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): August 08, 2023

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

(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 August 8, 2023, Lyra Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2023. 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 of this Current Report on Form 8-K shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on August 8, 2023.
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: August 8, 2023

By: /s/ Jason Cavalier

Jason Cavalier
Chief Financial Officer

Lyra Therapeutics Reports Second Quarter 2023 Financial Results and Provides Corporate Update

-- ENLIGHTEN I Pivotal Phase 3 Trial of LYR-210 in Pre-Surgical Chronic Rhinosinusitis (CRS) on Track to Complete Enrollment in the Coming Weeks, with Data Expected in 1H 2024 --

-- Initial Topline Results from BEACON Phase 2 Trial of LYR-220 in Post-Surgical CRS Now Anticipated Earlier Than Expected, in September 2023 --

WATERTOWN, Mass., August 8, 2023 -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) ("Lyra" or the "Company"), a clinical-stage biotechnology company developing long-acting anti-inflammatory therapies for the localized treatment of chronic rhinosinusitis (CRS), today reported its financial results for the second quarter ended June 30, 2023 and provided a corporate update.

"Lyra is approaching two exciting clinical milestones: We expect to complete enrollment in the ENLIGHTEN I pivotal trial of LYR-210 in pre-surgical CRS patients in the coming weeks, with data expected in the first half of 2024," said Maria Palasis, Ph.D., President and CEO of Lyra. "In addition, this September, we will report initial topline results from the BEACON Phase 2 trial of LYR-220. This 40-patient, proof-of-concept study is the first clinical evaluation of Lyra's technology in the post-surgical setting and is intended to demonstrate safety and evaluate the therapeutic potential of LYR-220 for CRS patients who continue to experience symptoms despite prior ethmoid sinus surgery."

Dr. Palasis continued, "We strengthened our balance sheet to support the Company well beyond these key milestones with the completion of a private placement in May 2023, resulting in net proceeds of $46.7 million from existing and new shareholders. We believe this successful financing speaks to the enthusiasm for Lyra's drug delivery technology for CRS patients in need."

Lyra Program Highlights

ENLIGHTEN Pivotal Program of LYR-210 in CRS Patients with Surgically Naïve Ethmoid Sinuses

- Enrollment in the pivotal Phase 3 ENLIGHTEN I trial is ongoing, with completion expected in the coming weeks. Initial topline results from the ENLIGHTEN I clinical trial are anticipated in the first half of 2024.
- Enrollment is ongoing in the second pivotal Phase 3 trial, ENLIGHTEN II; enrollment completion is expected in the second half of 2024.

The ENLIGHTEN program consists of two pivotal 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 ethmoid sinus surgery, randomized 2:1 to either LYR-210 (7500µg mometasone furoate (MF)) or control for 24 weeks. The aim of the two pivotal trials is to support a New Drug Application to the U.S. Food and Drug Administration for LYR-210. Lyra has manufactured LYR-210 in house for both ENLIGHTEN trials.

BEACON Phase 2 Clinical trial of LYR-220 in Post-Surgical CRS Patients

- Initial topline results from the BEACON trial are expected in September 2023.

The Phase 2 BEACON trial is a randomized, controlled, parallel-group study to evaluate the safety and placement feasibility of the LYR-220 (7500µg MF) matrix, over a 24-week period, in symptomatic adult CRS patients who have had prior bilateral ethmoid sinus surgery. Efficacy will also be assessed. The trial

enrolled 40 patients and has a primary objective of evaluating the safety of LYR-220 for the treatment of CRS.

In-House Manufacturing

- In Q4 2022, Lyra announced the transition of manufacturing from a third-party manufacturer to in-house, leveraging its expertise to reliably supply product. Lyra intends to continue to advance its in-house manufacturing capabilities to prepare for commercial production.

Second Quarter 2023 Financial Highlights

Cash, cash equivalents and short-term investments as of June 30, 2023 were $116.2 million, compared with $82.7 million at March 31, 2023. Based on our current business plan, we anticipate that our cash, cash equivalents and short-term investment balance is sufficient to fund our operating expenses and capital expenditures into the first quarter of 2025.

On May 31, 2023, Lyra closed a private placement of common stock, pre-funded warrants to purchase common stock and purchase warrants to purchase common stock, resulting in net proceeds of approximately $46.7 million. The private placement included participation from new and existing investors, including Perceptive Advisors, Venrock Healthcare Capital Partners, Armistice Capital, Surveyor Capital (a Citadel company), North Bridge Venture Partners, Nantahala Capital, Samsara BioCapital, and Woodline Partners LP.

Research and development expenses for the quarter ended June 30, 2023 were $10.8 million compared to $10.8 million for the same period in 2022. During the quarter ended June 30, 2023, clinical development costs increased by $1.2 million as we continued to enroll patients in our ENLIGHTEN I and ENLIGHTEN II Phase 3 clinical trials, while employee related costs increased by $0.7 million as we increased our headcount to support increased research and development activities. These increases were offset by decreased product development and manufacturing costs of $1.5 million related to bringing production efforts in-house, decreased depreciation costs of $0.3 million, decreased professional and consulting costs of $0.2 million and decreased support costs of $0.1 million.

General and administrative expenses for the quarter ended June 30, 2023 were $4.6 million compared to $4.1 million for the same period in 2022. The increase was primarily attributable to increased employee related costs of $0.5 million, of which $0.2 million was related to stock-based compensation as well as an increase in support costs of $0.3 million and increase in professional and consulting fees of $0.1 million. This increase was partially offset by decreased public company-related costs of $0.4 million and decreased allocated overhead costs of $0.2 million.

We recognized $1.6 million related to loss on impairment of long-lived research and development assets currently held by our former contract manufacturer.

Net loss for the quarter ended June 30, 2023 was $15.6 million compared to $14.4 million for the same period in 2022.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage biotechnology company developing long-acting anti- inflammatory therapies for the localized treatment of patients with chronic rhinosinusitis (CRS). 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 nasal implants designed to be inserted in a simple, in-office procedure and are intended to deliver six months of continuous mometasone furoate drug therapy (7500µg MF) to the sinonasal passages. LYR-210 is designed for surgically naïve patients and is being evaluated in the ENLIGHTEN Phase 3 clinical program, while LYR-220, an enlarged implant, is being evaluated in the BEACON Phase 2 clinical trial in patients who have recurrent symptoms despite prior ethmoid sinus surgery. 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.lyratx.com and follow us on LinkedIn.

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 into the first quarter of 2025, the Company's pipeline of product candidates, the timing, enrollment and success of the ENLIGHTEN Phase 3 program, the timing for reporting top line data from the Company's clinical trials, the Company's ability to manufacture its product candidates in-house, the safety and efficacy of the Company's product candidates and the outcome 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; the fact that the Company has never scaled up an in-house manufacturing facility for clinical or commercial use; 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 and commercial supply; 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 war 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 August 8, 2023 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 and Comprehensive Loss

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Collaboration revenue	$ 458	$ 525	$ 868	$ 993
Operating expenses:				
Research and development	10,799	10,793	23,395	19,298
General and administrative	4,570	4,132	9,697	8,020
Loss on impairment of long-lived assets	1,592	—	1,592	—
Total operating expenses	16,961	14,925	34,684	27,318
Loss from operations	(16,503)	(14,400)	(33,816)	(26,325)
Other income:				
Interest income	897	34	1,969	48
Total other income	897	34	1,969	48
Loss before income tax expense	(15,606)	(14,366)	(31,847)	(26,277)
Income tax expense	(12)	—	(26)	—
Net loss	(15,618)	(14,366)	(31,873)	(26,277)
Other comprehensive income:				
Unrealized holding loss on short-term investments, net of tax	(15)	—	(37)	—
Comprehensive loss	$ (15,633)	$ (14,366)	$ (31,910)	$ (26,277)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.36)	$ (0.42)	$ (0.79)	$ (1.12)
Weighted-average common shares outstanding—basic and diluted	43,676,387	33,946,428	40,273,472	23,535,442

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

	June 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 54,361	$ 32,550
Short-term investments	61,789	65,344
Restricted cash	303	—
Prepaid expenses and other current assets	1,800	2,935
Total current assets	118,253	100,829
Property and equipment, net	560	2,243
Operating lease right-of-use assets	1,420	2,223
Restricted cash	1,089	1,392
Other assets	4,353	3,281
Total assets	$ 125,675	$ 109,968
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,188	$ 2,616
Accrued expenses and other current liabilities	6,738	9,030
Operating lease liabilities	1,688	1,549
Deferred revenue	1,497	1,275
Total current liabilities	14,111	14,470
Operating lease liabilities, net of current portion	—	667
Deferred revenue, net of current portion	12,987	14,077
Total liabilities	27,098	29,214
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at June 30, 2023 and December 31, 2022; no shares issued and outstanding at June 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at June 30, 2023 and December 31, 2022; 49,545,039 and 31,827,659 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	50	32
Additional paid-in capital	379,102	329,387
Accumulated other comprehensive income (loss), net of tax	(27)	10
Accumulated deficit	(280,548)	(248,675)
Total stockholders' equity	98,577	80,754
Total liabilities and stockholders' equity	$ 125,675	$ 109,968

Contact Information:
Ellen Cavaleri, Investor Relations
615.618.6228
ecavaleri@lyratx.com