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): May 6, 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

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))

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. ☒

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**

Item 2.02 Results of Operations and Financial Condition.

On May 9, 2019, Akebia Therapeutics, Inc. (the "Company") announced financial results for the quarter ended March 31, 2019 and commented on certain corporate accomplishments and plans. The full text of the press release issued in connection with these announcements is furnished as Exhibit 99.1 to this Current Report on Form 8-K (this "Report") and is incorporated by reference into this Item 2.02.

The information in this 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On May 6, 2019, Rita Jain, M.D., announced that she intends to resign her current position as the Company's Senior Vice President, Chief Medical Officer, effective June 17, 2019. On May 9, 2019, the Company announced that Steven K. Burke, M.D., will succeed Dr. Jain as the Company's Senior Vice President, Chief Medical Officer on the effective date of Dr. Jain's resignation. Dr. Jain has advised the Company that she is committed to supporting the Company and her successor during a transitional period.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated May 9, 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: May 9, 2019

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

Akebia Therapeutics Reports First Quarter 2019 Financial Results; Announces Full Enrollment of Phase 3 INNO$_2$VATE Studies and Announces Key Executive Appointments

- *Net Product Revenue for Auryxia Increases to $23.1 Million for Q1'FY19, Up 12.1% from Q1'FY18;*
- *Full Enrollment of Phase 3 INNO$_2$VATE Studies; and*
- *Additions to Executive Leadership Team to Support Commercial and Clinical Operations.*

CAMBRIDGE, Mass.--May 9, 2019— Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company focused on the development and commercialization of therapeutics for patients with kidney disease, today reported financial results for the first quarter ended March 31, 2019. The company also announced full enrollment of its global Phase 3 INNO$_2$VATE studies for vadadustat, that it has bolstered its commercial capabilities with the addition of Dell Faulkingham as Senior Vice President, Chief Commercial Officer, and appointed Steven K. Burke, M.D., as Senior Vice President, Chief Medical Officer.

"The first quarter marked the achievement of another important milestone for Akebia with the announcement of positive top-line results from two Phase 3, active-controlled, pivotal studies evaluating vadadustat in Japanese patients with anemia due to chronic kidney disease (CKD)," stated John P. Butler, President and Chief Executive Officer of Akebia Therapeutics. "We are excited by these results as they increase our level of confidence in the hypoxia inducible factor (HIF) pathway and more specifically, the direction of our clinical program for vadadustat. These results are expected to serve as the basis for a New Drug Application in Japan (JNDA) by our collaboration partner, Mitsubishi Tanabe Pharma Corporation (MTPC), in 2019."

Butler continued, "We are also pleased to announce the completion of enrollment in our global Phase 3 INNO$_2$VATE studies evaluating vadadustat for the treatment of anemia due to CKD in dialysis-dependent CKD subjects. With the addition of Dell Faulkingham to our executive team, we have strengthened our commercial capabilities and believe we are well positioned to execute on our revenue growth strategies for Auryxia. Lastly, we look forward to welcoming Dr. Steven Burke as our new Chief Medical Officer as we continue to execute on the multiple catalysts expected with vadadustat's Phase 3 program over the next 12 to 18 months."

Auryxia Highlights

- Auryxia net product revenue for the first quarter of 2019 was $23.1 million, representing 12.1 percent growth over the first quarter of 2018.
- Total Auryxia prescriptions were 40,080, representing 22.5 percent growth over the first quarter of 2018.

