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): **July 18, 2023**

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

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.00001 per share	**AKBA**	**The Nasdaq Capital Market**

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 7.01. Regulation FD Disclosure.

On July 18, 2023, Akebia Therapeutics, Inc. (the "Company") issued the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The information in this Item 7.01 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On July 18, 2023, the Company announced that it completed an End of Dispute Type A meeting with the U.S. Food and Drug Administration ("FDA") to discuss the Company's forthcoming resubmission of its New Drug Application ("NDA") for vadadustat as a treatment for anemia due to chronic kidney disease in adult patients on dialysis. The Company expects to resubmit its NDA for vadadustat to the FDA by the end of the third quarter of 2023.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated July 18, 2023, issued by Akebia Therapeutics, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: July 18, 2023

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

Akebia Therapeutics Completed Type A Meeting with the FDA and Expects to Resubmit Vadadustat NDA in Third Quarter 2023

CAMBRIDGE, Mass.—July 18, 2023—Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced that Akebia completed an End of Dispute Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss Akebia's forthcoming resubmission of its New Drug Application (NDA) for vadadustat as a treatment for anemia due to chronic kidney disease (CKD) in adult patients on dialysis.

"We're pleased to report we recently met with the FDA to align on the content of our NDA resubmission for vadadustat," said John P. Butler, Chief Executive Officer of Akebia. "The meeting was informative and productive, and we're eager to advance the U.S. regulatory process and potentially bring a new oral treatment to dialysis patients with anemia due to CKD."

Akebia expects to receive the FDA's meeting minutes by mid-August and plans to resubmit its NDA for vadadustat by the end of the third quarter of 2023. Upon acceptance of the NDA, Akebia expects the FDA to set a PDUFA date of six months from the date of submission.

Vadadustat is currently approved for use in 34 countries, it was most recently approved by the Swiss Agency for Therapeutic Products (Swissmedic) in June 2023. Vafseo® (vadadustat) is marketed in Japan by Mitsubishi Tanabe Pharma Corporation.

About Akebia Therapeutics
Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease. The Company was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

About Vadadustat
Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxia-inducible factor, which can lead to increased red blood cell production and improved oxygen delivery to tissues. Vadadustat is not approved by the U.S. Food and Drug Administration (FDA). Vadadustat is approved in Europe for the treatment of symptomatic anemia due to CKD in adult patients on chronic maintenance dialysis. In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

Important Safety Information
For safety information, view the European Summary of Product Characteristics (SPC/SmPC) for Vafseo® (vadadustat) at https://ec.europa.eu/health/documents/community-register/2023/20230424158854/anx_158854_en.pdf, https://products.mhra.gov.uk/, and will be available via SwissMedic here.

Forward Looking Statement
Statements in this press release regarding Akebia Therapeutics, Inc.'s (Akebia's) strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, and include, but are not limited to, statements regarding: Akebia's expectations and plans with respect to the resubmission of its NDA for vadadustat, including the timing thereof and data to be included therein; Akebia's expectations regarding the timing for a decision by the FDA on its NDA for vadadustat once resubmitted and statements regarding the potential to bring vadadustat to dialysis patients with anemia due to CKD. The terms "expect," "intend," "believe," "plan," "goal," "potential," "will," "continue," derivatives of these words and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to, risks associated with: decisions made by the FDA with respect to Akebia's resubmission of its NDA for vadadustat; the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, vadadustat; the results of preclinical and clinical research; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; the direct or indirect impact of the COVID-19 pandemic on regulators and Akebia's business, operations and the markets and communities in which Akebia and its partners, collaborators, vendors and customers operate; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; and the competitive landscape for vadadustat, if approved. 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 March 31, 2023 and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

Akebia Therapeutics Contact
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