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 12, 2024

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 November 12, 2024, Lyra Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2024. 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 November 12, 2024.
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 12, 2024

By: /s/ Jason Cavalier

Jason Cavalier, Chief Financial Officer

Lyra Therapeutics Reports Third Quarter 2024 Financial Results and Provides Corporate Update

– *Company continues to focus on upcoming results from ENLIGHTEN 2 pivotal Phase 3 trial in CRS patients expected in 2Q 2025 –*
– *Company reports topline safety results from ENLIGHTEN 1 Phase 3 extension study indicating no product-related serious adverse events and general consistency with the primary treatment phase –*

WATERTOWN, Mass., November 12, 2024 – Lyra Therapeutics, Inc. (Nasdaq: LYRA) ("Lyra" or the "Company"), a clinical-stage biotechnology company developing long-acting, anti-inflammatory sinonasal implants for the treatment of chronic rhinosinusitis (CRS), today reported its financial results for the third quarter ended September 30, 2024 and provided a corporate update.

"We look forward to key milestones in the coming months from the two ongoing ENLIGHTEN Phase 3 trials that will provide us with a more complete data set and greater insight into determining a potential pathway to approval for LYR-210 in CRS patients with and without nasal polyps. The topline 52-week safety data from the ENLIGHTEN 1 safety extension study was in-line with the primary treatment phase, with no product-related serious adverse events, including for those patients that received a repeat dose, resulting in a 12-month treatment period. We are anticipating additional data from the ENLIGHTEN 1 safety extension study in the coming months, which will be presented at an upcoming medical conference, as well as topline results from the ENLIGHTEN 2 pivotal trial expected in Q2 2025," said Maria Palasis, Ph.D., President and CEO of Lyra Therapeutics.

Dr. Palasis continued, "We eagerly await the upcoming data readouts, and they will guide us in making data-driven evaluations as we determine the potential path for LYR-210 to add value for CRS patients, investors and other stakeholders."

The ENLIGHTEN program consists of two pivotal Phase 3 clinical trials, ENLIGHTEN 1 and ENLIGHTEN 2, to evaluate the efficacy and safety of LYR-210 for the treatment of CRS. Each ENLIGHTEN trial has enrolled approximately 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) or sham control for 24 weeks.

Topline Results from the ENLIGHTEN 1 52-week extension study

Today, Lyra reported topline 52-week safety data from the ENLIGHTEN 1 safety extension study:

- Safety data for LYR-210 was generally consistent with the 24-week primary treatment phase, including for those patients that received a repeat dosing, resulting in a 12-month treatment period.
- LYR-210 was generally well tolerated, with no product-related serious adverse events. The most commonly reported adverse events in the study population were chronic sinusitis, nasal odor, epistaxis, sinusitis, and nasopharyngitis.

Clinical Program Highlights

Enrollment in ENLIGHTEN 2 completed

- In October 2024, Lyra announced that the pivotal Phase 3 ENLIGHTEN 2 clinical trial of LYR-210 in adult patients with CRS who have not had prior ethmoid sinus surgery, was fully enrolled, achieving the expected enrollment timeframe of second half of 2024.

Milestones for Ongoing ENLIGHTEN Pivotal Program of LYR-210 in CRS

- Topline results from ENLIGHTEN 2 are expected in Q2 2025.

Third Quarter 2024 Financial Highlights

Cash, cash equivalents and short-term investments as of September 30, 2024 were $51.6 million, compared with $67.5 million at June 30, 2024. 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 2026.

Research and development expenses for the quarter ended September 30, 2024 were $5.9 million compared to $12.4 million for the same period in 2023, representing a decrease of $6.5 million. The decrease in research and development expenses for the three months ended September 30, 2024 was primarily attributable to a $3.8 million decrease in clinical related costs as we completed both the BEACON trial for LYR-220 and the primary study phase of the ENLIGHTEN 1 trial for LYR-210, a decrease of $2.5 million in employee related costs primarily driven by the reduction in force which occurred in May 2024, a decrease in professional and consulting costs of $0.4 million and a decrease in product development and manufacturing costs of $0.4 million. This decrease in costs was partially offset by an increase in allocated costs and depreciation of $0.6 million.

