

**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): August 5, 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 August 5, 2020, Lyra Therapeutics, Inc. (the “Company”) announced its financial results for the quarter ended June 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 August 5, 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: August 5, 2020

By: /s/ R. Don Elsey

R. Don Elsey

Chief Financial Officer



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

- On track to report topline Phase 2 results for LYR-210 in chronic rhinosinusitis in 4Q 2020 -

- Conference call and webcast today at 4:30 p.m. ET -

**WATERTOWN, MA – August 5, 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 diseases, today reported financial results for the quarter ended June 30, 2020 and provided a corporate update.

### Key Second Quarter 2020 and Subsequent Highlights

- **Appointed Pamela Nelson Senior Vice President of Regulatory Affairs.** In August, Lyra announced the appointment of Pamela Nelson to the position of Senior Vice President of Regulatory Affairs. Ms. Nelson brings with her more than 25 years of experience in the biotechnology industry, with regulatory expertise in drugs and drug/device combination products across a range of therapeutic areas from early development through to commercialization.
- **Appointed Robert Richard Senior Vice President of Research and Development.** In July, the company announced the appointment of Robert Richard, Ph.D., to the position of Senior Vice President of Research and Development. Dr. Richard is an industry veteran who possesses extensive leadership, product development, and commercialization experience in drug delivery and complex combination products. He will oversee the development of Lyra's two product candidates for the treatment of chronic rhinosinusitis, including the transfer of manufacturing to the contract manufacturer, and efforts on platform.
- **Closed Initial Public Offering (IPO) and Exercise in Full of Underwriters' Option to Purchase Additional Shares.** In May, Lyra announced the closing of its initial public offering of 4,025,000 shares of common stock at a public offering price of \$16.00 per share, which included the exercise in full by the underwriters of their option to purchase up to 525,000 additional shares. The gross proceeds to Lyra, before underwriting discounts, commissions, fees and expenses, were approximately \$64 million.

"Lyra's second quarter IPO has placed the company in a position of strength. We expect to report topline Phase 2 results from our study of LYR-210, our lead product candidate, in chronic rhinosinusitis, in the

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fourth quarter of 2020,” said Maria Palasis, Ph.D., President and Chief Executive Officer of Lyra Therapeutics. “We have also recently strengthened our management team with some key hires, which underscore our ongoing efforts to create further shareholder value by delivering on our existing drug candidates and expanding our development pipeline.”

### **Financial Highlights**

**Cash and cash equivalents** as of June 30, 2020 were \$86.6 million, compared with \$35.2 million as of March 31, 2020. The increase is attributable to proceeds received from Lyra’s IPO, which occurred during the second quarter.

**Research and development expenses** for the quarter ended June 30, 2020 were \$2.1 million compared to \$3.4 million for the same period in 2019. This decrease was driven primarily by the different stages for the Phase 1 and Phase 2 clinical trials of LYR-210.

**General and administrative expenses** for the second quarter 2020 were \$2.4 million compared to \$0.9 million for the same period in 2019. This increase was driven primarily by additional headcount and expenses associated with our operating as a public company.

**Total operating expenses** for the quarter ended June 30, 2020 were \$4.5 million compared to \$4.3 million for the same period in 2019.

**Net loss** for the second quarter was \$4.5 million compared to \$4.2 million for the same period in 2019.

### **Conference Call**

Individuals interested in listening to the conference call may do so by dialing (833) 519-1249 for domestic callers, or (914) 800-3822 for international callers, and using the conference ID: 5256524; or from the webcast link in the investor relations section of the company’s website at: [www.lyratherapeutics.com](http://www.lyratherapeutics.com). The recorded webcast will be available for replay for approximately 30 days following the call.

