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): September 12, 2023

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)**	**(IRS Employer Identification No.)**
480 Arsenal Way **Watertown, Massachusetts** **(Address of Principal Executive Offices)**		**02472** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: 617 393-4600

(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 8.01 Other Events.

On September 12, 2023, Lyra Therapeutics, Inc. (the "Company") posted a slide presentation in the "Investors & News" portion of its website at investors.lyratherapeutics.com, which includes information about the Company's topline results from the BEACON Phase 2 clinical study of LYR-220 in adult patients with chronic rhinosinusitis with and without polyps, who have had prior ethmoid sinus surgery. A copy of this slide presentation is attached to this Current Report on Form 8-K as Exhibit 99.1. The Company undertakes no obligation to update, supplement or amend the materials attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	BEACON Study Top Line Results
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: September 12, 2023

By: /s/ Jason Cavalier
Chief Financial Officer

Exhibit 99.1

LYRA THERAPEUTICS

BEACON Study

Topline Results

LYR-220-2021-001 A Phase II, Patient-blinded, Two-part, Randomized, Parallel-group Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of LYR-220 in Chronic Rhinosinusitis (CRS) Patients Who Have Had a Prior Ethmoidectomy

https://clinicaltrials.gov/study/NCT05035654

September 12, 2023

Disclaimer

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this presentation that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding the Company's pipeline and development of product candidates and the progress, efficacy and applicability of LYR-220 and LYR-210. 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 additional 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 has never scaled up an in-house manufacturing facility for clinical or commercial use; or 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 must scale its in-house manufacturing capabilities or rely on third parties for the manufacture of materials for its research programs, pre-clinical studies and clinical trials and commercial supply; 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, terrorism and wars (including the war between Ukraine and Russia); 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 August 8, 2023 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 presentation. Any such forward-looking statements represent management's estimates as of the date of this presentation. 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.

This presentation also includes statistical and market data that we obtained from industry, publications and research, surveys and studies conducted by third parties or us. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. All of the market data used in this presentation involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. The industry in which we operate is subject to a high degree of uncertainty, change and risk due to a variety of factors, which could cause results to differ materially from those expressed in the estimates made by the independent partners and by us.

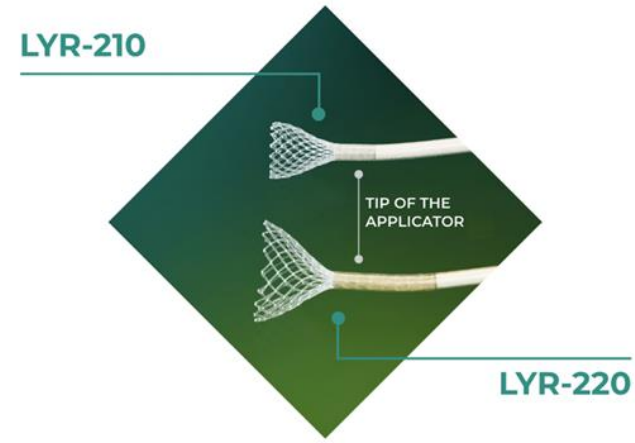
LYR-210 and LYR-220 are Designed to Address the Full Spectrum of CRS Patients

Topline results now available for the LYR-220 Phase 2 BEACON study

Candidate	CRS Patient Type	Phase 2	Phase 3
LYR-210 Long-acting Mometasone Furoate	Chronic Rhinosinusitis **Patients with Surgically-Naïve Anatomy** **ENLIGHTEN Phase 3 Program**		
LYR-220 Long-acting Mometasone Furoate	Chronic Rhinosinusitis **Patients with Post-Surgical Anatomy** **BEACON Phase 2 Trial**		

LYR-220 for CRS Patients who have Undergone Prior Sinus Surgery but have Persistent Symptoms