General and administrative expenses for the quarter ended September 30, 2024 were $3.9 million compared to $5.0 million for the same period in 2023, representing a decrease of $1.1 million. The decrease in general and administrative expenses for the three months ended September 30, 2024 was primarily driven by a decrease in professional and consulting fees of $1.0 million as we scaled back activities subsequent to announcing in May 2024 that the ENLIGHTEN 1 trial did not meet its primary endpoint, in addition to a decrease in employee related costs of $0.5 million primarily due to the reduction in force which occurred in May 2024. These cost decreases were partially offset by an increase in allocation and support costs of $0.4 million primarily due to the increased rent and facilities expenses for the Company's three leased facilities for the three months ended September 30, 2024 compared to the three months ended September 30, 2023.

Net loss for the quarter ended September 30, 2024 was $11.9 million compared to $15.7 million for the same period in 2023.

LYRA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Collaboration revenue	$ 195	$ 544	$ 1,325	$ 1,412
Operating expenses:				
Research and development	5,902	12,368	37,404	35,763
General and administrative	3,931	5,003	14,888	14,700
Impairment of property and equipment	—	—	1,883	1,592
Impairment of right-of-use assets	—	—	22,836	—
Restructuring and other related charges	2,804	—	9,254	—
Total operating expenses	12,637	17,371	86,265	52,055
Loss from operations	(12,442)	(16,827)	(84,940)	(50,643)
Other income:				
Interest income	576	1,192	2,517	3,161
Total other income	576	1,192	2,517	3,161
Loss before income tax expense	(11,866)	(15,635)	(82,423)	(47,482)
Income tax expense	(7)	(16)	(33)	(42)
Net loss	(11,873)	(15,651)	(82,456)	(47,524)
Other comprehensive loss:				
Unrealized holding gain (loss) on short-term investments, net of tax	24	20	(13)	(17)
Comprehensive loss	$ (11,849)	$ (15,631)	$ (82,469)	$ (47,541)
Net loss per share attributable to common stockholders— basic and diluted	$ (0.18)	$ (0.27)	$ (1.27)	$ (1.04)
Weighted-average common shares outstanding— basic and diluted	65,456,735	56,953,685	64,981,219	45,894,643

LYRA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(unaudited)
(in thousands, except share data)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 23,800	$ 22,353
Short-term investments	27,826	80,400
Prepaid expenses and other current assets	2,818	2,068
Total current assets	54,444	104,821
Property and equipment, net	1,613	2,043
Operating lease right-of-use assets	20,707	33,233
Restricted cash	1,992	1,392
Other assets	—	1,111
Total assets	$ 78,756	$ 142,600
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,292	$ 3,131
Restructuring liability	4,855	—
Accrued expenses and other current liabilities	3,197	9,374
Operating lease liabilities	4,003	5,434
Deferred revenue	607	1,658
Total current liabilities	14,954	19,597
Operating lease liabilities, net of current portion	31,321	21,447
Deferred revenue, net of current portion	11,862	12,136
Total liabilities	58,137	53,180
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; no shares issued and outstanding at September 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2024 and December 31, 2023; 65,456,735 and 57,214,550 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	65	57
Additional paid-in capital	414,345	400,685
Accumulated other comprehensive income, net of tax	20	33
Accumulated deficit	(393,811)	(311,355)
Total stockholders' equity	20,619	89,420
Total liabilities and stockholders' equity	$ 78,756	$ 142,600

About LYR-210

LYR-210 is an investigational product candidate for the treatment of chronic rhinosinusitis (CRS) in patients who have failed current therapies and require further intervention. LYR-210 is a bioresorbable nasal implant designed to be inserted in a simple, in-office procedure. LYR-210 is intended to deliver six months of continuous anti-inflammatory therapy, mometasone furoate, to the sinonasal passages to treat CRS. LYR-210 is being evaluated in the ENLIGHTEN pivotal Phase 3 clinical program.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage biotechnology company developing long-acting, anti-inflammatory sinonasal implants for the treatment of chronic rhinosinusitis (CRS). Lyra Therapeutics is developing therapies for CRS, a highly prevalent inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities. LYR-210, the company's lead product, is a bioabsorbable nasal implant designed to be administered in a simple, in-office procedure and is intended to deliver six months of continuous anti-inflammatory drug therapy (7500µg mometasone

furoate) to the sinonasal passages for the treatment of CRS with a single administration. LYR-210, being evaluated in the ENLIGHTEN Phase 3 clinical program, is intended for patients with and without nasal polyps. The company's therapies are intended 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 whether LYR-210 could potentially benefit patients with CRS, the completion of the Company's ENLIGHTEN 2 Phase 3 clinical trial, and the timing of the release of topline data from the ENLIGHTEN 2 Phase 3 clinical 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. 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 12, 2024 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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