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

August 12, 2025

– Positive ENLIGHTEN 2 Phase 3 results announced in June 2025 propel business activities in manufacturing, regulatory strategy and ENLIGHTEN clinical dataset analysis to advance path forward for LYR-210 for treatment of chronic rhinosinusitis (CRS) –

– Financing announced in June 2025 extends cash runway into 3Q 2026 –

WATERTOWN, Mass., Aug. 12, 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 second quarter ended June 30, 2025 and provided a corporate update.

"The positive results from our ENLIGHTEN 2 trial have enabled us to secure financing and are providing momentum to optimize our regulatory strategy and resume manufacturing activities, as we pursue our path to advance LYR-210 as a six-month treatment option for millions of patients who do not respond to standard CRS medical management," said Maria Palasis, Ph.D., President and CEO, Lyra Therapeutics, Inc. "We continue to review and analyze the totality of the dataset from the ENLIGHTEN 1 and ENLIGHTEN 2 trials as we execute on our business strategy and envision the opportunities ahead for LYR-210 to benefit patients with CRS."

Recent Business Highlights

- On June 27, Lyra announced a registered direct offering of common stock and pre-funded warrants pursuant to an effective shelf registration statement on Form S-3, as well as a concurrent private placement of warrants exempt from registration pursuant to Section 4(a)(2) and/or Rule 506 of the Securities Act of 1933, as amended, with gross proceeds to Lyra of approximately $5.0 million. With this financing, the Company expects its cash runway to extend into the third quarter of 2026. In addition, if the holders of the private placement warrants exercise such warrants in full in cash, the Company would receive additional gross proceeds of approximately $9.8 million, before deducting the placement agent's fees. Lyra intends to use the net proceeds from the offering for working capital and other general corporate purposes, including potential clinical development, manufacturing and other expenses for LYR-210.
- Lyra has reengaged with the U.S. Food and Drug Administration (FDA) following the positive results from the ENLIGHTEN 2 Phase 3 study in early June. The Company is preparing for an upcoming Type C meeting with the FDA in the second half of 2025, in order to align on a path forward for an NDA submission for LYR-210 as a treatment for CRS patients without nasal polyps.
- Lyra has resumed in-house chemistry, manufacturing and controls (CMC) activities to prepare for manufacturing LYR-210 for potential, future clinical trials and for compliance with applicable CMC regulations.
- On May 27, Lyra implemented a 1-for-50 reverse stock split of the Company's common stock in order to regain compliance with Nasdaq's $1.00 minimum bid price requirement.
- On June 13, Nasdaq notified the Company that it had regained compliance with the $1.00 minimum bid price requirement.

Highlights from ENLIGHTEN 2 Statistically Significant Phase 3 Results for LYR-210 in CRS

- On June 2, Lyra announced topline results from the Phase 3 ENLIGHTEN 2 trial showing that LYR-210 met its primary endpoint. LYR-210 demonstrated statistically significant improvement compared to sham control in a composite of the three cardinal symptoms (3CS) of CRS (nasal obstruction, nasal discharge, facial pain/pressure) at week 24 (-1.13; p=0.0078) in patients without nasal polyps. Consistent with previous studies, LYR-210 was generally well tolerated, with no product-related serious adverse events.
- The ENLIGHTEN 2 trial also met the key secondary endpoints of 3CS at 24 weeks in the full population (i.e., patients with and without nasal polyps) (-0.90; p=0.0209) and in the clinically-validated SNOT-22 score at 24 weeks (-8.7; p=0.0101), with symptom improvement observed as early as week 4.
- Additionally, in pooled data from ENLIGHTEN 2 and ENLIGHTEN 1 trials in 64 CRS patients with nasal polyps, LYR-210 demonstrated a consistent positive trend over 24 weeks in multiple key efficacy endpoints.

The ENLIGHTEN program consisted 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. While the ENLIGHTEN 2 trial met its primary endpoint and key secondary endpoints, the ENLIGHTEN 1 trial did not meet the primary endpoint or secondary endpoints, as previously reported in May 2024. Each ENLIGHTEN trial enrolled approximately 180 CRS patients who failed medical management and did not have prior ethmoid sinus surgery, randomized 2:1 to either LYR-210 (7500µg mometasone furoate) or sham control for 24 weeks.

Second Quarter 2025 Financial Highlights

Cash and cash equivalents as of June 30, 2025 were $29.8 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 third quarter of 2026.

Research and development expenses decreased by $8.2 million from $13.3 million to $5.1 million for the three months ended June 30, 2025 compared to the three months ended June 30, 2024.

