

**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 10, 2020**

**LYRA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

**001-39273**  
(Commission File Number)

**84-1700838**  
(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 10, 2020, Lyra Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended September 30, 2020. 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release issued on November 10, 2020</a>

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 10, 2020

By: /s/ R. Don Elsey

R. Don Elsey

Chief Financial Officer



## Lyra Therapeutics Reports Third Quarter 2020 Financial Results and Provides Corporate Update

- On course to report topline Phase 2 LANTERN study results in December 2020 -

**WATERTOWN, MA – November 10, 2020** - Lyra Therapeutics, Inc. (Nasdaq: LYRA), a clinical-stage therapeutics company focused on the development and commercialization of novel integrated drug and delivery solutions for the localized treatment of patients with ear, nose and throat (ENT) diseases, today reported financial results for the quarter ended September 30, 2020 and provided a corporate update.

### Key Third Quarter 2020 and Subsequent Highlights

- **Company On Track to Report Topline Phase 2 Results for LYR-210 in the Treatment of Chronic Rhinosinusitis.** Despite the challenges that COVID-19 has posed for the biotechnology community more generally, Lyra Therapeutics is pleased to report that it remains on track to announce topline Phase 2 results from its LANTERN study of LYR-210 in chronic rhinosinusitis (CRS) in December.
- **Appointed Nancy L. Snyderman to Board of Directors.** In October, the company announced that Dr. Snyderman joined the Lyra Therapeutics board. Dr. Snyderman is an accomplished Otolaryngologist-Head and Neck Surgeon and healthcare systems expert. She most recently served as Chief Medical Editor at NBC News and has more than three decades of experience as a leading voice in healthcare and medicine. Dr. Snyderman currently serves as a board member of Alkermes (NASDAQ: ALKS) and Axonics Modulation Technologies, Inc. (NASDAQ: AXNX).
- **Presented Clinical Data at the 66th Annual Meeting of the American Rhinologic Society (ARS) Demonstrating LYR-210's Local Anti-Inflammatory Effects for the Treatment of Chronic Rhinosinusitis.** In September, Lyra presented data showing that LYR-210 demonstrated a significant reduction of sinonasal Type 2 inflammation in surgically naïve patients with chronic rhinosinusitis (CRS). The reduction of Type 2 inflammation suggested a correlation with rhinologic symptom improvement in CRS and could be a potential measure of LYR-210's local anti-inflammatory effects at the site of inflammation in the sinonasal passages. The results showing LYR-210's influence on local Type 2 inflammatory response in CRS patients were secondary findings from the company's Phase 1 clinical study of LYR-210.

"Having completed our IPO in the second quarter, we were fully focused in the third quarter on executing our development plans for LYR-210 and LYR-220. I'm pleased to report that we are on track to deliver topline Phase 2 results from our LANTERN study in December, which we believe will be an important

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milestone for the company and shareholders alike,” said Maria Palasis, Ph.D., President and Chief Executive Officer of Lyra Therapeutics. “We have also continued to build awareness about LYR-210 throughout the scientific and medical communities, with ongoing outreach and three presentations at the ARS Annual Meeting. In addition, I am delighted to welcome Dr. Nancy Snyderman to our board. Nancy has a deep understanding of the value of medical innovation as well as the barriers that must be overcome in order to bring new therapies to ENT physicians and patients and will bring a valuable perspective to Lyra.”

### **Financial Highlights**

**Cash, cash equivalents** as of September 30, 2020 were \$81.6 million, compared with \$86.6 million as of June 30, 2020.

**Research and development expenses** for the quarter ended September 30, 2020 were \$3.7 million compared to \$2.8 million for the same period in 2019.

**General and administrative expenses** for the third quarter 2020 were \$2.7 million compared to \$1.4 million for the same period in 2019.

**Total operating expenses** for the quarter ended September 30, 2020 were \$6.4 million compared to \$4.2 million for the same period in 2019.

**Net loss** for the third quarter was \$6.3 million compared to \$4.2 million for the same period in 2019.

In terms of financial guidance, Lyra believes its current cash position is sufficient to fund the company through a planned Phase 3 study of LYR-210 in chronic rhinosinusitis. Additionally, the company projects its year-end 2020 cash balance will be in the range of \$67-70 million.

