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 13, 2025

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 March 13, 2025, Lyra Therapeutics, Inc. (the "Company") announced its financial results for the year ended December 31, 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 March 13, 2025.
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 13, 2025

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

Exhibit 99.1

Lyra Therapeutics Reports Fourth Quarter and Full Year 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* –

– *In parallel, the Company continues to analyze data and explore opportunities for LYR-210 in CRS patient cohort with nasal polyps* –

WATERTOWN, Mass., March 13, 2025 – 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 fourth quarter and full year ended December 31, 2024 and provided a corporate update.

"We eagerly await the upcoming readout from the ENLIGHTEN 2 Phase 3 study in Q2 2025 which we expect will provide us with important data and enable us to gain further insight about the potential efficacy of LYR-210 across a broad CRS population, including both patients with and without nasal polyps. The data from this pivotal study will enable us to determine the path for LYR-210 to potentially add value for patients, investors and our business," said Maria Palasis, Ph.D., President and CEO of Lyra Therapeutics.

Dr. Palasis continued, "At the same time, we continue to be encouraged about the positive post-hoc data analyses in the CRS patient cohort with nasal polyps, including the recent results from the 52-week ENLIGHTEN 1 Extension Study in the polyp cohort which are consistent with the previously-reported positive results from the polyp cohort of the ENLIGHTEN 1 main study stage. We are building more evidence in the therapeutic potential of LYR-210 in CRS patients with polyps, and we have also engaged with the FDA to align on details for a registration path in CRS with polyps."

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 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 for patients in the polyp cohort in ENLIGHTEN 1 52-week extension study

In early January 2025, in addition to safety data for the entire patient pool, post-hoc results were disclosed for patients in the polyp cohort of the ENLIGHTEN 1 52-week extension study:

- Polyp patients from the initial sham treatment group who crossed over to receive LYR-210 treatment exhibited a mean improvement in both symptoms and polyp size at 52 weeks.
- Polyp patients from the initial LYR-210 treatment group who crossed over to receive sham treatment demonstrated a durable response to LYR-210 treatment out to one year.

These new data from the polyp cohort in ENLIGHTEN 1 Extension Study are consistent with the previously-reported positive data from the polyp cohort in ENLIGHTEN 1 which showed:

- Improvement in patient symptoms for LYR-210 treated patients relative to the sham control group was observed.
- Nasal Congestion Scores improved in polyp patients with at least moderate nasal congestion at baseline.
- Polyp size was reduced despite inclusion of patients with only small polyps.

LYR-210 regulatory highlights

- In December 2024, Lyra received written responses from the U.S. Food and Drug Administration (FDA) to topics outlined in a briefing document supporting a Type C meeting to discuss the development of LYR-210 for patients who have chronic rhinosinusitis with nasal polyps (CRSwNP). Overall, the responses helped to clarify the potential path forward for LYR-210 for patients with CRSwNP, and signaled, importantly, the safety dataset of the proposed pivotal study should be sufficient, along with data from the ENLIGHTEN program and the LANTERN Phase 2 study, subject to no further safety concerns being observed in current studies with LYR-210.
- Based on this exchange with FDA, there is alignment on various elements of a potential Phase 3 pivotal study, e.g., choice of co-primary endpoints, sample size, inclusion criteria, and in-study assessments.

Milestones for ongoing ENLIGHTEN pivotal program of LYR-210 in CRS

- Topline results from the ENLIGHTEN 2 pivotal Phase 3 clinical trial of LYR-210 are expected in Q2 2025.
- We expect an additional ~30 polyp patients in the ENLIGHTEN 2 trial, which combined with the 35 polyp patients in the ENLIGHTEN 1 trial, would result in a total of ~65 polyp patients in the ENLIGHTEN program.

Planned Reverse Stock Split

Lyra intends to implement a reverse stock split in order to increase the per share trading price of the Company's common shares for the purpose of complying with the minimum $1.00 bid price requirement for continued listing on The Nasdaq Capital Market. The reverse stock split requires

approval by the Company's board of directors as well as the Company's stockholders at the annual stockholder meeting to be scheduled in Q2 2025, at which time the Company will be in a position to share the details of the proposed reverse stock split.

Fourth Quarter and Full Year 2024 Financial Highlights

Cash and cash equivalents as of December 31, 2024 were $40.6 million, compared with cash, cash equivalents and short-term investments of $51.6 million at September 30, 2024. Based on our current business plan, we anticipate that our cash, cash equivalents and any applicable 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 fourth quarter and full year ended December 31, 2024 were $6.4 million and $43.8 million, respectively, compared to $12.2 million and $48.0 million for the same periods in 2023. The decrease in research and development expenses year over year was primarily attributable to a decrease in clinical related costs of $5.5 million as we completed both the BEACON trial for LYR-220 and the ENLIGHTEN 1 trial for LYR-210, a decrease of $3.5 million in employee related costs primarily driven by the reduction in force which occurred in May 2024 and a decrease in product development and manufacturing costs of $1.0 million. This decrease in costs was partially offset by increases in allocated and support costs and depreciation of $4.7 million, an increase in professional and consulting costs of $0.4 million and a $0.6 million gain recorded in 2023 related to our legal settlement with a former contract manufacturer.