- LYR-220 is an enlarged version of LYR-210 to accommodate **post-surgical anatomy**
- LYR-220 is designed to provide **24 weeks** of mometasone furoate therapy directly to the site of disease
- LYR-220 dosage of mometasone furoate (7500 mcg) is the **same dose** being studied in the ongoing LYR-210 Phase 3 (ENLIGHTEN)



LYR-220 is being Developed to Address a Significant Proportion of the CRS Population

Current Treatments:

- **Medical Management**
  - Saline rinses, topical nasal steroids, oral steroids
- **Surgery**
  - ~400K sinus surgeries annually[1]

CRS in the United States Annually

~8M	CRS patients **treated**[2]
~4M	CRS patients **failing medical** management[3]
~1.4M	CRS patients **currently presenting to an ENT**[4]

40% of patients that present to an ENT have had a prior sinus surgery[5]

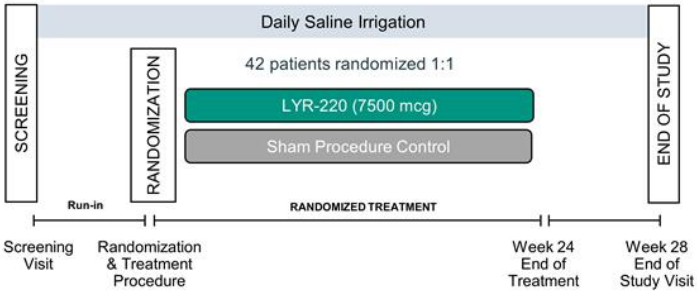
1) Biomedical Insights CRS Population Analysis, 1/2020 2)Jang et al. Otolaryngol Head Neck Surg. 2018; 3) Baguley et al. Int Forum Allergy Rhinol. 2014;4(7):525-32; 4) OM1 Real World Data Cloud (OM1, Inc, Boston, MA) 2015 – 4/2019. Analysis 9/2019 5) Biocom Consulting ENT Quantitative Market Research, 6/2019

BEACON: Phase 2 Clinical Study of LYR-220

- **CRS patients** who have had a prior bilateral ethmoidectomy
- Randomized, blinded, sham-controlled proof of concept study to assess safety and efficacy of LYR-220*
- **Safety endpoint:**
  - Serious adverse events
- **Key efficacy endpoints:**
  - 3 cardinal symptoms (3CS)** scores
  - SNOT-22 scores

*Preceded by feasibility phase to choose matrix design
**3 cardinal symptoms are defined as nasal blockage / obstruction, facial pain / pressure, and nasal discharge

