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): March 9, 2022

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 March 9, 2022, Lyra Therapeutics, Inc. (the "Company") announced its financial results for the year ended December 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 March 9, 2022
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.

LYRA THERAPEUTICS, INC.

Date: March 9, 2022

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

Lyra Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results and Provides Corporate Update

Treated first patient in pivotal Phase 3 ENLIGHTEN program for surgically naïve chronic rhinosinusitis patients

Initiated BEACON Phase 2 trial for LYR-220 in chronic rhinosinusitis patients with post-surgical anatomy

Appointed Harlan W. Waksal, MD, as Executive Chairman

WATERTOWN, Mass., March 9, 2022 – Lyra Therapeutics, Inc. (Nasdaq: LYRA), a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained and local delivery of medications to the ear, nose and throat (ENT) passages and other diseased tissues, today reported financial results for the quarter ended December 31, 2021, and highlighted recent accomplishments and upcoming milestones.

“2021 was a highly productive year for Lyra as we advanced our clinical programs in our first indication – chronic rhinosinusitis, or CRS – with the first patient treated in the pivotal Phase 3 ENLIGHTEN program for LYR-210 in patients with surgically-naïve anatomy and the initiation of the Phase 2 BEACON study for LYR-220 to treat CRS patients with post-surgical anatomy,” said Maria Palasis, PhD, President and Chief Executive Officer of Lyra Therapeutics.

Dr. Palasis added: “We expect 2022 to be a pivotal year as we enroll both late-stage clinical programs, report clinical data for Part 1 of the Phase 2 BEACON study around year end and present additional clinical data at the Combined Otolaryngology Spring Meetings (COSM) that further distinguishes LYR-210 from current treatment options. With a portfolio of products to cover both surgically-naïve and post-surgical CRS patients, Lyra is poised to excel in the estimated $6 billion target addressable market for CRS.”

Key Fourth Quarter 2021 and Subsequent Highlights

- **Announced Clinical Developments for LYR-210 and LYR-220.** In January 2022, Lyra announced the initiation of the pivotal Phase 3 ENLIGHTEN I clinical trial of LYR-210 in adult, surgically-naïve CRS patients. This month, the first patient was successfully dosed in the ENLIGHTEN I trial. In January, the Company also announced the initiation of the

BEACON Phase 2 trial for LYR-220, which is being evaluated for the treatment of adult patients who remain symptomatic despite having had a prior sinus surgery for CRS.

  - LYR-210 and LYR-220 are designed to be administered in a brief, non-invasive, in-office procedure and deliver up to six months of continuous anti-inflammatory medication to the sinonasal passages of CRS patients.

  - The global Phase 3 ENLIGHTEN program for LYR-210 is expected to enroll a total of 360 CRS patients in two studies. Each study will be randomized 2:1 to LYR-210 (7500µg MF) versus control. The primary endpoint will be the change from baseline in a composite score of three cardinal symptoms (i.e., nasal blockage, nasal discharge, and facial pain) at 24 weeks with secondary endpoints to include SNOT-22, rescue treatments, sinus CT scans, quality of life and pharmacoeconomic evaluations. The design is similar to the Phase 2 LANTERN study, which was highly statistically significant in the three cardinal symptoms at 24 weeks.

  - LYR-220 is designed to provide up to six months of symptom relief for CRS patients who have had a prior sinus surgery but have recurrent disease. The BEACON trial is a controlled, randomized, parallel-group study to evaluate safety, tolerability, pharmacokinetics, and efficacy comparing two designs of LYR-220 to control over a 24-week period in approximately 70 symptomatic adult CRS subjects.

- **LANTERN Phase 2 Results Receive Top Clinical Award at 67th Annual Meeting of the American Rhinologic Society (ARS) in October 2021.** The LANTERN Phase 2 manuscript won the ARS Clinical Science Maurice Cottle Award, honoring the best clinical or basic science research.

- **LANTERN 6-Month Post-Treatment Data and PK Study Presented at ARS and Received Distinction.** New, positive data from the LANTERN 6-month post-treatment evaluation of LYR-210 and data from a pharmacokinetic study (PK study), were the subject of two oral presentations at the ARS Annual Meeting. The PK study was selected as a top clinical presentation at the ARS Annual Meeting 2021.

- **Appointed Harlan W. Waksal, MD, as Executive Chairman of Lyra's Board of Directors.** Dr. Waksal most recently served as President, Chief Executive Officer and Member of the Board of Directors of Kadmon Holdings prior to its acquisition by Sanofi in November 2021. With more than 30 years of scientific, clinical development, business development

and management experience in the industry, Dr. Waksal holds a successful track record of founding, building and advising growth-oriented companies.

- **Appointed Jim Tobin to the Company's Board of Directors**. Mr. Tobin is the former President and Chief Executive Officer of Boston Scientific Corporation, President and Chief Executive Officer of Biogen Inc., and President and Chief Operating Officer of Baxter International. Currently, he serves as Chairman of the Board at TransMedics, Inc. and Board Member of Globus Medical, Impulse Dynamics, and Xenter Medical.

