

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
(State or other jurisdiction
of incorporation)

001-36352
(Commission
File Number)

20-8756903
(IRS Employer
Identification No.)

245 First Street

Cambridge, Massachusetts
(Address of principal executive offices)

02142
(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

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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