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 4, 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 November 4, 2021, Akebia Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021 and certain recent business highlights, as well as its plans to hold a conference call to discuss the Company's third quarter 2021 financial results, 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 November 4, 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: November 4, 2021

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

Exhibit 99.1

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

- Pre-commercialization activities underway in anticipation of March 29, 2022 PDUFA date
- Vadadustat marketing authorization application submitted to the European Medicines Agency
- Continued growth of Auryxia® (ferric citrate) with net product revenue of $36.8 million
- Company to host Conference Call on Tuesday, November 9 at 9:00 a.m. ET

CAMBRIDGE, Mass., Nov. 4, 2021 /PRNewswire/ — 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, 2021 and highlighted recent corporate milestones.

The Company will host a conference call on Tuesday, November 9, 2021, at 9:00 a.m. Eastern Time. Executives will highlight publications and scientific presentations of vadadustat Phase 3 clinical data, which will be presented at American Society of Nephrology Kidney Week 2021 beginning today. The Company will also discuss ongoing pre-commercialization activities ahead of a potential first-in-class U.S. launch for vadadustat, Akebia's investigational oral therapeutic for the treatment of anemia due to chronic kidney disease (CKD). Vadadustat is currently under review by the U.S. Food and Drug Administration (FDA) with a scheduled Prescription Drug User Fee Act (PDUFA) date of March 29, 2022.

"We are within five months of vadadustat's PDUFA date, which has the potential to be a pivotal catalyst for the company, and, if approved, would mean the availability of a novel, oral therapeutic for people living with anemia due to chronic kidney disease," said John P. Butler, Chief Executive Officer, Akebia Therapeutics. "We continue to value opportunities to share vadadustat efficacy and safety data with nephrologists through scientific congresses such as ASN Kidney Week. While our review with the FDA is ongoing, we remain confident that the data we have compiled and submitted for review makes a compelling case for approval in dialysis patients."

"Akebia has made substantial progress on pre-commercialization activities to prepare for a first-in-class product launch for vadadustat in the U.S. in 2022, subject to regulatory approval," added Dell Faulkingham, Chief Commercial Officer, Akebia Therapeutics. "As part of our commercialization preparation, we are focused on broad access initiatives, and are fortunate that, if approved, our specialized renal sales force will be ready to add a second product for use in the dialysis market. We are working closely with our partners at Vifor and Otsuka to ensure we are well-positioned to execute a successful launch, including preparedness for reimbursement for vadadustat under Transitional Drug Add-on Payment Adjustment (TDAPA) for dialysis organizations, which will be key to our launch."

Recent Business Highlights:

- Akebia announced that Otsuka submitted a marketing authorization application to the European Medicines Agency for vadadustat for the treatment of anemia due to CKD in adults.
- Vadadustat efficacy and safety data is being presented at the American Society of Nephrology Kidney Week 2021 beginning today, November 4, 2021. Eleven abstracts were accepted for presentation at Kidney Week 2021.

- Akebia has settled all patent litigation proceedings related to Abbreviated New Drug Applications filed with respect to Auryxia® (ferric citrate) tablets, which allows for generic versions of Auryxia beginning in March 2025.
- Akebia announced that Ron Frieson, Chief Operating Officer of Children's Healthcare of Atlanta (CHOA), joined Akebia's Board of Directors. Mr. Frieson previously held leadership roles in external affairs, public policy, and diversity at CHOA, the Atlanta Urban League and BellSouth Corporation.

Third Quarter Financial Results

- **Revenues:** Total revenue was $48.8 million for the third quarter of 2021 compared to $60.0 million for the third quarter of 2020. The decrease compared to the same period in 2020 was primarily due to lower collaboration revenue from Otsuka driven by lower development costs incurred subject to cost share provisions under both the Otsuka U.S. Agreement and the Otsuka International Agreement as the Company successfully completed the INNO$_2$VATE and PRO$_2$TECT global Phase 3 clinical programs and is currently engaged in close-out activities with respect to the programs. Collaboration revenue will continue to reflect collaboration development activities.
  - Collaboration revenue was $12.0 million for the third quarter of 2021 compared to $25.6 million for the third quarter of 2020.
  - Net product revenue for Auryxia was $36.8 million for the third quarter of 2021 compared to $34.4 million for the third quarter of 2020, an increase of 7.0% due to lower volume rebates related to the negative impact to sales volume as a result of COVID-19, and improved payor mix.
- **COGS:** Cost of goods sold was $15.9 million for the third quarter of 2021 and included a $6.0 million decrease to the liability for excess purchase commitments primarily due to the settlement of all patent litigation proceedings related to Abbreviated New Drug Applications filed with respect to Auryxia, which allows for generic versions of Auryxia beginning in March 2025. Cost of goods sold was $30.3 million for the third quarter of 2020 and included $8.4 million in non-cash charges related to the fair-value inventory step-up from the application of purchase accounting and $8.5 million primarily related to the write-down of inventory. These charges for the third quarter of 2020 were partially offset by a $0.7 million reduction to the excess purchase commitments liability within cost of goods sold.
- **R&D Expenses:** Research and development expenses were $40.5 million for the third quarter of 2021 compared to $46.9 million for the third quarter of 2020. The decrease compared to the prior year period was primarily due to the completion of the INNO$_2$VATE and PRO$_2$TECT global Phase 3 clinical programs.
- **SG&A Expenses:** Selling, general and administrative expenses were $46.4 million for the third quarter of 2021 compared to $40.2 million for the third quarter of 2020. The increase compared to the prior year period was due primarily to increases in headcount related costs and one-time legal costs.
- **Net Loss:** Net loss was $59.5 million for the third quarter of 2021 compared to $60.0 million for the third quarter of 2020.
- **Cash Position:** Cash, cash equivalents and available-for-sale securities as of September 30, 2021, were $207.2 million. The Company believes that its cash resources will be sufficient to fund its current operating plan through at least the next twelve months.

"We continue to be judicious in spend as we invest in pre-commercialization activities in anticipation of the U.S. launch of vadadustat in 2022, if approved, while also supporting the marketing, sales, and payor strategies necessary to continue to drive Auryxia revenue growth," said David A. Spellman, Chief Financial Officer, Akebia Therapeutics. "We're proud of the great work our renal sales and support teams have done to get a critical therapy to eligible kidney patients, especially in a market that has seen a decline over the past year due in part to the COVID-19 pandemic."

Conference Call

Akebia will host a conference call on Tuesday, November 9, 2021, at 9:00 a.m. Eastern Time to discuss its third 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 5389484. 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 November 15, 2021. To access the replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and reference conference ID number 5389484. 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 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 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. 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: the anticipated scheduled PDUFA date for vadadustat and the potential for such date to be a pivotal catalyst for the Company; vadadustat's potential first-in-class commercial launch in the U.S., the timing thereof, and, the Company's preparation related thereto, including as it relates to Company spend; the potential for vadadustat's approval by the FDA; Akebia's, including its renal sales force's, preparation and readiness for launch; 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; relationships between Auryxia revenue growth and the Company's support of marketing, sales and payor strategies; and the Company's expectations with respect to its cash resources and cash runway.

The terms "believe," "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 any 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 and 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 Akebia 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 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 or any other product candidates, and to operate the Company; the risks associated with potential generic entrants for Akebia's commercial product, vadadustat, if approved, or any other product candidate; 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 Auryxia, vadadustat, if approved, and any other product candidates; 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 product and 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 June 30, 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.

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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, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Revenues:				
Product revenue, net	$ 36,753	$ 34,392	$ 100,120	$ 94,297
License, collaboration and other revenue	12,003	25,596	53,853	144,311
Total revenues	48,756	59,988	153,973	238,608
Cost of goods sold:				
Product	6,933	24,239	76,012	92,840
Amortization of intangibles	9,011	6,106	27,032	24,307
Impairment of intangible asset	—	—	—	115,527
Total cost of goods sold	15,944	30,345	103,044	232,674
Operating expenses:				
Research and development	40,471	46,857	118,296	180,907
Selling, general and administrative	46,357	40,171	129,336	113,636
License expense	870	710	2,460	2,430
Total operating expenses	87,698	87,738	250,092	296,973
Operating loss	(54,886)	(58,095)	(199,163)	(291,039)
Other expense, net	(4,658)	(1,864)	(12,999)	(5,418)
Net loss	$ (59,544)	$ (59,959)	$ (212,162)	$ (296,457)
Net loss per share—basic and diluted	$ (0.34)	$ (0.42)	$ (1.30)	$ (2.18)
Weighted-average number of common shares—basic and diluted	173,782,151	143,314,729	163,050,769	136,230,889

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

	September 30, 2021	December 31, 2020
Cash, cash equivalents and available for sale securities	$ 207,204	$ 268,690
Working capital	140,879	184,291
Total assets	602,267	644,139
Total stockholders’ equity	137,150	247,618