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): January 08, 2024

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		**02472**
(Address of Principal Executive Offices)		**(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 7.01 Regulation FD Disclosure.

On January 8, 2024, Lyra Therapeutics, Inc. (the "Company") posted a corporate presentation to its website that representatives of the Company may use from time to time in presentations or discussions with investors, analysts or other parties. A copy of the presentation is being furnished as Exhibit 99.1, which is incorporated herein by reference.

The information in Item 7.01 of this Current Report on Form 8-K (the "Current Report") is intended to be furnished and 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 set forth by specific reference in such filing.

Item 8.01 Other Events.

The corporate presentation posted to the Company's website on January 8, 2024 includes data on file as of January 5, 2024 from the BEACON Phase 2 clinical trial, demonstrating statistically significant improvement in loss of smell in a subset of patients with impaired smell at baseline. The data demonstrated a 0.87 improvement over control at week 24 (p=0.026).

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report on Form 8-K that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding the Company's additional data on file as of January 5, 2024 from the BEACON Phase 2 clinical trial demonstrating statistically significant improvement in loss of smell in patients with impaired smell at baseline. 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 important factors discussed under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on November 7, 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 Current Report on Form 8-K. Any such forward-looking statements represent management's estimates as of the date of this Current Report on Form 8-K. 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.

Item 9.01 Financial Statements and Exhibits.

d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation by Lyra Therapeutics, Inc.

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: January 8, 2024

By: /s/ Jason Cavalier
Jason Cavalier, Chief Financial Officer

LYRA THERAPEUTICS

Corporate Presentation

January 2024

Forward Looking Statement

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “expect,” and similar expressions are intended to identify forward-looking statements.

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 cash runway into the first quarter of 2025, the Company’s pipeline of product candidates, the enrollment and success of the ENLIGHTEN Phase 3 program, the timing for reporting top line data from the Company’s clinical trials, the Company’s ability to manufacture its product candidates in-house, the safety and efficacy of the Company’s product candidates, clinical trial data being subject to change until the completion of the applicable clinical study report, the outcome of the Phase 2 BEACON trial and the commercial promise of the product candidates. 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 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; 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 7, 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.

Lyra’s product candidates, LYR-210 and LYR-220, have not been approved by FDA. This presentation is intended for the investor community only. Nothing herein is intended to promote the Company’s product candidates.

Company Overview

Clinical-stage biotechnology company developing innovative anti-inflammatory therapies for the localized treatment of chronic rhinosinusitis

- **Bioresorbable nasal implant designed to deliver 6 months of continuous anti-inflammatory therapy to the site of disease**
- **Indication: Chronic rhinosinusitis (CRS)**
  - ~12% of the US population[1]
  - ~50% of patients fail medical therapy[2]
- **Pivotal Phase 3 trials ongoing**
- **Patent protection through 2036**

Chronic Rhinosinusitis (CRS): An "Unrecognized Epidemic"[1]

CRS Cardinal Symptoms[1]

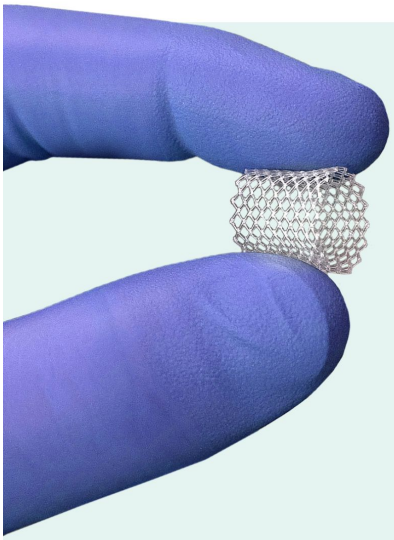
- Nasal obstruction and congestion
- Nasal discharge
- Facial pain and pressure
- Reduced sense of smell

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]

1) Tan BK et al. Am J Respir Crit Care Med, 2013;188(11):1275–7; 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, US), 2015 – 4/2019. Analysis 9/2019

