
**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)
March 9, 2016

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.)

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))
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Item 7.01 Regulation FD Disclosure.

On March 9, 2016, the Company issued a press release announcing the successful outcome of an oral hearing held March 8-9, 2016 before the Opposition Division of the European Patent Office regarding FibroGen's European Patent EP 1 463 823. A copy of the press release is attached to this report as Exhibit 99.1.

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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Akebia Therapeutics, Inc. dated March 9, 2016

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: March 9, 2016

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Akebia Therapeutics, Inc. dated March 9, 2016



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www.akebia.com

Akebia Prevails in European Patent Dispute and Preserves Access to Key Market for Vadadustat

CAMBRIDGE, Mass. – March 9, 2016 - Akebia Therapeutics, Inc. (NASDAQ:AKBA), a biopharmaceutical company focused on delivering innovative therapies to patients with kidney disease through the biology of hypoxia inducible factor (HIF), today announced that the Opposition Division (OD) of the European Patent Office (EPO) has revoked FibroGen, Inc.'s European Patent EP 1 463 823 (the '823 patent) in its entirety.

In an oral proceeding on March 8-9, 2016, the OD ruled that the patent as granted did not meet the requirements for patentability under the European Patent Convention. The written decision consistent with the oral ruling is expected within a few months.

"We are pleased with this decision by the European Patent Office and remain focused on executing our global commercialization strategy for vadadustat in anemia associated with chronic kidney disease," stated John P. Butler, President and Chief Executive Officer of Akebia. "We look forward to establishing a European collaboration that complements our recent agreement with Mitsubishi Tanabe in Japan and other Asian countries. In addition, we continue to advance enrollment in our PRO₂TECT Phase 3 program for non-dialysis patients, and look forward to beginning our program to evaluate vadadustat in dialysis patients later this year."

In June 2013, the EPO granted the '823 patent to FibroGen, Inc. The '823 patent claimed, among other things, the use of a heterocyclic carboxamide compound selected from the group consisting of pyridine carboxamides, quinoline carboxamides, isoquinoline carboxamides, cinnoline carboxamides, and beta-carboline carboxamides that inhibits HIF-PH enzyme activity in the manufacture of a medicament for increasing endogenous erythropoietin in the prevention, pretreatment or treatment of anemia. On December 5, 2013, Akebia filed an opposition to the '823 patent requesting that the '823 patent be revoked in its entirety. On August 4, 2015, the OD issued a non-binding preliminary opinion that none of the '823 patent's claims met the requirements for patentability. In today's decision, the OD confirmed that none of the '823 patent's claims met the requirements for patentability and, therefore, revoked the patent in its entirety.

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 (HIF) biology. Akebia has completed Phase 2 development of its lead product candidate, vadadustat (formerly AKB-6548), an oral therapy for the treatment of anemia related to chronic kidney disease (CKD) in both non-dialysis and dialysis patients. Enrollment in the PRO₂TECT Phase 3 program in non-dialysis commenced in late 2015 and the INNO₂VATE Phase 3 program in dialysis-dependent CKD patients is expected to commence in 2016. For more information, please visit our website at www.akebia.com.

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 timing of the INNO₂VATE and PRO₂TECT clinical programs, and the establishment of a European collaboration. 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 of vadadustat;

the funding required to develop Akebia's product candidates and operate the company, and the actual expenses associated therewith; the cost of the Phase 3 studies of vadadustat and the availability of financing to cover such costs; the timing and content of decisions made by the FDA and other regulatory authorities; the rate of enrollment in clinical studies of vadadustat; the actual time it takes to prepare for and initiate clinical studies; the success of competitors in developing product candidates for diseases for which Akebia is currently developing its product candidates; Akebia's ability to negotiate commercially reasonable terms with a European company to commercialize vadadustat; 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 September 30, 2015, 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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