BEACON Study Design

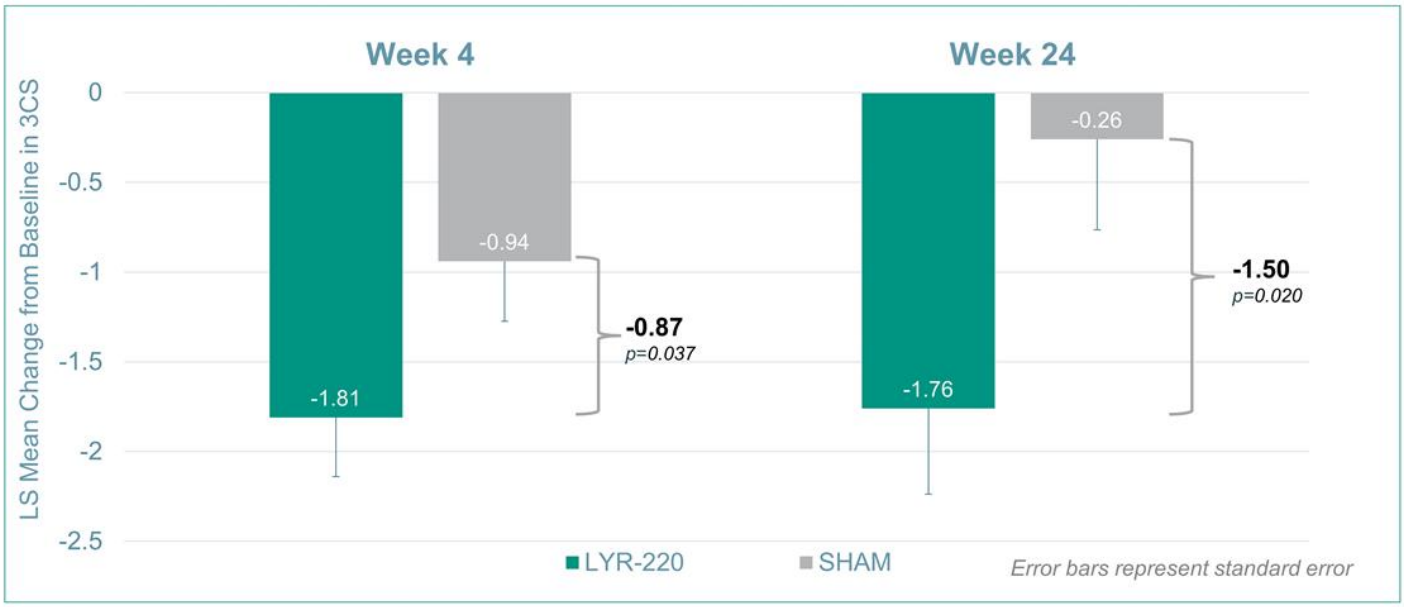


Note: Primary outcome measure was product-related serious adverse events

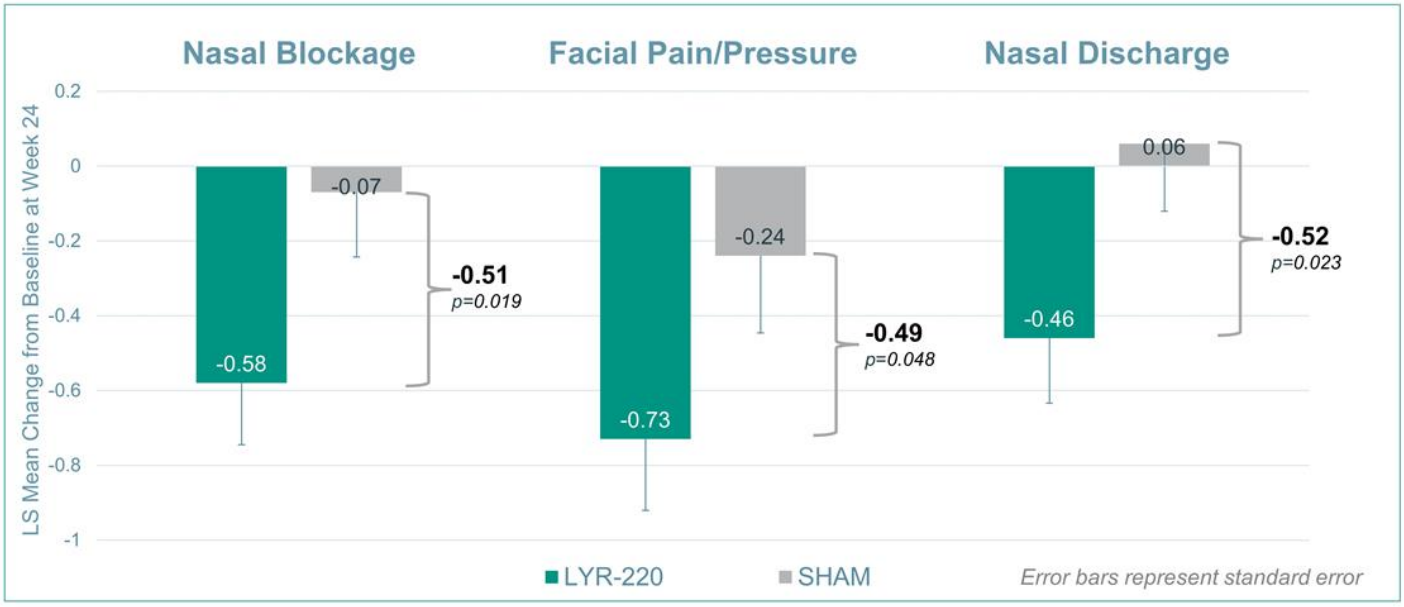
BEACON: Patient Demographics and Baseline Characteristics