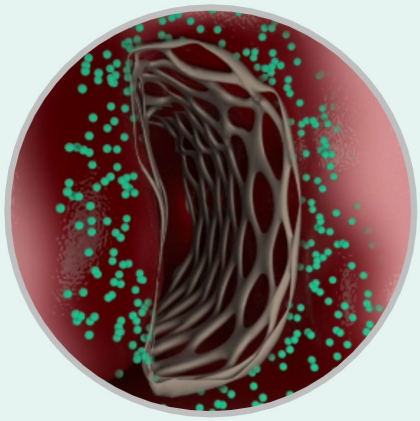
Lyra's Proprietary Drug-Eluting Implant



Polymer-Drug Complex
Designed to deliver 6 months of continuous, local drug therapy with a single placement

Engineered Elastomeric Matrix
Shape memory keeps implant in place

Biocompatible Mesh Scaffold
Maximizes surface area for drug release while maintaining underlying tissue function

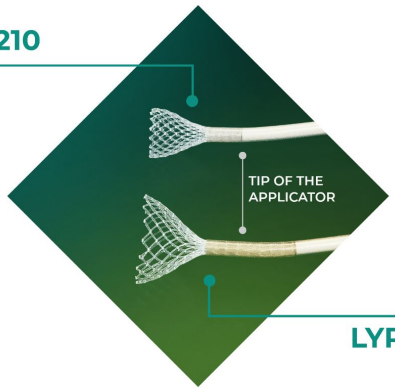


Lyra's "Family" of CRS Product Candidates

LYR-210 and LYR-220 are designed to address the full spectrum of CRS patients where ENTs select size based on patient anatomy

LYR-210

Smaller dimension for patients with narrow anatomy (includes surgery naïve patients)



LYR-220

Larger dimension for patients with enlarged anatomy due to previous ethmoid sinus surgery

Lyra Pipeline

LYR-210 and LYR-220 are designed to address the full spectrum of CRS patients where ENTs select size based on patient anatomy

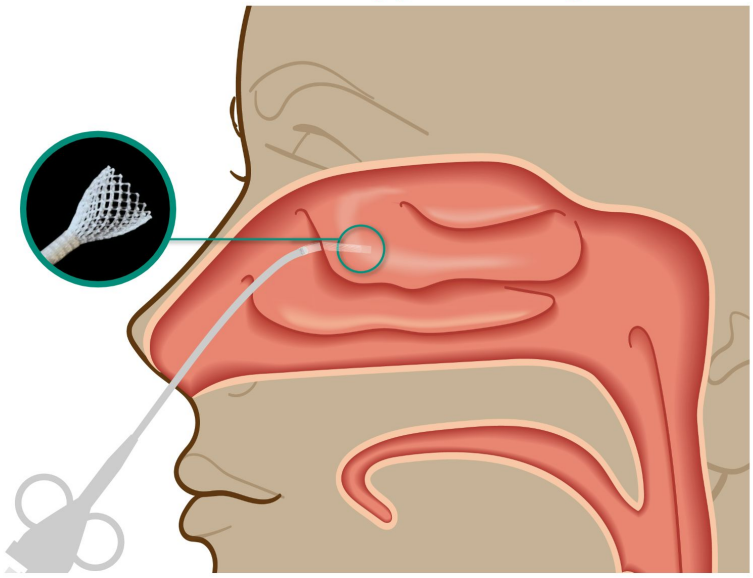
Candidate	CRS Patient Type	Phase 2	Phase 3
LYR-210 Long-acting Mometasone Furoate	Chronic Rhinosinusitis **Patients with Narrow Anatomy (Includes Surgically Naïve Patients)[1]** **ENLIGHTEN Phase 3 Program**		
LYR-220 Long-acting Mometasone Furoate	Chronic Rhinosinusitis **Patients with Enlarged Anatomy due to Prior Sinus Surgery[1]** **BEACON Phase 2 Trial**		

1) "Surgically naïve" and "sinus surgery" refer to ethmoid sinus surgery.

