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 5, 2020

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 5, 2020, Akebia Therapeutics, Inc. (the "Company") announced financial results for the quarter ended September 30, 2020 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 November 5, 2020, 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 5, 2020

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

Akebia Reports Third Quarter 2020 Financial Results and Recent Business Updates

- *Presented positive global Phase 3 data for vadadustat from the INNO$_2$VATE program for the treatment of anemia due to chronic kidney disease in adult patients on dialysis at ASN Kidney Week*
- *Completed pre-NDA meeting with the FDA and remain on track to submit vadadustat NDA*
- *Conference call today at 9:00 a.m. ET*

CAMBRIDGE, Mass.— November 5, 2020— 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 third quarter ended September 30, 2020 and provided business updates, including confirming completion of a pre-NDA meeting with the U.S. Food and Drug Administration (FDA) for vadadustat. Vadadustat is Akebia's investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) in development for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis and not on dialysis.

"We recently completed our pre-NDA meeting with the FDA. This was an important milestone for our vadadustat development program, and we remain on track to submit an NDA to the FDA as early as possible next year. A key component of this NDA is the positive data from our global Phase 3 INNO$_2$VATE program for the treatment of anemia due to CKD in adult patients on dialysis, which we shared most recently at ASN Kidney Week. These data were clear and consistent, and showed that vadadustat achieved both the primary and key secondary efficacy endpoints, as well as the primary and key secondary safety endpoints of the program for patients on dialysis. Based on our pre-NDA meeting, we remain confident that these results support the potential approval of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis," said John P. Butler, President and Chief Executive Officer of Akebia Therapeutics. "Subject to regulatory review and approval, we believe vadadustat has the potential to be a new oral standard of care to help address the unmet needs of adult patients on dialysis, including both incident and prevalent dialysis patients. We believe this could translate into a potential $2 billion market opportunity in the U.S., alone. Together with our collaborator, Otsuka, we look forward to bringing this innovative therapy to patients on dialysis globally, if approved."

Butler continued, "The pre-NDA meeting also allowed us the opportunity to clarify key questions regarding data from PRO$_2$TECT, our global Phase 3 program for the treatment of anemia due to CKD in adult patients not on dialysis, and we look forward to working with the FDA in their review of these data. While the PRO$_2$TECT data showed that vadadustat achieved both the primary and key secondary efficacy endpoints, it did not meet the program's primary safety endpoint for patients not on dialysis, and we remain appropriately cautious in our outlook for potential approval of vadadustat in patients not on dialysis. Importantly, we believe the PRO$_2$TECT data will not adversely impact the potential approvability of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis."

Akebia plans to submit a New Drug Application (NDA) to the FDA for vadadustat as early as possible in 2021 for two indications: (1) the treatment of anemia due to CKD in adult patients on dialysis, and (2) the treatment of anemia due to CKD in adult patients not on dialysis. In addition, Akebia and its collaborator, Otsuka Pharmaceutical Co. Ltd., are working in close collaboration to prepare a Marketing Authorization Application (MAA) for submission to the European Medicines Agency (EMA) next year.

Recent Business Highlights

- In October, the Company presented data from its global Phase 3 program at American Society of Nephrology Kidney Week 2020 Reimagined (ASN Kidney Week). Akebia's global Phase 3 program consists 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 ($INNO_2VATE$) and not on dialysis (PRO_2TECT).
    - Highlights of $INNO_2VATE$ ASN Kidney Week Presentation: As previously reported in May 2020, vadadustat achieved the primary and key secondary efficacy endpoints and the primary safety endpoint of the $INNO_2VATE$ program, defined as non-inferiority of vadadustat versus darbepoetin alfa in time to first occurrence of a major adverse cardiovascular event (MACE), which is the composite of all-cause mortality, non-fatal myocardial infarction (MI), or non-fatal stroke, across both $INNO_2VATE$ studies. Newly presented $INNO_2VATE$ data showed that vadadustat also achieved non-inferiority to darbepoetin alfa on key secondary safety endpoints including expanded MACE, cardiovascular MACE, cardiovascular mortality, and all-cause mortality.
    - Highlights of PRO_2TECT ASN Kidney Week Presentation: As previously reported in September 2020, vadadustat achieved the primary and key secondary efficacy endpoints of the PRO_2TECT program, but did not meet the primary safety endpoint. Newly presented pre-specified regional analyses of the PRO_2TECT program showed vadadustat demonstrated no clinically meaningful increase in cardiovascular risk compared to darbepoetin alfa in analyses of MACE, expanded MACE and all-cause mortality in U.S. patients treated to a target hemoglobin (Hb) range of 10 to 11 g/dL, consistent with U.S. treatment guidelines.
- In October, Akebia and Otsuka launched *Balancing Anemia Due to CKD*, a campaign and website designed to increase awareness and education of anemia due to CKD among healthcare providers with the goal of improving the management of this disease for patients.
- In August, the Company announced the launch of vadadustat in Japan by Mitsubishi Tanabe Pharma Corporation (MTPC), Akebia's partner in Japan, as a treatment for anemia due to CKD in both adult patients on dialysis and not on dialysis under the trade name VAFSEO™.
- In July, the Company announced an investigator-sponsored research study by The University of Texas Health Science Center at Houston (UTHealth) in Houston, Texas, evaluating the use of

vadadustat as a potential therapy to prevent and lessen the severity of acute respiratory distress syndrome (ARDS), a complication of COVID-19. The study is currently underway and actively enrolling patients.