Vadadustat Highlights

- Announced positive top-line results from two Phase 3, active-controlled, pivotal studies evaluating vadadustat in Japanese subjects with anemia due to CKD in March 2019. Data from these two pivotal studies as well as from two additional single-arm studies in peritoneal dialysis and hemodialysis subjects, also recently announced, are expected to serve as the basis for a JNDA submission by MTPC in 2019.
- Expanded license agreement with Vifor Pharma announced in April 2019 creates opportunity for accelerated introduction of vadadustat, if approved by the U.S. Food and Drug Administration (FDA), in up to 60 percent of U.S. dialysis patients.
- Enrollment in the global Phase 3 INNO$_2$VATE studies evaluating the safety and efficacy of vadadustat in dialysis-dependent CKD subjects with anemia due to CKD, has been completed. Enrollment in the smaller of the two INNO$_2$VATE studies (the "Correction Study"), was completed in April 2019, with a total of 369 subjects enrolled. Enrollment in the larger INNO$_2$VATE study (the "Conversion Study") was completed in February 2019, with a total of 3,554 subjects enrolled. The company continues to expect to report top-line data from both INNO$_2$VATE studies in the second quarter of 2020, subject to the accrual of major adverse cardiovascular events (MACE).
- The company expects enrollment in the global Phase 3 PRO$_2$TECT studies evaluating the safety and efficacy of vadadustat in non-dialysis dependent CKD subjects with anemia due to CKD, to be completed in 2019, with up to approximately 3,700 subjects expected to be enrolled. 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 first quarter of 2019 was $72.7 million, compared to $45.9 million in the first quarter of 2018.

Auryxia net product revenue for the first quarter of 2019 was $23.1 million, compared to $20.6 million, as reported by Keryx Biopharmaceuticals, Inc. ("Keryx") prior to its merger with the company, during the same period in 2018. This represents a 12.1 percent increase in net product revenue from the first quarter of 2018. Auryxia is the company's FDA approved oral iron tablet to treat non-dialysis dependent adult CKD patients for iron deficiency anemia (IDA) and dialysis-dependent adult CKD patients for hyperphosphatemia.

"As we previously discussed, the Centers for Medicare & Medicaid Services' (CMS) new prior authorization requirement for Auryxia caused delays in approvals of prescriptions and negatively impacted Auryxia product revenue for the first quarter. We believe our efforts to help patients and prescribers navigate this process are working and we're encouraged with the growth in weekly prescriptions that we are now seeing. In fact, the prescription demand we've seen in the first four weeks of the second quarter exceeded the first four weeks of any quarter since Auryxia was launched," stated Butler. "Looking ahead, we believe continued execution on our growth strategy and underlying market demand, will drive increased revenue for Auryxia in the second quarter and across the year."

Collaboration revenue for the first quarter of 2019 was $49.6 million, compared with $45.9 million in the first quarter of 2018. The increase was primarily due to increased collaboration revenue in the first quarter of 2019 from the company's cost sharing arrangement under its Otsuka collaboration agreements. The company expects Otsuka to begin funding 80 percent of its development costs for vadadustat in the second quarter of 2019.

Cost of goods sold was $31.3 million for the first quarter of 2019, consisting of $7.6 million of costs associated with the manufacture of Auryxia and $23.7 million related to the application of purchase accounting as a result of the merger with Keryx, including $14.6 million of inventory step-up and $9.1 million of amortization of intangibles.

Research and development expenses were $82.4 million for the first quarter of 2019 compared to $61.4 million for the first quarter of 2018. The increase was primarily attributable to an increase in external costs related to the continued advancement of the PRO_2TECT and $INNO_2$VATE Phase 3 studies.

Selling, general and administrative expenses were $34.3 million for the first quarter of 2019 compared to $9.0 million for the first 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 first quarter of 2018.

The company reported a net loss for the first quarter of 2019 of $72.4 million, or ($0.62) per share, as compared to a net loss of $23.4 million, or ($0.48) per share, for the first quarter of 2018. The company's net loss for the first quarter of 2019 includes the impact of merger-related accounting charges totaling $23.7 million, offset by a $2.8 million deferred tax benefit.