LYR-210 and LYR-220
Designed to be the New Standard of Care for CRS

Only product candidate designed to provide 6 months of CRS therapy with a single treatment

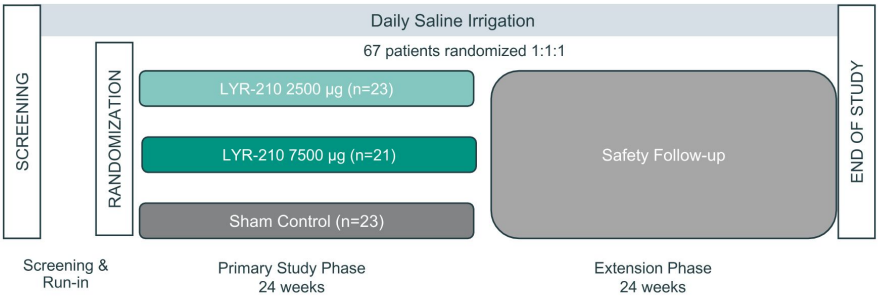
- FDA-approved API/steroid: Mometasone furoate
- Designed to provide continuous anti-inflammatory therapy
- Straightforward, office-based procedure with topical anesthesia
- Administered nasally via a single-use applicator
- Designed to be replaced every 6 months



LANTERN Study Design
LYR-210 Phase 2 Clinical Trial in CRS Patients

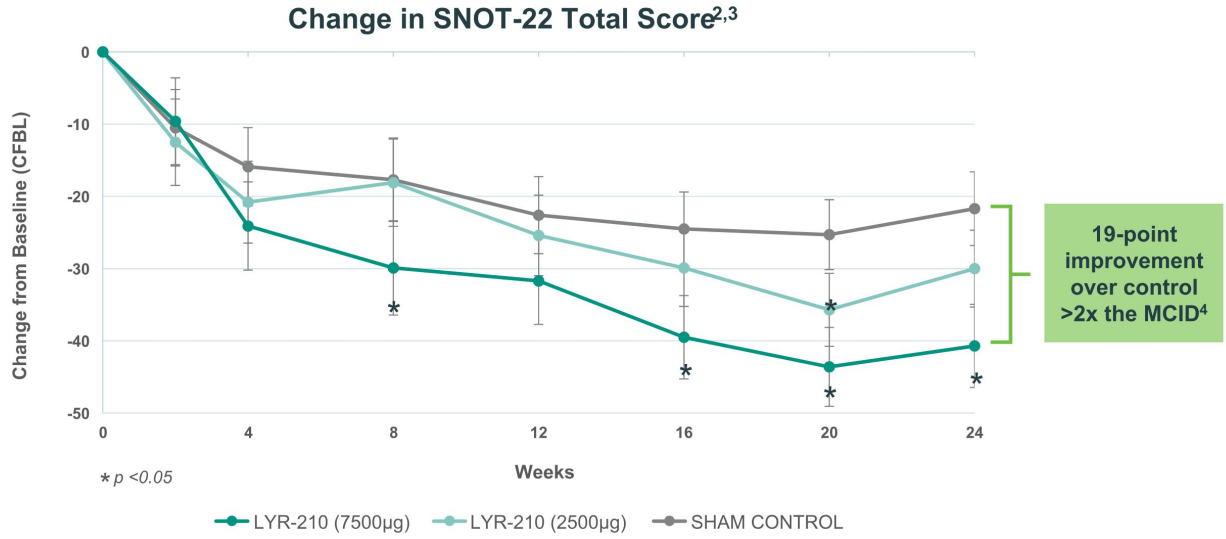
- Multicenter, randomized, blinded, controlled, dose-ranging trial
- Adult CRS patients who failed previous medical management and have not undergone FESS[1]
- **Primary endpoint:**
  - Change from baseline in 4 cardinal symptoms composite score (4CS) at Week 4[2,3]
- **Key secondary endpoints:**
  - SNOT-22[4]
  - Individual and composite cardinal symptom scores over 24 weeks

LANTERN



1) Functional endoscopic sinus surgery; 2) The study did not meet the primary endpoint at Week 4; however, the 7,500 ug dose group showed statistically significant improvements in 4CS over sham procedure control at weeks 16, 20, and 24. Due to COVID-19, study enrollment was curtailed at 67 patients (vs. 150 planned); 3) Four Cardinal Symptom Scores is a composite of nasal blockage/obstruction, facial pain/pressure, nasal discharge and loss of sense of smell; 4) SinoNasal Outcome Test is a patient reported score from 0 – 110 based on symptoms; 5) NCT04041609

