Lyra Therapeutics Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 9, 2022

Pivotal ENLIGHTEN Phase 3 clinical program and BEACON Phase 2 clinical trial targeting a broad spectrum of chronic rhinosinusitis (CRS) patients, continued enrollment

Industry leader Richard Nieman, MD, appointed Chief Medical Officer

In April 2022, secured $96.3 million in net proceeds in an at-the-market, private placement of common stock that is expected to support two pivotal data readouts; cash runway extended until mid-2024

WATERTOWN, Mass., Aug. 9, 2022 /PRNewswire/ -- Lyra Therapeutics, Inc. (Nasdaq: LYRA)("Lyra" or the "Company"), a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained and local delivery of medications to the ear, nose and throat (ENT) passages and other diseased tissues, today reported financial results for the second quarter ended June 30, 2022, and highlighted recent accomplishments.

"The second quarter marked continued progress for our ongoing clinical programs designed to address the full spectrum of CRS patients. The pivotal ENLIGHTEN Phase 3 program for LYR-210 is actively enrolling patients with chronic rhinosinusitis and surgically naïve anatomy," said Maria Palasis, PhD, President and Chief Executive Officer of Lyra Therapeutics. "The BEACON Phase 2 trial for LYR-220 is continuing enrollment of CRS patients with recurrent CRS despite surgical intervention. Together these two patient populations represent the roughly four million patients who fail medical management, highlighting the need for new therapies."

"CRS is a highly prevalent inflammatory disease of the paranasal sinuses leading to debilitating symptoms and significant morbidities for which there is no approved therapeutic treatment at this time," said Dr. Richard Nieman, Chief Medical Officer of Lyra Therapeutics. "While millions of CRS patients are treated by ENT physicians annually in the U.S., many suffer from persistent burdensome symptoms due to limited, ineffective treatment options and are seeking alternatives to invasive, non-curative sinus surgery, or continuous use of biologics. We have the potential to create a new standard of care for these patients and we look forward to the ongoing advancement of LYR-210 and LYR-220 through the clinic."

Corporate Highlights

- On July 5, 2022, Lyra announced the appointment of Richard Nieman, MD, as Chief Medical Officer, an industry leader with substantial U.S. and global experience in drug development and medical affairs and a proven track record of developing medicines through commercialization and beyond. His prior leadership roles include SVP & Worldwide Medical Head of Immunology at Bristol Myers Squibb (BMS), Head of R&D China at BMS, Global Medical Officer & Head of Medical at Teva, and Head of Asia Pacific Medical at Bayer. Dr. Nieman will guide the Company's late-stage product candidates as they advance in the clinic.
- In April 2022, Lyra closed a private placement of common stock of approximately $96.3 million in net proceeds with participation by funds affiliated with existing investors: Perceptive Advisors, North Bridge Venture Partners and Pura Vida Investments as well as funds affiliated with new investors: Venrock Healthcare Capital Partners, Nantahala Capital Management, LLC and Samsara BioCapital. The net proceeds, combined with the Company's existing cash balance, is expected to provide sufficient operating capital through mid-2024.

Clinical Developments for LYR-210 and LYR-220

- Enrollment in the pivotal ENLIGHTEN I Phase 3 trial is ongoing, while the ENLIGHTEN II Phase 3 trial is actively screening patients and we expect to enroll the first patient in the third quarter. Both ENLIGHTEN trials are expected to enroll patients in the U.S. and Europe. The global ENLIGHTEN Phase 3 program is expected to include a total of 360 adults, surgically-naïve CRS patients and enrollment is projected to be completed in mid-year 2023.
- In April 2022, the first patient was treated in Australia in the Part 1/non-randomized portion of the BEACON Phase 2 trial for LYR-220 for the treatment of adult CRS patients who remain symptomatic despite having had a prior sinus surgery. The Part 2/randomized portion of the trial is anticipated to commence in the U.S. in the third quarter. The BEACON Phase 2 trial is expected to include approximately 70 symptomatic adult CRS subjects who have had a prior sinus surgery, with enrollment anticipated to be complete around the end of 2022. We believe topline results from the Part 1/non-randomized portion of the trial are anticipated around year-end 2022.
- At the 2022 Combined Otolaryngology Spring Meetings (COSM) in April 2022, the Company presented two oral presentations that highlighted additional positive clinical data from the LANTERN Phase 2 trial of LYR-210 in adult patients with CRS. The Company's oral presentation on the impact of long-acting implantable corticosteroid matrices in CRS patients was selected as a top clinical abstract by the American Rhinologic Society. The Company's second presentation highlighted clinically meaningful improvement in mental and physical quality of life outcomes for CRS patients. These results are supportive of the previously reported, statistically significant 40-point improvement for LYR-210 (7,500µg) over

the average baseline SNOT-22 score of 68 at week 24.