### **About Lyra Therapeutics, Inc.**

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 diseases. The company’s proprietary technology platform, XTreo™, is designed to precisely and consistently deliver medicines directly to the affected tissue for sustained periods with a single administration. The company’s initial product candidates, LYR-210 and LYR-220, are bioresorbable polymeric matrices designed to be administered in a brief, non-invasive, in-office procedure and intended to deliver up to six months of continuous drug therapy to the sinonasal passages for the treatment of chronic rhinosinusitis (CRS). The therapeutic embedded within LYR-210 and LYR-220 is mometasone furoate, which is the active ingredient in various FDA-approved drugs and has a well-

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established efficacy and safety profile. CRS is an inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities and affects approximately 14 million people in the United States. The company is advancing LYR-210 as a potential preferred alternative to surgery in an ongoing Phase 2 clinical trial for CRS patients who have failed medical management. In its Phase 1 clinical trial, LYR-210 met its primary safety endpoint, and it was observed that patients generally experienced significant and rapid, clinically meaningful and durable improvement in SNOT-22 scores, an established patient symptom severity scale, through week 25, which was the end of the trial. The company is also developing LYR-220 for use in CRS patients who have an enlarged nasal cavity due to sinus surgery but continue to require treatment to manage CRS symptoms. Beyond CRS, the company believes its XTreo platform has potential applications in other disease areas, which it is actively exploring to further broaden the platform's therapeutic potential.

For more information, please visit [www.lyrtherapeutics.com](http://www.lyrtherapeutics.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 the company's existing product candidates, including anticipated topline Phase 2 results from the company's study of LYR-210, its lead product candidate, in chronic rhinosinusitis, and product development efforts. 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

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factors discussed under the caption “Risk Factors” in the company’s Quarterly Report on Form 10-Q filed with the SEC on May 28, 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)**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 2,103	\$ 3,416	\$ 5,067	\$ 6,180
General and administrative	2,442	865	3,726	1,725
Total operating expenses	<u>4,545</u>	<u>4,281</u>	<u>8,793</u>	<u>7,905</u>
Loss from operations	(4,545)	(4,281)	(8,793)	(7,905)
Other income:				
Interest income	<u>5</u>	<u>80</u>	<u>21</u>	<u>115</u>
Total other income	<u>5</u>	<u>80</u>	<u>21</u>	<u>115</u>
Net loss	<u>\$ (4,540)</u>	<u>\$ (4,201)</u>	<u>\$ (8,772)</u>	<u>\$ (7,790)</u>
Comprehensive loss	<u>\$ (4,540)</u>	<u>\$ (4,201)</u>	<u>\$ (8,772)</u>	<u>\$ (7,790)</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (0.56)</u>	<u>\$ (23.04)</u>	<u>\$ (2.11)</u>	<u>\$ (44.64)</u>
Weighted-average common shares outstanding—basic and diluted	<u>8,182,725</u>	<u>185,683</u>	<u>4,206,793</u>	<u>177,962</u>



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

	<u>June 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 86,599	\$ 9,808
Prepaid expenses and other current assets	<u>2,711</u>	<u>311</u>
Total current assets	<u>89,310</u>	<u>10,119</u>
Property and equipment, net	329	237
Operating lease right-of-use assets	2,755	3,182
Restricted cash	329	329
Deferred offering costs	—	<u>1,096</u>
Total assets	<u>\$ 92,723</u>	<u>\$ 14,963</u>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,146	\$ 1,069
Accrued expenses and other current liabilities	1,853	3,240
Operating lease liabilities	<u>943</u>	<u>899</u>
Total current liabilities	3,942	5,208
Operating lease liabilities, net of current portion	<u>1,958</u>	<u>2,427</u>
Total liabilities	<u>5,900</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 June 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 June 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 June 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 June 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 June 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 June 30, 2020 and December 31, 2019	<u>—</u>	<u>—</u>
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 June 30, 2020 and December 31, 2019, respectively; 12,924,563 and 230,860 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	13	—
Additional paid-in capital	223,339	4,419
Accumulated deficit	<u>(136,529)</u>	<u>(127,757)</u>
Total stockholders' equity (deficit)	<u>86,823</u>	<u>(123,338)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 92,723</u>	<u>\$ 14,963</u>