### **About Lyra Therapeutics**

Lyra Therapeutics, Inc. is a clinical-stage therapeutics company focused on the development and commercialization of novel integrated drug and delivery solutions for the localized treatment of patients with ear, nose and throat (ENT) diseases. The company’s lead product candidate, LYR-210, is designed to deliver up to six months of continuous anti-inflammatory drug therapy to the sinonasal passages for the treatment of chronic rhinosinusitis (CRS) in patients who have not undergone surgery for the disease. Lyra is also developing LYR-220 for CRS patients who have undergone a prior surgery and have persistent disease. Beyond CRS, the company believes its XTreo™ platform, comprised of drug administered through a bioresorbable polymeric matrix, has the potential to address other disease areas by precisely, consistently and locally delivering medicines for sustained periods with a single administration.

For more information, please visit [www.lyratherapeutics.com](http://www.lyratherapeutics.com) and follow us on LinkedIn and Twitter.

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## 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 the company's lead product candidate LYR-210 and its cash balance for fiscal year ended December 31, 2020. 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; 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 10, 2020 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 and Comprehensive Loss**  
**(unaudited)**  
**(in thousands, except share and per share data)**

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>		<b>September 30,</b>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Operating expenses:				
Research and development	\$ 3,712	\$ 2,841	\$ 8,779	\$ 9,021
General and administrative	2,651	1,385	6,377	3,110
Total operating expenses	<u>6,363</u>	<u>4,226</u>	<u>15,156</u>	<u>12,131</u>
Loss from operations	(6,363)	(4,226)	(15,156)	(12,131)
Other income:				
Interest income	29	63	50	178
Total other income	<u>29</u>	<u>63</u>	<u>50</u>	<u>178</u>
Net loss	<u>\$ (6,334)</u>	<u>\$ (4,163)</u>	<u>\$ (15,106)</u>	<u>\$ (11,953)</u>
Comprehensive loss	<u>\$ (6,334)</u>	<u>\$ (4,163)</u>	<u>\$ (15,106)</u>	<u>\$ (11,953)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.49)</u>	<u>\$ (19.20)</u>	<u>\$ (2.13)</u>	<u>\$ (63.33)</u>
Weighted-average common shares outstanding—basic and diluted	<u>12,924,682</u>	<u>220,902</u>	<u>7,133,967</u>	<u>192,433</u>



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

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 81,555	\$ 9,808
Prepaid expenses and other current assets	2,000	311
Total current assets	<u>83,555</u>	<u>10,119</u>
Property and equipment, net	917	237
Operating lease right-of-use assets	2,529	3,182
Restricted cash	329	329
Deferred offering costs	—	1,096
Total assets	<u>\$ 87,330</u>	<u>\$ 14,963</u>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 530	\$ 1,069
Accrued expenses and other current liabilities	3,214	3,240
Operating lease liabilities	964	899
Total current liabilities	<u>4,708</u>	<u>5,208</u>
Operating lease liabilities, net of current portion	1,708	2,427
Total liabilities	<u>6,416</u>	<u>7,635</u>
Commitments and contingencies (Note 11)		
Series A-1 redeemable convertible preferred stock, \$0.001 par value; no shares issued, authorized or outstanding at September 30, 2020; 34,017,033 shares authorized, issued and outstanding at December 31, 2019	—	39,742
Series A-2 redeemable convertible preferred stock, \$0.001 par value; no shares issued, authorized or outstanding at September 30, 2020; 26,680,202 shares authorized, issued and outstanding at December 31, 2019	—	18,393
Series A-3 redeemable convertible preferred stock, \$0.001 par value; no shares issued, authorized or outstanding at September 30, 2020; 30,070,487 shares authorized, issued and outstanding at December 31, 2019	—	38,114
Series A-4 redeemable convertible preferred stock, \$0.001 par value; no shares issued, authorized or outstanding at September 30, 2020; 19,999,999 shares authorized, issued and outstanding at December 31, 2019	—	6,000
Series B redeemable convertible preferred stock, \$0.001 par value; no shares issued, authorized or outstanding at September 30, 2020; 100,018,619 shares authorized and 98,351,953 shares issued and outstanding at December 31, 2019	—	28,417
Series C redeemable convertible preferred stock, \$0.001 par value; no shares authorized, issued or outstanding at September 30, 2020 and December 31, 2019	—	—
Total redeemable convertible preferred stock	—	130,666
Stockholders' equity (deficit):		
Common stock, \$0.001 par value; 200,000,000 and 275,000,000 shares authorized at September 30, 2020 and December 31, 2019, respectively; 12,924,817 and 230,860 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	13	—
Additional paid-in capital	223,764	4,419
Accumulated deficit	<u>(142,863)</u>	<u>(127,757)</u>
Total stockholders' equity (deficit)	<u>80,914</u>	<u>(123,338)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 87,330</u>	<u>\$ 14,963</u>