The company ended the quarter with cash, cash equivalents and available-for-sale securities of $168.0 million. The decrease from the fourth quarter of 2018 was primarily related to the timing of cash flows between quarters, including reimbursement amounts from the company's collaboration partners and payments related to its Phase 3 program for vadadustat, including $13.0 million of advanced purchases of comparator drug inventory in anticipation of Brexit. Additionally, cash was impacted by one-time payments of certain previously accrued, merger-related liabilities totaling $30.0 million. The company continues to expect its cash resources, including the prepaid quarterly committed cost-share funding from its collaboration partners, to fund its current operating plan into the third quarter of 2020.

Leadership Team Additions

Steven K. Burke, M.D. will succeed Rita Jain, M.D., who informed the company of her plans to step down from her position as Senior Vice President, Chief Medical Officer effective June 17, 2019 to pursue other opportunities. Dr. Jain has been a valued member of the company's leadership team, and during her tenure made important contributions to the vadadustat development program and enhanced the development organization. She has advised the company that she is committed to supporting the company during a transitional period and ensuring a seamless and successful transition to her successor, Dr. Burke.

Dr. Burke will join the company from Proteon Therapeutics, Inc., where he has been Senior Vice President and Chief Medical Officer since 2006. Prior to joining Proteon, Dr. Burke served as Senior Vice President of Medical and Regulatory Affairs at Genzyme Corporation, where he worked from 2001 to 2006. From 1994 to 2001, Dr. Burke held roles at GelTex Pharmaceuticals, Inc. including Vice President of Clinical Research and Medical Director, and before that he held positions at Glaxo, Inc.. Dr. Burke received an A.B. from Harvard College and an M.D. from Cornell University Medical College. He completed a medical residency and fellowship at Brigham and Women's Hospital and is certified by the American Board of Internal Medicine.

Dell Faulkingham joins the company with more than 20 years of commercial experience across a broad range of specialty pharmaceutical categories. His experience includes commercial leadership roles with Biogen Inc., where he held multiple positions of increasing responsibility, most recently serving as Senior Vice President and Head, U.S. Multiple Sclerosis (MS) Franchise. Mr. Faulkingham also recently served as Vice President, Head of U.S. MS Marketing and Field Operations at Biogen. Prior to joining Biogen, Mr. Faulkingham held several roles with Takeda Pharmaceuticals. Mr. Faulkingham began his career in sales at Forest Pharmaceuticals, Inc. and received a B.S. in biology from the University of Georgia.

Conference Call:

Akebia will host a conference call today, Thursday, May 9, 2019, at 9:00 a.m. Eastern Time to discuss its first quarter financial results. To listen to the conference call, please dial (877) 458-0977 (domestic) or (484) 653-6724 (international) using conference ID number 4271217. 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 May 15, 2019. To access the replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and reference conference ID number 4271217. 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 patients 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 timing and basis of the JNDA filing for vadadustat; 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; the anticipated timing of the availability and presentation 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; and expectations regarding financial position, including the period of time cash resources, including committed 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; 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 Annual Report on Form 10-K 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	
	March 31, 2019	March 31, 2018
Revenues:		
Product revenue, net	$ 23,111	$ —
License, collaboration and other revenue	49,555	45,930
Total revenues	72,666	45,930
Cost of goods sold:		
Product	22,157	—
Amortization of intangibles	9,100	—
Total cost of goods sold	31,257	—
Operating expenses:		
Research and development	82,351	61,404
Selling, general and administrative	34,291	9,024
License expense	736	—
Total operating expenses	117,378	70,428
Operating loss	(75,969)	(24,498)
Other income, net	791	1,080
Net loss before income taxes	(75,178)	(23,418)
Benefit from income taxes	(2,757)	—
Net loss	$ (72,421)	$ (23,418)
Net loss per share - basic and diluted	$ (0.62)	$ (0.48)
Weighted-average number of commons shares - basic and diluted	117,063,352	48,613,565

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

	March 31, 2019	December 31, 2018
Cash, cash equivalents and available for sale securities	$ 168,038	$ 321,640
Working capital	144,620	202,582
Total assets	890,793	996,540
Total stockholders' equity	566,379	635,928

Contacts

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