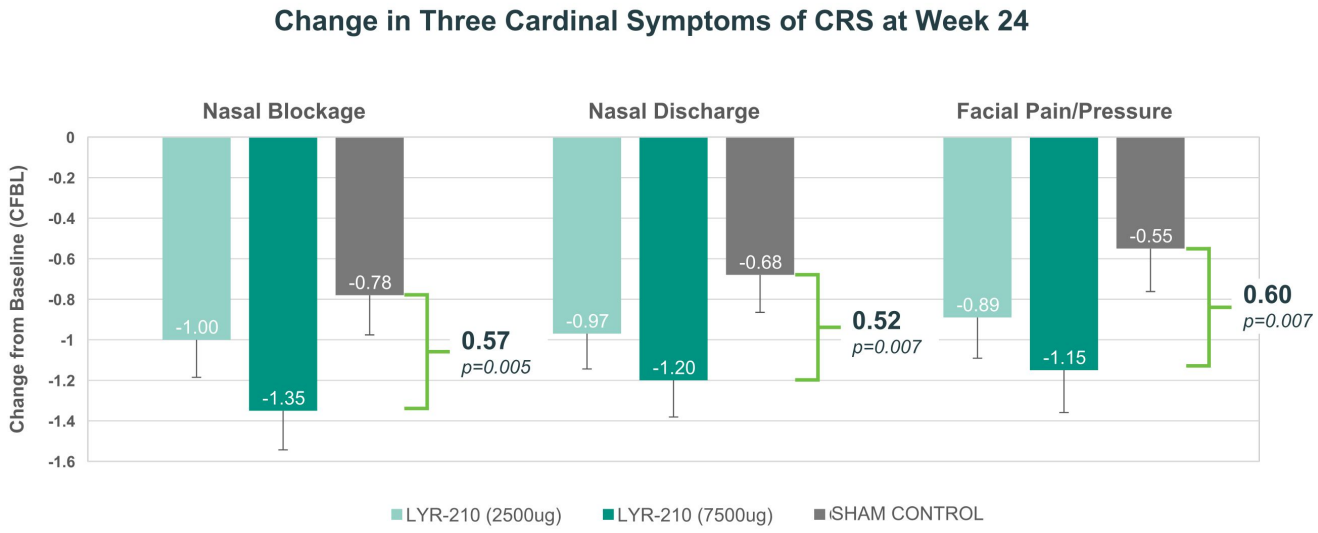
LANTERN Efficacy Results
Rapid and Durable Improvement in SNOT-22 Score over 24 Weeks[1]



Error bars represent standard error

1) Cervin A, et al. Long-acting implantable corticosteroid matrix for chronic rhinosinusitis: Results of LANTERN Phase 2 randomized controlled study. Int Forum AllergyRhinol. 2021;1-13; 2) SinoNasal Outcome Test is a patient reported score from 0 – 110 based on symptoms; 3) Data represents the least square mean. Missing data and data post use of rescue medication was imputed by LOCF method; 4) Minimum clinically important difference

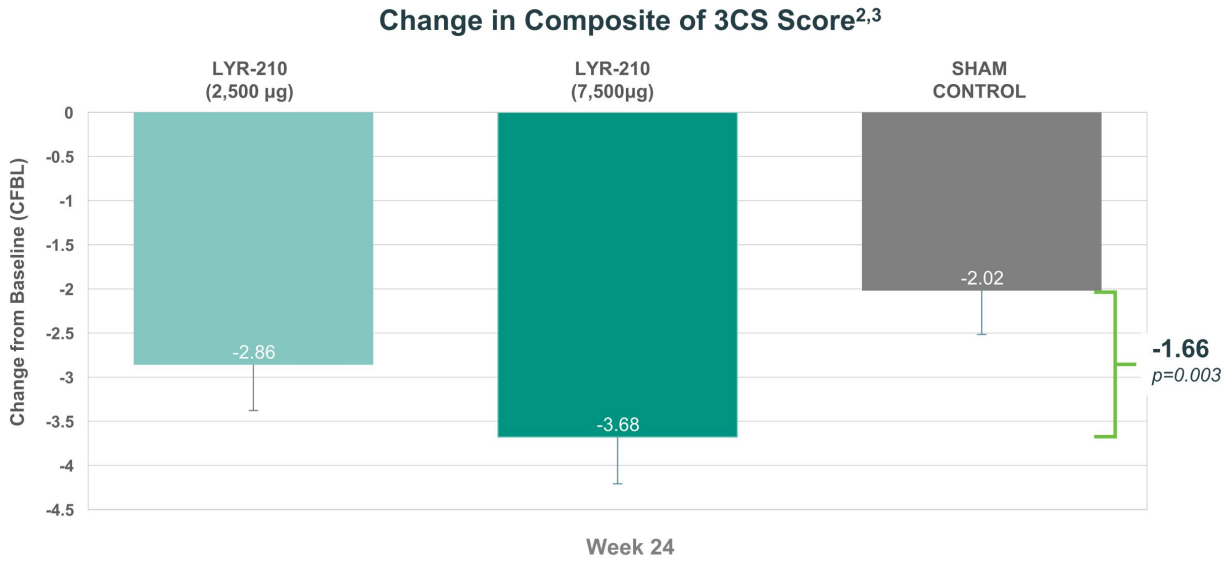
LANTERN Efficacy Results
Improvement Across Three Cardinal Symptoms of CRS[1]



