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 9, 2021

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)**	**(I.R.S. Employer Identification No.)**

480 Arsenal Way
Watertown, MA 02472
(Address of principal executive offices) (Zip Code)

(617) 393-4600
(Registrant's telephone number, include area code)

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 9, 2021, Lyra Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2021. 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 9, 2021
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 9, 2021

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

Lyra Therapeutics Reports Third Quarter 2021 Financial Results and Provides Corporate Update

- *LYR-210 Phase 3 ENLIGHTEN and LYR-220 Phase 2 BEACON studies on track to initiate around EOY -*
- *New LYR-210 Phase 2 LANTERN 6-month follow up data and LYR-210 PK study presented at ARS Annual Meeting -*
- *Jason Cavalier appointed as Chief Financial Officer -*

WATERTOWN, Mass., Nov. 9, 2021 - Lyra Therapeutics, Inc. (Nasdaq: LYRA), a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained, and local delivery of medications to the ear, nose and throat (ENT) passages and other diseased tissues, today reported financial results for the quarter ended September 30, 2021, and highlighted recent accomplishments.

Company Highlights

- Lyra expects to initiate the LYR-220 Phase 2 BEACON study in post-surgical chronic rhinosinusitis (CRS) patients this month, and remains on track to initiate the LYR-210 Phase 3 ENLIGHTEN program in surgically-naïve CRS patients around the end of the year.
- At the 67th Annual Meeting of the American Rhinologic Society (ARS), new positive data on LYR-210 were the subject of two presentations. The Phase 2 LANTERN 6-month post-treatment evaluation showed continued safety and that approximately half of treated CRS patients experienced a durable response six months post LYR-210 removal. The recently completed pharmacokinetic (PK) study showed that Mometasone Furoate (MF) blood levels were constant over the 56 days, providing further evidence that LYR-210 delivers a steady daily dose of MF with accompanying rapid symptom relief during this time period. The study showed LYR-210 to be effective in patients with less severe disease, with subjects' average baseline SNOT-22 scores of 36 points, compared to 68 points in the LANTERN study. The PK study was selected as a top clinical presentation at the meeting.
- In September, the Company appointed Jason Cavalier as Chief Financial Officer. Mr. Cavalier is a highly experienced investment banker with an extensive background in advising companies on financing and strategic alternatives, most recently serving at Cantor Fitzgerald as Managing Director, Head of Life Sciences Mergers & Acquisitions. He succeeds Don Elsey, who retired as the Company's CFO and is currently serving in an advisory role to assist with the transition.
- The LYR-210 Phase 2 LANTERN manuscript was published online in the peer-review journal, *International Forum of Allergy & Rhinology*, and also won the ARS Annual Meeting 2021 Clinical Science Maurice Cottle Award.
- Preclinical data on Lyra's XTreo™ platform were published online in the peer-review journal, *American Journal of Rhinology & Allergy*. The results demonstrate that XTreo™ technology platform provides targeted and sustained dosing of anti-inflammatory medication.
- The Company hosted two virtual events, in August and October, featuring key opinion leaders in CRS.

“We are incredibly proud of Lyra’s recent progress, with a growing body of clinical evidence supporting the potential for LYR-210 to become the new standard of care for chronic rhinosinusitis,” said Maria Palasis, PhD, President and Chief Executive Officer of Lyra Therapeutics. “Key opinion leaders in CRS are also sharing their enthusiasm for how they believe LYR-210 will provide a much-needed treatment option for the majority of their CRS patients, who fail medical management today. Looking ahead to the remainder of this year, we are excited to be initiating two later-stage clinical studies, our Phase 3 ENLIGHTEN study for LYR-210 and our Phase 2 BEACON study for LYR-220, in surgically-naïve and post-surgical CRS patients, respectively. Together these two products are designed to address the full range of CRS patients that present to an ENT office.”

