

**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): **August 11, 2023**

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 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 3.01. Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing.

On August 11, 2023, Akebia Therapeutics, Inc. (the “Company”) received a notification from the Nasdaq Stock Market (“Nasdaq”) informing the Company that since it has not yet filed its Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2023 (the “Quarterly Report”), the Company is not in compliance with Nasdaq Listing Rule 5250(c)(1) (the “Listing Rule”). The Listing Rule requires listed companies to timely file all required periodic financial reports with the Securities and Exchange Commission (“SEC”). The Nasdaq notification letter specifies that the Company has 60 calendar days, or until October 10, 2023, to submit a plan to regain compliance with the Listing Rule. If Nasdaq accepts a plan from the Company, Nasdaq can grant an exception of up to 180 calendar days from the Quarterly Report’s due date, or until February 5, 2024, to regain compliance. The Company’s common stock will continue to trade on the Nasdaq Capital Market pending Nasdaq’s review of the Company’s plan to regain compliance.

As previously disclosed in the Company’s Form 12b-25 filed on August 10, 2023, in the course of preparing its financial statements for the fiscal quarter ended June 30, 2023, the Company identified certain accounting errors relating to recording and reporting of return reserves for the Company’s product, Auryxia® (ferric citrate) (collectively, the “Return Reserve Errors”) in financial statements previously filed by the Company with the SEC for the fiscal years ended December 31, 2022, 2021 and 2020 and the fiscal quarter ended March 31, 2023. The Company requires additional time to complete its assessment of its internal control over financial reporting, and to prepare a complete and accurate Quarterly Report due to the Company’s ongoing assessment of the Return Reserve Errors. The Company intends to submit a plan to regain compliance with the Listing Rule prior to October 10, 2023 and to file the Quarterly Report with the SEC as soon as possible.

On August 17, 2023, the Company issued a press release announcing its receipt of the Nasdaq notification letter. A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

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 expectations regarding the timing of submission of a plan to regain compliance with the Listing Rule and filing the Form 10-Q and the Company’s ongoing review of its financial statements. The terms “believe,” “expect,” “potential,” “will,” “continue,” “intend,” 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 those identified under the heading “Risk Factors” in the Company’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, and other filings that the Company may make with the SEC 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 17, 2023, issued by Akebia Therapeutics, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: August 17, 2023

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

Akebia Therapeutics to Report Second Quarter Financial Results by August 25, 2023**Akebia Receives Notification of Deficiency from Nasdaq Regarding Late Form 10-Q Filing**

CAMBRIDGE, Mass. – August 17, 2023 – Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced plans to release its financial results for the second quarter ended June 30, 2023 by Friday, August 25, 2023 prior to the open of the financial markets. Akebia will schedule a conference call in parallel with reporting its financial results.

On August 10, 2023, Akebia filed with the SEC a Form 12b-25 Notification of Late Filing regarding its Quarterly Report on Form 10Q (the Form 10Q) for the quarter ended June 30, 2023. As a result of not having timely filed the Form 10-Q, Akebia received a notice of non-compliance from the Nasdaq Stock Market LLC (Nasdaq) on August 11, 2023, notifying the company that it is not in compliance with Nasdaq Listing Rule 5250(c)(1), which requires listed companies to timely file all required periodic financial reports with the SEC. Under Nasdaq's listing rules, Akebia has 60 calendar days from the date of the notice to submit a plan to regain compliance. The Nasdaq notice has no immediate effect on the listing of Akebia's common stock on Nasdaq.

Akebia plans to file the Form 10-Q by August 25, 2023, and expects to regain compliance with the Nasdaq listing requirements upon filing.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease. Akebia was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

Forward-Looking Statements

Statements in this press release regarding Akebia Therapeutics, Inc.'s ("Akebia'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: Akebia's plans regarding the timing of releasing its financial results for the second quarter ended June 30, 2023 and filing the Form 10-Q and its expectations for regaining compliance with the Nasdaq listing requirements upon filing the Form 10-Q. The terms "intend," "believe," "plan," "goal," "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 risk that additional information may arise in the process of completing the review or audit of any revised financial statements that would

require Akebia to make additional or different adjustments; the time, effort and expense required to complete any corrections in Akebia's financial statements; 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 ability of Akebia to attract and retain qualified personnel; Akebia's ability to implement cost avoidance measures and reduce operating expenses; decisions made by health authorities, such as the FDA, with respect to regulatory filings, including the anticipated resubmission of the New Drug Application for vadadustat; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; the results of preclinical and clinical research; the direct or indirect impact of the COVID-19 pandemic on regulators and Akebia's business, operations, and the markets and communities in which Akebia 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 Akebia's collaborations. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, and other filings that Akebia 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 press release, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

Akebia Therapeutics Contact

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