Lyra Therapeutics Reports Third Quarter 2023 Financial Results and Provides Corporate Update

November 7, 2023

– Additional Phase 2 BEACON trial CT scan data demonstrated statistically significant improvement in sinus opacification with LYR-220 and provided radiological evidence of improvement in chronic rhinosinusitis (CRS) patients who have had prior ethmoid sinus surgery –

– Emerging data further support the previously reported positive BEACON topline results demonstrating CRS symptom improvement –

– ENLIGHTEN I pivotal Phase 3 trial of LYR-210 in CRS patients who have not had ethmoid sinus surgery is fully enrolled; topline results expected in 1H 2024 –

WATERTOWN, Mass., Nov. 07, 2023 (GLOBE NEWSWIRE) -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) ("Lyra" or the "Company"), a clinical-stage biotechnology company developing long-acting anti-inflammatory therapies for the localized treatment of chronic rhinosinusitis (CRS), today reported its financial results for the third quarter ended September 30, 2023 and provided a corporate update.

The Company also announced additional positive data from the BEACON Phase 2 clinical trial of LYR-220 that demonstrated statistically significant, objective improvement and sustained symptomatic improvement in CRS patients who have had prior ethmoid sinus surgery and further support the positive topline results reported in September 2023:

- Data evaluating computed tomography (CT) scans, a pre-specified secondary endpoint, demonstrated statistically significant improvement in ethmoid sinus opacification in patients who received LYR-220, compared to sham control at week 24 (p=0.035). These data provide objective radiological evidence of improvement with LYR-220 treatment.
- At End of Study, Week 28, patients receiving LYR-220 showed continued symptomatic improvement compared to sham control in both Sino-Nasal Outcome Test (SNOT-22) score (-17.6 points; p=0.007) and in a composite of the 3 cardinal symptoms of CRS (nasal obstruction, nasal discharge, facial pain/pressure; 3CS) (-1.28; p=0.063).

The Company plans to submit results of the BEACON study for presentation at an upcoming medical meeting.

"We believe Lyra is on track to develop a robust CRS product portfolio based on the continued progress of our clinical programs, including the recently reported positive results of the BEACON Phase 2 trial of LYR-220 in post-surgical CRS patients and the completion of enrollment in the ENLIGHTEN I pivotal trial of LYR-210 in pre-surgical CRS patients," said Maria Palasis, Ph.D., President and CEO of Lyra. "Our optimism continues for LYR-220 with the additional positive CT data from the BEACON trial announced today that demonstrated objective improvement in CRS patients. We believe these findings provide additional confidence in the ongoing ENLIGHTEN pivotal Phase 3 program of LYR-210 in CRS patients who have not had ethmoid sinus surgery, for which we anticipate topline data will be available in the first half of 2024."

LYR-210 and LYR-220 are bioresorbable nasal implants designed to deliver six months of continuous anti-inflammatory medication (mometasone furoate; MF) to the sinonasal passages for the treatment of CRS.

Program Highlights

BEACON Phase 2 Clinical Trial of LYR-220 in CRS Patients who Have Had Prior Ethmoid Sinus Surgery

- In September 2023, Lyra announced positive topline results from the BEACON Phase 2 clinical trial of LYR-220 in adult patients with CRS, with and without polyps, who have recurrent symptoms despite prior ethmoid sinus surgery. The study met its primary safety endpoint, with no serious adverse events observed. LYR-220 demonstrated statistically significant and clinically relevant improvements in SNOT-22 (-16.8; p=0.007) scores and 3CS (-1.50; p=0.02) compared to sham control at 24 weeks, with statistically significant improvement observed as early as week 2 in SNOT-22 and at week 4 in 3CS. The most commonly reported adverse events included sinusitis, nasopharyngitis, bronchitis, and COVID-19.

The Phase 2 BEACON trial is a randomized, controlled, parallel-group study intended to evaluate the safety and placement feasibility of the LYR-220 (7500µg MF) matrix, over a 28-week period, in symptomatic CRS patients who have had prior ethmoid sinus surgery. The study consists of two parts: Part 1 was designed primarily to assess the feasibility and tolerability of two 7500µg MF matrix designs; in Part 2, 42 patients were randomized 1:1 to receive LYR-220 or sham control.

ENLIGHTEN Pivotal Program of LYR-210 in CRS Patients who have not had Ethmoid Sinus Surgery

- In August 2023, Lyra announced completion of enrollment in the pivotal Phase 3 ENLIGHTEN I clinical trial.
- Topline results from the ENLIGHTEN I clinical trial are anticipated in the first half of 2024.
- Enrollment is ongoing in the second pivotal Phase 3 trial, ENLIGHTEN II; enrollment completion is expected in the second half of 2024.

