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 8, 2019

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 8, 2019, Akebia Therapeutics, Inc. (the "Company") announced financial results for the quarter ended June 30, 2019 and commented on certain corporate accomplishments and plans.

The information in this Current Report on Form 8-K (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 8, 2019, issued by Akebia Therapeutics, Inc.

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 8, 2019

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

Exhibit 99.1

Akebia Therapeutics Reports Second Quarter 2019 Financial Results and Hosts Conference Call to Discuss Recent Business Highlights

- *Auryxia ® Revenue Increases to $29.1 Million for Q2'FY19, Up 21% from Q2'FY18 and Up 26% from Q1'FY19;*
- *ANDA Settlement Reinforces Strength of Auryxia IP; and,*
- *Vadadustat Achieves Key Regulatory Milestone with JNDA Submission*

CAMBRIDGE, Mass.—August 8, 2019— Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company focused on the development and commercialization of therapeutics for people living with kidney disease, today reported financial results for the second quarter ended June 30, 2019. The Company will host a conference call today, Thursday, August 8, 2019, at 9:00 a.m. Eastern Time to discuss its second quarter 2019 financial results and recent business highlights.

"Akebia continues to make great progress advancing our strategy. Fueled by strong operational execution, we increased Auryxia revenue by 21 percent compared to the same period last year and reinforced the strength of our Auryxia intellectual property with an important ANDA settlement. We also achieved significant milestones with our development program for vadadustat, including a JNDA submission that we believe may establish vadadustat as the first oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI) to file for regulatory approval for the treatment of anemia due to chronic kidney disease (CKD) in both dialysis dependent and non-dialysis dependent adult patients in a major market," stated John P. Butler, President and Chief Executive Officer of Akebia. "While there is still much work ahead of us, we remain confident and believe we have tremendous opportunities to advance our mission to better the lives of people with kidney disease and deliver significant value to all our stakeholders. We've been very purposeful in developing our strategy, and it's great to see the benefits of our work coming to light as the team continues to systematically execute on our priorities."

Butler continued, "We're excited by the opportunities to continue advancing Auryxia's long-term growth story. The 26 percent sequential revenue growth we achieved over the first quarter demonstrates that the team is successfully executing against our near-term growth initiatives. The prescription demand that

we've seen in the first four weeks of the third quarter is the highest of any quarter since Auryxia was launched, affirming our confidence that Auryxia is on a solid growth trajectory. We believe continued progress on our growth initiatives and underlying market demand will drive increased revenue for Auryxia across the second half of the year."

Auryxia Highlights

- Auryxia (ferric citrate) net product revenue increased 20.7 percent year-over-year to $29.1 million for the second quarter of 2019, and increased 26 percent when compared with the first quarter of 2019. Total Auryxia prescriptions increased 22 percent year-over-year to 49,200 in the second quarter of 2019.
- In August, Akebia settled Auryxia patent litigation with Par Pharmaceutical, Inc. (Par), resolving patent litigation brought in response to an Abbreviated New Drug Application (ANDA) filing by Par. The settlement allows Par to market its generic version of Auryxia in the United States beginning on March 20, 2025 (subject to U.S. FDA approval), or earlier under certain circumstances customary for settlement agreements of this nature.
- In July, Akebia's collaboration partner, Japan Tobacco, Inc. and its subsidiary Torii Pharmaceutical Co., Ltd., reported positive top-line results from their pivotal Phase 3 comparative study evaluating Riona® Tablets (generic name in Japan: ferric citrate hydrate) for the treatment of iron deficiency anemia (IDA) in adult patients in Japan. They have stated that they expect to file an application for approval of IDA as an additional indication for Riona in Japan upon successful completion of their Phase 3 program.

Vadadustat Highlights

- In July, Mitsubishi Tanabe Pharma Corporation (MTPC), Akebia's development and commercialization collaboration partner in Japan for vadadustat, submitted a Japanese New Drug Application (JNDA) to the Ministry of Health, Labor and Welfare in Japan for manufacturing and marketing approval of vadadustat as a treatment for anemia due to CKD. The JNDA is the first regulatory submission for marketing approval of vadadustat and, if approved, is expected to lead to the first launch of vadadustat worldwide. This JNDA submission triggered a $10 million milestone payment from MTPC to Akebia, which was received in August.
- In April, Akebia completed enrollment in its global Phase 3 INNO2VATE studies evaluating the safety and efficacy of vadadustat in dialysis-dependent CKD subjects with anemia due to CKD. The Company continues to expect to report top-line data from both INNO2VATE studies in the second quarter of 2020, subject to the accrual of major adverse cardiovascular events (MACE).

