

Akebia Therapeutics, Inc.
Form 8-K
December 14, 2015

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 11, 2015

AKEBIA THERAPEUTICS, INC.

(Exact name of registrant as specified in charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-36352
(Commission
File Number)

20-8756903
(I.R.S. Employer
Identification No.)

Edgar Filing: Akebia Therapeutics, Inc. - Form 8-K
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)

Not Applicable

(Former name or former address, if changed since last report)

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 11, 2015, Akebia Therapeutics, Inc. (Akebia) and Mitsubishi Tanabe Pharma Corporation (MTPC) entered into a collaboration agreement (the Agreement) providing MTPC with exclusive development and commercialization rights to vadadustat (formerly known as AKB-6548), Akebia s product candidate for the treatment of anemia related to chronic kidney disease, in Japan and certain other Asian countries (collectively, the Territory).

Pursuant to the Agreement, MTPC will have an exclusive license to develop and commercialize vadadustat in the Territory. In addition, Akebia will supply vadadustat to MTPC for both clinical and commercial use in the Territory. The countries included in the Territory are Japan, Taiwan, South Korea, Singapore, Malaysia, India, Indonesia, East Timor, Mongolia, the Philippines, Vietnam, Laos, Cambodia, Thailand, Brunei, Myanmar, Nepal, Sri Lanka, Bangladesh, Bhutan, Maldives, Palau and Tonga.

In consideration for the exclusive license and other rights contained in the Agreement, MTPC will make payments totaling up to \$100 million to fund the vadadustat global Phase 3 program, including \$40 million upon signing. In addition, Akebia is eligible to receive up to approximately \$250 million in additional milestone payments, based upon achievement of certain development and sales milestones. MTPC also agreed to make tiered royalty payments, from low teens up to twenty percent, on sales of vadadustat in the Territory.

Akebia and MTPC will establish a joint steering committee to oversee development and commercialization of vadadustat in the Territory, including approval of any development or commercialization plans. Unless earlier terminated, the Agreement will continue in effect on a country-by-country basis until the later of: expiration of the last-to-expire patent covering vadadustat in such country in the Territory; expiration of marketing or regulatory exclusivity in such country in the Territory; or ten (10) years after the first commercial sale of vadadustat in such country in the Territory. MTPC may terminate the Agreement upon twelve (12) months notice at any time after the second anniversary of the effective date of the Agreement. Either party may terminate the Agreement upon the material breach of the other party that is not cured within a specified time period or upon the insolvency of the other party.

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: December 14, 2015