Lyra Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

March 29, 2023

-- ENLIGHTEN I Pivotal Phase 3 Trial of LYR-210 in Pre-Surgical Chronic Rhinosinusitis (CRS) on Track to Complete Enrollment in mid-2023 --

-- Data from BEACON Phase 2 Trial of LYR-220 in Post-Surgical CRS Anticipated Q4 2023 --

-- Advancing In-House Manufacturing Capabilities to Prepare for Commercial Production --

WATERTOWN, Mass., March 29, 2023 (GLOBE NEWSWIRE) -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) ("Lyra" or the "Company"), a clinical-stage biotechnology company developing innovative therapies for the localized treatment of chronic rhinosinusitis (CRS), today reported its financial results for the fourth quarter and full year ended December 31, 2022 and provided a corporate update.

"2022 was a transformative year for Lyra. We initiated three clinical trials that we believe will build on the strong clinical data we have generated to date and confirm the value of Lyra's drug-device technology for patients living with chronic rhinosinusitis," said Maria Palasis, Ph.D., President and CEO of Lyra. "We look forward to sharing results from the BEACON Phase 2 trial in post-surgical CRS patients in Q4 2023 as we continue to advance the ENLIGHTEN pivotal Phase 3 program of LYR-210 in pre-surgical CRS patients."

Dr. Palasis continued, "Our recent decision to transition manufacturing in-house to optimize the quality and supply of our product positions Lyra for long-term success. We have manufactured product to enable us to resume enrollment in the second pivotal trial, ENLIGHTEN II, earlier than planned, and are now expanding our in-house capabilities to prepare for commercial-stage manufacturing."

2022 Key Program Highlights

- **Initiated two pivotal Phase 3 clinical trials of LYR-210 in Chronic Rhinosinusitis (CRS) in Surgically Naïve Patients (ENLIGHTEN I and ENLIGHTEN II)**:
  - The ENLIGHTEN program consists of two Phase 3 clinical trials (ENLIGHTEN I and ENLIGHTEN II) to evaluate the efficacy and safety of LYR-210 for the treatment of CRS. Each trial is enrolling 180 CRS patients who have failed medical management and have not had prior ethmoid sinus surgery, randomized 2:1 to either LYR-210 (7500µg mometasone furoate (MF)) or control. The aim of the two pivotal trials is to support an anticipated New Drug Application to the U.S. Food and Drug Administration for LYR-210.
  - Enrollment is ongoing in ENLIGHTEN I, with enrollment completion anticipated in mid- 2023.
  - As previously announced, Lyra temporarily paused enrollment in ENLIGHTEN II to align the trial with the availability of clinical supply. The Company anticipates resuming enrollment in the ENLIGHTEN II trial in Q2 2023, ahead of the previously reported timeline of Q3 2023.

- **Initiated BEACON Phase 2 trial of LYR-220 in CRS patients who remain symptomatic despite having had prior sinus surgery**:
  - The BEACON Phase 2 trial is a 24-week study evaluating the safety and efficacy of LYR-220 (7500µg MF) in 40 patients with CRS who remain symptomatic despite having had prior sinus surgery. Enrollment in BEACON is complete, with data expected in Q4 2023.
  - In September 2022, Lyra announced positive initial data from the Part 1, non-randomized portion of the BEACON trial, demonstrating the feasibility and tolerability of LYR-220 placement bilaterally in post-surgical CRS patients. All six patients were treated for at least six weeks and no serious or unexpected product-related adverse events were reported.

- **Transitioned manufacturing to in house:**
  - In Q4 2022, Lyra announced the transition of manufacturing to in-house, leveraging its expertise to reliably supply product without relying on third-party manufacturers.
  - Lyra is now advancing its in-house manufacturing capabilities to prepare for commercial production.

Upcoming 2023 Milestones

- Resume enrollment in ENLIGHTEN II Phase 3 pivotal trial of LYR-210 in Q2 2023
- Complete enrollment in ENLIGHTEN I Phase 3 pivotal trial of LYR-210 in mid-2023
- Report topline results from BEACON Phase 2 study of LYR-220 in Q4 2023

Fourth Quarter and Full Year 2022 Financial Highlights

- Cash, cash equivalents and short-term investments were $97.9 million as of December 31, 2022, compared to $109.6 million as of September 30, 2022. The Company expects its cash, cash equivalents and short-term investments balance to

be sufficient to fund its planned operations into mid-2024.

