# 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): June 8, 2021**

# LYRA THERAPEUTICS, INC.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **001-39273** | **84-1700838** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(I.R.S. Employer Identification No.)** |

**480 Arsenal Way**
**Watertown, MA 02472**
**(Address of principal executive offices) (Zip Code)**

**(617) 393-4600**
**(Registrant's telephone number, include area code)**

**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 8.01 Other Events.**

On June 8, 2021, Lyra Therapeutics, Inc. (the "Company") announced that, following an End-of-Phase 2 ("EOP2") meeting with the U.S. Food and Drug Administration (the "FDA") for LYR-210, its lead product candidate for the treatment of chronic rhinosinusitis ("CRS"), the Company and the FDA established key elements of the Phase 3 program to support a 502(b)(2) new drug application for LYR-210.

The single primary endpoint will evaluate improvement at week 24 using a composite score of three cardinal symptoms (3CS) of CRS: nasal blockage, nasal discharge, and facial pain. Based on the FDA's suggestion, Lyra intends to enroll a total of approximately 350 subjects split into two replicate, largely concurrent Phase 3 clinical trials, each powered to >95% to detect statistical significance. Both studies will evaluate a 7500µg dose of LYR-210, and additional key clinical aspects of the studies will also be the same.

This Phase 3 program provides the opportunity for an earlier read-out in one study, and the flexibility to potentially include patients from recently-licensed territory in Asia in the second study, without materially increasing the estimated cost or duration of the pivotal program overall. Additional outcomes from the EOP2 meeting include that the Company's pharmacokinetic data and previously conducted non-clinical studies support a 505(b)(2) pathway, and that the Company's Chemistry, Manufacturing and Controls specifications and stability plans are sufficient to move forward.

*Forward-Looking Statements*

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding the Company's Phase 3 Program and clinical advancement of LYR-210. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the fact that the Company has incurred significant losses since inception and expects to incur losses for the foreseeable future; the Company's need for additional funding, which may not be available; the Company's limited operating history; the fact that clinical trials required for the Company's product candidates are expensive and time-consuming, and their outcome is uncertain; and the Company's inability to obtain required FDA regulatory approvals. These and other important factors discussed under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q filed with the SEC on May 11, 2021 and its other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report on Form 8-K. Any such forward-looking statements represent management's estimates as of the date of this Current Report on Form 8-K. While the Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change.

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: June 11, 2021

By: /s/ R. Don Elsey
R. Don Elsey
Chief Financial Officer