Error bars represent standard error

1) Cervin A, et al. Long-acting implantable corticosteroid matrix for chronic rhinosinusitis: Results of LANTERN Phase 2 randomized controlled study. Int Forum AllergyRhinol. 2021;1-13

LANTERN Efficacy Results
Robust Effect in 3 Cardinal Symptom (3CS) Score at Week 24[1]



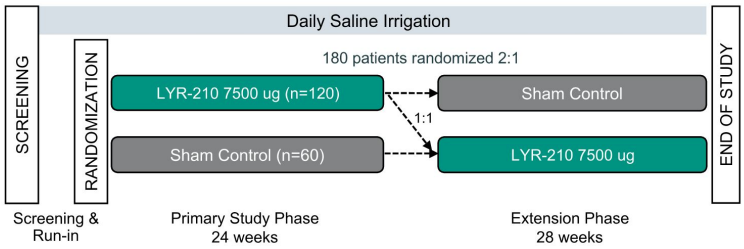
Error bars represent standard error

1) Cervin A, et al. Long-acting implantable corticosteroid matrix for chronic rhinosinusitis: Results of LANTERN Phase 2 randomized controlled study. Int Forum AllergyRhinol. 2021;1-13; 2) Mean change from baseline (CFBL) in the 7-day average score in the 3CS composite score of nasal blockage/obstruction, facial pain/pressure, and nasal discharge; 3) Post-hoc analysis; data represent LSM. P<0.05 is considered statistically significant to control.

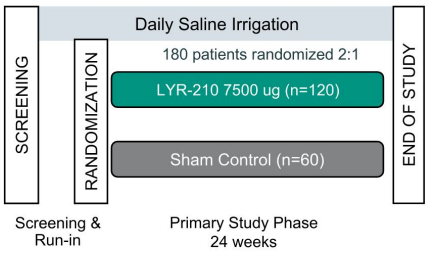
ENLIGHTEN Program Design
LYR-210 Ongoing Pivotal Phase 3 Program

- Two pivotal studies of ~180 subjects each
- Adult CRS patients each, without nasal polyps or with grade 1 nasal polyps, who have failed medical management[1]
- **Primary endpoint**
  - Change from baseline in 3CS[2] Score at Week 24 in patients without nasal polyps
- **Key secondary endpoints**
  - Individual cardinal symptoms
  - SNOT-22[3]
  - CT sinus opacification

ENLIGHTEN I[4]



ENLIGHTEN II[5]

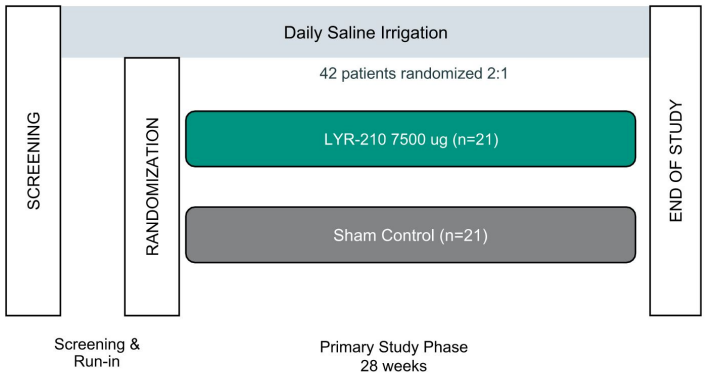


1) Up to 30 patients with nasal polyps per study; study population represents 95% of CRS patients; 2) Three Cardinal Symptom Score is as a composite of nasal blockage/obstruction, facial pain/pressure, and nasal discharge; 3) SinoNasal Outcome Test is a patient reported score from 0 – 110 based on symptoms; 4) NCT05219968; 5) NCT05295459

