Akebia Therapeutics, Inc.
Form 8-K
January 07, 2019

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): January 7, 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 7.01 Regulation FD Disclosure.

Spokespersons of Akebia Therapeutics, Inc. (the Company) plan to present the information in the J.P. Morgan Healthcare Conference Presentation attached hereto as Exhibit 99.1 (the Presentation) at the 37th Annual J.P. Morgan Healthcare Conference on January 9, 2019 at 9:30 a.m. Pacific Time and at various meetings beginning on January 7, 2019, including investor and analyst meetings.

In December 2018, the Independent Data Monitoring Committee held another meeting and recommended that the Company s global Phase 3 PRO$_2$TECT and INNO$_2$VATE programs for its product candidate, vadadustat, continue and did not recommend any modifications to the programs.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 hereto 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 under that Section. The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission (the SEC) made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

As previously disclosed, on December 12, 2018, the Company completed a merger, whereby Keryx Biopharmaceuticals, Inc. (Keryx) became a wholly owned subsidiary of the Company (the Merger). At the consummation of the Merger, each issued and outstanding share of common stock of Keryx, $0.001 par value per share, was converted into 0.37433 of a share of common stock of the Company, $0.00001 par value per share (Common Stock), and cash in lieu of fractional shares. At December 31, 2018, the Company had 116,887,518 shares of Common Stock outstanding.

As previously disclosed, on October 31, 2018 and November 6, 2018, Keryx received Paragraph IV certification notice letters regarding Abbreviated New Drug Applications (ANDAs) submitted to the U.S. Food and Drug Administration (FDA) by Lupin Atlantis Holdings SA (Lupin) and Teva Pharmaceuticals USA, Inc. (Teva), respectively, requesting approval for generic versions of Auryxia® (ferric citrate) tablets (210 mg iron per tablet). On December 13, 2018, Keryx and its licensors, Panion & BF Biotech, Inc. (Panion) and Chen Hsing Hsu, M.D., filed a complaint for patent infringement against Lupin and Lupin Ltd. (the Lupin Defendants) in the United States District Court for the District of Delaware (the Delaware Court) arising from Lupin s ANDA filing with the FDA, and on December 19, 2018, Keryx and Panion filed a complaint for patent infringement against Teva and Teva Pharmaceutical Industries Limited (the Teva Defendants) in the Delaware Court arising from Teva s ANDA filing with the FDA. As a result of the timely filing of these lawsuits in accordance with statute, a 30-month stay of approval will be imposed by the FDA on Lupin s and Teva s ANDAs, which stays are expected to remain in effect until April 2021 and May 2021, respectively, absent an earlier judgment by the Delaware Court in each of these lawsuits finding the patents at issue invalid, unenforceable or not infringed. The plaintiffs in each of these lawsuits seek, among other relief, an order that the effective date of FDA approval of the ANDA be a date no earlier than the expiration of each of the patents at issue, equitable relief enjoining the Lupin Defendants and Teva Defendants from infringing these patents, and monetary relief as a result of any such infringement.

On December 24, 2018, Keryx received a Paragraph IV certification notice letter regarding an ANDA submitted to the FDA by Chemo Research S.L. (Chemo) requesting approval to market, sell and use a generic version of the Auryxia tablets (210 mg iron per tablet). In its notice letter, Chemo alleges that Keryx s U.S. Patents Nos. 9,387,191; 5,753,706; 7,767,851; 8,093,423; 8,299,298; 8,338,642; 8,609,896; 8,754,257; 8,754,258; 8,846,976; 8,901,349; 9,050,316; 9,328,133; and 9,757,416 (the Patents), which cover the approved drug substance, drug product and/or methods of using Auryxia, are invalid, unenforceable and/or will not be infringed by Chemo s manufacture, use or sale

of the product described in its ANDA. Keryx is currently reviewing the notice letter and intends to vigorously enforce its intellectual property rights relating to Auryxia. By statute, Keryx has 45 days from receipt of the notice letter to initiate a patent infringement lawsuit against Chemo. Such a lawsuit would automatically preclude the FDA from approving Chemo s ANDA until the earlier of 30 months from December 24, 2018 or entry of a district court decision finding the Patents invalid, unenforceable or not infringed.

Going forward, the Company plans to provide updates on any additional Paragraph IV certification notices that Keryx may receive and about patent litigation against ANDA filers through the Company s Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K filed with the SEC.

By providing the information in Items 7.01 and 8.01 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, the Company is not making an admission as to the materiality of any information herein. The information contained in this Current Report on Form 8-K is intended to be considered in the context of more complete information included in the Company s filings with the SEC, the SEC filings of the Company s wholly owned subsidiary, Keryx, and other public announcements that the Company or Keryx has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures.

Cautionary Note on Forward-Looking Statements

This Current Report on Form 8-K, including Exhibit 99.1 hereto, includes forward-looking statements. These statements are not historical facts, but instead represent only the Company s beliefs regarding future events, many of which, by their nature, are inherently uncertain and outside of the Company s control.

For a discussion of risks related to the forward-looking statements in this Current Report on Form 8-K, including the risks related to the ANDA filings discussed in this Current Report on Form 8-K, see the Risk Factors section of the Company s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed by the Company on November 8, 2018, including the risk factor under the heading If generic products that compete with Keryx s marketed product, Auryxia, or any future product of the combined company are approved and launched, the combined company s business, financial position or results of operations would be adversely affected, and the Risk Factors section of Keryx s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed by the Keryx on November 8, 2018, including the risk factor under the heading If our competitors develop and market products that are less expensive, have a reduced pill burden, are or are promoted as more effective or safer than our drug product, or our drug product does not achieve market acceptance vis-à-vis existing treatments, our commercial opportunities may be reduced or eliminated. For additional important information about forward-looking statements, see also the slide titled Cautionary Note on Forward-Looking Statements in Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	J.P. Morgan Healthcare Conference Presentation

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: January 7, 2019

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