Lyra Therapeutics Reports First Quarter 2025 Financial Results and Provides Corporate Update

May 6, 2025

– Phase 3 results from ENLIGHTEN 2 pivotal Phase 3 trial of LYR 210 in Chronic Rhinosinusitis (CRS) expected in Q2 2025 –

WATERTOWN, Mass., May 06, 2025 (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, 2025 and provided a corporate update.

"With topline results imminently anticipated during Q2 for our ENLIGHTEN 2 pivotal Phase 3 study of LYR-210 in CRS, our team is keenly focused on delivering this clinical data, including symptomatic endpoints in both non-polyp and polyp patients, to enable us to gain further insight about the potential efficacy of LYR-210 across a broad CRS population," said Maria Palasis, Ph.D., President and CEO of Lyra Therapeutics.

Upcoming milestones for ongoing ENLIGHTEN pivotal program of LYR-210 in CRS

- Topline results from the ENLIGHTEN 2 pivotal Phase 3 clinical trial of LYR-210 in CRS patients are expected in Q2 2025.
- We expect an additional ~30 polyp patients in the ENLIGHTEN 2 trial, which combined with the 35 polyp patients in the ENLIGHTEN 1 trial, would result in a total of ~65 polyp patients in the ENLIGHTEN program.

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. Each ENLIGHTEN trial enrolled approximately 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) or sham control for 24 weeks.

Planned Reverse Stock Split

Lyra intends to implement a reverse stock split in order to increase the per share trading price of the Company's common shares for the purpose of complying with the minimum $1.00 bid price requirement for continued listing on The Nasdaq Capital Market. The reverse stock split requires approval by the Company's board of directors as well as the Company's stockholders at the annual stockholders meeting to be held on May 14, 2025.

First Quarter 2025 Financial Highlights

Cash and cash equivalents as of March 31, 2025 were $31.7 million, compared with cash and cash equivalents of $40.6 million at December 31, 2024. Based on our current business plan, we anticipate that our cash and cash equivalents balance is sufficient to fund our operating expenses and capital expenditures into the first quarter of 2026.

Research and development expenses for the quarter ended March 31, 2025 were $4.9 million, compared to $18.2 million for the same period in 2024. The decrease in research and development expenses year over year was primarily attributable to a decrease in clinical related costs of $4.7 million as we completed both the BEACON trial for LYR-220 and the primary phase for the ENLIGHTEN 1 trial for LYR-210, a decrease of $4.5 million in employee related costs primarily driven by the reduction in force that occurred in May 2024, a decrease in professional and consulting costs of $1.3 million, a decrease in product development and manufacturing costs of $1.3 million and a decrease in allocation, support and depreciation costs of $1.5 million.

General and administrative expenses for the quarter ended March 31, 2025 were $3.3 million, compared to $5.8 million for the same period in 2024. The decrease in general and administrative expenses for the three months ended March 31, 2025 was primarily driven by a decrease in professional, consulting and public company fees of $0.8 million as we scaled back activities subsequent to announcing in May 2024 that the ENLIGHTEN 1 trial did not meet its primary endpoint, in addition to a decrease in employee related costs of $1.9 million primarily due to the reduction in force that occurred in May 2024. These were partially offset by an increase in allocation, support and depreciation costs of $0.2 million primarily due to the increased rent and facilities expenses for the Company's three leased facilities for the three months ended March 31, 2025 compared to the three months ended March 31, 2024.

Net loss for the first quarter 2025 was $8.5 million, compared to $22.5 million for the same period in 2024.

LYRA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2025	**2024**
Collaboration revenue	$ 183	$ 532
Operating expenses:		
Research and development	4,876	18,238
General and administrative	3,263	5,818
Restructuring and other related charges	885	—

Total operating expenses	9,024	24,056
Loss from operations	(8,841)	(23,524)
Other income:		
Interest income	298	1,086
Total other income	298	1,086
Loss before income tax expense	(8,543)	(22,438)
Income tax expense	(4)	(14)
Net loss	(8,547)	(22,452)
Other comprehensive loss:		
Unrealized holding gain (loss) on short-term investments, net of tax	—	(8)
Comprehensive loss	$ (8,547)	$ (22,460)
Net loss per share attributable to common stockholders— basic and diluted	$ (0.13)	$ (0.35)
Weighted-average common shares outstanding—basic and diluted	65,757,860	64,011,360