The ENLIGHTEN program consists of two pivotal Phase 3 clinical trials, ENLIGHTEN I and ENLIGHTEN II, to evaluate the efficacy and safety of LYR-210 for the treatment of CRS. The Company designed each trial to evaluate 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 over 24 weeks. The goal of the two pivotal trials is to support a New Drug Application to the U.S. Food and Drug Administration for LYR-210.

Third Quarter 2023 Financial Highlights

Cash, cash equivalents and short-term investments as of September 30, 2023 were $102.6 million, compared with $116.2 million at June 30, 2023. Based on our current business plan, we anticipate that our cash, cash equivalents and short-term investment balance is sufficient to fund our operating expenses and capital expenditures into the first quarter of 2025.

Research and development expenses for the quarter ended September 30, 2023 were $12.4 million compared to $10.1 million for the same period in 2022. During the quarter ended September 30, 2023, clinical development costs increased by $2.4 million as we continued to enroll patients in our ENLIGHTEN I and ENLIGHTEN II Phase 3 clinical trials, employee related costs increased by $1.0 million, associated allocated costs increased by $0.4 million as we increased our headcount to support increased research and development activities and professional and consulting fees increased by $0.1 million. These increases were partially offset by decreased product development and manufacturing costs of $1.2 million related to bringing production efforts in house, and decreased depreciation costs of $0.4 million.

General and administrative expenses for the quarter ended September 30, 2023 were $5.0 million compared to $5.1 million for the same period in 2022. The decrease in general and administrative expenses for the three months ended September 30, 2023 was primarily attributable to decreased employee related costs of $0.6 million, of which $0.5 million was related to stock-based compensation, and decreased allocated costs of $0.4 million, as well as the decrease in public company-related costs of $0.1 million. This decrease was partially offset by increased professional and consulting costs of $0.6 million and increased support costs of $0.4 million.

Net loss for the quarter ended September 30, 2023 was $15.7 million compared to $14.8 million for the same period in 2022.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage biotechnology company developing long-acting anti- inflammatory 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 inserted in an 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 patients who have not had sinus surgery 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 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 into the first quarter of 2025, the timing, enrollment and success of the Company's clinical programs, the timing for reporting data from the Company's clinical trials, the safety and efficacy of the Company's product candidates, the Company's participation and presentation of results from the BEACON study at an upcoming medical meeting and the Company's development of a robust CRS product portfolio. 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 successfully commercialize its product candidates; the fact that clinical trials required for the Company's product candidates are expensive and time-consuming, and their outcomes are 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, international terrorism, conflicts 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 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 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Three Months Ended September 30,	Nine Months Ended September 30,

	2023	2022	2023	2022
Collaboration revenue	$ 544	$ 359	$ 1,412	$ 1,352
Operating expenses:				
Research and development	12,368	10,048	35,763	29,346
General and administrative	5,003	5,137	14,700	13,157
Loss on impairment of long-lived assets	—	—	1,592	—
Total operating expenses	17,371	15,185	52,055	42,503
Loss from operations	(16,827)	(14,826)	(50,643)	(41,151)
Other income:				
Interest income	1,192	60	3,161	108
Total other income	1,192	60	3,161	108
Loss before income tax expense	(15,635)	(14,766)	(47,482)	(41,043)
Income tax expense	(16)	—	(42)	—
Net loss	(15,651)	(14,766)	(47,524)	(41,043)
Other comprehensive income (loss):				
Unrealized holding gain (loss) on short-term investments, net of tax	20	—	(17)	—
Comprehensive loss	$ (15,631)	$ (14,766)	$ (47,541)	$ (41,043)
Net loss per share attributable to common stockholders— basic and diluted	$ (0.27)	$ (0.40)	$ (1.04)	$ (1.47)
Weighted-average common shares outstanding— basic and diluted	56,953,685	36,826,364	45,894,643	28,014,434

LYRA THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 24,850	$ 32,550
Short-term investments	77,700	65,344
Prepaid expenses and other current assets	2,370	2,935
Total current assets	104,920	100,829
Property and equipment, net	726	2,243
Operating lease right-of-use assets	6,074	2,223
Restricted cash	1,392	1,392
Other assets	7,463	3,281
Total assets	$ 120,575	$ 109,968
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,054	$ 2,616
Accrued expenses and other current liabilities	11,052	9,030
Operating lease liabilities	1,403	1,549
Deferred revenue	1,726	1,275
Total current liabilities	19,235	14,470
Operating lease liabilities, net of current portion	4,887	667
Deferred revenue, net of current portion	12,214	14,077
Total liabilities	36,336	29,214
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at September 30, 2023 and December 31, 2022; no shares issued and outstanding at September 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at September 30, 2023 and December 31, 2022; 49,545,559 and 31,827,659 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	50	32
Additional paid-in capital	380,395	329,387

Accumulated other comprehensive (loss) income, net of tax	(7)	10
Accumulated deficit	(296,199)	(248,675)
Total stockholders' equity	84,239	80,754
Total liabilities and stockholders' equity	$ 120,575	$ 109,968

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