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 18, 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. ☒

Item 2.02. Results of Operations and Financial Condition.

On March 18, 2019, Akebia Therapeutics, Inc. (the "Company") announced preliminary financial results for the quarter and fiscal year ended December 31, 2018 and commented on certain corporate accomplishments and plans. The Company also announced that it will be delayed in filing its Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (the "Annual Report"), as permitted under Rule 12b-25 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), due to additional time being needed to complete preparation of the Annual Report in light of the December 12, 2018 closing of the Company's business combination with Keryx Biopharmaceuticals, Inc. The Company plans to file its Annual Report within the 15 calendar-day period provided under Rule 12b-25. 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 Report (including Items 2.02 and Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of 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 March 18, 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: March 18, 2019

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

Exhibit 99.1

Akebia Therapeutics Announces Preliminary Full-Year 2018 Financial Results and Business Highlights

– Substantial revenue growth opportunity for Auryxia following robust 2018 commercial performance –

– First regulatory submission for vadadustat expected in 2019 in Japan, following positive top-line results from pivotal phase 3 studies in Japanese subjects with anemia due to chronic kidney disease –

– Multiple vadadustat phase 3 readouts expected over next 18 months –

CAMBRIDGE, Mass.—March 18, 2019—Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company focused on the development and commercialization of therapeutics for patients with kidney disease, today announced preliminary financial results for the full year ended December 31, 2018 and business highlights.

“2018 was a transformational year for Akebia,” said John P. Butler, President and Chief Executive Officer of Akebia Therapeutics. “We successfully executed a number of strategic initiatives to advance our mission, and with the recent completion of our merger with Keryx, we have emerged as a leading, fully-integrated renal company with the potential to greatly improve care for patients with kidney disease. We are pleased with the robust growth we have seen with Auryxia® (ferric citrate) during 2018. Looking ahead, we see the potential for substantial revenue growth in both the hyperphosphatemia and iron deficiency anemia markets.”

Mr. Butler continued, “With respect to vadadustat, our lead product candidate, we believe that it has the potential to set a new standard of care for patients with anemia due to chronic kidney disease with a differentiated clinical profile. We recently announced positive top-line results from two pivotal phase 3 studies in Japan conducted by our collaboration partner, Mitsubishi Tanabe Pharma Corporation, which adds to the body of data supporting vadadustat’s potential to serve as a much-needed therapeutic option for patients with anemia due to chronic kidney disease. In addition, we continue to drive our global phase 3 program for vadadustat, with enrollment completed in the larger of the two INNO$_2$VATE studies and enrollment expected to complete in the smaller INNO$_2$VATE study by April 2019. The next 18 months will be a very busy time, with significant catalysts ahead of us.”

Business Highlights

Auryxia

- Pro forma unaudited Auryxia sales in 2018 were $96 million, representing 72% growth over 2017.
- Total Auryxia prescriptions for 2018 were approximately 163,000, representing 85% growth over 2017.
- Exit market share for Auryxia tablets in 2018 was 6.6% compared to 4.2% in 2017, exceeding the share gain of all other phosphate binders (branded and generic) in the same period.

Vadadustat Japanese Phase 3 Program

- Announced positive top-line results from two phase 3, active-controlled, pivotal studies evaluating vadadustat in Japanese subjects with anemia due to chronic kidney disease (CKD).
- Data from these two pivotal studies as well as from two additional single-arm studies in peritoneal dialysis and hemodialysis subjects, also recently announced, is expected to serve as the basis for a Japanese New Drug Application (JNDA) submission by Mitsubishi Tanabe Pharma Corporation (MTPC), expected in 2019.