BEACON Study Design
LYR-220 Phase 2 Clinical Study

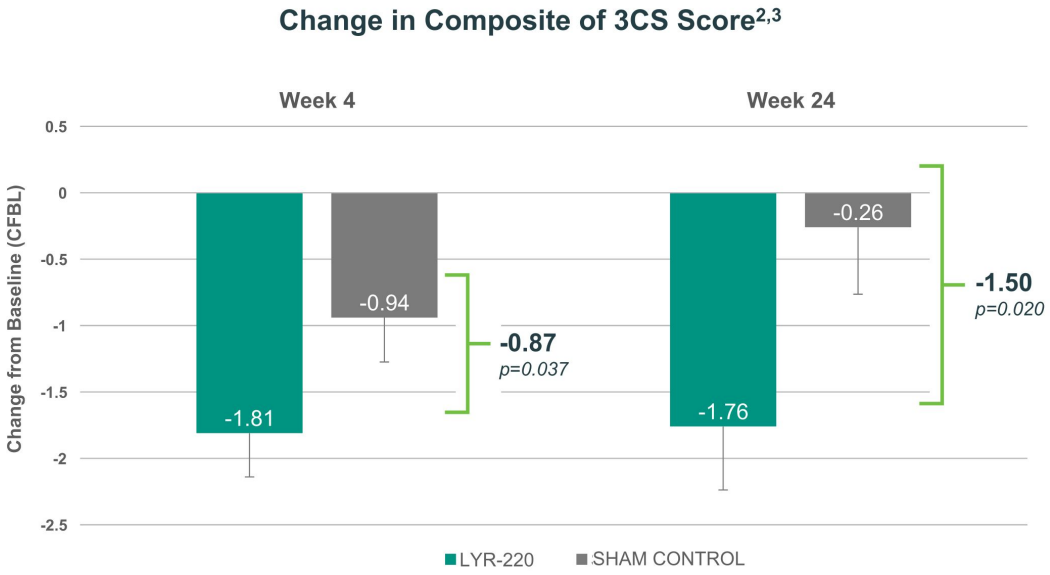
- Randomized, blinded, sham-controlled proof of concept study to assess safety and efficacy[1]
- Adult CRS patients who have had a prior bilateral FESS and failed medical management
- **Primary endpoint – safety**
  - Product-related serious adverse events
- **Key efficacy endpoints**
  - 3CS Score[2]
  - SNOT-22[3]

BEACON[4]



1) Preceded by feasibility phase to choose matrix design; 2) Three Cardinal Symptom Score is as a composite of nasal blockage/obstruction, facial pain/pressure, and nasal discharge; 3) SinoNasal Outcome Test is a patient reported score from 0 – 110 based on symptoms; 4) NCT05035654

BEACON Efficacy Results
Robust Effect in 3 Cardinal Symptoms (3CS) Score - Weeks 4 and 24[1]