	LYR-220 (n=21)	Sham (n=21)	Total (n=42)
Age in years (*mean, SD)*	48 (12.51)	55 (11.29)	**51 (12.35)**
Sex *(n, %)*			
Male	7 (33.3)	10 (47.6)	**17 (40.5)**
Female	14 (66.7)	11 (52.4)	**25 (59.5)**
Race *(n, %)*			
White	20 (95.2)	18 (85.7)	**38 (90.5)**
Black or African American	1 (4.8)	2 (9.5)	**3 (7.1)**
Baseline SNOT-22 Total Score (*mean, SD)*	56.1 (17.16)	50.0 (16.65)	**53.1 (16.9)**
Baseline 3CS Score (*mean, SD)*	6.4 (1.47)	6.8 (1.65)	**6.6 (1.56)**

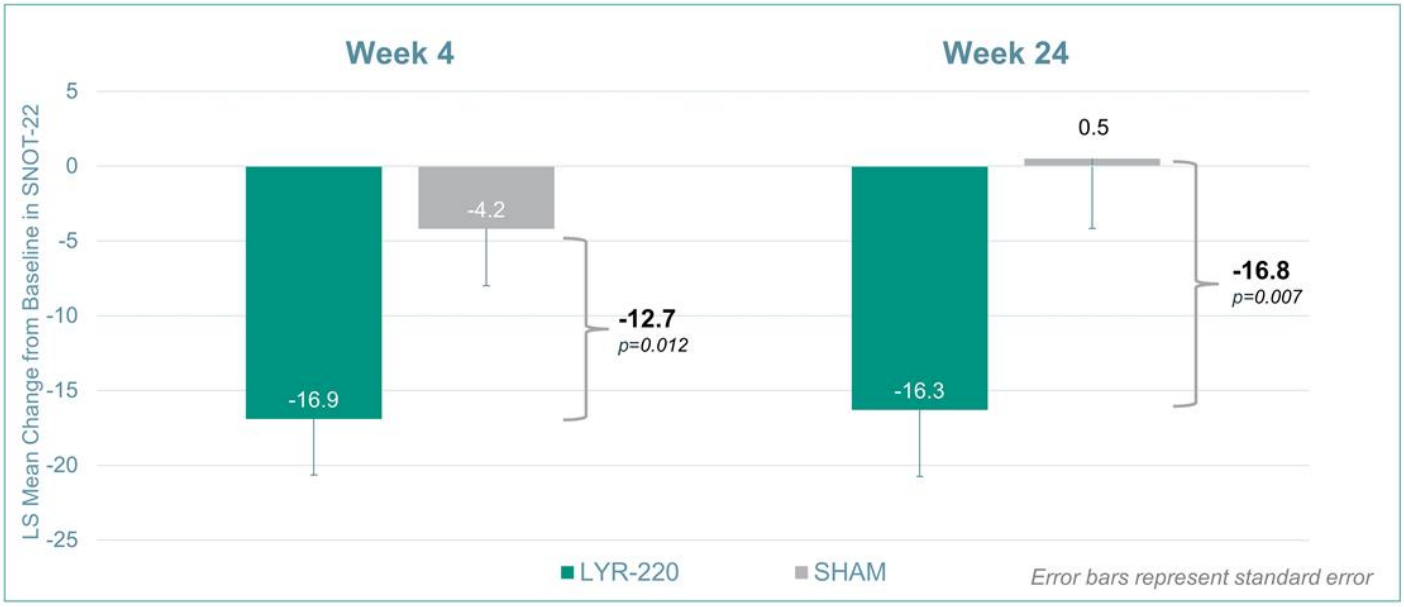
BEACON Efficacy Results:
Statistically Significant Improvement in 3CS Composite Score



