

**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): March 1, 2022

AKEBIA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36352
(Commission
File Number)

20-8756903
(IRS Employer
Identification No.)

245 First Street
Cambridge, Massachusetts
(Address of principal executive offices)

02142
(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 March 1, 2022, Akebia Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and fiscal year ended December 31, 2021 and commenting on certain recent business highlights and 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 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 1, 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: March 1, 2022

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer



Akebia Therapeutics Reports Fourth Quarter and Full-Year 2021 Financial Results and Recent Business Highlights

- Akebia is launch-ready pending FDA decision for vadadustat on PDUFA date, March 29, 2022
- Amended agreement with Vifor Pharma Group strengthens collaboration for a successful commercial launch of vadadustat, if approved
- Net Auryxia product revenue of \$142.2 million for 2021, an increase of approximately 10% over 2020

CAMBRIDGE, Mass.—March 1, 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 fourth quarter and full-year ended December 31, 2021 and recent business updates related to 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.

“The PDUFA date for vadadustat is fast approaching. We recognize how transformational the potential approval would be for Akebia and, true to our purpose as a company, our team continues to work tirelessly to deliver a new oral therapeutic option for the patients we serve,” said John P. Butler, Chief Executive Officer of Akebia. “We are prepared for what we believe will be a significant catalyst for the company marked by launching a potential first-in-class oral therapeutic for people living with anemia due to CKD, subject to regulatory approval.”

Last month Akebia and Vifor Pharma Group (Vifor Pharma) [amended and restated the terms of their license agreement](#), which provides important access to up to 60% of U.S. dialysis patients through existing Vifor Pharma relationships, supporting a successful commercial launch of vadadustat, if approved. Vifor Pharma completed a \$20 million equity investment in Akebia, and will pay Akebia a \$25 million upfront payment and contribute an initial \$40 million in refundable working capital to partially fund launch supply. The companies also defined profit share economics of potential vadadustat revenue.

“Many of our on-going pre-commercialization activities, including amending the terms of our relationship with Vifor Pharma, are aimed at ensuring patient access for vadadustat,” said Dell Faulkingham, Chief Commercial Officer of Akebia. “If approved, we will immediately initiate the process to secure reimbursement for vadadustat under the Transitional Drug Add-on Payment Adjustment (TDAPA) period for dialysis organizations, which we expect will take approximately six months. We believe TDAPA designation for vadadustat will be an important driver for adoption within U.S. dialysis organizations, if approved.”

Akebia continues to optimize its sales, marketing, and payor strategies to support Auryxia® (ferric citrate). Akebia ended 2021 with notable Auryxia net product revenue growth and the strongest quarter of net product revenue to date while the phosphate binder market declined by 8.1% year-over-year in the U.S., due in part to the impact of COVID-19 on kidney disease patients. Akebia achieved \$142.2 million in net product revenue in 2021 due to improved commercial contracts and payor mix.

“Both the 2021 and our expected 2022 Auryxia revenue growth is due to our team’s commitment to patients and healthcare providers, even against the backdrop of the COVID-19 pandemic,” added Dell Faulkingham. “Our renal focused field team has proven its ability to successfully engage with the kidney community and thoughtfully outline our value proposition. This expertise establishes a strong foundation from which to launch vadadustat, if approved.”

Fourth Quarter and Full-Year 2021 Financial Results

Revenues: Total revenue was \$59.6 million for the fourth quarter of 2021 compared to \$56.7 million for the fourth quarter of 2020, and \$213.6 million for the full-year 2021 compared to \$295.3 million for the full-year 2020.

- Collaboration revenue was \$17.5 million for the fourth quarter of 2021 compared to \$22.1 million for the fourth quarter of 2020, and \$71.4 million for the full-year 2021 compared with \$166.4 million for the full-year 2020. The decrease in both periods compared to the same periods in 2020 was primarily due to lower collaboration revenue from Otsuka Pharmaceuticals Co. Ltd (Otsuka) driven by lower development costs incurred subject to cost share provisions under both the Otsuka collaboration agreement for the U.S. and the Otsuka collaboration agreement for certain territories outside the U.S. as Akebia successfully completed the INNO₂VATE and PRO₂TECT global Phase 3 clinical programs in 2020 and is currently engaged in close-out activities with respect to the programs.
- Net product revenue was \$42.1 million for the fourth quarter of 2021 compared with \$34.6 million for the fourth quarter of 2020, an increase of approximately 22 percent. Net product revenue was \$142.2 million for the full-year 2021 compared to \$128.9 million for the full-year 2020, an increase of approximately 10 percent.

COGS: Cost of goods sold was \$50.4 million for the fourth quarter of 2021 compared to \$63.2 million for the fourth quarter of 2020. Cost of goods sold was \$153.4 million for the full-year 2021, compared with \$295.9 million for the full-year 2020. Cost of goods sold includes a non-cash charge related to excess purchase commitments of \$18.0 million and \$33.4 million, for the fourth quarter and full year 2021, respectively.

