

Akebia Therapeutics, Inc.
Form 8-K
October 06, 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):

October 6, 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
(IRS Employer
Identification No.)

245 First Street, Suite 1100, Cambridge, Massachusetts 02142

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(Address of Principal Executive Offices) (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 (*see* General Instruction A.2. below):

- .. 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 7.01 Regulation FD Disclosure.

On October 6, 2015, the Company issued a press release announcing that the company has reached agreement with the United States Food and Drug Administration and the European Medicines Agency regarding key elements of the global Phase 3 program for its lead product, vadadustat (formerly AKB-6548), for patients with anemia related to non-dialysis dependent chronic kidney disease. 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

| Exhibit No. | Description |
|--------------------|---------------------------------------|
| 99.1 | Press Release, dated October 6, 2015. |

SIGNATURE

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.

/s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

Date: October 6, 2015

EXHIBIT INDEX

| Exhibit No. | Description |
|--------------------|---|
| 99.1 | Press Release of Akebia Therapeutics, Inc. dated October 6, 2015. |