

**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 14, 2020

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
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 8.01. Other Events.

Letter Agreement Relating to a Priority Review Voucher

As previously disclosed, Akebia Therapeutics, Inc. (“Akebia” or the “Company”) and Vifor (International) Ltd. (“Vifor Pharma”) are parties to an Amended and Restated License Agreement, dated April 8, 2019, pursuant to which the Company granted Vifor Pharma an exclusive license to sell vadadustat, the Company’s investigational oral hypoxia-inducible factor prolyl hydroxylase inhibitor currently in Phase 3 development for the treatment of anemia due to chronic kidney disease (“CKD”), to Fresenius Kidney Care Group LLC and certain third party dialysis organizations in the United States. The license is subject to vadadustat’s approval by the U.S. Food and Drug Administration (the “FDA”) and satisfaction of certain other conditions.

On February 14, 2020, the Company entered into a letter agreement (the “Letter Agreement”) with Vifor Pharma relating to Vifor Pharma’s agreement with a third party to purchase a Priority Review Voucher issued by the FDA (the “PRV”), subject to satisfaction of customary closing conditions (the “PRV Purchase”). A PRV entitles the holder to priority review of a New Drug Application (“NDA”) or Biologics License Application for a new drug, which reduces the target FDA review time to six months after official acceptance of the submission, and could lead to expedited approval. Pursuant to the Letter Agreement, Akebia will pay Vifor Pharma \$10 million within fifteen business days after the closing of the PRV Purchase. Vifor Pharma is obligated to retain all rights to, and maintain the validity of, the PRV until Akebia and Vifor Pharma (a) enter into a definitive agreement setting forth the financial and other terms by which Vifor Pharma will assign the PRV to Akebia for use with Akebia’s planned NDA for vadadustat for the treatment of anemia due to CKD in both dialysis-dependent and non-dialysis dependent patients, or (b) make a mutual decision to sell the PRV and share the proceeds based on certain terms.

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 18, 2020

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer