Lexeo Therapeutics Reports First Quarter 2025 Financial Results and Operational Highlights

May 12, 2025

Announced positive interim data for LX2006 from Phase 1/2 studies in Friederich ataxia (FA) cardiomyopathy; frataxin expression and LVMI improvement exceeded co-primary target thresholds for planned registrational study

LX2006 registrational study expected to begin by early 2026; commencing enrollment in prospective natural history study, CLARITY-FA, in Q2 2025 to serve as concurrent external control

Phase 1/2 clinical trial of LX2020 (HEROIC-PKP2) currently enrolling patients in Cohort 3; interim clinical data update on track for second half of 2025

Redeployed $20 million to focus on clinical-stage programs; cash, cash equivalents and investments of $106.9 million expected to provide operational runway into 2027

NEW YORK, May 12, 2025 (GLOBE NEWSWIRE) -- Lexeo Therapeutics, Inc. (Nasdaq: LXEO), a clinical stage genetic medicine company dedicated to pioneering novel treatments for cardiovascular diseases, today provided business updates across its portfolio and reported first quarter 2025 financial results.

“Based on the highly encouraging clinical data shared to date, we believe LX2006 could be transformational and establish a new standard of care in FA cardiomyopathy,” said R. Nolan Townsend, Chief Executive Officer of Lexeo Therapeutics. “We look forward to beginning enrollment in the CLARITY-FA natural history study imminently and moving as quickly as possible to initiate a registrational study for LX2006 by early 2026. We were also proud to share the promising, early data for LX2020 for the treatment of PKP2-associated arrhythmogenic cardiomyopathy and we look forward to sharing additional clinical updates later in 2025 for this program.”

Business and Program Updates

- **LX2006 for the Treatment of FA Cardiomyopathy:** In April 2025, Lexeo announced positive interim data of LX2006 across both the Lexeo-sponsored SUNRISE-FA Phase 1/2 clinical trial (NCT05445323) and the Weill Cornell Medicine investigator-initiated Phase 1A trial (NCT05302271).
  - **Efficacy:** Clinically meaningful improvements were observed across cardiac biomarkers and functional measures in the majority of participants across both studies. Participants with abnormal left ventricular mass index (LVMI) at baseline achieved 25% mean reduction in LVMI by 12 months or sooner, exceeding the 10% target reduction in LVMI by 12 months aligned with the U.S. Food and Drug Administration (FDA) for the planned registrational study.
  - **Protein Expression**: Increases in cardiac frataxin expression were observed in all SUNRISE-FA participants at 3-months post treatment, with an average increase of 115% over baseline observed in the high-dose cohort.
  - **Safety:** LX2006 continues to be generally well tolerated with no new treatment-related serious adverse events to report.
  - **Regulatory Plans:** Lexeo expects final alignment with FDA on the LX2006 planned pivotal study protocol and statistical analysis plan in 2025. Lexeo previously aligned with FDA on co-primary endpoints for the study and measurement thresholds: greater than 10% reduction in LVMI as measured by cardiac MRI, and any increase from baseline cardiac frataxin expression as measured by liquid chromatography mass spectrometry (LCMS).
  - **Next Steps**: In Q2 2025, Lexeo expects to begin enrollment in a prospective natural history study serving as a concurrent external control arm for the registrational study. The Company expects to initiate a registrational study by early 2026 with a potential efficacy readout in 2027.
- **LX2020 for the Treatment of PKP2-ACM:** In March 2025, Lexeo shared positive interim data of LX2020 from the low-dose cohort in the HEROIC-PKP2 Phase 1/2 clinical trial.
  - **Cohort 1 Interim Update:** At 3-months post-treatment, cardiac biopsies from two participants in cohort 1 showed 71% and 115% increases, respectively, in PKP2 protein expression from baseline; the third cohort 1 participant elected not to undergo a post-treatment biopsy. The first participant evaluated 6-months post treatment experienced a 67% reduction in premature ventricular contractions (PVCs) from baseline.
  - **Safety:** LX2020 has been generally well tolerated with no treatment-related serious adverse events to date across both dose cohorts.
  - **Next Steps**: Currently enrolling cohort 3 of LX2020 HEROIC-PKP2 (n=4), with an interim clinical data update expected in the second half of 2025.
- **Capital Redeployment and Cash Runway**: In April 2025, Lexeo identified approximately $20 million in capital to redeploy towards the Company’s lead cardiac programs, LX2006 and LX2020. This capital was redeployed from preclinical and non-cardiac pipeline activities and included a limited reduction in force impacting approximately 15% of employees. The updated capital structure is expected to enable the Company to execute against key milestones for its clinical-stage pipeline, accelerate work to initiate a registrational study for LX2006 by early 2026, and maintain operational runway into 2027.