The decrease in research and development expenses for the three months ended June 30, 2025 was primarily attributable to a decrease in clinical related costs of $3.7 million as we completed the ENLIGHTEN 1 trial for LYR-210, a decrease of $1.4 million in employee related costs primarily driven by the reduction in force that occurred in May 2024, a decrease in professional and consulting fees of $0.6 million, a decrease in product development and manufacturing costs of $1.3 million and a decrease in allocation, support and depreciation costs shared between the general & administrative and research & development functions within the organization driven by headcount allocation of $1.2 million.

General and administrative expenses decreased by $1.6 million from $5.1 million to $3.5 million for the three months ended June 30, 2025 compared to the three months ended June 30, 2024.

The decrease in general and administrative expenses for the three months ended June 30, 2025 was primarily driven by a decrease in professional, consulting and public company fees of $0.7 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 $0.9 million primarily due to the reduction in force that occurred in May 2024.

The Company incurred no impairment costs related to property and equipment for the three months ended June 30, 2025 compared to $1.9 million of impairment costs related to property and equipment for the same period in 2024.

The Company incurred no impairment costs related to our right-of-use assets for the three months ended June 30, 2025 and incurred $22.8 million of impairment costs related to our right-of-use assets for the same period in 2024.

The Company incurred restructuring charges in the amount of $0.4 million primarily related to severance and retention costs for the three months ended June 30, 2025 and restructuring charges of $6.5 million primarily related to severance and retention costs for the same period in 2024.

Net loss for the second quarter 2025 was $7.4 million, compared to $48.1 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 June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Collaboration revenue	$ 183	$ 598	$ 366	$ 1,130
Operating expenses:				
Research and development	5,110	13,264	9,986	31,502
General and administrative	3,501	5,139	6,764	10,957
Impairment of property and equipment	—	1,883	—	1,883
Impairment of right-of-use assets	—	22,836	—	22,836
Restructuring and other related charges	398	6,450	1,283	6,450
Total operating expenses	9,009	49,572	18,033	73,628
Loss from operations	(8,826)	(48,974)	(17,667)	(72,498)
Other income:				
Interest income	410	855	708	1,941
Other income	981	—	981	—
Total other income	1,391	855	1,689	1,941
Loss before income tax expense	(7,435)	(48,119)	(15,978)	(70,557)
Income tax expense	(2)	(12)	(6)	(26)
Net loss	(7,437)	(48,131)	(15,984)	(70,583)
Other comprehensive loss:				
Unrealized holding loss on short-term investments, net of tax	—	(29)	—	(37)
Comprehensive loss	$ (7,437)	$ (48,160)	$ (15,984)	$ (70,620)
Net loss per share attributable to common stockholders— basic and diluted	$ (5.51)	$ (36.76)	$ (12.00)	$ (54.51)
Weighted-average common shares outstanding— basic and diluted	1,348,630	1,309,193	1,331,985	1,294,790

Share information reflects the effect of a 1-for-50 reverse stock split.

CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 29,784	$ 40,577
Prepaid expenses and other current assets	1,279	2,448
Total current assets	31,063	43,025
Property and equipment, net	1,159	1,404
Operating lease right-of-use assets	18,358	19,924
Restricted cash	1,993	1,993
Total assets	$ 52,573	$ 66,346
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 680	$ 1,179
Restructuring liability	3,486	4,347
Accrued expenses and other current liabilities	2,413	2,586
Operating lease liabilities	4,552	4,121
Deferred revenue	32	398
Total current liabilities	11,163	12,631
Operating lease liabilities, net of current portion	27,926	30,259
Deferred revenue, net of current portion	11,862	11,862
Total liabilities	50,951	54,752
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2025 and December 31, 2024; no shares issued and outstanding at June 30, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at June 30, 2025 and December 31, 2024; 1,625,376 and 1,310,308 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	2	1
Additional paid-in capital	422,394	416,383
Accumulated deficit	(420,774)	(404,790)
Total stockholders' equity	1,622	11,594
Total liabilities and stockholders' equity	$ 52,573	$ 66,346

Share information reflects the effect of a 1-for-50 reverse stock split.

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 candidate, 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 third quarter of 2026, whether LYR-210 could potentially benefit patients with CRS with or without polyps, the safety, efficacy, potential benefits of, and clinical design or progress of any of LYR-210 at any dosage or in any indication; the in-house CMC activities to prepare for manufacturing LYR-210 for potential, future clinical trials and for compliance with applicable CMC regulations; our expectations surrounding potential regulatory submissions, progress, or approvals and timing thereof for any of our

product candidates, including the anticipated Type C meeting with the FDA; the Company's business strategy and plans; and the timing of any of the foregoing. 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 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 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 August 12, 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.

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