Akebia Therapeutics, Inc.
Form 8-K
May 15, 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)

May 12, 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, 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

License Agreement

On May 12, 2017, Akebia Therapeutics, Inc. (Akebia) entered into a License Agreement (the Agreement) with Vifor (International) Ltd. (Vifor), pursuant to which Akebia will grant Vifor an exclusive license to sell vadadustat solely to Fresenius Kidney Care Group LLC (FKC), an affiliate of Fresenius Medical Care North America, in the United States (the Territory). Vadadustat is Akebia s oral hypoxia-inducible factor (HIF) stabilizer currently in development for the treatment of anemia related to chronic kidney disease (CKD).

The parties rights under the Agreement are conditioned upon the approval of vadadustat for dialysis-dependent CKD patients by the U.S. Food and Drug Administration (FDA), inclusion of vadadustat in a bundled reimbursement model, and payment by Vifor of a $20 million milestone upon the occurrence of these two events. The Agreement is structured as a profit share arrangement between Akebia and Vifor in which Akebia will receive a majority of the profit from Vifor s sales of vadadustat to FKC in the Territory. Akebia will share the milestone payment and the revenue from the profit share with Otsuka Pharmaceutical Co., Ltd. (Otsuka) pursuant to Akebia s Collaboration and License Agreement with Otsuka in the United States. Akebia retains all rights to commercialize vadadustat for use in the non-dialysis dependent CKD market and in other dialysis organizations in the Territory, which will be done in collaboration with Otsuka following FDA approval.

Prior to FDA approval of vadadustat, Akebia and Vifor will enter into a commercial supply agreement for vadadustat pursuant to which Akebia will supply all of Vifor s requirements for vadadustat in the Territory. In addition, Vifor will enter into a supply agreement with FKC that will govern the terms pursuant to which Vifor will supply vadadustat to FKC for use in patients at its dialysis centers. During the term of the Agreement, Vifor will not sell to FKC or its affiliates any HIF product that competes with vadadustat in the Territory.

Unless earlier terminated, the Agreement will expire upon the later of the expiration of all patents that claim or cover vadadustat, or expiration of data or regulatory exclusivity for vadadustat in the Territory. Vifor may terminate the Agreement its entirety upon 12 months prior written notice after the release of the first topline data in the vadadustat global Phase 3 program for dialysis-dependent CKD patients. Either party may, subject to a cure period, terminate the Agreement in the event of the other party s uncured material breach. Akebia may also terminate the Agreement upon the occurrence of other events, such as for specific violations of the Agreement or if there are changes in Vifor s relationship with FKC.

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.

Investment Agreement

In connection with the Agreement, on May 12, 2017, Akebia and Vifor entered into an investment agreement (the Investment Agreement) pursuant to which Akebia sold an aggregate of 3,571,429 shares of common stock (the Shares), par value $0.00001 per share, to Vifor at a price per share of $14, which is approximately a 40% premium to Akebia s 90-day average stock price, for a total of $50 million dollars.

Vifor has agreed to a lock-up restriction such that it agrees not to sell its shares for a period of time following the effective date of the Investment Agreement as well as a customary standstill agreement. In addition, the Investment Agreement contains voting agreements made by Vifor with respect to the Shares. The Shares have not been registered pursuant to Securities Act of 1933 (the Act) and were issued and sold in reliance upon the exemption from registration contained in Section 4(a)(2) of the Act and Rule 506 promulgated thereunder.

The foregoing description of the Investment Agreement does not purport to be complete and is qualified in its entirety by reference to the Investment Agreement, a copy of which we expect to file with our Quarterly Report on Form 10-Q for the quarter ending June 30, 2017.

Item 3.02 Unregistered Sales of Equity Securities

The information regarding the Investment Agreement set forth in Item 1.01 is incorporated herein by reference.

Forward-Looking Statements

This current report includes forward-looking statements. Such forward-looking statements include those about Akebia s strategy, future plans and prospects, including statements about Akebia s relationship with Vifor, statements regarding the anticipated milestone and profit sharing payments from Vifor pursuant to the Agreement, and the potential commercialization of vadadustat if approved by the FDA. The words anticipate, appear, believe, estimate, expect, intend, may, plan, predict, project, target, potential, will, would, could, should, co expressions are intended to identify forward-looking 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 the milestone; the potential termination of the Agreement by Akebia or Vifor; 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 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. Other risks and uncertainties include those identified under the heading Risk Factors in Akebia s Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, 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 May 15, 2017, the Company issued a press release announcing the agreements described in Items 1.01 and 3.02 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

99.1 Press release of Akebia Therapeutics, Inc. dated May 15, 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: May 15, 2017