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): May 31, 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 1.01 Entry into a Material Definitive Agreement.

On May 31, 2021, Lyra Therapeutics, Inc. (the "Company") entered into a license and collaboration agreement (the "Agreement"), with LianBio Inflammatory Limited ("LianBio") pursuant to which, among other things, the Company granted LianBio an exclusive license to develop and commercialize the Company's product candidate LYR-210 (an anti-inflammatory, intra-nasal drug matrix designed to treat chronic rhinosinusitis) (the "Licensed Product") in Greater China (mainland China, Hong Kong, Macau, and Taiwan), Singapore, South Korea, and Thailand (the "Territory") under the oversight of a joint steering committee to be formed by the parties. Lyra will retain its rights to LYR-210 outside of the Territory.

Under the terms of the Agreement, the Company will receive an upfront cash payment of $12.0 million in connection with the execution of the Agreement and is eligible to receive up to $135.0 million in future payments based upon the achievement of specified development, regulatory and commercialization milestones. The Company is also eligible to receive tiered royalties based on net sales of Licensed Products in the Territory, subject to reduction in specified circumstances. Unless earlier terminated, the Agreement will expire on a region-by-region basis with respect to the Licensed Product on the latest to occur of (i) the expiration of the last valid patent claim owned or exclusively controlled by the Company, (ii) the expiration of regulatory exclusivity or (iii) a specified number of years from the first commercial sale of the Licensed Product in a given region. As part of the Agreement, LianBio will have the first right to obtain a license to develop and commercialize Lyra's product candidate LYR-220 (an anti-inflammatory, intra-nasal, drug matrix in development for the treatment of chronic rhinosinusitis patients who have undergone a prior sinus surgery but continue to have persistent disease) in the Territory.

Under the terms of the Agreement, LianBio must use commercially reasonable efforts to develop, seek regulatory approval for, and commercialize the Licensed Products in the Territory, and will fund all such expenses. The Company must use commercially reasonable efforts to complete a global Phase III clinical trial for the Licensed Product and seek regulatory approval for the Licensed Product in the U.S., and will continue to have sole responsibility for development and regulatory activities for the Licensed Products outside of the Territory. LianBio may participate in a global Phase III clinical trial, including by using commercially reasonable efforts to engage clinical sites and enroll patients in the Territory and being responsible for any costs and expenses incurred by or on behalf of LianBio for such participation. The Company will supply clinical and commercial quantities of Licensed Product to LianBio in accordance with supply agreements to be negotiated by the parties.

The Agreement contains customary representations, warranties and covenants by the parties, and will continue in effect unless terminated by either party pursuant to its terms. The Agreement may be terminated by either party upon the other party's uncured material breach of the Agreement, by either party in the event of the other party's bankruptcy, insolvency or certain similar occurrences, by the Company if LianBio brings any action or proceeding challenging the validity or enforceability of any of the licensed patents, by the Company if LianBio ceases to conduct material development or commercialization activities for a certain period if such cessation is not due to specified circumstances, and by LianBio for convenience. Upon termination of the Agreement, LianBio will grant to the Company an exclusive license under LianBio's patent rights and know-how actually used for the Licensed Product to develop, manufacture and commercialize the Licensed Product in the Territory.

Michael A. Altman and Konstantin Poukalov are members of the Company's Board of Directors and Managing Directors at Perceptive Advisors, LLC ("Perceptive"), a significant stockholder of the Company and the founder of LianBio. Mr. Poukalov is also Executive Chairman of the LianBio Board of Directors. There are no other material relationships between the Company or its affiliates and LianBio.

The foregoing is a summary description of certain terms of the Agreement, is not complete and is qualified in its entirety by reference to the text of the Agreement, which the Company expects to file as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2021, with certain confidential provisions redacted.

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 4, 2021

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