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 8, 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.

Amended and Restated License Agreement with Vifor (International) Ltd.

On April 8, 2019, Akebia Therapeutics, Inc. ("Akebia") and Vifor (International) Ltd. ("Vifor Pharma") amended the License Agreement that they entered into on May 12, 2017 (the "Original Agreement") by entering into an Amended and Restated License Agreement (the "Amended Agreement"), pursuant to which Akebia granted Vifor Pharma an exclusive license (the "License") to sell vadadustat to Fresenius Kidney Care Group LLC ("FKC"), an affiliate of Fresenius Medical Care North America ("FMCNA"), and to certain third party dialysis organizations approved by Akebia ("Third Party Dialysis Organizations") in the United States (the "Territory"). Vadadustat is Akebia's investigational oral hypoxia-inducible factor ("HIF") prolyl hydroxylase inhibitor currently in Phase 3 development for the treatment of anemia due to chronic kidney disease ("CKD").

The License granted under the Amended Agreement is subject to (i) the approval of vadadustat for dialysis-dependent CKD patients by the U.S. Food and Drug Administration ("FDA"), (ii) the earlier of a determination by the Centers for Medicare & Medicaid Services ("CMS") that vadadustat will be included in Medicare's bundled reimbursement model or that vadadustat will be reimbursed using the Transitional Drug Add-On Payment Adjustment ("TDAPA"), and (iii) payment by Vifor Pharma of a $25 million milestone upon the occurrence of (i) and (ii). Like the Original Agreement, the Amended Agreement is structured as a profit share arrangement between Akebia and Vifor Pharma in which Akebia will receive a majority of the profit, after deduction of certain amounts relating to Vifor Pharma's costs, from Vifor Pharma's sales of vadadustat to FKC and the Third Party Dialysis Organizations 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 currently retains 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.

The Amended Agreement provides that Akebia and Vifor Pharma will enter into a commercial supply agreement for vadadustat pursuant to which Akebia will supply all of Vifor Pharma's requirements for vadadustat in the Territory. In addition, Vifor Pharma will enter into supply arrangements with FKC and the Third Party Dialysis Organizations that will govern the terms pursuant to which Vifor Pharma will supply vadadustat to FKC and the Third Party Dialysis Organizations for use in patients at its dialysis centers. During the term of the Amended Agreement, Vifor Pharma is not permitted to sell any HIF product that competes with vadadustat in the Territory to FKC or its affiliates or to any Third Party Dialysis Organization, and Akebia may not directly supply vadadustat to FKC or any other affiliate of FMCNA or any Third Party Dialysis Organization.

Like the Original Agreement, unless earlier terminated, the Amended Agreement will expire upon the later of the expiration of all patents that claim or cover vadadustat or expiration of marketing or regulatory exclusivity for vadadustat in the Territory. Vifor Pharma may terminate the Amended 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 for dialysis-dependent CKD patients. In addition, either party may, subject to a cure period, terminate the Amended Agreement in the event of the other party's uncured material breach or bankruptcy. Akebia may also terminate the Amended Agreement (or suspend the License) upon the occurrence of other events, such as for specific violations of the Amended Agreement, Vifor Pharma's failure to achieve certain sales levels, or if there are changes in Vifor Pharma's relationship with FKC or in applicable laws and regulations related to the reimbursement of drugs like vadadustat at dialysis clinics, or if Vifor Pharma contests the validity or enforceability of any patent controlled by Akebia that covers vadadustat. The Amended Agreement also continues to include a standstill provision and customary representations and warranties.

Commercial Supply Agreement with Esteve Química, S.A.

On April 9, 2019, Akebia entered into a Supply Agreement ("Supply Agreement") with Esteve Química, S.A. ("Esteve"). The Supply Agreement includes the terms and conditions under which Esteve will manufacture vadadustat drug substance ("API") for commercial use.

Pursuant to the Supply Agreement, Akebia shall provide rolling forecasts to Esteve on a quarterly basis (the "Forecast"). The Forecast shall reflect Akebia's needs for API produced by Esteve over a certain number of months, represented as a quantity of API per calendar quarter. The parties have agreed to a volume-based pricing structure under the Supply Agreement.

The Supply Agreement has an initial term of four years, beginning April 9, 2019 and ending April 9, 2023. The Supply Agreement may be extended by mutual agreement of Akebia and Esteve. The Supply Agreement allows Akebia to terminate the relationship within one hundred and eighty (180) days' written notice for any reason, or by either party in the event of a material breach.

The Supply Agreement includes customary terms relating to, among others, indemnification, intellectual property protection, confidentiality, remedies, warranties, as well as certain quality requirements.

The foregoing descriptions of the Amended Agreement and the Supply Agreement do not purport to be complete and are qualified in their entirety by reference to the Amended Agreement and the Supply Agreement, respectively, copies of which Akebia expects to file as exhibits to its Quarterly Report on Form 10-Q for the quarter ending June 30, 2019.

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 the Amended Agreement, the commercial supply agreement with Vifor Pharma and the Supply Agreement. The words "anticipate," "appear," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar 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 or will not receive expected profits under the Amended Agreement; the potential termination of the Amended Agreement, the commercial supply agreement with Vifor Pharma, and/or the Supply Agreement; 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 or judicial 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 receipt and maintenance of regulatory approval of vadadustat; whether CMS will determine that vadadustat will be included in Medicare's bundled reimbursement model and/or that vadadustat will be reimbursed using the TDAPA; 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 Annual Report on Form 10-K for the year ended December 31, 2018, and other filings that Akebia may make with the U.S. 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.

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 10, 2019

By: /s/ John P. Butler

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