

**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): February 10, 2021**

**AKEBIA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36352**  
(Commission  
File Number)

**20-8756903**  
(IRS Employer  
Identification No.)

**245 First Street**  
**Cambridge, Massachusetts**  
(Address of principal executive offices)

**02142**  
(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
<b>Common Stock, par value \$0.00001 per share</b>	<b>AKBA</b>	<b>The Nasdaq Global Market</b>

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.**

### *Supply Agreement with WuXi STA for Vadadustat Drug Product*

On February 10, 2021, Akebia Therapeutics, Inc. (the “Company”) entered into a Supply Agreement (“WuXi STA Supply Agreement”) with STA Pharmaceutical Hong Kong Limited, a subsidiary of WuXi AppTec (“WuXi STA”). The WuXi STA Supply Agreement includes the terms and conditions under which WuXi STA will manufacture and supply vadadustat drug product (“Product”) for commercial purposes. As previously disclosed, the Company entered into a supply agreement with Patheon Inc. in March 2020 for the commercial manufacture of Product. Entry into the WuXi STA Supply Agreement is consistent with the Company’s previously disclosed plans to enter into an additional supply arrangement for commercial manufacture of Product. In addition, also as previously disclosed, the Company has entered into supply agreements with each of Esteve Química, S.A. and WuXi STA for the commercial manufacture of vadadustat drug substance.

Pursuant to the WuXi STA Supply Agreement, Akebia will provide rolling forecasts to WuXi STA on a quarterly basis (each, a “Forecast”). Each Forecast will reflect the quantities of Product that the Company expects to order from WuXi STA over a certain number of months, represented as a quantity of Product per calendar quarter. Pursuant to the WuXi STA Supply Agreement, the Company has agreed to purchase a certain percentage of global demand for Product from WuXi STA. The parties have agreed to a volume-based pricing structure under the WuXi STA Supply Agreement. The Product price will remain fixed for the first 12 months and thereafter shall be annually reviewed by the Company and WuXi STA. The Company will also reimburse WuXi STA for certain reasonable expenses.

The WuXi STA Supply Agreement has an initial term of four years, beginning February 10, 2021 and ending February 10, 2025. The WuXi STA Supply Agreement may be renewed or extended by mutual agreement of Akebia and WuXi STA with at least 18 months’ prior written notice. The WuXi STA Supply Agreement allows Akebia to terminate the relationship on 180 calendar days’ prior written notice to WuXi STA for any reason. In addition, each party has the ability to terminate the WuXi STA Supply Agreement upon the occurrence of certain conditions.

The WuXi STA Supply Agreement includes customary indemnification, intellectual property protection, confidentiality, remedies, and representations and warranties terms, as well as certain quality requirements.

The foregoing description of the WuXi STA Supply Agreement does not purport to be complete and is qualified in its entirety by reference to the WuXi STA Supply Agreement, a copy of which the Company expects to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2021.

### *Amendment No. 3 to Master Manufacturing Services and Supply Agreement with Siegfried for Auryxia Drug Substance*

On February 11, 2021, Keryx Biopharmaceuticals, Inc., a wholly owned subsidiary of the Company (“Keryx”), and Siegfried Evionnaz SA (“Siegfried”) entered into Amendment No. 3 to Master Manufacturing Services and Supply Agreement (the “Amendment”), which amends the Master Manufacturing Services and Supply Agreement, dated December 20, 2017, between Keryx and Siegfried (as previously amended, the “Original Siegfried Agreement” and as amended by the Amendment, the “Siegfried Agreement”). The Siegfried Agreement includes the terms and conditions under which Siegfried will manufacture and supply finished Auryxia drug substance for commercial purposes. The terms and conditions of the Original Siegfried Agreement are described in [“Note 14–Commitments and Contingencies–Manufacturing Agreements”](#) in the Company’s Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2020, filed with the U.S. Securities and Exchange Commission on November 5, 2020, which description is incorporated herein by reference.

Siegfried currently manufactures Auryxia drug substance at two approved sites. Pursuant to the Amendment, the term of the Original Siegfried Agreement was extended for one site such that the Siegfried Agreement will expire on December 31, 2022, subject to Keryx’s option to extend the term for such site through December 31, 2023 by providing 12 months’ prior written notice to Siegfried (as so extended, the “Term”). The Amendment provides for minimum annual quantity commitments and predetermined prices for the remainder of the Term as well as certain other changes.

The foregoing description does not purport to be complete and is qualified in its entirety by reference to the Siegfried Agreement, a copy of which was filed as Exhibit 10.57 to the Company’s Annual Report on Form 10-K for the year ended December 31, 2019, and the amendments to the Siegfried Agreement, including the Amendment, copies of which the Company expects to file as exhibits to the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2020.

**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: February 17, 2021

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer