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): December 22, 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 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 1.01 Entry into a Material Definitive Agreement.

Averoa License Agreement

On December 22, 2022 (the "Effective Date"), Akebia Therapeutics, Inc. (the "Company"), Keryx Biopharmaceuticals, Inc., a wholly-owned subsidiary of the Company ("Keryx"), and Averoa SAS ("Averoa") entered into a License Agreement (the "License Agreement") pursuant to which the Company granted to Averoa an exclusive license to develop and commercialize ferric citrate (the "Licensed Product") in the European Economic Area, Turkey, Switzerland and the United Kingdom (the "Territory").

Under the License Agreement, the Company is entitled to receive tiered, escalating royalties ranging from a mid-single digit percentage to a low double-digit percentage of Averoa's annual net sales of the Licensed Product in the Territory, including certain minimum royalty amounts in certain years, and subject to reduction in certain circumstances. The royalties will expire on a country-by-country basis upon the latest to occur of (a) 10 years following the date of first commercial sale of the Licensed Product in such country; (b) expiration of the last valid claim of Company patent rights and joint patent rights in such country; and (c) the date of expiration of the data, regulatory, or marketing exclusivity period conferred by the applicable regulatory authority in such country with respect to the Licensed Product.

The Company and Averoa will establish a joint steering committee to oversee the development, manufacturing and commercialization of the Licensed Product in the Territory.

The License Agreement expires on the date of expiration of all royalty obligations due thereunder with respect to the Licensed Product on a country-by-country basis in the Territory, unless earlier terminated in accordance with the agreement. Either party may, subject to a cure period, terminate the License Agreement in the event of the other party's uncured material breach. Averoa has the right to terminate the License Agreement for convenience upon 12 months' prior written notice delivered on or after the date that is 12 months after the Effective Date. In addition, Averoa has the right to terminate the License Agreement upon 30 days' notice if the European Medicines Agency (EMA) rejects Averoa's marketing authorization application ("MAA") for the Licensed Product and the parties in good faith agree that submitting a new MAA to the EMA will not result in approval. The License Agreement includes customary terms relating to, among others, indemnification, confidentiality, remedies, and representations and warranties.

The License Agreement provides that the Company and Averoa will enter into a supply agreement pursuant to which the Company will supply the Licensed Product to Averoa for commercial use in the Territory. The Company will have the right to terminate the Supply Agreement for convenience upon 24 months' notice, which may be provided on or after January 1, 2024.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirety by reference to the License Agreement, a copy of which the Company expects to file as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2022.

BioVectra Termination Agreement

On December 22, 2022, Keryx and BioVectra Inc. ("BioVectra"), entered into a termination and settlement agreement (the "Termination Agreement"). Pursuant to the Termination Agreement, Keryx and BioVectra agreed, among other things, to terminate, effective immediately, any and all existing agreements entered into between the parties in connection with the manufacture and supply, by BioVectra to the Company, of ferric citrate drug substance (the "Product") for the Company's proprietary product, Auryxia, including but not limited to that certain Manufacture and Supply Agreement, dated May 26, 2017, as amended by the Amendment to Manufacture and Supply Agreement, dated December 11, 2017 (the "Manufacture and Supply Agreement"), and that certain Amended and Restated Product Manufacture and Supply and Facility Construction Agreement, dated September 4, 2020 (the "Supply and Facility Construction Agreement") (such agreements, collectively, the "BioVectra Agreements"). The parties agreed to terminate the BioVectra Agreements for business reasons.

Under the terms of the Termination Agreement, the Company has agreed to pay to BioVectra a total of $32,500,000, consisting of (i) an upfront payment of $17,500,000 and (ii) six quarterly payments of $2,500,000 starting in April 2024, in consideration for the termination of the BioVectra Agreements and all obligations thereunder, and the covenants and agreements set forth in the Termination Agreement, including the settlement and release of all disputes and claims and the return of certain materials and documents as provided therein. In addition, each of the Company and BioVectra have released one another from all existing and future claims and liabilities arising from the BioVectra Agreements, subject to certain customary exceptions.

The Manufacture and Supply Agreement and the Supply and Facility Construction Agreement provided that the Company would purchase minimum quantities of the Product annually at predetermined prices. In addition, the Manufacture and Supply Agreement and the Supply and Facility Construction Agreement required the Company to reimburse BioVectra for certain costs in connection with construction of a new facility for the manufacture and supply of the Product. The foregoing summary of the BioVectra Agreements do not purport to be complete, and are subject to and are qualified in their entirety by the terms of each of (i) the Manufacture and Supply Agreement (incorporated by reference to Exhibit 10.61 to the Company's Annual Report on Form 10-K (001-36352), filed on March 26, 2019) and (ii) the Supply and Facility Construction Agreement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (001-36352), filed on September 11, 2020).

The foregoing description of the Termination Agreement does not purport to be complete and is qualified in its entirety by reference to the Termination Agreement, a copy of which the Company expects to file as an exhibit to its Annual Report on Form 10-K for the year ending December 31, 2022.

Item 1.02 Termination of a Material Definitive Agreement.

The information contained in Item 1.01 of this Current Report on Form 8-K under the heading "BioVectra Termination Agreement" is incorporated by reference herein and made a part hereof.

Item 2.05 Costs Associated with Exit or Disposal Activities.

The information contained in Item 1.01 of this Current Report on Form 8-K under the heading "BioVectra Termination Agreement" is incorporated by reference herein and made a part hereof.

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: December 28, 2022

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