- Akebia expects enrollment in its global Phase 3 PROTECT studies evaluating the safety and efficacy of vadadustat in non-dialysis dependent CKD subjects with anemia due to CKD to be completed in 2019. The Company continues to expect to report top-line results in mid-2020, subject to the accrual of MACE.

Financial Results

Total revenue for the second quarter of 2019 was $100.8 million, compared to $48.8 million in the second quarter of 2018.

Auryxia net product revenue for the second quarter of 2019 was $29.1 million, compared to $24.1 million, as reported by Keryx Biopharmaceuticals, Inc. (Keryx) prior to its merger with the Company, during the same period in 2018. This represents a 20.7 percent increase in net product revenue from the second quarter of 2018 and a 26 percent increase compared to the first quarter of 2019. Auryxia is the Company's FDA approved oral iron tablet to treat non-dialysis dependent adult CKD patients for IDA and dialysis-dependent adult CKD patients for hyperphosphatemia.

Collaboration revenue for the second quarter of 2019 was $71.7 million, compared with $48.8 million in the second quarter of 2018. The increase was primarily due to increased collaboration revenue of $11.4 million from Otsuka Pharmaceutical Co. Ltd (Otsuka), and $10.0 million from MTPC in accordance with the Company's collaboration agreements. Otsuka began funding 80 percent of the development costs for vadadustat in the second quarter of 2019.

Cost of goods sold was $37.7 million for the second quarter of 2019, consisting of $9.6 million of costs associated with the manufacture of Auryxia and non-cash charges of $28.1 million related to the application of purchase accounting as a result of the merger with Keryx. Thesenon-cash, merger-related charges include a $19.0 million inventory step-up charge and $9.1 million of amortization of intangibles.

Research and development expenses were $85.7 million for the second quarter of 2019 compared to $71.9 million for the second quarter of 2018. The increase was primarily attributable to an increase in external costs related to the continued advancement of the PROTECT and INNOVATE Phase 3 studies of vadadustat as well as increases in headcount to support our research and development programs.

Selling, general and administrative expenses were $36.1 million for the second quarter of 2019 compared to $12.5 million for the second quarter of 2018. The increase in selling, general and administrative expenses was primarily attributable to commercialization costs associated with Auryxia, as there were no comparable commercialization costs in the second quarter of 2018.

The Company reported a net loss for the second quarter of 2019 of $58.2 million, or ($0.49) per share, as compared to a net loss of $34.1 million, or ($0.60) per share, for the second quarter of 2018. The Company's net loss for the second quarter of 2019 includes the impact of non-cash charges of $28.1 million related to the application of purchase accounting as a result of the merger with Keryx.

The Company ended the quarter with cash, cash equivalents and available-for-sale securities of $136.8 million. "As we continue to effectively manage and leverage our operations, we expect our cash resources, including committed research and development funding from collaborators, to fund our current operating plan beyond the next twelve months, into the third quarter of 2020," stated Jason A. Amello, Chief Financial Officer of Akebia.

Conference Call

Akebia will host a conference call today, Thursday, August 8, 2019, at 9:00 a.m. Eastern Time to discuss its second quarter 2019 financial results and recent business updates. To listen to the conference call, please dial (877) 458-0977 (domestic) or (484) 653-6724 (international) using conference ID number 7274126. 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 14, 2019. To access the replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and reference conference ID number 7274126. 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 focused on the development and commercialization of therapeutics for people living with 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 currently in global Phase 3 development for the treatment of anemia due to CKD. Vadadustat's proposed mechanism of action is designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with increased production of hypoxia-inducible factor, which coordinates the interdependent processes of iron mobilization and erythropoietin production to increase red blood cell production and, ultimately, improve oxygen delivery. Vadadustat is an investigational therapy and is not approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority.

