Akebia Therapeutics, Inc.
Form 8-K
April 25, 2017

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 25, 2017

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

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 25, 2017, Akebia Therapeutics, Inc. (Akebia) entered into a Collaboration and License Agreement (the Agreement) with Otsuka Pharmaceutical Co. Ltd. (Otsuka), pursuant to which Akebia granted Otsuka an exclusive license for the development and commercialization of vadadustat, Akebia s oral hypoxia-inducible factor (HIF) stabilizer currently in development for the treatment of anemia related to chronic kidney disease. The territory covered by the Agreement includes the European Union, Russia, China, Australia, Canada, the Middle East and certain other countries (the Territory), but excludes Latin America and other previously licensed countries. Under the Agreement, Otsuka will be responsible for certain development activities and commercializing vadadustat in the Territory, while Akebia will continue to lead the ongoing global Phase 3 development program. Otsuka will fund a significant percentage of the costs of such global development program regardless of the total actual costs ultimately incurred. This Agreement follows a previously announced collaboration between Akebia and Otsuka dated December 18, 2016 (the Prior Agreement) in which the parties equally share the costs of developing and commercializing vadadustat, as well as potential future sales of vadadustat, in the United States.

Financial Terms

Under the terms of the Agreement, Akebia expects Otsuka to pay Akebia at least $208 million, comprised of $73 million upon execution of the Agreement and at least $135 million of development funding. In addition, Akebia is eligible to receive from Otsuka up to an aggregate of $657 million in development and commercial milestones. Otsuka also agreed to make tiered, escalating royalty payments ranging from low double digits up to thirty percent of net sales of vadadustat within the Territory. In limited circumstances, upper tier royalties may be subject to reduction if the supply price charged by Akebia to Otsuka for vadadustat exceeds certain agreed upon thresholds. Otsuka may elect to conduct additional studies of vadadustat in the European Union, subject to Akebia s right to delay such studies based on its objectives outside the Territory. Otsuka will pay a percentage of the costs of any such studies, and Akebia will pay its portion of the costs in the form of a credit against future amounts due to Akebia under the Agreement.

Governance

The collaboration will be governed by joint committees and operational teams, leveraging the governance structure established in the Prior Agreement. Akebia will retain final decision making authority with respect to the manufacture and supply of vadadustat in the Territory, the global Phase 3 development program, and the global brand strategy for vadadustat. Otsuka will have final decision making authority with respect to certain Territory-specific development activities and commercialization matters in the Territory.

Term and Termination

Unless earlier terminated, the Agreement will expire upon the expiration of the royalty term in the last country in the Territory. The royalty term ends upon the later of the expiration of the patents licensed under the Agreement, the expiration of data or regulatory exclusivity for vadadustat, or 10 years from first commercial sale of vadadustat. Otsuka may terminate the Agreement for a certain sub-territory or 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.

The foregoing description of the Agreement does not purport to be complete, and is qualified in its entirety by reference to the Agreement, a copy of which we expect to file with our Quarterly Report on Form 10-Q for the quarter ending June 30, 2017. A copy of the Prior Agreement was filed with our Annual Report on Form 10-K for the fiscal year ending December 31, 2016 and is incorporated herein by reference.

Forward-Looking Statements

This current report includes forward-looking statements. Such forward-looking statements include those about Akebia s collaboration with Otsuka, including statements regarding the anticipated contributions from Otsuka pursuant to the Agreement, Otsuka s responsibilities pursuant to the Agreement and expectations for Otsuka s funding obligations pursuant to the Agreement, and the potential commercialization of vadadustat if approved by regulatory authorities. The words anticipate, appear, believe, estimate, expect, intend, may, plan, predict, proj potential, will, would, could, should, continue, and similar expressions are intended to identify forward-looki 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 Akebia will not achieve development or commercial milestones with vadadustat; the ability of Akebia or its collaborators to successfully complete the clinical development of vadadustat; that the funding required to develop Akebia s product candidates and operate the company and the actual expenses associated therewith may be greater than currently anticipated by management; the actual costs incurred in the global Phase 3 program for vadadustat and the availability of financing to cover such costs; the timing of any additional studies initiated by Akebia or its collaborators for vadadustat; the timing and content of decisions made by regulatory authorities; potential delays in Akebia s clinical programs as a result of capital constraints; the rate of enrollment in clinical studies of vadadustat; the actual time it takes to initiate and complete clinical studies; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; and Akebia s ability to obtain, maintain and enforce patent and other intellectual property protection for vadadustat around the world. Other risks and uncertainties include those identified under the heading Risk Factors in Akebia s Annual Report on Form 10-K for the year ended December 31, 2016, and other filings that Akebia may make with the Securities and Exchange Commission in the future. Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this current report.

Item 7.01 Regulation FD Disclosure

The information contained in this Item shall not be deemed filed for any purpose, and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, regardless of any general incorporation language in any such filing.

On April 25, 2017, the Company issued a press release announcing the agreement described in Item 1.01 of this Current Report on Form 8-K. A copy of the press release is attached to this report as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(d)

Exhibit No.	Description
99.1	Press Release of Akebia Therapeutics, Inc. dated April 25, 2017.

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.

By: /s/ John P. Butler
John P. Butler

President and Chief Executive Officer

Date: April 25, 2017