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 21, 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 March 21, 2024, Lyra Therapeutics, Inc. (the "Company") announced its financial results for the year ended December 31, 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 March 21, 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: March 21, 2024

By: /s/ Jason Cavalier

Jason Cavalier, Chief Financial Officer

Lyra Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Corporate Update

-- Data from ENLIGHTEN I Pivotal Phase 3 Trial of LYR-210 in Chronic Rhinosinusitis (CRS) Anticipated Q2 2024 --

WATERTOWN, Mass., March 21, 2024 -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) ("Lyra" or the "Company"), a clinical-stage biotechnology company developing long-acting, anti-inflammatory nasal inserts for the treatment of chronic rhinosinusitis (CRS), today reported its financial results for the fourth quarter and full year ended December 31, 2023 and provided a corporate update.

"We look forward to reporting topline results from our ENLIGHTEN I pivotal Phase 3 trial of our lead product candidate, LYR-210, in CRS patients in the second quarter of this year," said Maria Palasis, Ph.D., President and CEO of Lyra. "We believe the positive findings from our Phase 2 studies, including the recent BEACON trial results of our next product candidate, LYR-220, de-risk our pivotal program and validate the potential of our nasal insert to treat CRS."

Dr. Palasis continued, "By maintaining a steady dose of corticosteroid at the site of disease for six months with a single administration of LYR-210 or LYR-220, we believe our product candidates have the potential to address the needs of up to four million CRS patients who fail current medical management in the United States."

LYR-210 and LYR-220 are bioabsorbable nasal inserts designed to be administered 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 for the treatment of CRS with a single administration. LYR-210 has a smaller dimension and is intended for patients with narrow anatomy, primarily those who have not undergone ethmoid sinus surgery (ESS). LYR-220, a larger insert, is designed for CRS patients whose nasal cavity is enlarged due to previous ESS.

Upcoming 2024 Milestones

- Report topline results from ENLIGHTEN I pivotal Phase 3 clinical trial of LYR-210 in Q2 2024
- Complete enrollment in ENLIGHTEN II, the second pivotal Phase 3 clinical trial of LYR-210, in the second half of 2024
- Report results from ENLIGHTEN I 52-week extension study in Q4 2024
- End of Phase 2 meeting for LYR-220 with the U.S. Food and Drug Administration (FDA) in the second half of 2024

Program Highlights

BEACON Phase 2 Clinical Trial of LYR-220 in CRS Patients who Have Had Prior Ethmoid Sinus Surgery

- In September 2023, Lyra announced positive topline results from the BEACON Phase 2 clinical trial of LYR-220 in adult patients with CRS who have recurrent symptoms despite prior ESS:

- LYR-220 demonstrated statistically significant and clinically relevant improvements in Sino-Nasal Outcome Test (SNOT-22) score (-16.8; p=0.007) and in a composite of the 3 cardinal symptoms of CRS (nasal obstruction, nasal discharge, facial pain/pressure; 3CS) (-1.50; p=0.02) compared to sham control at 24 weeks, with statistically significant improvement observed as early as week 2 in SNOT-22 and at week 4 in 3CS.
- Patients with impaired smell at baseline showed statistically significant improvement in their sense of smell compared to control at week 24 (-0.87; p=0.026).
- LYR-220 demonstrated statistically significant improvement in ethmoid sinus opacification as measured by computed tomography (CT) scans at week 24 (p=0.035). These data provide objective radiological evidence of improvement with LYR-220 treatment.
- At End of Study, Week 28, patients receiving LYR-220 showed continued symptomatic improvement compared to sham control in both SNOT-22 (-17.6; p=0.007) and in 3CS (-1.28; p=0.063).
- The study met its primary safety endpoint, with no serious adverse events observed. The most commonly reported adverse events included sinusitis, nasopharyngitis, bronchitis, and COVID-19.

The Phase 2 BEACON trial was a randomized, controlled, parallel-group study intended to evaluate the safety and placement feasibility of the LYR-220 (7500µg MF) matrix, over a 28-week period, in symptomatic CRS patients who have had prior ESS. The study consisted of two parts: Part 1 was designed primarily to assess the feasibility and tolerability of two 7500µg MF matrix designs; in Part 2, 42 patients were randomized 1:1 to receive LYR-220 or sham control.

ENLIGHTEN Pivotal Program of LYR-210 in CRS Patients who have not had Ethmoid Sinus Surgery

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. The Company designed each trial to evaluate 180 CRS patients who have failed medical management and have not had prior ESS, randomized 2:1 to either LYR-210 (7500µg MF) or control over 24 weeks. The ENLIGHTEN I trial also includes an extension phase to further assess the safety and repeat use of LYR-210 through 52 weeks. The goal of the two pivotal trials is to support a New Drug Application to the FDA for LYR-210.

