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)
December 18, 2016

AKEBIA THERAPEUTICS, INC.
(Exact name of registrant as specified in charter)

Delaware	**001-36352**	**20-8756903**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

245 First Street, Suite 1100, Cambridge, Massachusetts 02142
(Address of Principal Executive Offices, including Zip Code)

(617) 871-2098
(Registrant's telephone number, including area code)

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))

Item 1.01 Entry into a Material Definitive Agreement.

On December 18, 2016, Akebia Therapeutics, Inc. (“Akebia”) entered into a Collaboration and License Agreement (the “Agreement”) with Otsuka Pharmaceutical Co. Ltd. (“Otsuka”), pursuant to which Akebia agreed to co-exclusively collaborate with Otsuka with respect to the development and commercialization in the United States (the “Territory”) of vadadustat, Akebia’s oral hypoxia-inducible factor (HIF) stabilizer currently in development for the treatment of anemia related to chronic kidney disease. Under the Agreement, the parties will co-exclusively commercialize vadadustat in the Territory, subject to approval of vadadustat by the United States Food and Drug Administration. Akebia will continue to lead the ongoing global Phase 3 development program for vadadustat.

Financial Terms

Under the terms of the Agreement, Otsuka will pay Akebia an upfront payment of $125 million and, by the end of the first quarter of 2017, will reimburse Akebia approximately $35 million for the global expenses previously incurred by Akebia for its ongoing global development program for vadadustat in dialysis dependent and non-dialysis dependent patients with chronic kidney disease. The Agreement also provides for additional funding for the global development program for vadadustat, totaling $105 million or more (depending on the actual global costs incurred). In addition, if the development costs exceed a certain threshold, Akebia may require Otsuka to pay a higher percentage of the global development costs. In such event, Otsuka would be reimbursed for such additional funding out of milestone payments and net sales of vadadustat in the Territory. In addition, Akebia is eligible to receive from Otsuka up to $765 million in specified development and commercial milestones.

The Agreement establishes a profit share for the commercialization of vadadustat in the Territory. Under the Agreement, the parties will equally share all net sales of vadadustat in the Territory, and each party will bear half of all costs in the Territory (including medical affairs, commercialization and manufacturing costs).

Under the Agreement, Otsuka has a limited window in which to exercise an option to convert the economic arrangement under the Agreement from a profit share arrangement to a mid-single digit royalty to be paid by Akebia to Otsuka based on sales of vadadustat in the Territory, in consideration for all prior non-reimbursable payments made by Otsuka. If Otsuka exercises this royalty conversion option, then the collaborative elements of the Agreement would terminate and Akebia would be solely responsible for all commercialization activities in the Territory and free to enter into another collaboration in the Territory.

Development

Under the Agreement, Akebia will control and retain final decision making authority with respect to all development of vadadustat, including the currently ongoing global Phase 3 program. Either party may propose and conduct additional development activities for new formulations, line extensions or new indications, subject to Akebia’s final decision making authority. The costs of any such additional development activities will be subject to a cost sharing or reimbursement arrangement to be determined by the parties.

Commercialization and Manufacturing

Under the Agreement, the parties will jointly conduct, and will have equal responsibility for, all medical affairs and commercialization activities pursuant to plans agreed by the parties. Akebia will remain responsible for manufacturing vadadustat.

Governance

The collaboration will be governed by a series of committees and working groups established by the parties and comprised of equal membership from each party. Akebia will retain final decision making authority with respect to all development matters, pricing and certain other key commercialization matters.

Term and Termination

Unless earlier terminated, the Agreement will expire when a generic version of vadadustat achieves 90% market penetration. Otsuka may terminate the Agreement in its entirety upon 12 months’ prior written notice after the release of the first topline data in the vadadustat global Phase 3 program. Either party may, subject to a cure period, terminate the Agreement in the event of the other party’s uncured material breach.

SIGNATURE

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 20, 2016

AKEBIA THERAPEUTICS, INC.

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