First Quarter Financial Results

- **Cash Position:** As of March 31, 2025, cash, cash equivalents, and investments were $106.9 million, which Lexeo believes will be sufficient to fund operations into 2027.
- **Research and Development Expenses:** Research and Development expenses were $17.2 million for the three months ended March 31, 2025, compared to $15.7 million for the three months ended March 31, 2024.
- **General and Administrative Expenses:** General and Administrative expenses were $16.6 million for the three months ended March 31, 2025, compared to $7.5 million for the three months ended March 31, 2024.
- **Net Loss:** Net loss was $32.7 million or $0.99 per share (basic and diluted) for the three months ended March 31, 2025, compared to $21.7 million or $0.77 per share (basic and diluted) for the three months ended March 31, 2024.

About Lexeo Therapeutics
Lexeo Therapeutics is a New York City-based, clinical stage genetic medicine company dedicated to reshaping heart health by applying pioneering science to fundamentally change how cardiovascular diseases are treated. The Company is advancing a portfolio of therapeutic candidates that take aim at the underlying genetic causes of conditions, including LX2006 for the treatment of Friedreich ataxia (FA) cardiomyopathy, LX2020 for the treatment of plakophilin-2 (PKP2) arrhythmogenic cardiomyopathy, and others for devastating diseases with high unmet need.

Cautionary Note Regarding Forward-Looking Statements
Certain statements in this press release may constitute "forward-looking statements" within the meaning of the federal securities laws, including, but not limited to, Lexeo's expectations and plans regarding its current product candidates and programs and the timing for receipt and announcement of data from its clinical trials, the timing and likelihood of potential regulatory developments and approval, expectations regarding the time period over which Lexeo's capital resources will be sufficient to fund its anticipated operations and estimates regarding Lexeo's financial condition. Words such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "design," "estimate," "predict," "potential," "develop," "plan" or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While Lexeo believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements. These forward-looking statements are based upon current information available to the company as well as certain estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in Lexeo's filings with the U.S. Securities and Exchange Commission (SEC)), many of which are beyond the company's control and subject to change. Actual results could be materially different from those indicated by such forward-looking statements as a result of many factors, including but not limited to: risks and uncertainties related to global macroeconomic conditions and related volatility; expectations regarding the initiation, progress, and expected results of Lexeo's preclinical studies, clinical trials and research and development programs; the unpredictable relationship between preclinical study results and clinical study results; delays in submission of regulatory filings or failure to receive regulatory approval; liquidity and capital resources; and other risks and uncertainties identified in Lexeo's Annual Report on Form 10-K for the annual period ended December 31, 2024, filed with the SEC on March 24, 2025, and subsequent future filings Lexeo may make with the SEC. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Lexeo claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. Lexeo expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

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Lexeo Therapeutics, Inc.
Selected Financial Information
(in thousands, except share and per share amounts)

Statements of Operations

	Three Months Ended March 31,	
	2025	**2024**
	(unaudited)	**(unaudited)**
Operating expenses		
Research and development	$ 17,171	$ 15,742
General and administrative	16,634	7,549
Total operating expenses	33,805	23,291
Operating loss	(33,805)	(23,291)
Other income and expense		
Other income (expense), net	(4)	(5)
Interest expense	(28)	(37)
Interest income	1,193	1,651
Amortization of premium on investments	(12)	-
Total other income and expense	1,149	1,609
Loss from operations before income taxes	(32,656)	(21,682)
Income taxes	-	-
Net loss	$ (32,656)	$ (21,682)
Net loss per common share, basic and diluted	$ (0.99)	$ (0.77)
Weighted average number of shares outstanding used in computation of net loss per common share, basic and diluted	33,113,991	27,979,838

Balance Sheet Data

	March 31, 2025	December 31, 2024
	(unaudited)	
Cash, cash equivalents, and investments	$ 106,866	$ 128,530
Total assets	125,690	146,942
Total liabilities	37,575	30,100
Total stockholders' equity	88,115	116,842