

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 9, 2021

LYRA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

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 March 9, 2021, Lyra Therapeutics, Inc. (the “Company”) announced its financial results for the year ended December 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:

| <u>Exhibit No.</u> | <u>Description</u>                                    |
|--------------------|---|
| 99.1               | <a href="#">Press Release issued on March 9, 2021</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: March 9, 2021

By: /s/ R. Don Elsey

R. Don Elsey

Chief Financial Officer



## Lyra Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results, Provides Corporate Update

- Positive Topline Results for LANTERN Phase 2 Study of LYR-210-

- Robert Kern, MD, appointed Chief Medical Officer -

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

**WATERTOWN, MA – March 9, 2021** - 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 fourth quarter and full year ended December 31, 2020 and provided a corporate update.

### Key Fourth Quarter 2020 and Subsequent Highlights

- **Company Announced Positive Topline Results for LANTERN Phase 2 Study of LYR-210.** In December, Lyra announced positive topline results from its LANTERN Phase 2 study of LYR-210 for the treatment of Chronic Rhinosinusitis, including:
  - LYR-210 is the first nasal implant to achieve a benefit of up to six months after a single administration in a clinical testing, and the first nasal implant to achieve a benefit in both polyp and non-polyp patients in clinical testing.
  - 7500 mcg dose achieved statistically significant improvement in both 4 Cardinal Symptoms and SNOT-22 scores at 24 weeks and at several earlier timepoints, compared to control.
  - Lyra believes the results support a clear path to regulatory submission for LYR-210 and plans to move forward into a pivotal Phase 3 trial using the 7500 mcg dose, subject to an end of Phase 2 meeting with the FDA.

“The positive results from the LANTERN Phase 2 study point to LYR-210’s potential as an easily administered, six-month treatment for CRS patients who have failed medical management,” said Professor Anders Cervin, Garnett Passe and Rodney Williams Foundation Chair in Otolaryngology at the University of Queensland, and a Principal Investigator for Lyra’s LANTERN trial. “An intranasal implant, like LYR-210, ensures treatment compliance on the part of patients and efficiently delivers drug directly to inflamed tissue. Based on these results, I believe LYR-210 could represent a viable alternative to invasive nasal surgery for CRS patients, with as few as two ENT office visits a year.”

- **Appointed Robert Kern, MD, Chief Medical Officer.** In February, Lyra announced that Robert Kern, MD had been named the company’s Chief Medical Officer. In addition to his role at Lyra,
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Dr. Kern will remain in his current position as the George A. Sisson Professor and Chair, Department of Otolaryngology – Head and Neck Surgery, Northwestern University Feinberg School of Medicine. Dr. Kern is the immediate past president of the American Rhinologic Society and current President of the International Society of Inflammation and Allergy of the Nose. He is a renowned physician in the ENT field and a world-leading expert in chronic rhinosinusitis with a proven track record of global leadership in otolaryngology, in both academic research and clinical rhinology.

- **Added Nancy L. Snyderman, M.D. to Board of Directors.** In October, the company announced that Dr. Snyderman had joined 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).

“We were pleased to end our first calendar year as a public company by announcing positive topline data from our LANTERN Phase 2 Study for LYR-210. In addition, we recently strengthened our team with the additions of Dr. Kern to our management team and Dr. Snyderman to our board,” said Maria Palasis, Ph.D., President and Chief Executive Officer of Lyra Therapeutics. “Looking ahead, 2021 should be another pivotal year for Lyra as we read out the data from our PK study and plan to conduct an end of Phase 2 meeting with the FDA for LYR-210, followed by the potential initiation of a Phase 2 study for LYR-220 in the second half, and a Phase 3 pivotal trial of LYR-210 at the end of the year. I look forward to updating you on our progress.”

## Financial Highlights

**Cash and cash equivalents** as of December 31, 2020 were \$74.6 million, compared with \$81.6 million as of September 30, 2020.

**Research and development expenses** for the quarter and full year ended December 31, 2020 were \$3.7 million and \$12.5 million, respectively, compared to \$3.0 million and \$12.0 million for the same periods in 2019, respectively.

**General and administrative expenses** for the fourth quarter and full year ended December 31, 2020 were \$3.3 million and \$9.7 million, respectively, compared to \$1.4 million and \$4.5 million for the same periods in 2019, respectively.