Second Quarter 2022 Financial Highlights

- Cash and cash equivalents as of June 30, 2022 were $120.7 million, compared with $33.8 million at March 31, 2022. The Company expects its cash and cash equivalents balance to be sufficient to fund its planned operations through mid-2024.
- Research and development expenses for the quarter ended June 30, 2022 were $10.8 million compared to $7.5 million for the same period in 2021. The increase was primarily driven by an increase in clinical expenses related to the Company's three clinical trials and employee-related expenses.
- General and administrative expenses for the quarter ended June 30, 2022 were $4.1 million compared to $3.6 million for the same period in 2021. The increase was primarily driven by an increase in employee related costs.
- Net loss for the quarter ended June 30, 2022 was $14.5 million compared to $11.0 million for the same period in 2021.

About Lyra Therapeutics

Lyra Therapeutics, Inc. is a clinical-stage therapeutics company leveraging its proprietary XTreo™ platform to enable precise, sustained, local delivery of medications to diseased tissues not accessible with conventional therapeutic approaches. Lyra's XTreo™ platform is comprised of a biocompatible mesh scaffold, an engineered elastomeric matrix and a versatile polymer-drug complex. The company's current pipeline of therapeutics target tissues deep in the ear, nose and throat passages and are designed to deliver continuous drug therapy for up to six months following a single non-invasive, in-office administration. Lyra has two product candidates 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, for surgically naïve patients is being evaluated in the ENLIGHTEN Phase 3 clinical program, and LYR-220, is being evaluated in patients who have recurrent symptoms despite surgery in the BEACON Phase 2 clinical trial. These two product candidates are designed to treat the estimated four million CRS patients in the U.S. that fail medical management each year. For more information, please visit www.lyratherapeutics.com and follow us on LinkedIn and Twitter.

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 through mid-2024, the Company's pipeline of product candidates, the enrollment and success of the ENLIGHTEN II Phase 3 program, the enrollment and success of the Phase 2 BEACON trial (including the timelines for commencement of the Part 2/randomized portion of the trial in the U.S. later in the third quarter and topline results from the Part 1/non-randomized portion of the trial around year-end), Dr. Nieman's role at the Company, and the success of the XTreo™ platformThese 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; 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 relies on third parties for the manufacture of materials for its research programs, pre-clinical studies and clinical trials; 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 August 9, 2022 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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LYRA THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 407	$ —	$ 5,774	$ —
Operating expenses:				
Research and development	10,793	7,505	19,298	12,275
General and administrative	4,132	3,560	8,020	6,621
Total operating expenses	14,925	11,065	27,318	18,896
Loss from operations	(14,518)	(11,065)	(21,544)	(18,896)
Other income:				
Interest income	34	26	48	55
Total other income	34	26	48	55
Net loss	$ (14,484)	$ (11,039)	$ (21,496)	$ (18,841)
Net loss per share attributable to common stockholders—basic and Diluted	$ (0.43)	$ (0.85)	$ (0.91)	$ (1.45)
Weighted-average common shares outstanding—basic and diluted	33,946,428	12,991,837	23,535,442	12,968,820

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

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 120,669	$ 45,747
Restricted cash	329	—
Prepaid expenses and other current assets	1,383	2,171
Total current assets	122,381	47,918
Property and equipment, net	4,009	4,503
Operating lease right-of-use assets	860	1,355
Restricted cash	1,089	329
Other assets	1,696	762
Total assets	$ 130,035	$ 54,867
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,670	$ 3,125
Accrued expenses and other current liabilities	5,465	4,258
Operating lease liabilities	926	1,074
Deferred revenue	1,811	9,789
Total current liabilities	9,872	18,246
Operating lease liabilities, net of current portion	3	379
Deferred revenue, net of current portion	9,130	1,926
Total liabilities	19,005	20,551
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2022 and December 31, 2021; no shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized at June 30, 2022 and December 31, 2021; 31,826,357 and 13,007,178 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	32	13
Additional paid-in capital	325,891	227,700
Accumulated deficit	(214,893)	(193,397)
Total stockholders' equity	111,030	34,316
Total liabilities and stockholders' equity	$ 130,035	$ 54,867

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