Vadadustat Global Phase 3 Program

- Enrollment in the larger of the two INNO$_2$VATE studies (the “Conversion Study”) was completed in February 2019, with a total of 3,554 subjects enrolled. Enrollment in the smaller INNO$_2$VATE study (the “Correction Study”), enrolling approximately 350 subjects, is expected to be completed by April 2019. The company expects to report top-line data from both INNO$_2$VATE studies in the second quarter of 2020, subject to the accrual of major adverse cardiac events (MACE).
- The company expects enrollment in the PRO$_2$TECT studies to complete in 2019, with up to approximately 3,700 subjects expected to be enrolled. Top-line results are anticipated in mid-2020, subject to the accrual of MACE.
- The two INNO$_2$VATE studies evaluating dialysis-dependent CKD subjects and the two PRO$_2$TECT studies evaluating non-dialysis dependent CKD subjects are global, phase 3, active-controlled, open-label, non-inferiority, cardiovascular outcome studies of vadadustat for the treatment of anemia due to CKD.

Preliminary Financial Results (unaudited)

As a result of the completion of the company's business combination with Keryx Biopharmaceuticals, Inc. (Keryx) on December 12, 2018 and the time required to complete the allocation of the merger consideration to the fair value of the acquired assets and liabilities as well as the assessment of the associated tax impacts, the company is announcing preliminary results for the full year 2018, which are based on currently available information and are subject to revision, as further discussed below. The company anticipates a delayed filing of its Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (Annual Report) and plans to file a Form 12b-25, Notification of Late Filing, with the Securities and Exchange Commission, which will provide the company with a 15 calendar-day extension.

Net product revenues for Auryxia from December 12, 2018, the date of our merger with Keryx, through December 31, 2018 were $6.8 million. The company did not have any product revenue prior to our merger with Keryx.

Collaboration revenues for the fourth quarter of 2018 were $53.0 million, compared with $90.6 million during the same period in 2017. The decrease was primarily due to $42.9 million of deferred revenue associated with the MTPC collaboration agreement being recognized as revenue during the fourth quarter of 2017, as the criteria for revenue recognition were satisfied in that quarter. No revenue was recognized under the MTPC collaboration agreement in the fourth quarter of 2018.

Collaboration revenues for the full year 2018 were $200.9 million compared to $181.2 million for the full year 2017. The increase was due to increased revenues recognized under the collaboration agreements with Otsuka Pharmaceutical Co. Ltd. (Otsuka). Through 2018, Otsuka has funded 52.5% of the company's phase 3 development costs for vadadustat, and in the second quarter of 2019, Otsuka is expected to increase its contribution to 80%.

Cost of goods sold was $6.3 million for the period from December 12, 2018 through December 31, 2018, consisting primarily of costs associated with the manufacture of Auryxia and $4.8 million for the fair-value inventory step-up as a result of the merger accounting.

Research and development expenses were $87.1 million for the fourth quarter of 2018 compared to $68.4 million for the fourth quarter of 2017, and $291.1 million for the full year 2018 compared to $230.9 million for the full year 2017. The increase for both periods is primarily attributable to an increase in external costs related to the continued advancement of the PRO_2TECT and $INNO_2$VATE phase 3 program, as well as increased headcount and consulting costs required to support our expanding research and development programs.

Selling, general and administrative expenses were $55.1 million for the fourth quarter of 2018 compared to $7.6 million for the fourth quarter of 2017, and $87.1 million for the full year 2018 compared to $27.0 million for the full year 2017. The increase in selling, general and administrative expenses is primarily attributable to merger-related costs of $49.5 million, of which $41.7 million was incurred in the fourth quarter of 2018, including a non-cash expense of $13.4 million related to the issuance of shares to Baupost Group Securities, L.L.C. in connection with its conversion of Keryx convertible notes. The increase for both periods was also attributable to an increase in costs to support our research and development programs, including headcount, information technology and compensation-related costs.

Akebia reported a pre-tax net loss for the fourth quarter of 2018 of $88.4 million, as compared to a pre-tax net income of $15.5 million for the fourth quarter of 2017. The pre-tax net loss for the fourth quarter of 2018 includes total merger-related costs of $46.5 million. The pre-tax net income reported for the fourth quarter of 2017 was attributable to $42.9 million of collaboration revenue recognized in connection with the MTPC collaboration agreement, as the criteria for revenue recognition was satisfied in the fourth quarter.

