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): May 28, 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:

5.
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:

<u>Title of each class</u> Common Stock, \$0.001 par value per share Trading Symbol(s)
LYRA

Name of each exchange on which registered
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 ⊠

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		ange Act. □	

Item 2.02. Results of Operations and Financial Condition.

On May 28, 2020, Lyra Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended March 31, 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:

Exhibit

No. Description

99.1 Press Release issued on May 28, 2020

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.

Date: May 28, 2020

LYRA THERAPEUTICS, INC.

By: /s/ R. Don Elsey

R. Don Elsey

Chief Financial Officer



Lyra Therapeutics Reports First Quarter 2020 Financial Results and Provides Corporate Update

WATERTOWN, MA - May 28, 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 March 31, 2020 and provided a corporate update.

Key First Quarter 2020 and Subsequent Highlights

- Announced Closing of Initial Public Offering 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 and commissions and fees and expenses, were approximately \$64 million. Lyra's common stock began trading on The Nasdaq Global Market on May 1, 2020 under the ticker symbol "LYRA.".
- Completed Series C Financing. In January, Lyra completed a Series C financing which raised approximately \$30 million in new funds. The investment was led by Perceptive Advisors and included new investors including Clifton Capital as well as participation by existing investors RA Capital Management, Soleus Capital, ArrowMark Partners, Polaris Venture Partners, North Bridge Venture Partners and Intersouth Partners.
- Announced FDA Clearance of IND for a Phase 2 Clinical Trial of LYR-210 for Chronic Rhinosinusitis. In January, Lyra announced that the U.S. Food and Drug Administration (FDA) cleared the company's Investigational New Drug (IND) application for LYR-210 for the treatment of chronic rhinosinusitis (CRS). Prior to the COVID-19 pandemic, Lyra planned to open U.S. sites for its Phase 2 LANTERN clinical trial. However, in light of the fallout from COVID-19, the company decided to discontinue enrollment in the trial at 67 patients and not to open any sites in the U.S. Lyra plans instead to leverage remote electronic data collection to complete clinical assessments and generate sufficient information to design a Phase 3 clinical trial.

"Lyra made substantial progress in the first quarter of 2020, FDA's approval of our IND for LYR-210, the closing of our Series C financing, and most recently our Nasdaq listing," said Maria Palasis, Ph.D., President and Chief Executive Officer of Lyra Therapeutics. "The achievement of these milestones



positions Lyra to further progress our CRS product candidates, LYR-210 and LYR-220, both of which utilize our proprietary XTreo™ platform. I would like to thank all of Lyra's stakeholders for their support, and I look forward to updating you on our clinical and corporate progress in the coming months and years."

Financial Highlights

Cash, cash equivalents as of March 31, 2020 were \$35.2 million. This figure does not include proceeds from Lyra's subsequent IPO, the gross proceeds from which, before underwriting discounts and commissions and fees and expenses, were approximately \$64 million.

Research and development expenses for the quarter ended March 31, 2020 were \$3.0 million compared to \$2.8 million for the same period in 2019. This was driven primarily by an increase in clinical expenses associated with the Ph2 trial of LYR-210.

General and administrative expenses for the first quarter 2020 were \$1.3 million compared to \$0.9 million for the same period in 2019. This increase was driven primarily by additional headcount and support expenses in preparation for our public offering.

Total operating expenses for the quarter ended March 31, 2020 were \$4.2 million compared to \$3.6 million for the same period in 2019.

Net loss for the first quarter was \$4.2 million compared to \$3.6 million for the same period in 2019.

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-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.lyratherapeutics.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 without limitation statements regarding our product candidate development, the status of our Phase 2 clinical trial of LYR-210, planned clinical trials for LYR-220, and the sufficiency of our cash, cash equivalents and short-term investments, including in light of the COVID-19 pandemic. These forwardlooking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause Lyra'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: our plans to develop and commercialize product candidates; the timing of ongoing or planned clinical trials for LYR-210, LYR-220 and any future product candidates; the timing of and ability to obtain and maintain regulatory approvals; the clinical utility of our product candidates; commercialization, marketing and manufacturing capabilities and strategy; expectations about the willingness of healthcare professionals to use LYR-210, LYR-220 and any future product candidates; our intellectual property position; our ability to raise additional funds through equity or debt financings or through collaborations, licensing arrangements or other sources; our competitive position and developments and projections relating to our competitors or our industry; our ability to identify, recruit and retain key personnel; impact of laws and regulations; risks associated with the COVID-19 global pandemic, which may adversely impact Lyra's business and clinical trials; plans to identify additional product candidates with significant commercial potential that are consistent with our commercial objectives; research and development costs; estimates and statements regarding our future revenue, future results of operations and financial position; our business strategy; research and development costs; and plans and objectives of management for future operations. These and other important factors discussed under the caption "Risk Factors" in Lyra's final prospectus dated April 30, 2020 and filed pursuant to Rule 424(b)(4) on May 1, 2020 with the U.S. Securities and Exchange Commission, and Lyra's 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 forwardlooking statements speak only as of the date of this press release and are based on information available to Lyra as of the date of this release, and Lyra assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.



