Lexeo Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Operational Highlights

Lexeo announces $95.0M equity financing, which in addition to 2023 year-end cash and cash equivalents of $121.5M, extends runway to fund operations into 2027

Reports frataxin protein expression data from a subset of the second dose cohort of SUNRISE-FA, a Phase 1/2 clinical trial of LX2006 for the treatment of Friedreich's ataxia (FA) cardiomyopathy, showing positive change in post-treatment frataxin levels

Additional interim data readout from SUNRISE-FA expected in mid-2024, with follow-up out to one year from the low-dose and multiple time points of follow-up expected from at least three patients treated at the mid-dose

Initiated SNAPSHOT-PKP2, a natural history study designed to evaluate PKP2-ACM disease progression up to two years retrospectively and over twelve months prospectively, in up to 20 patients in the U.S. All milestones for LX2020 remain on track

NEW YORK – March 11, 2024 (GLOBE NEWSWIRE) – Lexeo Therapeutics, Inc. (Nasdaq: LXEO), a clinical stage genetic medicine company dedicated to pioneering treatments for genetically defined cardiovascular diseases and APOE4-associated Alzheimer's disease, today reported fourth quarter and full year 2023 financial results and provided operational highlights.

"The past year has been transformative for Lexeo as we successfully completed our initial public offering and continued to advance our pipeline of genetic medicines," stated R. Nolan Townsend, Chief Executive Officer of Lexeo Therapeutics. "Building on our success in 2023, we are pleased to report that we have observed a positive change in frataxin levels now in Cohort 2 of the SUNRISE-FA trial. The low baseline protein levels observed in these patients provide unique insights into the biology of FA and we believe the increases in post treatment protein expression mediated by LX2006 may be sufficient to restore mitochondrial function with physiological improvement. These data, combined with our recent financing and progress across our pipeline, reflect exciting developments and add to our track record of clinical execution."

SUNRISE-FA Liquid Chromatography Mass Spectrometry (LCMS) Assay Protein Expression Data

Subject	Pre-Treatment FXN Levels (ng/mg protein)	Post-Treatment FXN Levels (ng/mg protein)	Change from Baseline (ng/mg protein)
Cohort 1 Subject 1 ($1.8x10^{11}$ vg/kg)	0.75	0.97	0.22
Cohort 2 Subject 1 ($5.6x10^{11}$ vg/kg)	0.97	2.77	1.81
Cohort 2 Subject 2 ($5.6x10^{11}$ vg/kg)	1.83	2.23	0.40

Note: Only one patient in Cohort 1 underwent pre and post treatment cardiac biopsy.

- Average pre-treatment FXN level across three subjects was 1.18ng/mg. Compared to FXN levels observed in 29 cadaver tissue samples from 16 individuals without heart disease, we believe the average pre-treatment FXN level represents approximately two percent of healthy individual frataxin levels in the heart.
- To our knowledge, SUNRISE-FA is the first clinical trial to evaluate frataxin levels in the target organ of FA cardiomyopathy patients via cardiac biopsy. Data to date suggest that FA patients may have lower FXN levels in the heart versus peripheral tissues.
- Across all three cardiac biopsies, we observed an increase in FXN levels as measured by liquid chromatography mass spectrometry relative to pre-treatment baseline levels.
- We observed an approximately five-fold increase in protein on average in the second cohort ($5.6x10^{11}$ vg/kg) to date, relative to the first cohort ($1.8x10^{11}$ vg/kg). A dose-dependent response was also seen in our IND-enabling preclinical studies, where a non-linear relationship was observed between dose delivered and frataxin protein expression.

Lexeo expects to present additional interim data from SUNRISE-FA Cohorts 1 and 2 in mid-2024, including measures of hypertrophy and other cardiac biomarkers at multiple timepoints(1). Ahead of this interim readout, Lexeo expects to provide an analysis of baseline characteristics from LX2006-treated patients to characterize the cardiovascular disease phenotype seen in FA as well as baseline levels of hypertrophy and other cardiac biomarkers that will be reported at mid-year.

(1) Trial participants receive immune suppression with prednisone beginning on the day prior to treatment/infusion through 14 weeks following LX2006 administration. Given the potential impact of corticosteroids on systemic status and cardiac biomarkers, efficacy data in the mid-2024 data readout will be presented for timepoints following cessation of corticosteroid administration.

