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 11, 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 2.02. Results of Operations and Financial Condition.

On May 11, 2021, Lyra Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on May 11, 2021

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: May 11, 2021

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

Lyra Therapeutics Reports First Quarter 2021 Financial Results and Provides Corporate Update

- Presented positive full data from LANTERN Phase 2 study of LYR-210 at COSM –

- Appointed Robert Kern, MD, as Chief Medical Officer -

- Conference call and webcast today at 4:30 p.m. ET -

WATERTOWN, MA – May 11, 2021 - Lyra Therapeutics, Inc. (Nasdaq: LYRA), a clinical-stage therapeutics company focused on the development and commercialization of novel integrated drug and delivery solutions for the localized treatment of patients with ear, nose and throat (ENT) diseases, today reported financial results for the quarter ended March 31, 2021 and provided a corporate update.

Key First Quarter 2021 and Subsequent Highlights

- **Presented positive full data set from LANTERN Phase 2 Study of LYR-210 at COSM 2021 Virtual Event.** In April, the company presented the positive full data set from its LANTERN Phase 2 study of LYR-210 for the treatment of chronic rhinosinusitis (CRS) at the COSM 2021 Virtual Event. The new data demonstrated that LYR-210 is effective in both non-polyp and polyp patients in a clinical trial with 100% of patients in both groups achieving SNOT-22 MCID at week 24 at 7500 µg. Further, LYR-210 decreased ethmoid opacification at week 24 as well as reduced patient need for rescue medication. Previously, Lyra announced positive topline from the data in December 2020. We expect that the results from Lyra's LANTERN Phase 2 Study will be used to design a Phase 3 pivotal trial, subject to an End-of-Phase 2 meeting with the FDA in the second quarter 2021.

- **Tech transfer to Contract Manufacturing Organization (CMO) on Track.** The company commenced our first manufacturing lot at our CMO to support the IND supplement and the commencement of our phase 3 clinical trial for LYR-210 around the end of the year.

- **Appointed Robert Kern, MD, as Chief Medical Officer.** In February, the company appointed Dr. Robert Kern as Chief Medical Officer. Dr. Kern is a highly regarded clinician and researcher in the field of sinonasal disorders. With more than 30 years of experience in the ENT medical field and currently serving as the George A. Sisson Professor and Chair, Department of Otolaryngology –

Head and Neck Surgery at Northwestern University Feinberg School of Medicine. Dr. Kern is expected to be a valuable asset to the company as clinical trials progress for LYR-210 and LYR-220.

“We were thrilled to present the full data set from our LANTERN Phase 2 Study of LYR-210 at the virtual COSM event, and to share data that we believe demonstrates how effective our product candidate is at treating chronic rhinosinusitis. Dr. Cervin did a wonderful job detailing the symptom improvements observed in both polyp and non-polyp patients, as well as revealing evidence of disease modification through patient’s improved bilateral ethmoid Zinreich scores,” said Maria Palasis, Ph.D., President and Chief Executive Officer of Lyra Therapeutics. “Additionally, we announced a separate analysis of the LANTERN study that showed statistically significant improvement in a composite of three cardinal symptoms, which includes nasal blockage, nasal discharge and facial pain, that we believe could inform our design for a pivotal Phase 3 study. “

Dr. Palasis continued: “Turning to the near term, we intend to share results from our PK study of LYR-210 in the second quarter, and to share feedback from our End-of Phase-2 meeting with the FDA around mid-year. Subject to guidance from the FDA, we then plan to initiate a Phase 2 trial for LYR-220 in the second half of 2021, and a Phase 3 trial of LYR-210 around the end of the year.”

Financial Highlights

Cash and cash equivalents as of March 31, 2021 were $66.1 million, compared with $74.6 million at December 31, 2020.

Research and development expenses for the quarter ended March 31, 2021 were $4.8 million compared to $3.0 million for the same period in 2020.

General and administrative expenses for the first quarter 2021 were $3.1 million compared to $1.3 million for the same period in 2020.

Total operating expenses for the quarter ended March 31, 2021 were $7.8 million compared to $4.2 million for the same period in 2020.

