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

May 12, 2023

-- ENLIGHTEN I Pivotal Phase 3 Trial of LYR-210 in Pre-Surgical Chronic Rhinosinusitis (CRS) on Track to Complete Enrollment, with Data Expected in 1H 2024 --

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

WATERTOWN, Mass., May 12, 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 first quarter ended March 31, 2023 and provided a corporate update.

"We've had a highly productive start to 2023, positioning us for anticipated key data readouts over the next 12 months," said Maria Palasis, Ph.D., President and CEO of Lyra. "Enrollment is progressing well in the ENLIGHTEN I pivotal trial of LYR-210 in pre-surgical CRS, with data expected in the first half of 2024. Following our successful transition to in-house manufacturing of clinical supply, we restarted enrollment in ENLIGHTEN II, the second pivotal trial of LYR-210. Furthermore, we completed enrollment in the BEACON Phase 2 trial of LYR-220 in post-surgical CRS, with data expected in Q4 2023. We believe BEACON will provide further evidence of the efficacy and safety of our bioresorbable nasal implant to address the unmet needs of CRS patients and their physicians."

Lyra Program Highlights

ENLIGHTEN Pivotal Program of LYR-210 in Surgically Naïve Patients CRS

- Enrollment in the pivotal ENLIGHTEN I Phase 3 trial is ongoing, with data anticipated in 1H 2024.
- In April 2023, the Company restarted enrollment in the ENLIGHTEN II trial; 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. 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 a New Drug Application to the U.S. Food and Drug Administration for LYR-210.

Lyra announced in November 2022 that it temporarily paused enrollment in ENLIGHTEN II due to a transition to in-house manufacturing to ensure consistent clinical supply of LYR-210. Lyra has successfully manufactured LYR-210 in house to fully supply both ENLIGHTEN trials.

BEACON Phase 2 Clinical trial of LYR-220 in Post-Surgical CRS

- Enrollment in BEACON is complete, with data expected in Q4 2023.

The BEACON Phase 2 clinical 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.

In-House Manufacturing

- 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.

First Quarter 2023 Financial Highlights

Cash, cash equivalents and short-term investments as of March 31, 2023 were $82.7 million, compared with $97.9 million at December 31, 2022. 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 mid-second quarter of 2024. Please see our Quarterly Report filed on Form 10-Q for the three months ended March 31, 2023 for further information regarding our cash runway guidance and other financial results.

Research and development expenses for the quarter ended March 31, 2023 were $12.6 million compared to $8.5 million for the same period in 2022. The increase was primarily attributable to increased clinical development costs as we continued to enroll patients in our ENLIGHTEN I Phase 3 clinical trial and employee related costs of $1.4 million as we increased our headcount to support additional research and development activities.

General and administrative expenses for the quarter ended March 31, 2023 were $5.1 million compared to $3.9 million for the same period in 2022. The increase was primarily attributable to increased employee related costs mainly driven by stock-based compensation as well as the write-off of deferred financing costs of $0.4 million and increase in support costs of $0.3 million.

Net loss for the first quarter 2023 was $16.3 million compared to $11.9 million for the same period in 2022.

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 into mid-second quarter of 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 in-house, the safety and efficacy of the company's 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 and ability to operate as a going concern, 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 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 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 Quarterly Report on Form 10-Q filed with the SEC on May 12, 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 March 31,	
	2023	**2022**
Collaboration revenue	$ 410	$ 468
Operating expenses:		
Research and development	12,596	8,505
General and administrative	5,127	3,888
Total operating expenses	17,723	12,393
Loss from operations	(17,313)	(11,925)
Other income:		
Interest income	1,072	14
Total other income	1,072	14
Loss before income tax expense	(16,241)	(11,911)
Income tax expense	(14)	—
Net loss	(16,255)	(11,911)
Other comprehensive income:		
Unrealized holding loss on short-term investments, net of tax	(22)	—
Comprehensive loss	$ (16,277)	$ (11,911)
Net loss per share attributable to common stockholders—		
basic and diluted	$ (0.44)	$ (0.92)
Weighted-average common shares outstanding—		

basic and diluted	36,832,747	13,008,779

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

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 22,019	$ 32,550
Short-term investments	60,688	65,344
Prepaid expenses and other current assets	2,092	2,935
Total current assets	84,799	100,829
Property and equipment, net	2,004	2,243
Operating lease right-of-use assets	1,825	2,223
Restricted cash	1,392	1,392
Other assets	3,848	3,281
Total assets	$ 93,868	$ 109,968
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,951	$ 2,616
Accrued expenses and other current liabilities	6,793	9,030
Operating lease liabilities	1,900	1,549
Deferred revenue	1,510	1,275
Total current liabilities	14,154	14,470
Operating lease liabilities, net of current portion	191	667
Deferred revenue, net of current portion	13,432	14,077
Total liabilities	27,777	29,214
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at March 31, 2023 and December 31, 2022; no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2023 and December 31, 2022; 31,836,815 and 31,827,659 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	32	32
Additional paid-in capital	331,001	329,387
Accumulated other comprehensive income (loss), net of tax	(12)	10
Accumulated deficit	(264,930)	(248,675)
Total stockholders' equity	66,091	80,754
Total liabilities and stockholders' equity	$ 93,868	$ 109,968

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