Business and Program Updates

- **LX2006 for the Treatment of FA Cardiomyopathy:** Announced preliminary frataxin protein expression data from the second dose cohort of SUNRISE-FA showing positive change in post-treatment frataxin levels three months following administration of LX2006. Lexeo expects to report additional interim data from the SUNRISE-FA Phase 1/2 clinical trial in mid-2024 with follow-up out to one year from the low-dose and multiple timepoints of follow-up expected from at least three patients treated at the mid-dose.
- **LX2020 for the Treatment of PKP2-ACM:** In December 2023, the FDA granted Fast Track designation (FTD) and Orphan Drug designation (ODD) to LX2020, which allows more frequent interactions with FDA to facilitate development and expedite review processes. The ODD also provides additional benefits to Lexeo, such as market exclusivity upon regulatory approval. Clinical trial start-up activities are underway and Lexeo expects to dose the first patient in the HEROIC-PKP2 Phase 1/2 clinical trial of LX2020 in 1H 2024, with an interim data readout from Cohort 1 expected in 2H 2024. Lexeo has also initiated SNAPSHOT-PKP2, a natural history study designed to evaluate PKP2-ACM disease progression up to two years retrospectively and over twelve months prospectively in up to 20 patients in the United States.
- **APOE4-associated Alzheimer's Disease Programs:** Lexeo completed enrollment of all four cohorts in the LEAD Phase 1/2 clinical trial of LX1001 for the treatment of APOE4-associated Alzheimer's disease in Q4 2023. The Company expects to provide an interim data readout of all cohorts in 2H 2024.
- **Pricing of $95 Million Equity Financing:** Lexeo today announced that it has entered into a common stock purchase agreement with certain new and existing investors to issue and sell an aggregate of 6,278,905 shares of its common stock at a price of $15.13 per share, through a private placement. Lexeo anticipates the gross proceeds from the private placement to be approximately $95.0 million, before deducting any offering related expenses. The financing is expected to close on or about March 13, 2024, subject to customary closing conditions. The proceeds from this financing, combined with current cash, cash equivalents and marketable securities, are expected to fund operating and capital expenditures into 2027.
- **Completed Initial Public Offering:** In November 2023, Lexeo completed its underwritten initial public offering of 10,139,656 shares of its common stock, including the exercise of the underwriter's option to purchase 1,048,746 additional shares of its common stock. The aggregate gross proceeds from the offering were $111.5 million, before deducting underwriting discounts and commissions and offering expenses payable by Lexeo.

Expected Upcoming Milestones

- **LX2006 for the treatment of Friedreich's ataxia cardiomyopathy**
  - Interim data readout in mid-2024
- **LX2020 for the treatment of PKP2-ACM**
  - First patient dosed in 1H 2024
  - Interim data readout (Cohort 1) in 2H 2024
- **LX1001 for the treatment of APOE4-associated Alzheimer's disease**
  - Interim Phase 1/2 data readout (all cohorts) in 2H 2024
- **LX2021 for the treatment of DSP cardiomyopathy**
  - Initiate IND-enabling studies in 2024

Fourth Quarter and Full Year Financial Results

- **Cash Position:** As of December 31, 2023, cash and cash equivalents were $121.5 million, excluding the $95.0 million gross proceeds expected to be raised in the private placement announced today. Lexeo expects the additional funds raised in the financing to extend its runway into 2027.
- **R&D Expenses:** R&D expenses were $8.2 million for the three months ended December 31, 2023, compared to $11.4 million for the three months ended December 31, 2022. Research and Development expenses were $53.1 million for the year ended December 31, 2023, compared to $49.2 million for the same period in 2022.
- **G&A Expenses:** G&A expenses were $6.8 million for the three months ended December 31, 2023, compared to $3.8 million for the three months ended December 31, 2022. G&A expenses were $15.4 million for the year ended December 31, 2023, compared to $12.0 million for the same period in 2022.
- **Net Loss:** Net loss was $14.2 million or $0.86 per share (basic and diluted) for the three months ended December 31, 2023, compared to $14.6 million or $8.86 per share (basic and diluted) for the three months ended December 31, 2022. Net loss was $66.4 million or $12.40 per share (basic and diluted) for the year ended December 31, 2023, compared to $59.3 million or $36.36 per share (basic and diluted) for the year ended December 31, 2022.

About Lexeo Therapeutics

Lexeo Therapeutics is a New York City-based, clinical stage genetic medicine company dedicated to transforming healthcare by applying pioneering science to fundamentally change how genetically defined cardiovascular diseases and APOE4-associated Alzheimer's disease are treated. Using a stepwise development approach, Lexeo is leveraging early proof-of-concept functional and biomarker data to advance a pipeline of cardiovascular and APOE4-associated Alzheimer's disease programs.

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, our expectations and plans regarding our current product candidates and programs, including the anticipated timing of the initiation of and results from our clinical trials, expectations regarding the time period over which our capital resources will be sufficient to fund our 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 (the 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 our 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, including the anticipated closing of the private placement and anticipated runway extension; and other risks and uncertainties identified in our Quarterly Report of 10-Q for the quarterly period ended September 30, 2023, filed with the SEC on December 11, 2023, and subsequent future filings we 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 Condensed Financial Information
(unaudited, in thousands, except share and per share amounts)

Condensed Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenue				
Grant revenue	$ -	$ -	$ -	$ 654
Total revenue	-	-	-	654
Operating expenses				
Research and development	8,210	11,437	53,130	49,162
General and administrative	6,764	3,760	15,383	12,001
Total operating expenses	14,974	15,197	68,513	61,163
Operating loss	(14,974)	(15,197)	(68,513)	(60,509)
Other income and expense				
Loss on fair value adjustment to convertible SAFE Note	(258)	-	(530)	-
Other income (expense), net	(8)	(1)	(13)	(2)
Interest expense	(51)	(54)	(205)	(91)
Interest income	1,103	675	2,867	1,325
Total other income and expense	786	620	2,119	1,232
Loss from operations before income taxes	(14,188)	(14,577)	(66,394)	(59,277)
Income taxes	-	-	-	-
Net loss and comprehensive loss	$ (14,188)	$ (14,577)	$ (66,394)	$ (59,277)
Net loss per common share, basic and diluted	$ (0.86)	$ (8.86)	$ (12.40)	$ (36.36)
Weighted average number of shares outstanding used in computation of net loss per common share, basic and diluted	16,438,237	1,644,403	5,354,368	1,630,348

Condensed Consolidated Balance Sheet Data

	December 31, 2023	December 31, 2022
Cash, cash equivalents, and investments	$ 121,466	$ 77,335
Total assets	139,807	97,076
Total liabilities	26,272	24,997
Total convertible preferred stock	-	185,033
Total stockholders' equity (deficit)	113,535	(112,954)