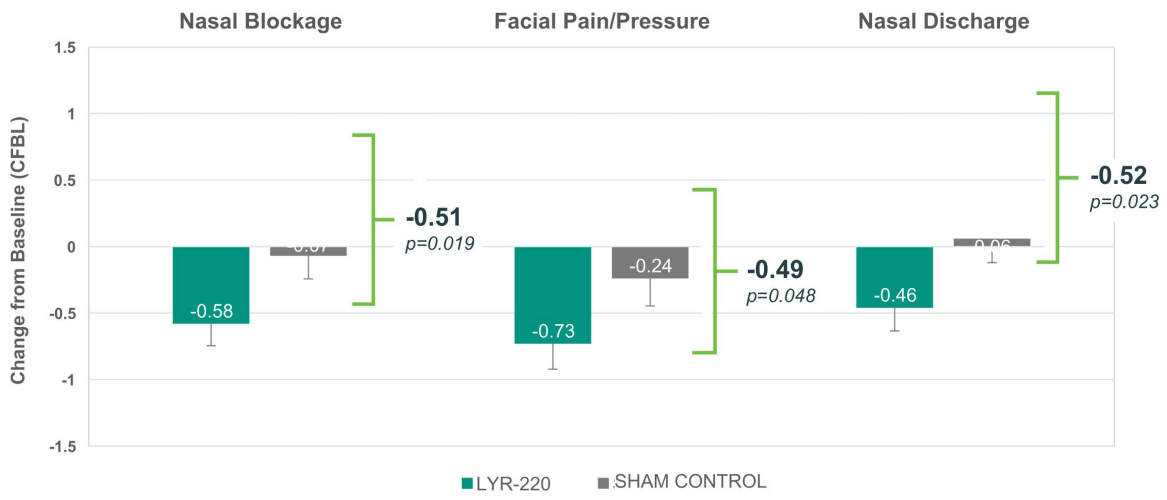


Error bars represent standard error

1) Data on file as of January 5, 2024; 2) Mean change from baseline (CFBL) in the 7-day average score in the 3CS composite score of nasal blockage/obstruction, facial pain/pressure, and nasal discharge; 3) Data represent least square means. Data post rescue was censored and imputed using patient's worst observed post-baseline score. P<0.05 is considered statistically significant to control.

BEACON Efficacy Results
Improvement Across Three Cardinal Symptoms of CRS[1]

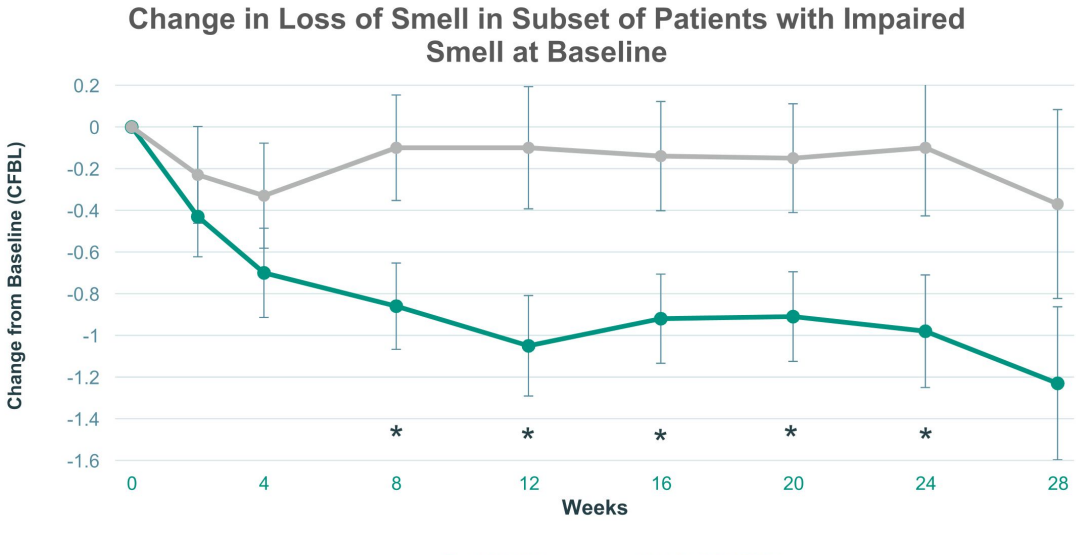
Change in Three Cardinal Symptoms of CRS at Week 24[2,3]



Error bars represent standard error

1) Data on file as of January 5, 2024; 2) Mean change from baseline (CFBL) in the 7-day average score in each individual CS of nasal blockage/obstruction, facial pain/pressure, and nasal discharge; 3) Data represent least square means. Data post rescue was censored and imputed using patient's worst observed post-baseline score. P<0.05 is considered statistically significant to control.