- Research and development expenses for the fourth quarter and full year ended December 31, 2022 were $9.5 million and $38.8 million, respectively, compared to $10.3 million and $29.7 million for the same periods in 2021. The increase year over year was primarily driven by higher clinical development costs related to the Company's three ongoing clinical trials and employee-related expenses.
- General and administrative expenses for the fourth quarter and full year ended December 31, 2022 were $4.4 million and $17.6 million, respectively, compared to $3.6 million and $14.2 million for the same periods in 2021. The increase was primarily driven by higher employee-related costs, including stock-based compensation.
- The Company recorded an impairment charge of $1.3 million related to long-lived assets for the year ended December 31, 2022.
- Net loss for the fourth quarter and full year ended December 31, 2022 was $14.2 million and $55.3 million, respectively, compared to $13.6 million and $43.5 million for the same periods in 2021.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage biotechnology company developing therapies for the localized treatment of patients with chronic rhinosinusitis (CRS). Lyra has two investigational product candidates, LYR-210 and LYR-220, in late-stage development for CRS, a highly prevalent inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities. LYR-210 and LYR-220 are bioresorbable nasal implants designed to be administered in a brief, in-office procedure and are intended to deliver six months of continuous mometasone furoate drug therapy (7500µg MF) to the sinonasal passages. LYR-210 is designed for surgically naïve patients and is being evaluated in the ENLIGHTEN Phase 3 clinical program, while LYR-220, an enlarged implant, is being evaluated in the BEACON Phase 2 clinical trial in patients who have recurrent symptoms despite having had prior ethmoid sinus surgery. These two product candidates are designed to treat the estimated four million CRS patients in the United States who fail medical management each year. For more information, please visit www.lyratx.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 cash runway through mid-2024, 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, and the success of the Phase 2 BEACON trial. 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; 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; 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 developing conflict 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 Annual Report on Form 10-K filed with the SEC on March 29, 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 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.

LYRA THERAPEUTICS, INC.
Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

	Year Ended December 31,	
	2022	**2021**
Collaboration revenue	$ 1,363	$ 285
Operating expenses:		
Research and development	38,797	29,694

General and administrative	17,556	14,206
Loss on impairment of long-lived assets	1,316	—
Total operating expenses	57,669	43,900
Loss from operations	(56,306)	(43,615)
Other income:		
Interest income	1,041	102
Total other income	1,041	102
Loss before income tax expense	(55,265)	(43,513)
Income tax expense	(13)	—
Net loss	(55,278)	(43,513)
Other comprehensive income:		
Unrealized holding gain on short-term investments, net of tax	10	—
Comprehensive loss	$ (55,268)	$ (43,513)
Net loss per share —basic and diluted	$ (1.83)	$ (3.35)
Weighted-average common shares outstanding—basic and diluted	30,235,689	12,986,101

LYRA THERAPEUTICS, INC.
Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 32,550	$ 45,747
Short-term investments	65,344	—
Prepaid expenses and other current assets	2,935	2,171
Total current assets	100,829	47,918
Property and equipment, net	2,243	4,503
Operating lease right-of-use assets	2,223	1,355
Restricted cash	1,392	329
Other assets	3,281	762
Total assets	$ 109,968	$ 54,867
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,616	$ 3,125
Accrued expenses and other current liabilities	9,030	4,258
Operating lease liabilities	1,549	1,074
Deferred revenue	1,275	9,789
Total current liabilities	14,470	18,246
Operating lease liabilities, net of current portion	667	379
Deferred revenue, net of current portion	14,077	1,926
Total liabilities	29,214	20,551
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2022 and 2021; no shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at December 31, 2022 and 2021; 31,827,659 and 13,007,178 shares issued and outstanding at December 31, 2022 and 2021, respectively	32	13
Additional paid-in capital	329,387	227,700
Accumulated other comprehensive income, net of tax	10	—
Accumulated deficit	(248,675)	(193,397)
Total stockholders' equity	80,754	34,316
Total liabilities and stock and stockholders' equity	$ 109,968	$ 54,867

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