**Total operating expenses** for the quarter ended and full year ended December 31, 2020 were \$7.1 million and \$22.2 million, respectively, compared to \$4.4 million and \$16.5 million for the same periods in 2019, respectively.

**Net loss** for the fourth quarter and full year 2020 was \$7.0 million and \$22.1 million, respectively, compared to \$4.4 million and \$16.3 million for the same periods in 2019, respectively.

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**In terms of financial guidance for 2021**, we believe that Lyra has sufficient cash to fund the company through planned operations into 2023.

### **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: 6979948; 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.

### **Annual Meeting Date**

The Board of Directors of Lyra Therapeutics, Inc. has established May 26, 2021 as the date of its Annual Meeting of Stockholders (the "2021 Annual Meeting"). The 2021 Annual Meeting will be held virtually by means of remote communication. The details of the virtual annual meeting, including how stockholders can log into the virtual meeting, vote and submit questions, will be disclosed in the Company's definitive proxy statement for the 2021 Annual Meeting to be filed with the Securities and Exchange Commission.

Any stockholder seeking to bring business before the 2021 Annual Meeting or to nominate a director must provide timely notice, as set forth in the Company's Amended and Restated Bylaws (the "Bylaws"). Specifically, written notice of any proposed business or nomination must be received at the Company's principal executive offices no later than the close of business on March 19, 2021 (which is the tenth day following this public announcement of the date of the 2021 Annual Meeting). Any notice of proposed business or nomination must comply with the specific requirements set forth in the Company's Bylaws.

### **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 (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.

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## 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 lead product candidate LYR-210 and its financial guidance for 2021. 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 Annual Report on Form 10-K filed with the SEC on March 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.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands, except share and per share data)

|  | Year Ended<br>December 31, |             |
|--|----------------------------|-------------|
|  | 2020                       | 2019        |
| Operating expenses:  |                            |             |
| Research and development   | \$ 12,522                  | \$ 12,032   |
| General and administrative   | 9,687                      | 4,487       |
| Total operating expenses   | 22,209                     | 16,519      |
| Loss from operations   | (22,209)                   | (16,519)    |
| Other income:  |                            |             |
| Interest income  | 82                         | 213         |
| Total other income   | 82                         | 213         |
| Net loss   | \$ (22,127)                | \$ (16,306) |
| Comprehensive loss   | \$ (22,127)                | \$ (16,306) |
| Net loss per share attributable to common stockholders—basic and diluted | \$ (2.59)                  | \$ (82.23)  |
| Weighted-average common shares outstanding—basic and diluted             | 8,590,205                  | 202,093     |

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

|   | December 31,     |                  |
|---|------------------|------------------|
|   | 2020             | 2019             |
| <b>Assets</b>   |                  |                  |
| Current assets:   |                  |                  |
| Cash and cash equivalents   | \$ 74,593        | \$ 9,808         |
| Prepaid expenses and other current assets   | 1,324            | 311              |
| Total current assets  | <u>75,917</u>    | <u>10,119</u>    |
| Property and equipment, net   | 2,165            | 237              |
| Operating lease right-of-use assets   | 2,301            | 3,182            |
| Restricted cash   | 329              | 329              |
| Other assets  | 118              | 1,096            |
| Total assets  | <u>\$ 80,830</u> | <u>\$ 14,963</u> |
| <b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)</b>   |                  |                  |
| Current liabilities:  |                  |                  |
| Accounts payable  | \$ 922           | \$ 1,069         |
| Accrued expenses and other current liabilities  | 2,977            | 3,240            |
| Operating lease liabilities   | 985              | 899              |
| Total current liabilities   | <u>4,884</u>     | <u>5,208</u>     |
| Operating lease liabilities, net of current portion   | 1,454            | 2,427            |
| Total liabilities   | <u>6,338</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 December 31, 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 December 31, 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 December 31, 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 December 31, 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 December 31, 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 December 31, 2020 and 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 December 31, 2020 and 2019, respectively; 12,932,377 and 230,860 shares issued and outstanding at December 31, 2020 and 2019, respectively          | 13               | —                |
| Additional paid-in capital  | 224,363          | 4,419            |
| Accumulated deficit   | <u>(149,884)</u> | <u>(127,757)</u> |
| Total stockholders' equity (deficit)  | <u>74,492</u>    | <u>(123,338)</u> |
| Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)  | <u>\$ 80,830</u> | <u>\$ 14,963</u> |