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia and its collaborations partners and vendors; expected reliance on third parties, including with respect to the development, manufacturing, supply or commercialization of Akebia's product and product candidates; the Company's expectations, projections and estimates regarding its capital requirements; and Akebia's intellectual property position, including its ability to obtain, maintain and enforce patent and other intellectual property protection for its commercial product, vadadustat and any other product candidates. 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, 2021 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.

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

	Three Months Ended		Six Months Ended	
	June 30, 2021	June 30, 2020	June 30, 2021	June 30, 2020
Revenues:				
Product revenue, net	$ 32,959	$ 30,696	$ 63,367	$ 59,905
License, collaboration and other revenue	19,954	59,446	41,850	118,715
Total revenues	52,913	90,142	105,217	178,620
Cost of goods sold:				
Product	43,484	49,988	69,079	68,601
Amortization of intangibles	9,011	9,101	18,021	18,201
Impairment of intangible asset	—	115,527	—	115,527
Total cost of goods sold	52,495	174,616	87,100	202,329
Operating expenses:				
Research and development	37,214	52,819	77,825	134,050
Selling, general and administrative	41,651	35,482	82,979	73,465
License expense	894	1,044	1,590	1,720
Total operating expenses	79,759	89,345	162,394	209,235
Operating loss	(79,341)	(173,819)	(144,277)	(232,944)
Other expense, net	(3,697)	(1,932)	(8,341)	(3,554)
Net loss	$ (83,038)	$ (175,751)	$ (152,618)	$ (236,498)
Net loss per share - basic and diluted	$ (0.51)	$ (1.28)	$ (0.97)	$ (1.78)
Weighted-average number of common shares - basic and diluted	161,329,990	136,906,968	157,596,143	132,651,066

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

	June 30, 2021	December 31, 2020
Cash, cash equivalents and available for sale securities	$ 246,992	$ 268,690
Working capital	165,481	184,291
Total assets	611,863	644,139
Total stockholders' equity	174,631	247,618