About Auryxia® (ferric citrate) Tablets

Auryxia (ferric citrate) was approved by the FDA on September 5, 2014 for the control of serum phosphorus levels in adult patients with CKD on dialysis and approved by the FDA on November 6, 2017 for the treatment of iron deficiency anemia in adult patients with CKD not on dialysis. For more information about Auryxia and the U.S. full prescribing information, please visit www.auryxia.com.

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 benefits of vadadustat; the potential for the JNDA filing for vadadustat to form the basis of a launch, if approved; the rate and timing of enrollment of our clinical trials; the potential benefits of the combined company post-merger; the market and growth potential of Auryxia, including expectations related to an increase in revenue; the anticipated timing of the availability and reporting of clinical trial data and results; management and key personnel changes and transitional periods; potential and anticipated payments from our collaborators, including the timing thereof; management and leverage of operations and resources dedicated thereto; continued funding and advancement of development efforts; and expectations regarding financial position, including the period of time cash resources (including committed research and development funding from our collaborators) will fund our current operating plan. The terms "anticipate," "believe," "expect," "opportunity," "planned," "potential," "target," "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 the rate of enrollment in clinical studies of vadadustat; risks associated with market acceptance and coverage and reimbursement of Auryxia; the risks associated with potential generic entrants for Auryxia; the rate of major adverse cardiovascular events in our global phase 3 clinical trials for vadadustat; the risk that clinical trials may not be successful; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; manufacturing risks; the quality and manner of the data that will result from clinical studies of vadadustat; risks associated with management and key personnel changes and transitional periods; the actual funding required to develop and commercialize Akebia's product candidates and operate the company, and the actual expenses

associated therewith; the actual costs incurred in the clinical studies of vadadustat and the availability of financing to cover such costs; the risk that clinical studies are discontinued or delayed for any reason, including for safety, tolerability, enrollment, manufacturing or economic reasons; early termination of any of Akebia's collaborations; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements; the timing and content of decisions made by regulatory authorities; the timing of any additional studies initiated for vadadustat; the actual time it takes to initiate and complete preclinical and clinical studies; the competitive landscape for Auryxia and vadadustat; the scope, timing, and outcome of any ongoing legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia and its partners; the risk that we lose, or settle on less favorable terms, other ANDA litigation, or that other ANDA filers enter the market earlier than March 20, 2025, as well as any other potential settlements; and Akebia's ability to obtain, maintain and enforce patent and other intellectual property protection for Auryxia, 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 quarterly period ended March 31, 2019 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.

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

	Three Months Ended		Six Months Ended	
	June 30, 2019	June 30, 2018	June 30, 2019	June 30, 2018
Revenues:				
Product revenue, net	$ 29,089	$ —	$ 52,200	$ —
License, collaboration and other revenue	71,714	48,793	121,269	94,723
Total revenues	100,803	48,793	173,469	94,723
Cost of goods sold:				
Product	28,569	—	50,726	—
Amortization of intangibles	9,100	—	18,200	—
Total cost of goods sold	37,669	—	68,926	—
Operating expenses:				
Research and development	85,694	71,917	168,045	133,321
Selling, general and administrative	36,068	12,538	70,359	21,562
License expense	895	—	1,631	—
Total operating expenses	122,657	84,455	240,035	154,883
Operating loss	(59,523)	(35,662)	(135,492)	(60,160)
Other income, net	508	1,593	1,299	2,673
Net loss before income taxes	(59,015)	(34,069)	(134,193)	(57,487)
Benefit from income taxes	(845)	—	(3,602)	—
Net loss	$ (58,170)	$ (34,069)	$ (130,591)	$ (57,487)
Net loss per share—basic and diluted	$ (0.49)	$ (0.60)	$ (1.11)	$ (1.09)
Weighted-average number of commons shares—basic and diluted	118,268,832	56,890,295	117,669,422	52,774,794

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

	June 30, 2019	December 31, 2018
Cash, cash equivalents and available for sale securities	$136,765	$ 321,640
Working capital	130,778	202,582
Total assets	823,528	996,540
Total stockholders' equity	519,356	635,928

Contacts

Kristen K. Sheppard, Esq

ksheppard@akebia.com