Third Quarter 2021 Financial Highlights

- Cash and cash equivalents as of September 30, 2021 were $58.1 million, compared with $69.0 million at June 30, 2021. The Company expects its cash balance to be sufficient to fund its planned operations through 2022.
- Research and development expenses for the quarter ended September 30, 2021 were $7.1 million compared to $3.7 million for the same period in 2020, primarily attributable to an increase in product development and manufacturing expenses and an increase in research and development headcount and consulting expenses.
- General and administrative expenses for the third quarter 2021 were $4.0 million compared to $2.7 million for the same period in 2020, primarily attributable to an increase in professional and consulting expenses, stock-based compensation and general and administrative headcount.
- Total operating expenses for the quarter ended September 30, 2021 were $11.1 million compared to $6.4 million for the same period in 2020.
- Net loss for the third quarter was $11.1 million compared to $6.3 million for the same period in 2020.

Conference Call and Webcast Details

LYRA will host a conference call and live webcast today at 4:30 p.m. ET. To access the live call by phone, dial (833) 519-1249 (domestic) or (914) 800-3822 (international) and use the conference ID: 5064627. To access the live webcast of the call, please visit the Investor Relations section of the Lyra Therapeutics website at https://investors.lyratherapeutics.com/. The recorded webcast will be available for replay for approximately 30 days following the call.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained, local delivery of medications to diseased tissues not accessible with conventional therapeutic approaches. Lyra's XTreo™ platform is comprised of a biocompatible mesh scaffold, an engineered elastomeric matrix and a versatile polymer-drug complex. The company's current pipeline of therapeutics target tissues deep in the ear, nose and throat passages and are designed to deliver continuous drug therapy for up to six months following a single non-invasive, in-office administration. Lyra's lead product candidate, LYR-210, is entering Phase 3 clinical development for the treatment of chronic rhinosinusitis (CRS) as an alternative to primary sinus surgery. Lyra's second product candidate, LYR-220, is entering Phase 2 development and is designed to be an alternative to revision CRS sinus surgery and post-surgical medical management. For more information, please visit www.lyratherapeutics.com and follow us on LinkedIn and Twitter.

Forward-Looking Statement

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 plans for the LYR-220 Phase 2 BEACON study in post-surgical chronic rhinosinusitis (CRS) patients and the LYR-210 Phase 3 ENLIGHTEN program in surgically-naïve CRS patients, as well as the sufficiency of the company's cash balance to fund its planned operations through 2022. 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 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; our 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 relies 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; 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 9, 2021 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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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,	
	2021	**2020**	**2021**	**2020**
Collaboration revenue	$ 14	$ —	$ 14	$ —
Operating expenses:				
Research and development	7,077	3,712	19,352	8,779
General and administrative	4,018	2,651	10,639	6,377
Total operating expenses	11,095	6,363	29,991	15,156
Loss from operations	(11,081)	(6,363)	(29,977)	(15,156)
Other income:				
Interest income	26	29	81	50
Total other income	26	29	81	50
Net loss	$ (11,055)	$ (6,334)	$ (29,896)	$ (15,106)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.85)	$ (0.49)	$ (2.30)	$ (2.13)
Weighted-average common shares outstanding—basic and diluted	13,001,514	12,924,682	12,979,837	7,133,967

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

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 58,131	$ 74,593
Prepaid expenses and other current assets	2,755	1,324
Total current assets	60,886	75,917
Property and equipment, net	4,706	2,165
Operating lease right-of-use assets	1,596	2,301
Restricted cash	329	329
Other assets	245	118
Total assets	$ 67,762	$ 80,830
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,912	$ 922
Accrued expenses and other current liabilities	3,968	2,977
Operating lease liabilities	1,052	985
Deferred revenue	9,841	—
Total current liabilities	17,773	4,884
Operating lease liabilities, net of current portion	656	1,454
Deferred revenue, net of current portion	2,145	—
Total liabilities	20,574	6,338
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2021 and December 31, 2020; 13,004,578 and 12,932,377 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	13	13
Additional paid-in capital	226,955	224,363
Accumulated deficit	(179,780)	(149,884)
Total stockholders' equity	47,188	74,492
Total liabilities and stockholders' equity	$ 67,762	$ 80,830