General and administrative expenses for the fourth quarter and full year ended December 31, 2024 were $3.6 million and $18.5 million, respectively, compared to $4.4 million and $19.1 million for the same periods in 2023. The decrease in general and administrative expenses year over year was primarily driven by a decrease in professional, consulting and public company fees of $0.7 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 $0.8 million primarily due to the reduction in force which occurred in May 2024 and $0.4 million incurred in 2023 related to our financing efforts. This decrease in costs was partially offset by a net increase in allocation, support, depreciation and financing costs of $1.3 million primarily due to the increased rent and facilities expenses for the Company's three leased facilities for the full year 2024 compared to the full year 2023.

Net loss for the fourth quarter and full year ended December 31, 2024 was $11.0 million and $93.4 million, respectively, compared to $15.1 million and $62.7 million for the same periods in 2023.

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

	Year Ended December 31,	
	2024	2023
Collaboration revenue	$ 1,534	$ 1,558
Operating expenses:		
Research and development	43,766	48,029
General and administrative	18,501	19,057
Impairment of property and equipment	1,883	1,592
Impairment of right-of-use assets	22,836	—
Restructuring and other related charges	10,896	—
Total operating expenses	97,882	68,678
Loss from operations	(96,348)	(67,120)
Other income:		
Interest income	2,952	4,499
Total other income	2,952	4,499
Loss before income tax expense	(93,396)	(62,621)
Income tax expense	(39)	(59)
Net loss	(93,435)	(62,680)
Other comprehensive (loss) income:		
Unrealized holding (loss) gain on short-term investments, net of tax	(33)	23
Comprehensive loss	$ (93,468)	$ (62,657)
Net loss per share —basic and diluted	$ (1.43)	$ (1.26)
Weighted-average common shares outstanding—basic and diluted	65,113,859	49,804,283

LYRA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 40,577	$ 22,353
Short-term investments	—	80,400
Prepaid expenses and other current assets	2,448	2,068
Total current assets	43,025	104,821
Property and equipment, net	1,404	2,043
Operating lease right-of-use assets	19,924	33,233
Restricted cash	1,993	1,392
Other assets	—	1,111
Total assets	$ 66,346	$ 142,600
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,179	$ 3,131
Restructuring liability	4,347	—
Accrued expenses and other current liabilities	2,586	9,374
Operating lease liabilities	4,121	5,434
Deferred revenue	398	1,658
Total current liabilities	12,631	19,597
Operating lease liabilities, net of current portion	30,259	21,447
Deferred revenue, net of current portion	11,862	12,136
Total liabilities	54,752	53,180
Commitments and contingencies (Note 17)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2024 and 2023; no shares issued and outstanding at December 31, 2024 and 2023	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2024 and 2023; 65,515,440 and 57,214,550 shares issued and outstanding as of December 31, 2024 and 2023, respectively	65	57
Additional paid-in capital	416,319	400,685
Accumulated other comprehensive income, net of tax	—	33
Accumulated deficit	(404,790)	(311,355)
Total stockholders' equity	11,594	89,420
Total liabilities and stock and stockholders' equity	$ 66,346	$ 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. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," and similar expressions are intended to identify forward-looking statements. 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 2026, whether LYR-210 could potentially benefit patients with CRS, the completion of the Company's ENLIGHTEN 2 Phase 3 clinical trial, the timing of the release of topline data from the ENLIGHTEN 2 Phase 3 clinical trial, whether the ENIGHTEN results will include important data or enable the Company to gain further insight about the efficacy of LYR-210, and the Company's intentions concerning the implementation of a reverse stock split to comply with the minimum bid price rule to maintain its listing on the Nasdaq Capital 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 Company's failure to meet its primary endpoint in its ENLIGHTEN 1 Phase 3 clinical trial; the fact the Company terminated the employment of approximately 87 employees following the announcement that it failed to attain its primary endpoint; 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 fact that the Company needs to conduct at least one additional phase 3 clinical trial; the Company's ability to continue as a going concern; the Company's limited operating history; the fact that the Company has no approved products; the fact that clinical trial data is subject to change until the completion of the applicable clinical study report; the fact that clinical trials required for the Company's product candidates are expensive and time-consuming, and their outcome is uncertain; effects of recently enacted and future legislation; the possibility of system failures or security breaches; effects of significant competition; the Company's reliance on third parties to conduct its preclinical studies and clinical trials; failure to obtain and maintain or adequately protect the Company's intellectual property rights; failure to retain key personnel; 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 13, 2025 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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