

**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): September 22, 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
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.

On September 22, 2021, Keryx Biopharmaceuticals, Inc. (“Keryx”), a wholly owned subsidiary of Akebia Therapeutics, Inc., and its licensors, Panion & BF Biotech, Inc. (“Panion”) and Chen Hsing Hsu, M.D. (“Dr. Hsu”) entered into a settlement and license agreement (the “Agreement”) with Mylan Pharmaceuticals Inc. (“Mylan”). This settlement resolves patent litigation brought by Keryx, Panion and Dr. Hsu in response to Mylan’s Paragraph IV certification notice letter regarding their Abbreviated New Drug Application (“ANDA”) seeking approval to market a generic version of Auryxia® (ferric citrate) tablets prior to the expiration of the applicable patents. Pursuant to the terms of the Agreement and, consistent with Keryx’s prior ANDA settlements with Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Par Pharmaceutical, Inc., Lupin Atlantis Holdings SA, and Chemo Research S.L., Keryx, Panion and Dr. Hsu will grant Mylan a license to market a generic version of Auryxia® in the United States beginning on March 20, 2025 (subject to U.S. Food and Drug Administration approval), or earlier under certain circumstances customary for settlement agreements of this nature. Additionally, in accordance with the Agreement, the parties will terminate all ongoing litigation among Keryx, Panion, Dr. Hsu and Mylan regarding Auryxia patents pending in the United States District Court for the District of Delaware and the North District Court of West Virginia. The Agreement is confidential and subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice.

Keryx, Panion and, as applicable, Dr. Hsu have now entered into settlement and license agreements resolving all patent litigation proceedings brought by Keryx, Panion and, as applicable, Dr. Hsu, in response to ANDAs filed by third parties seeking approval to market generic versions of Auryxia® (ferric citrate) tablets prior to the expiration of the applicable patents.

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: September 28, 2021

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer