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): November 08, 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)**	**(IRS Employer Identification No.)**

480 Arsenal Way **Watertown, Massachusetts**	**02472**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: 617 393-4600

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 November 8, 2022, Lyra Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 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:

Exhibit No.	Description
99.1	Press Release issued on November 8, 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: November 8, 2022

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

Exhibit 99.1

Lyra Therapeutics Reports Third Quarter 2022 Financial Results and Provides Corporate Update

-- Company Prioritizing ENLIGHTEN I Pivotal Phase 3 Trial of LYR-210 in Chronic Rhinosinusitis (CRS); Study Remains on Track, with Full Enrollment Anticipated mid-2023 --

-- Company to Manufacture All Clinical Trial Supply to Leverage its In-House Expertise and Capabilities; Temporarily Pausing Enrollment in ENLIGHTEN II Trial of LYR-210 in CRS to Align with Manufacturing Timelines; Enrollment Expected to Resume in the Third Quarter of 2023 --

WATERTOWN, Mass., November 8, 2022 /PRNewswire/ -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) ("Lyra" or the "Company"), a clinical-stage biotechnology company developing novel, integrated drug and delivery solutions for the localized treatment of patients with chronic rhinosinusitis (CRS), today reported its financial results for the third quarter ended September 30, 2022 and provided a corporate update.

“We continue to advance toward our goal of bringing transformative therapies to the full spectrum of CRS patients,” said Maria Palasis, Ph.D., President and CEO of Lyra. “We are focusing our efforts on the ENLIGHTEN I pivotal Phase 3 trial in surgically naïve CRS patients and remain on track to complete enrollment in mid-2023. In addition, the BEACON Phase 2 trial of LYR-220 in post-surgical CRS patients has advanced to the randomized stage, based on positive initial data that were previously announced. We remain encouraged by the promise of these early results and our potential to treat pre- and post-surgical CRS patients.”

“Following a detailed assessment, we believe that Lyra’s in-house manufacturing capabilities, which uniquely combine drug quality systems with device manufacturing operations, allow us to produce our clinical trial supply in a more capital-efficient and consistent way than relying on a third-party manufacturer,” Dr. Palasis continued. “To ensure uninterrupted clinical trial supply for patients across both ENLIGHTEN studies, we are dedicating existing clinical supply, manufactured by Lyra, to ENLIGHTEN I. We will temporarily pause enrollment in ENLIGHTEN II to benefit from this opportunity to leverage our in-house expertise and capabilities. We expect to resume enrollment in ENLIGHTEN II in the third quarter of 2023.”

The ENLIGHTEN program consists of two Phase 3 clinical trials (ENLIGHTEN I and ENLIGHTEN II) to evaluate the efficacy and safety of LYR-210 for the treatment of CRS. Each trial is enrolling 180 CRS patients who have failed medical management and have not had prior sinus surgery, randomized 2:1 to either LYR-210 (7500µg MF) or control. Together, the aim of the two pivotal trials is to support an anticipated New Drug Application to the U.S. Food and Drug Administration for LYR-210.

Harlan W. Waksal, M.D., Executive Chairman of Lyra, commented, “We remain confident in the potential of Lyra’s technology to establish a new standard of care for millions of CRS patients seeking a non-surgical treatment that provides significant symptom relief. We believe that focusing on our in-house manufacturing capabilities mitigates risk associated with technology transfer to third parties, reduces regulatory risk, and empowers us to expedite our promising candidates toward approval and commercialization.”

Clinical Developments for LYR-210 and LYR-220

- Enrollment is ongoing in the ENLIGHTEN I Phase 3 trial of LYR-210 in surgically naïve CRS adult patients, with enrollment completion anticipated in mid-year 2023. ENLIGHTEN I clinical trial supply has been manufactured by Lyra.
- The Company is temporarily pausing enrollment in the ENLIGHTEN II Phase 3 trial of LYR-210 to align the trial with the availability of clinical supply, which it will manufacture in house. The Company anticipates resuming enrollment in the ENLIGHTEN II trial in the third quarter of 2023.
- In September 2022, the first patients were treated in the Part 2, randomized stage of the BEACON Phase 2 trial of LYR-220 in adult CRS patients who remain symptomatic despite having had prior sinus surgery. The trial is expected to enroll approximately 40 patients, with enrollment completion anticipated around year-end 2022.
- In September 2022, Lyra announced positive initial data from the Part 1, non-randomized portion of the BEACON trial, demonstrating the feasibility and tolerability of LYR-220 placement bilaterally in this patient population. All six patients were treated for at least six weeks and no serious or unexpected product related adverse events have been reported. Lyra has submitted these data for presentation at a scientific meeting in 2023.
- In September 2022, additional positive analyses from the LANTERN Phase 2 trial of LYR-210 in adult CRS patients were presented in oral sessions at the 68th Annual Meeting of the American Rhinologic Society (ARS) in Philadelphia. The data demonstrated that LYR-210 (7500µg) significantly improved symptom severity from baseline of 3 cardinal symptoms (3CS) of CRS – nasal blockage, nasal discharge, and facial pain/pressure – when assessed in a responder analysis at week 24.

