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 10, 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 March 10, 2020, Akebia Therapeutics, Inc. (the "Company") announced financial results for the quarter and fiscal year ended December 31, 2019 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 March 10, 2020, 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 10, 2020

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

Exhibit 99.1

Akebia Therapeutics Reports Fourth Quarter and Full-Year 2019 Financial Results and Hosts Conference Call to Discuss Recent Business Highlights

- *Top-line data readouts of global Phase 3 program for vadadustat on track for Q2 of 2020 and mid-2020*
- *Company extends cash runway well into 2021*

CAMBRIDGE, Mass.—March 10, 2020— Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company focused on the development and commercialization of therapeutics for people living with kidney disease, today announced financial results for the fourth quarter and full-year ended December 31, 2019. The Company will host a conference call today, Tuesday, March 10, 2020, at 9:00 a.m. Eastern Time to discuss its fourth quarter and full-year 2019 financial results and recent business highlights.

“2019 was a year of considerable progress for Akebia and with many milestones on the horizon, 2020 is shaping up to be equally, if not more, exciting,” stated John P. Butler, Chief Executive Officer of Akebia. “Our highest priority remains the successful execution of our global Phase 3 program for vadadustat, our investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF-PHI). We have a tremendous amount of confidence in our vadadustat clinical program and believe we’ve developed an exciting path forward to drive significant value for all our stakeholders. We believe our ability to potentially access a Priority Review Voucher (PRV) for the vadadustat New Drug Application (NDA) to expedite FDA review would meaningfully enhance the potential of bringing vadadustat to patients as quickly as possible, subject to regulatory approval.”

Butler continued, “We look forward to sharing data from our global Phase 3 studies of vadadustat, starting with top-line data from INNO$_2$VATE on track for the second quarter of 2020 followed by PRO$_2$TECT in mid-2020. We expect vadadustat to be the first drug of the HIF-PHI class to deliver clear data that directly compare its outcomes to the current standard of care in dialysis-dependent and non-dialysis dependent patients for the treatment of anemia due to chronic kidney disease (CKD).”

Agreement with Vifor Pharma regarding a Priority Review Voucher

In February 2020, Akebia entered into a letter agreement with Vifor (International) Ltd. (Vifor Pharma) relating to Vifor Pharma's agreement with a third party to purchase a PRV issued by the U.S. Food and Drug Administration (FDA), subject to satisfaction of customary closing conditions. Akebia will pay Vifor Pharma $10.0 million following the closing of the PRV purchase. In exchange, Vifor Pharma is obligated to reserve the PRV for the vadadustat NDA for the treatment of anemia due to CKD in dialysis-dependent and non-dialysis dependent patients until Akebia and Vifor Pharma agree on the financial and other terms under which it will assign the PRV to Akebia or make a mutual decision to sell the PRV. A PRV entitles the holder to priority review of an NDA or a Biologics License Application for a new drug, which reduces the target FDA review time to six months after official acceptance of the submission and could lead to expedited approval.

Jason A. Amello, Chief Financial Officer of Akebia stated, "We are pleased to have extended our cash runway well into 2021 through planned, disciplined spending and the identification of operating efficiencies, coupled with the sales of common stock via our At-the-Market facility over the last few months." The Company's cash runway, consistent with previous commentary, includes the receipt of a $15.0 million regulatory milestone from Mitsubishi Tanabe Pharma Corporation, Akebia's development and commercialization collaboration partner in Japan for vadadustat, assuming approval of vadadustat in Japan.

Fourth Quarter and Full-Year 2019 Financial Results

- **Cash Position:** Cash, cash equivalents and available-for-sale securities as of December 31, 2019 were $147.7 million.
- **Revenues:** Total revenue was $69.6 million for the fourth quarter of 2019 compared to $59.9 million for the fourth quarter of 2018(1), and $335.0 million for the full-year 2019 compared to $207.7 million for the full-year 2018(1).
    - Collaboration revenue was $40.6 million for the fourth quarter of 2019 compared to $53.0 million in the fourth quarter of 2018, and $223.9 million for the full-year 2019 compared with $200.9 million for the full-year 2018. The change in both periods is due to the timing in which vadadustat development expenses are incurred and the associated revenue is recognized on a percentage-of-completion basis.
    - Net product revenue was $28.9 million for the fourth quarter of 2019 compared with $6.8 million in the fourth quarter of 2018(1), and $111.1 million for the full-year 2019 compared to $6.8 million for the full-year 2018(1). Pro forma net product revenue for the full-year 2018, inclusive of pre-merger net product revenue recorded by Keryx Biopharmaceuticals, Inc. (Keryx), was approximately $96 million.