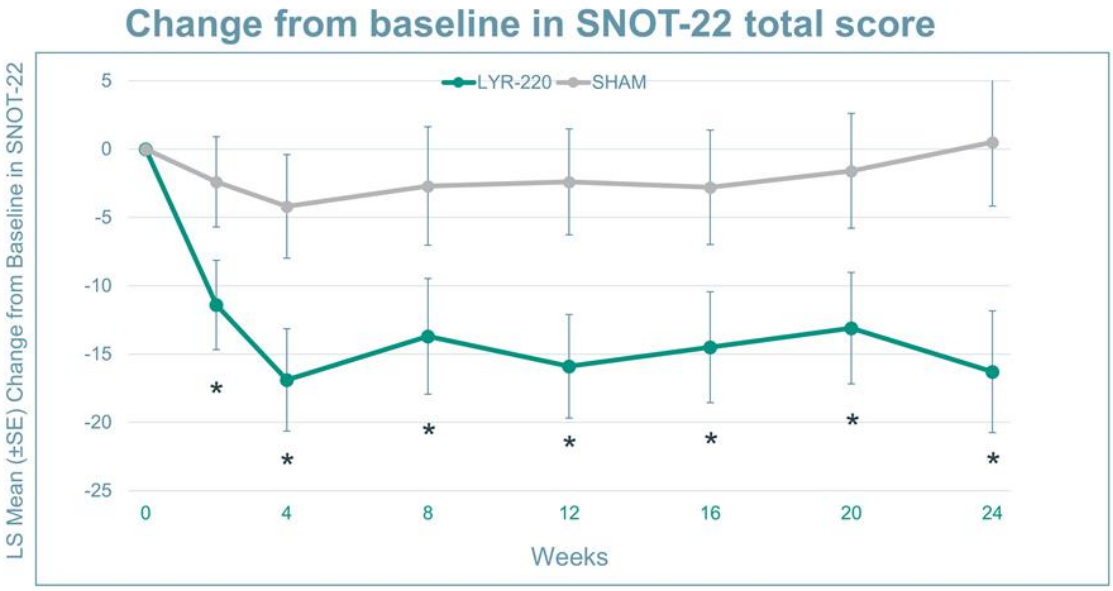
BEACON Efficacy Results:
Statistically Significant Improvements in Individual CS at Week 24



BEACON Efficacy Results:
Statistically Significant Improvement in SNOT-22 Score



BEACON Efficacy Results:
Early and Sustained Improvement in SNOT-22 Score



* p <0.05

BEACON Study Summary

No SAEs and statistically significant, clinically relevant improvements in key efficacy endpoints

- No serious adverse events observed. Most commonly observed adverse events included sinusitis, nasopharyngitis, bronchitis, and COVID-19
- Statistically significant improvement in a composite of the 3 cardinal symptoms of CRS (nasal obstruction, nasal discharge, facial pain/pressure) at week 24 (-1.50; p=0.02)
  - Statistically significant improvement for each individual cardinal symptom at week 24
- Statistically significant improvements in Sino-Nasal Outcome Test (SNOT-22) score compared to sham control at week 24 (-16.8; p=0.007)
- Statistically significant improvement in a composite of the 3 cardinal symptoms of CRS (nasal obstruction, nasal discharge, facial pain/pressure) as early as week 4 (-0.87; p=0.037)
- Statistically significant improvements in SNOT-22 were observed as early as week 2 (-9.0; p=0.031)
- Improvements in SNOT-22 were sustained throughout the study and clinically meaningful with almost twice the minimal clinically important difference observed at week 24 compared to sham (-16.8 points)

LYRA THERAPEUTICS