Key Additional Milestones Anticipated in 2022

LYR-210

- First patient dosed (FPI) in the ENLIGHTEN II Phase 3 study for LYR-210 is anticipated in mid-year 2022.
- Two presentations of new LYR-210 data at COSM to be held April 27–May 1. Both of the Company's abstracts were selected for oral presentation with one selected as a top clinical abstract.

LYR-220

- Screening is ongoing, and the FPI in the Part 1/non-randomized portion of the Phase 2 BEACON study for LYR-220 is anticipated in the first half of 2022 with topline results from Part 1 expected around year end.
- FPI in the Part 2/randomized portion of the Phase 2 BEACON study is anticipated in the first half of the year.
- Enrollment completion in the Phase 2 BEACON study is anticipated around year end.

Financial Highlights

- **Cash and cash equivalents** as of December 31, 2021 were $45.7 million, compared with $58.1 million as of September 30, 2021. The Company expects its cash balance to be sufficient to fund its planned operations into 4Q 2022.
- **Research and development expenses** for the quarter and full year ended December 31, 2021 were $10.3 million and $29.7 million, respectively, compared to $3.7 million and $12.5 million for the same periods in 2020, respectively. The increase was primarily driven by an increase in clinical expenses, product development and manufacturing expenses, employee-related expenses and consulting costs as the Company ramped up to launch three clinical trials.
- **General and administrative expenses** for the fourth quarter and full year ended December 31, 2021 were $3.6 million and $14.2 million, respectively, compared to $3.3

million and $9.7 million for the same periods in 2020, respectively. The increase was primarily driven by an increase in professional and consulting expenses, public company costs and employee related costs.

- **Total operating expenses** for the quarter ended and full year ended December 31, 2021 were $13.9 million and $43.9 million, respectively, compared to $7.0 million and $22.2 million for the same periods in 2020, respectively.
- **Net loss** for the fourth quarter and full year 2021 was $13.6 million and $43.5 million, respectively, compared to $7.0 million and $22.1 million for the same periods in 2020, respectively.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained, local delivery of medications to diseased tissues not accessible with conventional therapeutic approaches. Lyra's XTreo™ platform is comprised of a biocompatible mesh scaffold, an engineered elastomeric matrix and a versatile polymer-drug complex. The company's current pipeline of therapeutics target tissues deep in the ear, nose and throat passages and are designed to deliver continuous drug therapy for up to six months following a single non-invasive, in-office administration. Lyra has two product candidates in development for CRS, a highly prevalent inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities: LYR-210, for surgically naïve patients, and LYR-220, for patients who have recurrent symptoms despite surgery. Together they are designed to treat the estimated four million CRS patients in the U.S. that fail medical management each year. For more information, please visit www.lyratherapeutics.com and follow us on LinkedIn and Twitter.

Forward-Looking Statements

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 our pipeline of product candidates, the enrollment and success of the ENLIGHTEN II Phase 3 study, the enrollment and success of the Phase 2 BEACON study, the success of the XTreo™ platform, presentation of additional clinical data at COSM, and our ability to capture market share. 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; or 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, terrorism and wars (including the developing conflict between Ukraine and Russia); 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 Annual Report on Form 10-K filed with the SEC on March 9, 2022 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.

Investor Contact:
Argot Partners
212-600-1902
lyra@argotpartners.com

Media Contact:
Kathryn Morris
914-204-6412
kathryn@theyatesnetwork.com

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

	Year Ended December 31,	
	2021	2020
Collaboration revenue	$ 285	$ —
Operating expenses:		
Research and development	29,694	12,522
General and administrative	14,206	9,687
Total operating expenses	43,900	22,209
Loss from operations	(43,615)	(22,209)
Other income:		
Interest income	102	82
Total other income	102	82
Net loss	$ (43,513)	$ (22,127)
Net loss per share attributable to common stockholders—basic and diluted	$ (3.35)	$ (2.59)
Weighted-average common shares outstanding—basic and diluted	12,986,101	8,590,205

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 45,747	$ 74,593
Prepaid expenses and other current assets	2,171	1,324
Total current assets	47,918	75,917
Property and equipment, net	4,503	2,165
Operating lease right-of-use assets	1,355	2,301
Restricted cash	329	329
Other assets	762	118
Total assets	$ 54,867	$ 80,830
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,125	$ 922
Accrued expenses and other current liabilities	4,258	2,977
Operating lease liabilities	1,074	985
Deferred revenue	9,789	—
Total current liabilities	18,246	4,884
Operating lease liabilities, net of current portion	379	1,454
Deferred revenue, net of current portion	1,926	—
Total liabilities	20,551	6,338
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2021 and 2020; 13,007,178 and 12,932,377 shares issued and outstanding at December 31, 2021 and 2020, respectively	13	13
Additional paid-in capital	227,700	224,363
Accumulated deficit	(193,397)	(149,884)
Total stockholders' equity	34,316	74,492
Total liabilities and stock and stockholders' equity	$ 54,867	$ 80,830