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

	March 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 31,735	$ 40,577
Prepaid expenses and other current assets	2,170	2,448
Total current assets	33,905	43,025
Property and equipment, net	1,276	1,404
Operating lease right-of-use assets	19,142	19,924
Restricted cash	1,993	1,993
Total assets	$ 56,316	$ 66,346
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 725	$ 1,179
Restructuring liability	4,039	4,347
Accrued expenses and other current liabilities	2,247	2,586
Operating lease liabilities	4,243	4,121
Deferred revenue	216	398
Total current liabilities	11,470	12,631
Operating lease liabilities, net of current portion	29,113	30,259
Deferred revenue, net of current portion	11,861	11,862
Total liabilities	52,444	54,752
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2025 and December 31, 2024; no shares issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at March 31, 2025 and December 31, 2024; 65,880,561 and 65,515,440 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	66	65
Additional paid-in capital	417,143	416,319
Accumulated deficit	(413,337)	(404,790)
Total stockholders' equity	3,872	11,594
Total liabilities and stockholders' equity	$ 56,316	$ 66,346

About LYR-210

LYR-210 is an investigational product candidate for the treatment of chronic rhinosinusitis (CRS) in patients who have failed current therapies and require further intervention. LYR-210 is a bioabsorbable nasal implant designed to be inserted in a simple, in-office procedure. LYR-210 is intended to deliver six months of continuous anti-inflammatory therapy, mometasone furoate, to the sinonasal passages to treat CRS. LYR-210 is being evaluated in the ENLIGHTEN pivotal Phase 3 clinical program.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage biotechnology company developing long-acting, anti-inflammatory sinonasal implants for the treatment of chronic rhinosinusitis (CRS). Lyra Therapeutics is developing therapies for CRS, a highly prevalent inflammatory disease of the paranasal sinuses which leads to debilitating symptoms and significant morbidities. LYR-210, the company's lead product, is a bioabsorbable nasal implant designed to be administered in a simple, in-office procedure and is intended to deliver six months of continuous anti-inflammatory drug therapy (7500µg mometasone furoate) to the sinonasal passages for the treatment of CRS with a single administration. LYR-210, being evaluated in the ENLIGHTEN Phase 3 clinical program, is intended for patients with and without nasal polyps. The company's therapies are intended 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. The words "believe," "may," "will," "plan", "estimate," "continue," "anticipate," "intend," "expect," and similar expressions are intended to identify forward-looking statements. 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 2026, whether LYR-210 could potentially benefit patients with CRS with or without polyps, the completion of the Company's ENLIGHTEN 2 Phase 3 clinical trial, the timing of the release of topline data from the ENLIGHTEN 2 Phase 3 clinical trial, whether the ENLIGHTEN 2 trial will net an additional ~30 polyp patients, whether the ENLIGHTEN results will include important data or enable the Company to gain further insight about the efficacy of LYR-210, and the Company's intentions concerning the implementation of a reverse stock split to comply with the minimum bid price rule to maintain its listing on the Nasdaq Capital Market. 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 Company's failure to meet its primary endpoint in its ENLIGHTEN 1 Phase 3 clinical trial; the fact the Company terminated the employment of approximately 87 employees following the announcement that it failed to attain the primary endpoint of its ENLIGHTEN 1 Phase 3 clinical trial; 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 fact that the Company needs to conduct at least one additional phase 3 clinical trial; the Company's ability to continue as a going concern; the Company's limited operating history; the fact that the Company has no approved products; the fact that clinical trial data is subject to change until the completion of the applicable clinical study report; the fact that clinical trials required for the Company's product candidates are expensive and time-consuming, and their outcome is uncertain; effects of recently enacted and future legislation; the possibility of system failures or security breaches; effects of significant competition; the Company's reliance on third parties to conduct its preclinical studies and clinical trials; failure to obtain and maintain or adequately protect the Company's intellectual property rights; failure to retain key personnel; 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 6, 2025 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.

Contact Information: Jason Cavalier, Chief Financial Officer 917.584.7668 jcavalier@lyratx.com Media Contact: Kathryn Morris, The Yates Network LLC 914.204.6412 kathryn@theyatesnetwork.com