

**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): October 26, 2022

Lyra Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39273
(Commission File Number)

84-1700838
(IRS Employer
Identification No.)

480 Arsenal Way
Watertown, Massachusetts
(Address of Principal Executive Offices)

02472
(Zip Code)

Registrant's Telephone Number, Including Area Code: 617 393-4600

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, \$0.001 par value per share	LYRA	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 4.02. Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review.

On October 26, 2022, the Audit Committee of the Board of Directors of Lyra Therapeutics, Inc. (the “Company”), after discussion with its independent registered public accounting firm, BDO USA, LLP (“BDO”) and its legal advisors, concluded that (i) the Company’s previously issued condensed consolidated financial statements as of and for the three months ended March 31, 2022 (the “Q1 Financial Statements”) included in the Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the “SEC”) on May 10, 2022 and (ii) the Company’s previously issued condensed consolidated financial statements as of and for the three and six months ended June 30, 2022 (the “Q2 Financial Statements” and, together with the Q1 Financial Statements, the “Prior Financial Statements”) included in the Quarterly Report on Form 10-Q filed with the SEC on August 9, 2022 should no longer be relied upon. Similarly, any previously furnished or filed reports, related earnings releases, investor presentations or similar communications of the Company describing the Prior Financial Statements should no longer be relied upon.

The determination results from an error identified in the Prior Financial Statements by the Company related to a non-cash transaction that was made in the application of revenue recognition for the \$5.0 million development milestone achieved in February 2022 under the License and Collaboration Agreement (the “LianBio License Agreement”) with LianBio Inflammatory Limited, which was entered into on May 31, 2021. In connection with the original accounting for the LianBio License Agreement, the Company determined there were two distinct performance obligations: (1) the license to develop and commercialize LYR-210, manufacturing activities related to the clinical supply of LYR-210, and the non-exclusive license to manufacture LYR-210 and obligation to transfer manufacturing technology in the case of a supply failure, and (2) the Company’s performance of the development activities related to the global Phase 3 clinical trial. The restatement is anticipated to reflect the correction of the immediate recognition as revenue, of the \$5.0 million development milestone in the quarter ended March 31, 2022 by properly allocating the amount to the two identified performance obligations and recognizing the allocated amounts in accordance with the revenue recognition model previously developed for each performance obligation. The correction will not impact the cash position previously disclosed.

The Company intends to restate the Prior Financial Statements as soon as practicable. In connection with such restatement, the Company has concluded that there is a material weakness in internal control over financial reporting related to the accounting for certain complex and nonrecurring transactions. The Company's internal controls were not designed to include all necessary reviews of certain assumptions, estimates and computations made in establishing a reasonable method for the revenue recognition of variable consideration, such as development milestones, in the Company's collaboration agreements.

The Company's management and the Audit Committee have discussed the matters described herein with BDO.

Cautionary Note Regarding Forward-Looking Statements.

This Current Report on Form 8-K includes information that constitutes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are based on the Company’s current beliefs, assumptions and expectations regarding future events, which in turn are based on information currently available to the Company. Such forward-looking statements include statements regarding the timing of the filing of the aforementioned periodic reports. By their nature, forward-looking statements address matters that are subject to risks and uncertainties. A variety of factors could cause actual events and results to differ materially from those expressed in or contemplated by the forward-looking statements, including the risk that the completion and filing of the aforementioned periodic reports will take longer than expected and that additional information may become known prior to the expected filing of the aforementioned periodic reports with the SEC. Other risk factors affecting the Company are discussed in detail in the Company’s filings with the SEC. The Company undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by applicable laws.

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.

LYRA THERAPEUTICS, INC.

Date: October 26, 2022

By: /s/ Jason Cavalier
Jason Cavalier
Chief Financial Officer