For the full year 2018, the Company reported a pre-tax net loss of $171.9 million, as compared to a pre-tax net loss for the full year 2017 of $73.7 million. The pre-tax net loss for the full year 2018 includes total merger-related costs of $54.3 million.

Akebia ended 2018 with cash, cash equivalents and available-for-sale securities of $321.6 million. The company expects 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.

Conference Call and Webcast

Akebia management will host its full-year 2018 and business highlights conference call and webcast beginning at 4:30 p.m. Eastern Time today, March 18, 2019.

The conference call can be accessed by dialing (877) 458-0977 within the United States and Canada and (484) 653-6724 for all other locations. The confirmation code is 1376157. Participants should dial in 10 minutes prior to the scheduled start time.

A live webcast of the conference call will be available in the “Investors” section of the company’s website at www.akebia.com.

Beginning the morning of March 19, 2019, the call will be available for replay via telephone and the archived webcast will be available on Akebia’s website. To listen to the telephone replay, dial (855) 859-2056 (U.S. and Canada) or (404) 537-3406 (international) using conference ID number 1376157. The telephone replay will be available for six days following the call.

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

Note Regarding Preliminary Financial Results (unaudited)

As a result of the completion of the company's business combination with Keryx on December 12, 2018 and the time required to complete the allocation of the merger consideration to the fair value of the acquired assets and liabilities as well as the assessment of the associated tax impacts, Akebia is finalizing its financial results for the fourth quarter and year ended December 31, 2018. The unaudited, preliminary pre-tax financial results and the other financial information included in this press release are based upon currently available information and management's current analysis and estimates of the financial results for the fourth quarter and year ended December 31, 2018, and are subject to revision as Akebia completes its internal review and audit procedures. Akebia's independent registered public accounting firm, Ernst & Young LLP, has not audited or reviewed these preliminary financial results, and does not express an opinion with respect to, these preliminary financial results. This summary is not a comprehensive statement of Akebia's financial results for the fourth quarter and year ended December 31, 2018. Actual results may differ materially from these preliminary financial results and other financial information due to the completion of Akebia's quarterly and year-end internal procedures, final adjustments, items that may be identified in the course of completing audit procedures and other developments that may arise between now and the time the results are finalized.

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; potential and anticipated payments from our collaborators, including the timing thereof; the preliminary unaudited financial results under the heading "Preliminary Financial Results (Unaudited)" and the other financial information included in this press release; 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 that the preliminary fourth quarter and full-year 2018 results may require updates and revisions in connection with the completion of the company's internal review and auditing procedures; 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; 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 most recently filed Quarterly Report on Form 10-Q and other filings that Akebia may make with the 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		Twelve Months Ended	
	December 31, 2018	December 31, 2017	December 31, 2018	December 31, 2017
Revenues:				
Product revenue, net	$ 6,824	$ —	$ 6,824	$ —
License, collaboration and other revenue	53,026	90,559	200,918	181,227
Total revenues	59,850	90,559	207,742	181,227
Operating expenses:				
Cost of goods sold	6,251	—	6,251	—
Amortization of intangibles	1,434	—	1,434	—
Research and development	87,113	68,382	291,068	230,893
Selling, general and administrative	55,121	7,567	87,061	27,008
License expense	67	—	67	—
Total operating expenses	149,986	75,949	385,881	257,901
Operating income (loss)	(90,136)	14,610	(178,139)	(76,674)
Other income, net	$ 1,766	913	6,235	3,003
Net income (loss) before taxes	$ (88,370)	$ 15,523	$ (171,904)	$ (73,671)

Akebia Therapeutics
Argot Partners
Melissa Forst / Maghan Meyers

akebia@argotpartners.com
(212) 600-1902