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," "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 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

Akebia and Otsuka Expand Relationship with Collaboration to Develop and Commercialize Vadadustat in Europe, China and Other Territories

– Maximizes Efficiency of Global Development and Commercialization –

– Committed Capital and Potential Milestone Payments from Otsuka of up to $865 Million, Including $208 million or More in Upfront Payment and Development Funding, as well as Tiered, Double-Digit Royalties –

– Total Committed Development Funding from all of Akebia's Vadadustat Collaborations Plus Cash Exceeds $600 Million –

– Akebia to Host Conference Call at 4:30 p.m. Eastern Time Today –

CAMBRIDGE, MA & TOKYO, JAPAN — April 25, 2017 Akebia Therapeutics, Inc. (NASDAQ: AKBA) and Otsuka Pharmaceutical Co., Ltd. today announced that they have expanded their collaboration for vadadustat by entering into a collaboration and license agreement for Europe, China and other territories. Vadadustat is an oral hypoxia-inducible factor (HIF) stabilizer currently in Phase 3 development for the treatment of anemia associated with chronic kidney disease (CKD). Anemia related to CKD arises from the kidney's failure to produce adequate amounts of erythropoietin, a key hormone stimulating the production of red blood cells.[1] Left untreated, anemia significantly accelerates patients' overall deterioration of health with increased morbidity and mortality. [2, 3]

This agreement follows a previously announced collaboration between the companies in which they equally share the costs of developing and commercializing vadadustat in the United States, as well as the profits from potential future sales of vadadustat in the $3.5 billion renal anemia market. The total committed development funding from all vadadustat collaborations, combined with Akebia's cash, is expected to exceed $600 million.

Under the terms of this collaboration agreement, Akebia will receive $208 million or more in committed capital from Otsuka, including $73 million upon signing and $135 million or more of development funding. In addition, Akebia is eligible to receive up to $657 million in milestone payments, representing a total transaction value of approximately $865 million. Otsuka will also make tiered, double-digit royalty payments of up to 30% on net sales of vadadustat in Otsuka's territory, which includes Europe, Russia, China, Canada, Australia and the Middle East, but excludes Latin America and other previously licensed countries. In the five major markets in Europe, sales of erythropoiesis stimulating agents (ESAs), the current standard of care for the treatment of renal anemia, were approximately $1.5 billion. [4]

Mr. Tatsuo Higuchi, president and representative director of Otsuka Pharmaceutical Co., Ltd., commented, "Thanks to Akebia's expertise in developing vadadustat, we anticipate that it holds significant promise for renal anemia. We are also convinced that by strengthening our cardio-renal portfolio with a drug candidate like this, following our own tolvaptan, we can contribute to changing the standard of care worldwide for patients with complex kidney diseases."

“We are very pleased to expand our strategic relationship with Otsuka, a company who shares our vision to improve the lives of patients with kidney disease,” stated John P. Butler, President and Chief Executive Officer of Akebia. “We now have a single, strong collaborator for the two largest markets, the U.S. and Europe. This simplifies governance and decision making, maximizing the efficiency of our global Phase 3 development program and ultimately the commercialization of vadadustat. We are able to accomplish this while obtaining substantial funding for our vadadustat development program and retaining significant long-term value for Akebia.”

Akebia has established three significant collaborations for vadadustat in a little over a year, which together total more than $2.2 billion in potential value and include $573 million or more in upfront payments and committed development funding. In addition to this agreement and the U.S. collaboration with Otsuka, Akebia has established a collaboration with Mitsubishi Tanabe Pharma Corporation for the development and commercialization of vadadustat in Japan, Taiwan, South Korea, Indonesia, India and select other countries in Asia.

Conference Call and Webcast

Akebia management will host a conference call to review the details of the transaction beginning at 4:30 p.m. Eastern Time today, Tuesday, April 25, 2017. A live audio webcast of the presentation will be available on the company’s website at http://ir.akebia.com/events.cfm. An archived presentation will be available for 90 days.

