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): April 1, 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 2.05 Costs Associated with Exit or Disposal Activities.

On April 4, 2022, the Board of Directors of Akebia Therapeutics, Inc. (the "Company") approved a reduction of the Company's workforce by approximately 42% across all areas of the Company (47% inclusive of the closing of the majority of open positions) following the receipt of a complete response letter from the U.S. Food and Drug Administration ("FDA") to the Company's new drug application for vadadustat for the treatment of anemia due to chronic kidney disease in adult patients (the "CRL"). This workforce reduction is expected to be substantially completed by the end of the second quarter of 2022. The reduction in force reflects the Company's determination to refocus its strategic priorities around its commercial product, Auryxia®, and its development portfolio, and is the first step in a cost savings plan to significantly reduce the Company's expense profile in line with being a single commercial product company. The Company plans to seek to effect additional measures to further reduce its operating expenses and increase revenue from Auryxia.

Affected employees will be offered separation benefits, including severance payments, healthcare coverage and related benefits. The Company expects to record a one-time restructuring charge of approximately $12 million primarily related to severance, non-cash stock-based compensation expense, healthcare and related benefits in the second quarter of 2022. The Company may incur additional costs not currently contemplated due to events associated with or resulting from the workforce reduction. The Company expects that the reduction in force will result in an approximate range of $60-65 million reduction in net cash required for operating activities through the end of 2023. The charges that the Company expects to incur in connection with the workforce reduction and expectations with respect to reduction in net cash required for operating activities are estimates and subject to a number of assumptions, and actual results may differ materially.

Item 8.01 Other Events.

On April 1, 2022, the Company was notified by the FDA that the FDA had placed a partial clinical hold on the Company's clinical trials of vadadustat in pediatric patients with anemia due to chronic kidney disease in the United States. This letter followed the CRL that the FDA issued on March 29, 2022 to the Company's new drug application for vadadustat for the treatment of anemia due to chronic kidney disease in adult patients. As a result of the partial clinical hold, all activities in the United States for and related to the Company's clinical trials of vadadustat in pediatric patients will be suspended.

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: the Company's workforce reduction, future charges expected to be incurred in connection therewith, estimated reductions in net cash required for operating activities in connection therewith, and the Company's ability to effect additional measures to further reduce its operating expenses and increase Auryxia revenue. The terms "believe," "expect," "potential," "will," "continue," 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, but not limited to, risks associated with: the Company's ability to successfully implement its workforce reduction plan and reduce expenses; the impact of the workforce reduction on the Company's business; the ability of the Company to attract and retain qualified personnel; decisions made by health authorities, such as the FDA and the European Medicines Agency, with respect to regulatory filings; the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia, including estimates regarding the potential market opportunity; the competitive landscape for Auryxia, including potential generic entrants; the direct or indirect impact of the COVID-19 pandemic on regulators and the Company's business, operations, and the markets and communities in which the Company and its partners, collaborators, vendors and customers operate; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; and early termination of any of the Company's collaborations. Other risks and uncertainties include those identified under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, and other filings that the Company may make with the U.S. Securities and Exchange Commission 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: April 7, 2022

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