R&D Expenses: Research and development expenses were \$29.6 million for the fourth quarter of 2021 compared to \$37.6 million for the fourth quarter of 2020, and \$147.9 million for the full-year 2021 compared to \$218.5 million for the full-year 2020. Fourth quarter 2021 expenses included a one-time credit of \$8.6 million representing a reimbursement from Vifor Pharma following the sale of the Priority Review Voucher (PRV), which proceeds were subsequently paid to Otsuka as reimbursement for their contribution to purchase the PRV.

SG&A Expenses: Selling, general and administrative expenses were \$44.8 million for the fourth quarter of 2021 compared to \$40.3 million for the fourth quarter of 2020, and \$174.2 million for the full-year 2021 compared to \$153.9 million for the full-year 2020. The increase for the full year 2021 was primarily due to higher marketing expenses, increased headcount-related costs, and one-time legal costs.

Net Loss: Net loss was \$70.7 million for the fourth quarter of 2021 compared to \$87.0 million for the fourth quarter of 2020, and \$282.8 million for the full-year 2021 compared to \$383.5 million for the full-year 2020. The decrease in net loss for the full-year 2021 compared to the prior year was due primarily to higher product revenues, lower cost of goods sold and lower operating expenses, partially offset by lower collaboration revenue.

Cash Position: Cash and cash equivalents as of December 31, 2021 were \$149.8 million. Akebia believes that its cash resources will be sufficient to fund its current operating plan through at least the next twelve months. Akebia's base operating plan assumes a timely regulatory approval of vadadustat for the treatment of anemia due to CKD in dialysis dependent patients, as well as milestones and product revenues as an important source of funding of our cash runway.

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 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 (NDA) and Marketing Authorization Application (MAA) for vadadustat for the treatment of anemia due to chronic kidney disease (CKD) are under review by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), respectively. 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 vadadustat to be a significant catalyst and transformational for Akebia; Akebia's expectations regarding net product revenue growth for Auryxia in 2022; the potential for vadadustat's approval by the FDA; vadadustat's potential as a first-in-class oral therapeutic for the treatment of anemia due to CKD; vadadustat's potential first-in-class commercial launch in the U.S., the timing thereof, and Akebia's preparation and readiness related thereto; the ability of Akebia's pre-commercialization activities to ensure patient access for vadadustat; the market opportunity for vadadustat; Akebia's plans to secure reimbursement for vadadustat under TDAPA, the timing related thereto and the importance of such reimbursement with respect to adoption of vadadustat in U.S. dialysis organizations, if approved; COVID-19's impact on the overall phosphate binder market and the impact that may have on Akebia's revenues; and Akebia's expectations with respect to its base operating plan, cash resources and sources of funding for Akebia's cash runway.

The terms "believe," "expect," "anticipate," "potential," "continue," "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 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 Akebia's product and product candidates, including vadadustat; the direct or indirect impact of the COVID-19 pandemic on Akebia's 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 Auryxia, 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 Auryxia, to develop and commercialize vadadustat or any other product candidates, and to operate Akebia; the risks associated with potential generic entrants for Auryxia, 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 collaborators; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements, including the license agreement with Vifor Pharma; 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 collaboration 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; Akebia's expectations, projections and estimates regarding its capital requirements, going concern and material weaknesses; 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 September 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.

Akebia Therapeutics® and Auryxia® (ferric citrate) are registered trademarks of Akebia Therapeutics, Inc. and its affiliates.

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

	Three Months Ended		Twelve Months Ended	
	December 31, 2021	December 31, 2020	December 31, 2021	December 31, 2020
Revenues:				
Product revenue, net	\$ 42,096	\$ 34,604	\$ 142,216	\$ 128,901
License, collaboration and other revenue	17,509	22,095	71,362	166,406
Total revenues	59,605	56,699	213,578	295,307
Cost of goods sold:				
Product	41,340	56,026	117,352	148,866
Amortization of intangibles	9,010	7,208	36,042	31,515
Impairment of intangible asset	—	—	—	115,527
Total cost of goods sold	50,350	63,234	153,394	295,908
Operating expenses:				
Research and development	29,556	37,578	147,852	218,485
Selling, general and administrative	44,825	40,311	174,161	153,947
License expense	1,029	979	3,489	3,409
Total operating expenses	75,410	78,868	325,502	375,841
Operating loss	(66,155)	(85,403)	(265,318)	(376,442)
Other income (expense), net	(4,523)	(1,597)	(17,522)	(7,015)
Net loss before income taxes	(70,678)	(87,000)	(282,840)	(383,457)
Benefit from income taxes	—	—	—	—
Net loss	\$ (70,678)	\$ (87,000)	\$ (282,840)	\$ (383,457)
Net loss per share - basic and diluted	\$ (0.40)	\$ (0.60)	\$ (1.70)	\$ (2.77)
Weighted-average number of common shares - basic and diluted	175,605,992	145,111,415	165,949,695	138,463,152

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

	December 31, 2021	December 31, 2020
Cash, cash equivalents and available for sale securities	\$ 149,800	\$ 268,690
Working capital	15,517	184,291
Total assets	525,550	644,139
Total stockholders' equity	76,456	247,618