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): May 12, 2022

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 Global 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 1.02 Termination of a Material Definitive Agreement.

International Collaboration and License Agreement with Otsuka Pharmaceutical Co. Ltd.

On May 12, 2022, Akebia Therapeutics, Inc. (the "Company") received written notice from Otsuka Pharmaceutical Co. Ltd. ("Otsuka") that Otsuka has elected to terminate the Collaboration and License Agreement dated April 25, 2017 (the "Otsuka International Agreement"). Otsuka exercised its right to terminate the Otsuka International Agreement for convenience and, in accordance with the terms of the Otsuka International Agreement and the notice of termination, the termination will be effective on May 13, 2023 (the "International Termination Effective Date").

Under the terms of the Otsuka International Agreement, the Company granted to Otsuka an exclusive, sublicensable license under certain intellectual property controlled by the Company to develop and commercialize vadadustat, the Company's lead investigational product candidate for which it received a complete response letter from the U.S. Food and Drug Administration (the "FDA") in March 2022, in Europe, Russia, China, Canada, Australia, the Middle East and certain other territories (collectively, the "Otsuka International Territory"). Additionally, under the terms of the Otsuka International Agreement, the Company is responsible for leading the development of vadadustat, and Otsuka has the sole responsibility, at its own cost, for the commercialization of vadadustat in the Otsuka International Territory, subject to the approval by the relevant regulatory authorities.

Otsuka submitted a Marketing Authorization Application for vadadustat for the treatment of anemia due to chronic kidney disease in adult patients on dialysis and not on dialysis to the European Medicines Agency (the "EMA") in October 2021 and submitted applications for regulatory approval in the United Kingdom, Switzerland and Australia in March 2022. The Company has supported, and intends to continue to support, the regulatory approval process in those jurisdictions.

The foregoing summary of the terms of the Otsuka International Agreement is qualified in its entirety by reference to the full text of the Otsuka International Agreement, which was filed with the U.S. Securities and Exchange Commission (the "SEC") as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (001-36352) on August 8, 2017 and is incorporated by reference herein.

U.S. Collaboration and License Agreement with Otsuka Pharmaceutical Co. Ltd.

On May 12, 2022, the Company also received written notice from Otsuka that Otsuka has elected to terminate the Collaboration and License Agreement dated December 18, 2016 (the "Otsuka U.S. Agreement"). Otsuka exercised its right to terminate the Otsuka U.S. Agreement for convenience, and in accordance with the terms of the Otsuka U.S. Agreement and the notice of termination, the termination will be effective on May 13, 2023 (the "U.S. Termination Effective Date"). In addition and in the alternative, Otsuka has provided notice of termination for alleged material breaches by the Company under the Otsuka U.S. Agreement, which alleged breaches, if not cured, could result in an earlier termination of the Otsuka U.S. Agreement effective as early as June 12, 2022. However, the Company disagrees with, and intends to dispute, Otsuka's allegations of material breach and does not believe that Otsuka has a right to terminate the Otsuka U.S. Agreement for material breach, and accordingly believes that the termination of the Otsuka U.S. Agreement should not be effective prior to the U.S. Termination Effective Date.

The Otsuka U.S. Agreement provides that that Company will co-commercialize vadadustat in the United States with Otsuka, subject to the approval of vadadustat by the FDA, and that the Company would control and retain final decision-making authority with respect to certain matters. The Company is responsible for leading the development of vadadustat. Under the Otsuka U.S. Agreement and the Otsuka International Agreement, Otsuka currently funds 80% of our global development costs for vadadustat.

In addition, as a result of the termination of the Otsuka U.S. Agreement as well as the Otsuka International Agreement, the Company will regain exclusive rights to develop and commercialize vadadustat worldwide, other than in Japan and certain other Asian countries, which territory is the subject of the Company's Collaboration Agreement with Mitsubishi Tanabe Pharma Corporation.

The foregoing summary of the terms of the Otsuka U.S. Agreement is qualified in its entirety by reference to the full text of the Otsuka U.S. Agreement, which was filed with the SEC as Exhibit 10.26 to the Company's Annual Report on Form 10-K (001-36352) on March 6, 2017 and is incorporated by reference herein.

Item 3.01 Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On May 12, 2022, the Company received a deficiency letter from the Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market ("Nasdaq") notifying the Company that, for the last 30 consecutive business days, the bid price for the Company's common stock, par value $0.00001 per share (the "Common Stock"), had closed below the $1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Bid Price Requirement").

In accordance with Nasdaq Listing Rule 5810(c)(3)(A) (the "Compliance Period Rule"), the Company has been provided a period of 180 calendar days, or until November 8, 2022 (the "Compliance Date"), to regain compliance with the Bid Price Requirement. If, at any time before the Compliance Date, the bid price for the Common Stock closes at $1.00 or more for a minimum of 10 consecutive business days as required under the Compliance Period Rule (unless the Staff exercises its discretion to extend this ten-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H)), the Staff will provide written notification to the Company that it has regained compliance with the Bid Price Requirement.

If the Company does not regain compliance with the Bid Price Requirement by the Compliance Date, the Company may be eligible for an additional 180 calendar day compliance period. To qualify, the Company would need to transfer the listing of the Common Stock to the Nasdaq Capital Market, provided that it meets the continued listing requirement for the market value of publicly held shares and all other initial listing standards, with the exception of the Bid Price Requirement. To effect such a transfer, the Company would also need to pay an application fee to Nasdaq and will need to provide written notice to the Staff of its intention to cure the deficiency during the additional compliance period by effecting a reverse stock split, if necessary. As part of its review process, the Staff will make a determination of whether it believes the Company will be able to cure this deficiency.

Should the Staff conclude that the Company will not be able to cure the deficiency, or should the Company determine not to submit an application for transfer to the Nasdaq Capital Market or notify the Staff of its intention to cure the deficiency, the Staff will provide written notification to the Company that the Common Stock will be subject to delisting. At that time, the Company may appeal the Staff's delisting determination to a Nasdaq Listing Qualifications Panel (the "Panel"). However, there can be no assurance that, if the Company receives a delisting notice and appeals the delisting determination by the Staff to the Panel, such appeal would be successful.

The Company intends to monitor the closing bid price of the Common Stock and may, if appropriate, consider available options to regain compliance with the Bid Price Requirement, which could include seeking to effect a reverse stock split. However, there can be no assurance that the Company will be able to regain compliance with the Bid Price Requirement.

Forward-Looking Statements

Statements in this Current Report on Form 8-K regarding the Company'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. The terms "believe," "expect," "potential," "will," "continue," "intend," 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 those identified under the heading "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, and other filings that the Company may make with the SEC in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this Current Report on Form 8-K, and, except as required by law, the Company does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this Current Report on Form 8-K.

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: May 13, 2022

By: /s/ John P. Butler
Name: John P. Butler
Title: President and Chief Executive Officer