Lyra Therapeutics Reports First Quarter 2024 Financial Results and Provides Corporate Update

April 30, 2024

-- Phase 3 Results from ENLIGHTEN 1 Trial of LYR-210 in Chronic Rhinosinusitis (CRS) Expected in May --

WATERTOWN, Mass., April 30, 2024 (GLOBE NEWSWIRE) -- Lyra Therapeutics, Inc. (Nasdaq: LYRA) ("Lyra" or the "Company"), a clinical-stage biotechnology company developing long-acting, anti-inflammatory sinonasal implants for the treatment of chronic rhinosinusitis (CRS), today reported its financial results for the first quarter ended March 31, 2024 and provided a corporate update.

"With results imminent for our ENLIGHTEN 1 pivotal Phase 3 study of LYR-210 in CRS, we are laser-focused on delivering the topline data in May," said Maria Palasis, Ph.D., President and CEO of Lyra Therapeutics. "We believe that LYR-210 has the potential to revolutionize the treatment of CRS by delivering a six-month therapy designed to provide long-acting relief that addresses the widespread need to overcome current treatment limitations faced by millions of patients."

Lyra Therapeutics is developing LYR-210 and LYR-220, its two product candidates in late-stage development for the treatment of CRS. LYR-210 and LYR-220 are bioabsorbable sinonasal implants designed to be administered in a simple, in-office procedure and are intended to deliver six months of continuous mometasone furoate drug therapy (7500µg MF) to the sinonasal passages for the treatment of CRS with a single administration. LYR-210 is intended for patients with standard anatomy, primarily those who have not undergone ethmoid sinus surgery. LYR-220, a larger implant, is designed for CRS patients whose nasal cavity is enlarged due to previous surgery.

Clinical Program Highlights

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

- Results from the ENLIGHTEN 1 pivotal Phase 3 clinical trial of LYR-210 are expected in May 2024.
- Enrollment in ENLIGHTEN 2, the second pivotal Phase 3 trial of LYR-210, is ongoing; enrollment completion is expected in the second half of 2024.
- Results from the ENLIGHTEN 1 52-week extension study are expected in Q4 2024.

The ENLIGHTEN program consists of two pivotal Phase 3 clinical trials, ENLIGHTEN 1 and ENLIGHTEN 2, 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 who have not had ethmoid sinus surgery, randomized 2:1 to either LYR-210 (7500µg mometasone furoate (MF)) or control over 24 weeks. The ENLIGHTEN 1 trial also includes an extension phase to further assess the safety and repeat use of LYR-210 through 52 weeks. The goal of the two pivotal trials is to support a New Drug Application to the U.S. Food and Drug Administration (FDA) for LYR-210.

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

- The Company plans to present additional secondary endpoint data from the BEACON Phase 2 clinical trial of LYR-220 at the 2024 Combined Otolaryngology Spring Meetings (COSM) being held May 15-19, 2024 in Chicago, IL. The presentation, "Impact of LYR-220 on ethmoid opacification and CRS symptoms in the BEACON study," is scheduled to take place on May 15, 2024 by Brent A. Senior, M.D., Nathaniel and Sheila Harris Distinguished Professor and Chief, Division of Rhinology, Allergy, and Endoscopic Skull Base Surgery in the Department of Otolaryngology/Head and Neck Surgery, UNC School of Medicine and Coordinating Investigator for the BEACON study.
- An end-of-Phase 2 meeting for LYR-220 with the FDA is anticipated in the second half of 2024.

The Phase 2 BEACON trial was a randomized, controlled, parallel-group study intended to evaluate the safety and placement feasibility of the LYR-220 (7500µg mometasone furoate (MF)) implant, over a 28-week period, in symptomatic CRS patients who have had ethmoid sinus surgery. In September 2023, Lyra Therapeutics announced positive topline results from the BEACON Phase 2 clinical trial of LYR-220 in adult patients with CRS who have recurrent symptoms despite having had surgery.

First Quarter 2024 Financial Highlights

Cash, cash equivalents and short-term investments as of March 31, 2024 were $87.1 million, compared with $102.8 million at December 31, 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. Please see our Quarterly Report filed on Form 10-Q for the three months ended March 31, 2024 for further information regarding our cash runway guidance and other financial results.