Net loss for the first quarter was $7.8 million compared to $4.2 million for the same period in 2020.

In terms of financial guidance for 2021, management believes Lyra has sufficient cash to fund the company through planned operations into 2023.

Conference Call

Individuals interested in listening to the conference call may do so by dialing (833) 519-1249 for domestic callers, or (914) 800-3822 for international callers, and using the conference ID: 3067707; or from the webcast link in the investor relations section of the company's website at: www.lyratherapeutics.com. The recorded webcast will be available for replay for approximately 30 days following the call.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage therapeutics company focused on the development and commercialization of novel integrated drug and delivery solutions for the localized treatment of patients with ear, nose and throat (ENT) diseases. The company's lead product candidate, LYR-210, is designed to deliver up to six months of continuous anti-inflammatory drug therapy to the sinonasal passages for the treatment of chronic rhinosinusitis (CRS) in patients who have not undergone surgery for the disease. Lyra is also developing LYR-220 for CRS patients who have undergone a prior surgery and have persistent disease. Beyond CRS, the company believes its XTreo™ platform, comprised of drug administered through a bioresorbable polymeric matrix, has the potential to address other disease areas by precisely, consistently and locally delivering medicines for sustained periods with a single administration.

For more information, please visit www.lyratherapeutics.com and follow us on LinkedIn and Twitter.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding the company's development of LYR-210 and LYR-220, including the anticipated timeline for sharing results of the company's studies and meetings with the FDA, and initiating future clinical trials. 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 the company has no approved products; the fact that the company's product candidates are in various stages of development; the fact that the company may not be successful in its efforts to identify and successfully commercialize its product candidates; the fact that clinical trials required for the company's product candidates are expensive and time-consuming, and their outcome is uncertain; the fact that the FDA may not conclude that certain of the company's product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway; the company's inability to obtain required regulatory approvals; effects of recently enacted and future legislation; the possibility of system failures or security breaches; effects of significant competition; the fact that the successful

commercialization of the company's product candidates will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and pricing policies; failure to achieve market acceptance; product liability lawsuits; the fact that the company relies on third parties for the manufacture of materials for its research programs, pre-clinical studies and clinical trials; the company's reliance on third parties to conduct its preclinical studies and clinical trials; the company's inability to succeed in establishing and maintaining collaborative relationships; the company's reliance on certain suppliers critical to its production; failure to obtain and maintain or adequately protect the company's intellectual property rights; failure to retain key personnel or to recruit qualified personnel; difficulties in managing the company's growth; effects of natural disasters; the fact that the global pandemic caused by COVID-19 could adversely impact the company's business and operations, including the company's clinical trials; the fact that the price of the company's common stock may be volatile and fluctuate substantially; significant costs and required management time as a result of operating as a public company and any securities class action litigation. 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 press release. Any such forward-looking statements represent management's estimates as of the date of this press release. 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.

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LYRA THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 4,770	$ 2,964
General and administrative	3,061	1,284
Total operating expenses	7,831	4,248
Loss from operations	(7,831)	(4,248)
Other income:		
Interest income	29	16
Total other income	29	16
Net loss	$ (7,802)	$ (4,232)
Comprehensive loss	$ (7,802)	$ (4,232)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.60)	$ (18.70)
Weighted-average common shares outstanding—basic and diluted	12,945,546	230,860

LYRA THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share data)

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 66,105	$ 74,593
Prepaid expenses and other current assets	1,246	1,324
Total current assets	67,351	75,917
Property and equipment, net	3,168	2,165
Operating lease right-of-use assets	2,069	2,301
Restricted cash	329	329
Other assets	—	118
Total assets	$ 72,917	$ 80,830
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,169	$ 922
Accrued expenses and other current liabilities	1,994	2,977
Operating lease liabilities	1,007	985
Total current liabilities	4,170	4,884
Operating lease liabilities, net of current portion	1,196	1,454
Total liabilities	5,366	6,338
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 12,962,768 and 12,932,377 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	13	13
Additional paid-in capital	225,224	224,363
Accumulated deficit	(157,686)	(149,884)
Total stockholders' equity	67,551	74,492
Total liabilities and stockholders' equity	$ 72,917	$ 80,830