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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 March 31,	
	2020	2019	
Operating expenses:			
Research and development	\$ 2,964	\$ 2,764	
General and administrative	1,284	860	
Total operating expenses	4,248	3,624	
Loss from operations	(4,248)	(3,624)	
Other income:			
Interest income	16	35	
Total other income	16	35	
Net loss	\$ (4,232)	\$ (3,589)	
Comprehensive loss	\$ (4,232)	\$ (3,589)	
Net loss per share attributable to common stockholders—basic and diluted	\$ (18.70)	\$ (21.54)	
Weighted-average common shares outstanding—basic and diluted	230,860	170,156	



LYRA THERAPEUTICS, INC. Condensed Consolidated Balance Sheets (unaudited)

(in thousands, except share and per share data)

	March 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 35,247	\$ 9,808
Prepaid expenses and other current assets	293	311
Total current assets	35,540	10,119
Property and equipment, net	284	237
Operating lease right-of-use asset	2,963	3,182
Restricted cash	329	329
Deferred offering costs	1,650	1,096
Total assets	\$ 40,766	\$ 14,963
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 1,358	\$ 1,069
Accrued expenses and other current liabilities	2,881	3,240
Operating lease liability	919	899
Total current liabilities	5,158	5,208
Operating lease liability, net of current portion	2,192	2,427
Total liabilities	7,350	7,635
Commitments and contingencies		
Series A-1 redeemable convertible preferred stock, \$0.001 par value; 34,017,033 shares authorized, issued and		
outstanding at March 31, 2020 and December 31, 2019 (aggregate liquidation preference of \$14,157 at March 31,		
2020)	39,742	39,742
Series A-2 redeemable convertible preferred stock, \$0.001 par value; 26,680,202 shares authorized, issued and		
outstanding at March 31, 2020 and December 31, 2019 (aggregate liquidation preference of \$9,063 at March 31,		
2020)	18,393	18,393
Series A-3 redeemable convertible preferred stock, \$0.001 par value; 30,070,487 shares authorized, issued and		
outstanding at March 31, 2020 and December 31, 2019 (aggregate liquidation preference of \$18,779 at March 31,		
2020)	38,114	38,114
Series A-4 redeemable convertible preferred stock, \$0.001 par value; 19,999,999 shares authorized, issued and		
outstanding at March 31, 2020 and December 31, 2019 (aggregate liquidation preference of \$6,000 at March 31,		
2020)	6,000	6,000
Series B redeemable convertible preferred stock, \$0.001 par value; 98,351,953 and 100,018,619 shares authorized at		
March 31, 2020 and December 31, 2019, respectively; 98,351,953 shares issued and outstanding at March 31, 2020	20.405	20 44 5
and December 31, 2019 (aggregate liquidation preference of \$29,506 at March 31, 2020)	28,496	28,417
Series C redeemable convertible preferred stock, \$0.001 par value; 90,180,614 shares authorized at March 31, 2020;		
78,306,611 shares issued and outstanding at March 31, 2020 (aggregate liquidation preference of \$30,392 at	20.452	
March 31, 2020)	29,452	
Total redeemable convertible preferred stock	160,197	130,666
Stockholders' deficit:		
Common stock, \$0.001 par value; 400,000,000 and 275,000,000 shares authorized at March 31, 2020 and		
December 31, 2019, respectively; 230,860 shares issued and outstanding at March 31, 2020 and December 31, 2019	 5,208	4,419
Additional paid-in capital Accumulated deficit	(131,989)	(127,757)
Total stockholders' deficit		
	(126,781)	(123,338)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	\$ 40,766	\$ 14,963