Fourth Quarter and Full Year 2023 Financial Highlights

- Cash, cash equivalents and short-term investments were $102.8 million as of December 31, 2023, compared to $102.6 million as of September 30, 2023. Management believes its existing cash, cash equivalents and short-term investments balance are sufficient to fund the Company’s planned operations into the first quarter of 2025.
- Research and development expenses for the fourth quarter and full year ended December 31, 2023 were $12.2 million and $48.0 million, respectively, compared to $9.5 million and $38.8 million for the same periods in 2022. The increase year over year was primarily driven by higher

clinical development costs related to the Company's three clinical trials and employee-related expenses.

- General and administrative expenses for the fourth quarter and full year ended December 31, 2023 were $4.4 million and $19.1 million, respectively, compared to $4.4 million and $17.6 million for the same periods in 2022. The increase year over year was primarily driven by higher employee-related costs.
- The Company recorded an impairment charge of $1.6 million related to long-lived assets for the year ended December 31, 2023. The Company recorded an impairment charge of $1.3 million related to long-lived assets for the year ended December 31, 2022.
- Net loss for the fourth quarter and full year ended December 31, 2023 was $15.1 million and $62.7 million, respectively, compared to $14.2 million and $55.3 million for the same periods in 2022.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage biotechnology company developing long-acting, anti-inflammatory nasal inserts for the treatment of chronic rhinosinusitis (CRS). Lyra has two 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 bioabsorbable nasal inserts designed to be administered 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 for the treatment of CRS with a single administration. LYR-210, being evaluated in the ENLIGHTEN Phase 3 clinical program, has a smaller dimension and is intended for patients with narrow anatomy, primarily patients who have not undergone ethmoid sinus surgery. LYR-220 is a larger insert designed for CRS patients whose nasal cavity is enlarged due to previous 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. 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 2025, the enrollment and success of the ENLIGHTEN Phase 3 program and BEACON Phase 2 program, the timing for reporting top line data from the Company's clinical trials including ENLIGHTEN I, whether positive results from our Phase 2 studies, including the BEACON trial of LYR-220 de-risk our pivotal program and validate the potential of our nasal insert to treat CRS, whether our product candidates maintain a steady dose of corticosteroid at the site of disease for six months with a single

administration, the anticipated demand and market size for our product candidates, and the safety and efficacy of the our product candidates. 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 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 the Company's product candidates are in various stages of development; the fact that clinical trial data is subject to change until the completion of the applicable clinical study report, 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 the Company's product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway; the Company's potential 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; 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 Annual Report on Form 10-K filed with the SEC on March 22, 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.

LYRA THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share data)

	Year Ended December 31,	
	2023	2022
Collaboration revenue	$ 1,558	$ 1,363
Operating expenses:		
Research and development	48,029	38,797
General and administrative	19,057	17,556
Loss on impairment of long-lived assets	1,592	1,316
Total operating expenses	68,678	57,669
Loss from operations	(67,120)	(56,306)
Other income:		
Interest income	4,499	1,041
Total other income	4,499	1,041
Loss before income tax expense	(62,621)	(55,265)
Income tax expense	(59)	(13)
Net loss	(62,680)	(55,278)
Other comprehensive income:		
Unrealized holding gain on short-term investments, net of tax	23	10
Comprehensive loss	$ (62,657)	$ (55,268)
Net loss per share —basic and diluted	$ (1.26)	$ (1.83)
Weighted-average common shares outstanding—basic and diluted	49,804,283	30,235,689

LYRA THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 22,353	$ 32,550
Short-term investments	80,400	65,344
Prepaid expenses and other current assets	2,068	2,935
Total current assets	104,821	100,829
Property and equipment, net	2,043	2,243
Operating lease right-of-use assets	33,233	2,223
Restricted cash	1,392	1,392
Other assets	1,111	3,281
Total assets	$ 142,600	$ 109,968
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,131	$ 2,616
Accrued expenses and other current liabilities	9,374	9,030
Operating lease liabilities	5,434	1,549
Deferred revenue	1,658	1,275
Total current liabilities	19,597	14,470
Operating lease liabilities, net of current portion	21,447	667
Deferred revenue, net of current portion	12,136	14,077
Total liabilities	53,180	29,214
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2023 and 2022; no shares issued and outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2023 and 2022; 57,214,550 and 31,827,659 shares issued and outstanding at December 31, 2023 and 2022, respectively	57	32
Additional paid-in capital	400,685	329,387
Accumulated other comprehensive income, net of tax	33	10
Accumulated deficit	(311,355)	(248,675)
Total stockholders' equity	89,420	80,754
Total liabilities and stock and stockholders' equity	$ 142,600	$ 109,968

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