BEACON Efficacy Results
Improvement in Loss of Smell[1]



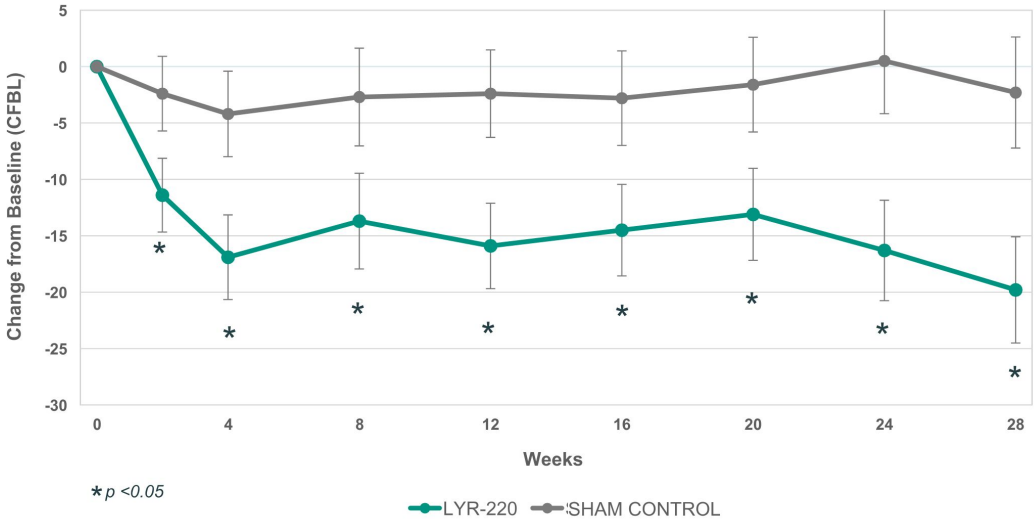
Statistically significant (0.87-point) improvement over control at week 24 (p=0.026)

*p <0.05

1) Data on file as of January 5, 2024.

BEACON Efficacy Results
Rapid and Durable Improvement in SNOT-22 Score over 28 Weeks[1]

Change in SNOT-22 Total Score[2,3]



Achieved 17-point improvement over control (1.9x the MCID[4]) as early as two weeks and through 28 weeks

Error bars represent standard error

1) Data on file as of January 5, 2024; 2) SinoNasal Outcome Test is a patient reported score from 0 – 110 based on symptoms; 3) Data represent the least square means. Data post rescue was censored and imputed using patient's worst observed post-baseline score. P<0.05 is considered statistically significant to control; 4)Minimum clinically important difference.

LYRA Product Candidates, if Approved, are Expected To Align With Current ENT Practices

- Office-based procedure that ENTs are accustomed to performing
- Treatment option for patients who are unwilling to undergo surgery, allowing ENTs to serve more patients in their care
- Expected to fit into ENT practice reimbursement models

LYRA THERAPEUTICS

Targeted Go-to-Market Strategy

Targeted Patient & Physician Base

Highly Accessible Patients

1.4M failed CRS patients actively seek care from ENT annually[1]

Specialist Physicians

2,500 ENTs perform ~90% of CRS procedures[2]

Specialty Field Force

Anticipate 20-40 sales reps & 3-5 medical science liaisons

1) OM1 Real World Data Cloud (OM1, Inc, Boston, MA, US), 2015 – 4/2019. Analysis 9/2019; 2) IQVIA In-Office Medical Claims Data, June 2021.

Anticipated Milestones

LYR-210: ENLIGHTEN Phase 3 Program

- ✓ Mid-2023: Complete enrollment in ENLIGHTEN I
- • Q2 2024: Topline pivotal data from ENLIGHTEN I
- • 2H 2024: Extension study data from ENLIGHTEN I
- • 2H 2024: Complete enrollment in ENLIGHTEN II

LYR-220: BEACON Phase 2 Program

- ✓ Early 2023: Complete enrollment
- ✓ September 2023: Topline data
- • 2024: End of Phase 2 meeting

Financial Profile

- Cash, cash equivalents and short-term investments of $102.6 million as of September 30, 2023
- On October 2, 2023, the Company sold an aggregate of 3,017,568 shares of common stock under the ATM Sales Agreement, at a weighted average price of $3.71 per share, which generated net proceeds of $10.9 million. These net proceeds were not included in cash and cash equivalents or short-term investments as of September 30, 2023
- 52.6 million common shares outstanding as of November 1, 2023

LYRA THERAPEUTICS