Research and development expenses for the quarter ended March 31, 2024 were $18.2 million, an increase of $5.6 million compared to $12.6 million for the same period in 2023. The increase in research and development expenses for the three months ended March 31, 2024 was primarily attributable to increased headcount costs of $2.1 million, an increase of $2.1 million of allocated and support costs for shared activities within the organization, an increase of $1.0 million in professional and consulting fees and increased clinical costs of $0.4 million as we continued to advance our clinical trials.

General and administrative expenses for the quarter ended March 31, 2024 were $5.8 million, an increase of $0.7 million compared to $5.1 million for the same period in 2023. The increase in general and administrative expenses for the three months ended March 31, 2024 was primarily attributable to an increase of $0.7 million in headcount costs as we expand headcount within the organization, as well as $0.4 million of support costs for shared

activities within the organization driven by headcount allocation and rent increases. These costs were partially offset by a decrease in other fees of $0.4 million due to prior year write-off of deferred financing costs.

Net loss for the first quarter 2024 was $22.5 million compared to $16.3 million for the same period in 2023.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage biotechnology company developing therapies for the localized treatment of patients with chronic rhinosinusitis (CRS), a highly prevalent inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities. LYR-210 and LYR-220 are bioabsorbable sinonasal implants designed to be administered in a simple, 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 with standard anatomy, primarily those who have not undergone ethmoid sinus surgery, and is being evaluated in the ENLIGHTEN Phase 3 clinical program, while LYR-220, an enlarged implant, was evaluated in the BEACON Phase 2 clinical trial in patients who have recurrent symptoms despite having had 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 timing of the availability of top-line results for ENLIGHTEN 1, the results from the 52-week extension study of ENLIGHTEN 1 being available in Q4 2024, the completion of enrollment for ENLIGHTEN 2 in the second half of 2024, the presentation of additional secondary endpoint data from the BEACON Phase 2 clinical trial of LYR-220 at COSM on May 15, 2024, whether an end-of-Phase 2 meeting for LYR-220 with the FDA will take place in the second half of 2024, the Company's cash runway into the first quarter of 2025, , and the safety and efficacy of the Company's 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 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 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 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 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 April 30, 2024 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,	
	2024	**2023**
Collaboration revenue	$ 532	$ 410
Operating expenses:		
Research and development	18,238	12,596
General and administrative	5,818	5,127
Total operating expenses	24,056	17,723
Loss from operations	(23,524)	(17,313)
Other income:		
Interest income	1,086	1,072
Total other income	1,086	1,072
Loss before income tax expense	(22,438)	(16,241)
Income tax expense	(14)	(14)
Net loss	(22,452)	(16,255)
Other comprehensive loss:		
Unrealized holding loss on short-term investments, net of tax	(8)	(22)

Comprehensive loss	$ (22,460)	$ (16,277)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.35)	$ (0.44)
Weighted-average common shares outstanding—basic and diluted	64,011,360	36,832,747

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 15,799	$ 22,353
Short-term investments	71,319	80,400
Prepaid expenses and other current assets	2,325	2,068
Total current assets	89,443	104,821
Property and equipment, net	3,783	2,043
Operating lease right-of-use assets	45,626	33,233
Restricted cash	1,992	1,392
Other assets	683	1,111
Total assets	$ 141,527	$ 142,600
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,844	$ 3,131
Accrued expenses and other current liabilities	10,057	9,374
Operating lease liabilities	4,504	5,434
Deferred revenue	1,319	1,658
Total current liabilities	18,724	19,597
Operating lease liabilities, net of current portion	33,356	21,447
Deferred revenue, net of current portion	11,943	12,136
Total liabilities	64,023	53,180
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; no shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2024 and December 31, 2023; 60,964,775 and 57,214,550 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	61	57
Additional paid-in capital	411,225	400,685
Accumulated other comprehensive income, net of tax	25	33
Accumulated deficit	(333,807)	(311,355)
Total stockholders' equity	77,504	89,420
Total liabilities and stockholders' equity	$ 141,527	$ 142,600

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