Akebia Therapeutics, Inc.
Form 8-K
April 18, 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): April 17, 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 1.01 Entry into a Material Definitive Agreement.

On April 17, 2019 (the Effective Date), Akebia Therapeutics, Inc. (the Company) and Panion & BF Biotech, Inc. (Panion) entered into a second amended and restated license agreement (the Amended License Agreement). The Amended License Agreement amends and restates in full the prior amended and restated license agreement effective March 17, 2008, as amended, between Panion and Keryx Biopharmaceuticals, Inc. (Keryx) pursuant to which Keryx in-licensed exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development, marketing and commercialization of ferric citrate (the Original Agreement). As previously disclosed, the Company and Keryx completed a merger on December 12, 2018, and as a result, Keryx is now the Company s wholly owned subsidiary. The Amended License Agreement reflects certain revisions consistent with the terms of the letter agreement among the Company, Panion and Keryx entered into on October 24, 2018 that was previously disclosed (the Letter Agreement).

Like the Original Agreement, the Amended License Agreement provides the Company with an exclusive license under Panion-owned know-how and patents covering the rights to sublicense, develop, make, use, sell, offer for sale, import and export ferric citrate worldwide, excluding certain Asian-Pacific countries. Consistent with the terms set forth in the Letter Agreement, the Amended License Agreement also provides Panion with an exclusive license under Keryx-owned patents covering the rights to sublicense (with the Company s written consent), develop, make, use, sell, offer for sale, import and export ferric citrate in certain countries in the Asia-Pacific region (the Licensor Territory). Consistent with the Original Agreement, under the Amended License Agreement, Panion is eligible to receive from the Company or any sublicensee royalty payments based on a mid-single digit percentage of sales of ferric citrate in the Company s licensed territories. Consistent with the terms set forth in the Letter Agreement, under the Amended License Agreement, the Company is eligible to receive from Panion or any sublicensee royalty payments based on a mid-single digit percentage of net sales of ferric citrate in Panion s licensed territories.

Pursuant to the terms of the Amended License Agreement and consistent with the terms set forth in the Letter Agreement, a joint steering committee (JSC) consisting of Panion and Company representatives will be formed to oversee the development and commercialization of Fexeric in Europe. As set forth in the Letter Agreement, the JSC will work together to reach consensus on a commercialization plan and, in the event a commercialization plan is not agreed upon within a certain period after the Effective Date, the Company, in its discretion, may launch ferric citrate in certain European countries within a certain period after the Effective Date, pay an annual license maintenance fee to Panion, or expand the Licensor Territory to include the European Union on terms to be negotiated by the parties. The Amended License Agreement further provides that each of the Company and Panion has the right, but not the obligation, to conduct litigation against any infringer of certain patent rights under the agreement in certain territories.

The Amended License Agreement terminates upon the expiration of each of the Company s and Panion s obligations to pay royalties thereunder. In addition, the Company may terminate the Amended License Agreement (i) in its entirety or (ii) with respect to one or more countries in the Company s licensed territory, in either case upon 90 days notice. The Company and Panion also each have the right to terminate the Amended License Agreement upon the occurrence of a material breach of the Amended License Agreement by the other party, subject to certain cure provisions, or certain insolvency events. The Amended License Agreement also provides that, on a country-by-country basis, until the second anniversary of the expiration of the obligation of the Company or Panion, as applicable, to pay royalties in a country in which such party has ferric citrate for sale on the date of such expiration, neither the other party nor its affiliates will, directly or indirectly, sell, distribute or otherwise commercialize or supply or cause to supply ferric citrate to a third party for sale or distribution in such country.

The Amended License Agreement includes customary terms relating to, among others, indemnification, confidentiality, remedies, and representations and warranties.

The foregoing description of the Amended License Agreement does not purport to be complete and is qualified in its entirety by reference to the Amended License Agreement, a copy of which the Company expects to file as an exhibit

to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2019.

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: April 18, 2019

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