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): June 30, 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 1.01 Entry into a Material Definitive Agreement.

On June 30, 2022, Akebia Therapeutics, Inc. (the "**Company**") and Otsuka Pharmaceutical Co. Ltd. ("**Otsuka**") entered into a Termination and Settlement Agreement (the "**Termination Agreement**"), pursuant to which, among other things, the Company and Otsuka agreed to terminate, effective as of June 30, 2022 (the "**Termination Effective Date**"), (i) the Collaboration and License Agreement, dated April 25, 2017, by and between the Company and Otsuka (the "**Otsuka International Agreement**") and (ii) the Collaboration and License Agreement, dated December 18, 2016, by and between the Company and Otsuka (the "**Otsuka U.S. Agreement**" and, together with the Otsuka International Agreement, collectively, the "**Collaboration Agreements**").

As the Company previously announced on a Current Report on Form 8-K filed with the Securities and Exchange Commission on May 13, 2022, Otsuka gave the Company notice of termination of the Collaboration Agreements. Under the terms of the Termination Agreement, Otsuka will (i) pay the Company a nonrefundable and non-creditable payment of $55,000,000 in consideration for the covenants and agreements set forth in the Termination Agreement, including the settlement and release of all disputes and claims as provided therein; (ii) if, on or prior to May 13, 2023, Otsuka is refunded any fees that it has paid to a relevant regulatory authority in connection with the filing or review of a marketing authorization application ("**MAA**") for vadadustat, and the Company is required to pay fees in connection with the transfer of such MAA from Otsuka to the Company, Otsuka will pay to the Company the amount of such fees refunded to Otsuka; and (iii) if, on or prior to May 13, 2023, Otsuka is refunded any fees that it has paid to the National Institute for Health and Care Excellence ("**NICE**") in connection with the Health Technology Assessment ("**HTA**") process for vadadustat, and the Company is required to pay fees to NICE in connection with the transfer of the HTA process from Otsuka to the Company, Otsuka will pay to the Company the amount of such fees refunded to Otsuka. Pursuant to the Termination Agreement, the Company and Otsuka expressly waived any right to receive any other or additional payment under the Collaboration Agreements (and certain other agreements between the Company and Otsuka), including any amounts associated with milestone payments, royalties, research and development cost sharing, revenue sharing, excess cost sharing or intellectual property matters. In addition, each of the Company and Otsuka have released one another from all existing and future claims and liabilities arising from the Collaboration Agreements and certain other agreements between the Company and Otsuka, subject to certain customary exceptions.

Subject to certain conditions, until the transfer of each MAA held by Otsuka for vadadustat to the Company with respect to the EU, the United Kingdom, Switzerland and Australia (or, if applicable, until withdrawal of the MAA(s)), Otsuka will remain the "sponsor" of such MAAs and will be the party responsible for submitting all regulatory submissions related to such MAAs in such jurisdictions; however, the Company and Otsuka will collaborate with respect to such MAA regulatory submissions, and the Company will have final decision-making authority with respect to the content of such regulatory submissions. The Company and Otsuka have agreed to a schedule by which the parties will work to transfer the MAA for vadadustat with the European Medicines Agency (the "**EMA**") to the Company. If such MAA transfer request is disapproved or not approved by the EMA within a specified timeframe, then Otsuka will have the right to withdraw such MAA. Upon receipt of approval from the EMA for the transfer of the MAA, Otsuka will assign and transfer to the Company such MAA, together with all other related regulatory submissions that are in the possession or control of Otsuka or any of its affiliates.

Similarly, the Company and Otsuka have agreed to discuss a schedule by which the parties will work to transfer the MAA for vadadustat in each of the United Kingdom, Switzerland, and Australia. If the parties cannot agree on such schedule for work related to the transfer of such MAAs or if such MAA transfer requests are not approved by the relevant regulatory authorities within specified timeframes, then Otsuka will have the right to withdraw such MAAs. Upon approval by the relevant regulatory authority, Otsuka will assign and transfer to the Company each such MAA, together with all other related regulatory submissions that are in the possession or control of Otsuka or any of its affiliates submitted to or received from the relevant regulatory authorities in such jurisdiction.

Pursuant to the terms of the Termination Agreement, each of Otsuka and the Company will complete certain agreed clinical activities, in accordance with the current study protocol, at each of its own respective cost and expense, related to the Phase 3b clinical trial of vadadustat Otsuka is conducting (the "**MODIFY Study**"). In addition, Otsuka will complete certain agreed packaging validation activities related to European supply at its sole cost and

expense. Otsuka has notified NICE that responsibility for the Health Technology Assessment (the "**HTA**") process relating to pricing and reimbursement of vadadustat in England and Wales should be transferred to the Company and has requested that the HTA process with NICE be deferred for a period of at least twelve (12) months. If, notwithstanding such request, the HTA process cannot be deferred, Otsuka will have the right to withdraw from the HTA process.

The foregoing description of the Termination Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement, a copy of which will be filed as an exhibit to a subsequent filing with the Securities and Exchange Commission.

Item 1.02 Termination of a Material Definitive Agreement.

The information contained in Item 1.01 of this Current Report on Form 8-K is incorporated by reference herein and made a part hereof.

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, and include, but are not limited to, statements regarding activities under the Termination Agreement. 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: June 30, 2022

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