Third Quarter 2022 Financial Highlights

- Cash and cash equivalents as of September 30, 2022 were $109.6 million, compared with $120.7 million at June 30, 2022. The Company expects its cash and cash equivalents balance to be sufficient to fund its planned operations through mid-2024.
- Research and development expenses for the quarter ended September 30, 2022 were $10.0 million compared to $7.1 million for the same period in 2021. The increase was primarily driven by an increase in clinical development costs related to the Company's three clinical trials and employee-related expenses.
- General and administrative expenses for the quarter ended September 30, 2022 were $5.1 million compared to $4.0 million for the same period in 2021. The increase was primarily driven by an increase in employee-related costs, including stock-based compensation.
- Net loss for the quarter ended September 30, 2022 was $14.8 million compared to $11.1 million for the same period in 2021.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage biotechnology company developing novel, integrated drug and delivery solutions for the localized treatment of patients with chronic rhinosinusitis (CRS) and other chronic diseases. Lyra has two investigational product candidates, LYR-210 and LYR-220, 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 and LYR-220 are bioresorbable polymeric matrices designed to be administered in a brief, non-invasive, in-office procedure and are intended to deliver up to six months of continuous mometasone furoate drug therapy to the sinonasal passages as an alternative to sinus surgery. LYR-210 is designed for surgically naïve patients and is being evaluated in the ENLIGHTEN Phase 3 clinical program, while LYR-220, an enlarged matrix, 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 United States who 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 the Company's cash runway through mid-2024, the Company's pipeline of product candidates, the enrollment and success of the ENLIGHTEN Phase 3 program, the Company's ability to manufacture its product candidates, and the enrollment and success of the Phase 2 BEACON trial. 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 additional 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 must scale its in-house manufacturing capabilities or rely 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 Quarterly Report on Form 10-Q filed with the SEC on November 8, 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.

LYRA THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 359	$ 14	$ 1,352	$ 14
Operating expenses:				
Research and development	10,048	7,077	29,346	19,352
General and administrative	5,137	4,018	13,157	10,639
Total operating expenses	15,185	11,095	42,503	29,991
Loss from operations	(14,826)	(11,081)	(41,151)	(29,977)
Other income:				
Interest income	60	26	108	81
Total other income	60	26	108	81
Net loss	$ (14,766)	$ (11,055)	$ (41,043)	$ (29,896)
Net loss per share attributable to common stockholders— basic and diluted	$ (0.40)	$ (0.85)	$ (1.47)	$ (2.30)
Weighted-average common shares outstanding—basic and diluted	36,826,364	13,001,514	28,014,434	12,979,837

LYRA THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(unaudited)

(in thousands, except share and per share data)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 109,558	$ 45,747
Restricted cash	329	—
Prepaid expenses and other current assets	2,343	2,171
Total current assets	112,230	47,918
Property and equipment, net	3,753	4,503
Operating lease right-of-use assets	608	1,355
Restricted cash	1,089	329
Other assets	1,783	762
Total assets	$ 119,463	$ 54,867
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,900	$ 3,125
Accrued expenses and other current liabilities	7,321	4,258
Operating lease liabilities	654	1,074
Deferred revenue	2,730	9,789
Total current liabilities	13,605	18,246
Operating lease liabilities, net of current portion	3	379
Deferred revenue, net of current portion	12,633	1,926
Total liabilities	26,241	20,551
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2022 and December 31, 2021; no shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 31,827,008 and 13,007,178 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	32	13
Additional paid-in capital	327,630	227,700
Accumulated deficit	(234,440)	(193,397)
Total stockholders' equity	93,222	34,316
Total liabilities and stockholders' equity	$ 119,463	$ 54,867

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