

**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 10, 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**  
(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 10, 2022, Lyra Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2022. 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release issued on May 10, 2022</a>
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: May 10, 2022

By: /s/ Jason Cavalier

Jason Cavalier

Chief Financial Officer



## Lyra Therapeutics Reports First Quarter 2022 Financial Results and Provides Corporate Update

*In April 2022, secured \$100.5 million in gross proceeds in an at-the-market, private placement of common stock that is expected to support two pivotal data readouts; cash runway extended until mid-2024*

*Pivotal ENLIGHTEN Phase 3 clinical program and BEACON Phase 2 clinical trial targeting a broad spectrum of CRS patients actively recruiting patients*

WATERTOWN, Mass., May 10, 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 first quarter ended March 31, 2022, and highlighted recent accomplishments.

“The first quarter marked progress in our two ongoing clinical programs: the pivotal ENLIGHTEN Phase 3 program and the BEACON Phase 2 trial, both of which are actively recruiting patients with chronic rhinosinusitis,” said Maria Palasis, PhD, President and Chief Executive Officer of Lyra Therapeutics.

“The recent capital raise of approximately \$100.5 million in an at-the-market private placement of common stock is expected to fund several important milestones in our ongoing clinical programs, including pivotal data readouts for ENLIGHTEN I and ENLIGHTEN II trials for LYR-210, as well as the topline data readout in the BEACON Phase 2 trial for LYR-220. Given today’s challenging capital markets, we view the robust investor support in the recent financing as a testament to our compelling product candidates that have the potential to change the treatment paradigm in the estimated \$6 billion target addressable market for CRS patients,” said Dr. Palasis.

### Corporate Highlights

- In April 2022, Lyra closed a private placement of common stock of approximately \$100.5 million in gross proceeds with participation by funds affiliated with existing investors: Perceptive Advisors, North Bridge Venture Partners and Pura Vida Investments as well as funds affiliated with new investors: Venrock Healthcare Capital Partners, Nantahala Capital Management, LLC and Samsara BioCapital. The proceeds, combined with the Company’s existing cash balance and anticipated milestones, under its license agreement with LianBio, is expected to provide sufficient operating capital through mid-2024.

### Clinical Developments for LYR-210 and LYR-220

- At the 2022 Combined Otolaryngology Spring Meetings (COSM), two oral presentations were presented that highlighted additional positive clinical data from the LANTERN Phase 2 trial of LYR-210 in adult patients with chronic rhinosinusitis (CRS). The Company’s oral presentation on the impact of long-acting implantable corticosteroid matrices in CRS patients was selected as a top clinical abstract by the American Rhinologic Society. A second presentation highlighted

clinically meaningful improvement in mental and physical quality of life outcomes for CRS patients. These results are supportive of the previously reported, statistically significant 40-point improvement for LYR-210 (7500µg) over the average baseline SNOT-22 score of 68 at week 24.

- Enrollment in the pivotal ENLIGHTEN I Phase 3 trial is ongoing, while the initiation of the ENLIGHTEN II Phase 3 trial is targeted to begin mid-year. Both ENLIGHTEN trials are expected to enroll patients in the U.S. and Europe. The global ENLIGHTEN Phase 3 program is expected to include a total of 360 adult, surgically-naïve CRS patients and enrollment is on track to be completed in the first half of 2023.
- Last month, the first patient was treated in Australia in the Part 1/non-randomized portion of the BEACON Phase 2 trial for LYR-220 for the treatment of adult CRS patients who remain symptomatic despite having had a prior sinus surgery. The Part 2/randomized portion of the trial is anticipated to commence in the U.S. later in the second quarter. The BEACON Phase 2 trial is expected to include approximately 70 symptomatic adult CRS subjects who have had a prior sinus surgery, with enrollment anticipated to be complete around the end of 2022. Topline results from the Part 1/non-randomized portion of the trial are anticipated around year-end.

### **First Quarter 2022 Financial Highlights**

- Cash and cash equivalents as of March 31, 2022 were \$33.8 million, compared with \$45.7 million at December 31, 2021, and Lyra received an additional \$100.5 million of gross proceeds from the April 2022 private placement. The Company expects its cash balance to be sufficient to fund its planned operations through mid-2024.
- Research and development expenses for the quarter ended March 31, 2022 were \$8.5 million compared to \$4.8 million for the same period in 2021. The increase was primarily driven by an increase in clinical expenses, product development and manufacturing expenses, employee-related expenses and consulting costs related to the Company's three clinical trials.
- General and administrative expenses for the first quarter 2022 were \$3.9 million compared to \$3.1 million for the same period in 2021. The increase was primarily driven by an increase in professional and consulting expenses and employee related costs.
- Total operating expenses for the quarter ended March 31, 2022 were \$12.4 million compared to \$7.8 million for the same period in 2021.
- Net loss for the first quarter 2022 was \$7.0 million compared to \$7.8 million for the same period in 2021.

### **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-

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office administration. Lyra has two product candidates in late-stage 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 is being evaluated in the ENLIGHTEN Phase 3 clinical program, and LYR-220, is being evaluated in patients who have recurrent symptoms despite surgery in the BEACON Phase 2 clinical trial. These two product candidates 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](http://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 cash runway through 2024 and the use of proceeds from the April private placement, our pipeline of product candidates, the enrollment and success of the ENLIGHTEN II Phase 3 program, the enrollment and success of the Phase 2 BEACON trial (including the timelines for commencement of the Part 2/randomized portion of the trial in the U.S. later in the second quarter and topline results from the Part 1/non-randomized portion of the trial around year-end), the success of the XTreo™ platform, and our ability to capture market share in the estimated \$6 billion addressable market. 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*

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*factors discussed under the caption "Risk Factors" in the company's Quarterly Report on Form 10-Q filed with the SEC on May 10, 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.*

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

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2022</b>	<b>2021</b>
Collaboration revenue	\$ 5,367	\$ —
Operating expenses:		
Research and development	8,505	4,770
General and administrative	3,888	3,061
Total operating expenses	12,393	7,831
Loss from operations	(7,026)	(7,831)
Other income:		
Interest income	14	29
Total other income	14	29
Net loss	\$ (7,012)	\$ (7,802)
Net loss per share attributable to common stockholders—basic and diluted	\$ (0.54)	\$ (0.60)
Weighted-average common shares outstanding—basic and diluted	13,008,779	12,945,546



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

	<u>March 31,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 33,755	\$ 45,747
Collaboration revenue receivable	5,000	—
Prepaid expenses and other current assets	1,800	2,171
Total current assets	<u>40,555</u>	<u>47,918</u>
Property and equipment, net	4,275	4,503
Operating lease right-of-use assets	1,109	1,355
Restricted cash	329	329
Other assets	1,077	762
Total assets	<u>\$ 47,345</u>	<u>\$ 54,867</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,408	\$ 3,125
Accrued expenses and other current liabilities	4,237	4,258
Operating lease liabilities	1,097	1,074
Deferred revenue	10,060	9,789
Total current liabilities	<u>17,802</u>	<u>18,246</u>
Operating lease liabilities, net of current portion	99	379
Deferred revenue, net of current portion	1,288	1,926
Total liabilities	<u>19,189</u>	<u>20,551</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value; 200,000,000 shares authorized at March 31, 2022 and December 31, 2021; 13,009,896 and 13,007,178 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	13	13
Additional paid-in capital	228,552	227,700
Accumulated deficit	(200,409)	(193,397)
Total stockholders' equity	<u>28,156</u>	<u>34,316</u>
Total liabilities and stockholders' equity	<u>\$ 47,345</u>	<u>\$ 54,867</u>