Third Quarter Financial Results

- **Revenues:** Total revenue was $60.0 million for the third quarter of 2020 compared to $92.0 million for the third quarter of 2019. The decline versus the prior year period was driven by lower collaboration revenue consistent with the Company completing the INNO$_2$VATE and PRO$_2$TECT studies.
    - Collaboration revenue was $25.6 million for the third quarter of 2020 compared to $62.0 million in the third quarter of 2019, and included $0.4 million in royalty revenue related to the commercial sale of vadadustat (VAFSEO™) in Japan from MTPC.
    - Net product revenue for Auryxia® (ferric citrate) was $34.4 million for the third quarter of 2020 compared with $30.0 million in the third quarter of 2019, an increase of 14.6 percent.
- **COGS:** Cost of goods sold was $30.3 million for the third quarter of 2020 compared to $38.3 million for the third quarter of 2019 and includes the impact of $9.9 million in non-cash inventory write-downs largely related to a previously disclosed manufacturing quality issue related to Auryxia.
- **R&D Expenses:** Research and development expenses were $46.9 million for the third quarter of 2020 compared to $74.5 million for the third quarter of 2019. The decline versus the prior year period was primarily driven by a decrease in costs consistent with the Company completing the INNO$_2$VATE and PRO$_2$TECT studies.
- **SG&A Expenses:** Selling, general and administrative expenses were $40.2 million for the third quarter of 2020 compared to $34.2 million for the third quarter of 2019. The increase was primarily a result of higher professional service fees related to marketing and pre-commercialization activities for vadadustat and legal fees.
- **Net Loss:** Net loss was $60.0 million for the third quarter of 2020 compared to $54.6 million for the third quarter of 2019. The increase in net loss compared to the prior year period was due primarily to lower total revenue and more specifically, lower collaboration revenue, partially offset by lower operating expenses.
- **Cash Position:** Cash, cash equivalents and available-for-sale securities as of September 30, 2020 were $269.3 million. The Company expects its cash resources to fund its current operating plan beyond the expected U.S. launch of vadadustat, assuming regulatory approval.

Conference Call

Akebia will host a conference call at 9:00 a.m. Eastern Time today, Thursday, November 5th, 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 2860285. 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 11, 2020. To access the replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and reference conference ID number 2860285. 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 an 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. Vadadustat recently completed its global Phase 3 development program for the treatment of anemia due to CKD. Vadadustat is not approved by the U.S. Food and Drug Administration (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 the potential for obtaining approval of vadadustat in dialysis and the potential for vadadustat to be a new oral standard of care in dialysis; the potential indications for and benefits of vadadustat; submitting filings for

marketing approval of vadadustat, and the timing thereof; the market and clinical opportunity for vadadustat; the belief that the PRO_2TECT data will not adversely impact the potential approvability of vadadustat for the treatment of anemia due to CKD in adult patients on dialysis; the expectation regarding the Company's cash resources; and the timing of our cash runway in relation to the expected timing of the U.S. launch of vadadustat. The terms "believe," "confident," "expect," "look forward," "on track," "plan," "potential," "will," "working" 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 the timing and content of advice given and decisions made by health authorities, including approval and labeling decisions; the actual time it takes to make regulatory submissions for vadadustat to health authorities, including the submission of the NDA to the FDA and the submission of the MAA to the EMA; risks associated with the Priority Review Voucher for vadadustat; the potential direct or indirect impact of the COVID-19 pandemic on our business, operations, and the markets and communities in which we and our partners, collaborators, vendors and customers operate; manufacturing and quality risks; risks associated with management and key personnel changes and transitional periods; the actual funding required to continue to commercialize our commercial product, to develop and commercialize vadadustat, and to operate the Company; market acceptance and coverage and reimbursement of our commercial product and vadadustat, if approved; the risks associated with potential generic entrants for our commercial product and vadadustat, if approved; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the competitive landscape for our commercial product and vadadustat; 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; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for our 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 June 30, 2020 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 Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

Investor Contact:

Kristen K. Sheppard, Esq.
ir@akebia.com

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

	Three Months Ended		Nine Months Ended	
	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Revenues:				
Product revenue, net	$ 34,392	$ 30,004	$ 94,297	$ 82,204
License, collaboration and other revenue	25,596	61,973	144,311	183,242
Total revenues	59,988	91,977	238,608	265,446
Cost of goods sold:				
Product	24,239	29,162	92,840	79,888
Amortization of intangibles	6,106	9,101	24,307	27,301
Impairment of intangible asset	—	—	115,527	—
Total cost of goods sold	30,345	38,263	232,674	107,189
Operating expenses:				
Research and development	46,857	74,512	180,907	242,557
Selling, general and administrative	40,171	34,178	113,636	104,537
License expense	710	929	2,430	2,560
Total operating expenses	87,738	109,619	296,973	349,654
Operating loss	(58,095)	(55,905)	(291,039)	(191,397)
Other income (expense), net	(1,864)	43	(5,418)	1,342
Net loss before income taxes	(59,959)	(55,862)	(296,457)	(190,055)
Benefit from income taxes	—	(1,277)	—	(4,879)
Net loss	$ (59,959)	$ (54,585)	$ (296,457)	$ (185,176)
Net loss per share - basic and diluted	$ (0.42)	$ (0.46)	$ (2.18)	$ (1.57)
Weighted-average number of common shares - basic and diluted	143,314,729	118,863,063	136,230,889	118,071,674

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

	September 30, 2020	December 31, 2019
Cash, cash equivalents and available for sale securities	$ 269,255	$ 147,694
Working capital	209,542	101,415
Total assets	676,143	771,201
Total stockholders' equity	317,962	394,757