- **COGS**: Cost of goods sold was $38.1 million for the fourth quarter of 2019, which includes non-cash charges, related to the application of purchase accounting as a result of the merger with Keryx, of $18.8 million for inventory step-up and $9.1 million for amortization of intangibles. Cost of goods sold was $145.3 million for the full-year 2019, which includes non-cash charges of $70.4 million for inventory step-up and $36.4 million for amortization of intangibles.
- **R&D Expenses:** Research and development expenses were $80.4 million for the fourth quarter of 2019 compared to $87.1 million for the fourth quarter of 2018(1), and $323.0 million for the full-year 2019 compared to $291.0 million for the full-year 2018(1). The change in both periods was largely attributable to a change in costs associated with our research and development programs, including vadadustat.
- **SG&A Expenses:** Selling, general and administrative expenses were $44.9 million for the fourth quarter of 2019 compared to $55.1 million for the fourth quarter of 2018(1) (which included $41.7 million of merger-related expenses), and $149.5 million for the full-year 2019 compared to $87.1 million for the full-year 2018(1) (which included $49.5 million of merger-related expenses).
- **Net Loss:** Net loss was $94.5 million for the fourth quarter of 2019 compared to $60.1 million for the fourth quarter of 2018(1), and $279.7 million for the full-year 2019 compared to $143.6 million for the full-year 2018(1).

(1) Includes only 18 days of operating results of Keryx following completion of Akebia's merger with Keryx on December 12, 2018, whereby Keryx became Akebia's wholly owned subsidiary.

Conference Call

Akebia will host a conference call at 9:00 a.m. Eastern Time today, Tuesday, March 10th, to discuss its fourth quarter and full-year 2019 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 6572299. 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 March 16, 2020. To access the replay, dial (855) 859-2056 (domestic) or (404) 537-3406 (international) and reference conference ID number 6572299. 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 (HIF-PH) inhibitor currently in global Phase 3 development for the treatment of anemia due to CKD. Vadadustat is 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 is an investigational therapy and is not approved by the U.S. Food and Drug Administration (FDA) or any regulatory authority.

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 safety and efficacy of vadadustat, the potential launch of vadadustat, the potential indications for and benefits of vadadustat, and market size, commercial potential, prevalence, and the growth in, and potential demand for, vadadustat; clinical trial data and results and the anticipated timing of the availability and reporting thereof; access to a Priority Review Voucher for vadadustat and the agreement relating thereto; the potential to bring vadadustat to patients and the potential timing thereof by utilizing the Priority Review Voucher; potential and anticipated payments from our collaborators, including the timing thereof; continued funding and advancement of development efforts; and expectations regarding financial position, including the cash runway. 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 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 the Priority Review Voucher for vadadustat; risks associated with management and key personnel changes and transitional periods; the actual funding required to develop and commercialize our commercial product, vadadustat and other 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; market acceptance and coverage and reimbursement of our commercial product; the risks associated with potential generic entrants for our commercial product; 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 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 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 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 quarterly period ended September 30, 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		Twelve Months Ended	
	December 31, 2019	December 31, 2018	December 31, 2019	December 31, 2018
Revenues:				
Product revenue, net	$ 28,915	$ 6,824	$ 111,119	$ 6,824
License, collaboration and other revenue	40,640	53,026	223,882	200,918
Total revenues	69,555	59,850	335,001	207,742
Cost of goods sold:				
Product	29,047	6,251	108,935	6,251
Amortization of intangibles	9,100	1,517	36,401	1,517
Total cost of goods sold	38,147	7,768	145,336	7,768
Operating expenses:				
Research and development	80,412	87,052	322,969	291,007
Selling, general and administrative	44,918	55,121	149,455	87,061
License expense	969	67	3,529	67
Total operating expenses	126,299	142,240	475,953	378,135
Operating loss	(94,891)	(90,158)	(286,288)	(178,161)
Other income (expense), net	(1,344)	1,766	(2)	6,235
Net loss before taxes	(96,235)	(88,392)	(286,290)	(171,926)
Benefit from income taxes	(1,752)	(28,338)	(6,631)	(28,338)
Net loss	$ (94,483)	$ (60,054)	$ (279,659)	$ (143,588)
Net loss per share - basic and diluted	$ (0.79)	$ (0.87)	$ (2.36)	$ (2.47)
Weighted-average number of common shares - basic and diluted	119,358,081	69,404,187	118,395,919	58,038,252

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

	December 31, 2019	December 31, 2018
Cash, cash equivalents and available for sale securities	$ 147,694	$ 321,640
Working capital	101,415	202,582
Total assets	771,201	996,540
Total stockholders' equity	394,757	635,928

Contacts

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