To access the conference call, follow these instructions:

Dial: (877) 458-0977 (U.S.); (484) 653-6724 (international)
Conference ID: 12787133

About Vadadustat

Vadadustat is an oral hypoxia-inducible factor (HIF) stabilizer currently in development for the treatment of anemia related to chronic kidney disease. Vadadustat exploits the same mechanism of action used by the body to adapt naturally to lower oxygen availability associated with a moderate increase in altitude. At higher altitudes, the body responds to lower oxygen availability with increased production of HIF, which coordinates the interdependent processes of iron mobilization and erythropoietin production to increase red blood cell production and, ultimately, improve oxygen delivery.

About Anemia Associated with CKD

Anemia results from the body’s inability to coordinate red blood cell production in response to lower oxygen levels due to the progressive loss of kidney function with inadequate erythropoietin production. Left untreated, anemia significantly accelerates patients’ overall deterioration of health with increased morbidity and mortality. Anemia is currently treated with injectable recombinant erythropoiesis stimulating agents, which are associated with inconsistent hemoglobin responses and well-documented safety risks.[5] The prevalence of anemia increases with the severity of CKD and is higher in people with CKD who are over age 60.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a biopharmaceutical company headquartered in Cambridge, Massachusetts, focused on delivering innovative therapies to patients with kidney disease through hypoxia-inducible factor biology. Akebia's lead product candidate, vadadustat, is an oral, investigational therapy in development for the treatment of anemia related to chronic kidney disease in both non-dialysis and dialysis patients. Akebia's global Phase 3 program for vadadustat, which includes the PRO_2TECT studies for non-dialysis patients with anemia secondary to chronic kidney disease and the $INNO_2VATE$ studies for dialysis-dependent patients, is currently ongoing. For more information, please visit our website at www.akebia.com.

About Otsuka

Otsuka Pharmaceutical is a global healthcare company with the corporate philosophy: "Otsuka – people creating new products for better health worldwide." Otsuka researches, develops, manufactures and markets innovative and original products, with a focus on pharmaceutical products to meet unmet medical needs and nutraceutical products for the maintenance of everyday health.

In pharmaceuticals, Otsuka is a leader in the challenging area of mental health and also has research programs on several under-addressed diseases including tuberculosis, a significant global public health issue. These commitments illustrate how Otsuka is a "big venture" company at heart, applying a youthful spirit of creativity in everything it does.

Otsuka Pharmaceutical is a subsidiary of Otsuka Holdings Co., Ltd., headquartered in Tokyo, Japan, with 2016 consolidated sales of approximately $11 billion.

All Otsuka stories start by taking the road less travelled. Learn more about Otsuka in the U.S. at www.otsuka-us.com and connect with us on LinkedIn and Twitter at @OtsukaUS. Otsuka Pharmaceutical Co., Ltd.'s global website is accessible at www.otsuka.co.jp/en/.

Forward-Looking Statements

This press release includes forward-looking statements. Such forward-looking statements include those about Akebia's strategy, future plans and prospects, including statements regarding the potential indications and benefits of vadadustat, the potential commercialization of vadadustat if approved by regulatory authorities, anticipated contributions from Otsuka pursuant to the Collaboration and License Agreement, Otsuka's responsibilities pursuant to the Agreement, and the amount of collaboration-related funds able to be realized by Akebia. 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 existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; the ability of

Akebia to successfully complete the clinical development program for vadadustat; the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the actual costs incurred in the global Phase 3 studies of 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; the rate of enrollment in clinical studies of vadadustat; the actual time it takes to initiate and complete clinical studies; Akebia's ability to satisfy its obligations under the Collaboration and License Agreement; early termination of the Collaboration and License Agreement by Akebia or Otsuka, 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 press release.

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2 Culleton B, Manns B, Zhang J, et al. Impact of anemia on hospitalization and mortality in older adults. Blood. 2006;107(10): 3841-3846.
3 Portolés J, Gorriz J, Rubio E, et al. The development of anemia is associated to poor prognosis in NKF/KDOQI stage 3 chronic kidney disease. BMC Nephrology. 2013;14 (1):2.
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