
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 12, 2024

Lexeo Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41855
(Commission File Number)

85-4012572
(IRS Employer
Identification No.)

345 Park Avenue South, Floor 6
New York, New York
(Address of Principal Executive Offices)

10010
(Zip Code)

Registrant's Telephone Number, Including Area Code: 212 547-9879

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	LXEO	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On August 12, 2024, Lexeo Therapeutics, Inc. (the “Registrant”) issued a press release announcing business highlights and its financial results for the three and six months ended June 30, 2024. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

The information in this Item 2.02, and Exhibit 99.1 hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any of the Registrant’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Lexeo Therapeutics, Inc.

Date: August 12, 2024

By: /s/ R. Nolan Townsend

R. Nolan Townsend, Chief Executive Officer



Lexeo Therapeutics Reports Second Quarter 2024 Financial Results and Operational Highlights

Announced positive interim data from Phase 1/2 studies in Friedreich ataxia (FA) cardiomyopathy, which showed LX2006 was well tolerated with no treatment-related serious adverse events and demonstrated evidence of sustained and consistent treatment effect across multiple cardiac measures

Recently initiated formal engagements with FDA on surrogate endpoints for LX2006 registrational study; expects to provide update by end of year

Phase 1/2 clinical trial of LX2020 (HEROIC-PKP2) currently recruiting patients; data update from Cohort 1 on track for 2H 2024

Cash and cash equivalents of \$175.0 million expected to provide operational runway into 2027

NEW YORK – August 12, 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 second quarter 2024 financial results and provided operational highlights.

“We were proud to present the recent interim data of LX2006 for the treatment of FA cardiomyopathy, the first ever to show promise of treating this rare and fatal condition,” said R. Nolan Townsend, Chief Executive Officer of Lexeo Therapeutics. “Based on the favorable evidence to date, we have initiated engagements with FDA on surrogate endpoints for a registrational study so we can work to bring this potentially transformative gene therapy to patients as quickly as possible.”

Business and Program Updates

- **LX2006 for the Treatment of FA Cardiomyopathy:** In July 2024, Lexeo announced positive interim data of LX2006 across both the Lexeo SUNRISE-FA Phase 1/2 clinical trial ([NCT05445323](#)) and the Weill Cornell Medicine investigator-initiated Phase 1A trial ([NCT05302271](#)).
 - **Safety and Tolerability:** Interim safety results showed LX2006 was well tolerated with no treatment-related serious adverse events to date in either study.
 - **Efficacy and Protein Expression:** Sustained and consistent improvements were observed across multiple cardiac biomarkers associated with outcomes in FA cardiomyopathy, and increased frataxin protein levels were observed in all SUNRISE-FA participants post-treatment.
 - **Regulatory Plans:** In light of the evidence of treatment effect with improvements across multiple cardiac measures, Lexeo recently initiated formal engagements with FDA to discuss surrogate endpoints for a future registrational study and expects to provide an update on ongoing regulatory engagements by end of 2024. LX2006 was also granted Orphan Medicinal Product designation for the treatment of Friedreich ataxia by the European Commission in July 2024.
- **Appointment of Tim Van Hauwermeiren to Board of Directors:** In July 2024, Lexeo announced the appointment of Tim Van Hauwermeiren to its Board of Directors. Mr. Van Hauwermeiren currently serves as the co-founder and CEO of argenx SE, a global immunology company focused on severe autoimmune diseases, and he brings over 20 years of life sciences business development and general management experience to Lexeo.

Expected Upcoming Milestones

- **LX2006 for the treatment of Friedreich ataxia cardiomyopathy**
 - Previously disclosed data, and one additional cardiac biopsy from Cohort 2, will be shared at a scientific conference in Fall 2024
 - Update on ongoing regulatory engagements expected by end of 2024
- **LX2020 for the treatment of PKP2-ACM**
 - 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**

- o Initiate IND-enabling studies in 2024

Second Quarter Financial Results

- **Cash Position:** As of June 30, 2024, cash and cash equivalents were \$175.0 million, which Lexeo believes will be sufficient to fund operations into 2027.
- **R&D Expenses:** R&D expenses were \$16.6 million for the three months ended June 30, 2024, compared to \$11.2 million for the three months ended June 30, 2023.
- **G&A Expenses:** G&A expenses were \$7.0 million for the three months ended June 30, 2024, compared to \$2.7 million for the three months ended June 30, 2023.
- **Net Loss:** Net loss was \$21.2 million or \$0.64 per share (basic and diluted) for the three months ended June 30, 2024, compared to \$13.4 million or \$8.30 per share (basic and diluted) for the three months ended June 30, 2023.

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.

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, including statements regarding the potential benefits of LX2006 for the treatment of Friedreich ataxia cardiomyopathy and the timing for receipt and announcement of data from its clinical trials, the timing and likelihood of potential regulatory 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, 2023, filed with the SEC on March 11, 2024, Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024, filed with the SEC on May 9, 2024, 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 Condensed Financial Information
(unaudited, in thousands, except share and per share amounts)

Condensed Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	\$ 16,560	\$ 11,236	\$ 32,302	\$ 27,674
General and administrative	6,990	2,739	14,539	5,592
Total operating expenses	<u>23,550</u>	<u>13,975</u>	<u>46,841</u>	<u>33,266</u>
Operating loss	<u>(23,550)</u>	<u>(13,975)</u>	<u>(46,841)</u>	<u>(33,266)</u>
Other income and expense				
Other income (expense), net	(1)	(3)	(6)	(7)
Interest expense	(35)	(53)	(72)	(103)
Interest income	2,348	590	3,999	1,277
Total other income and expense	<u>2,312</u>	<u>534</u>	<u>3,921</u>	<u>1,167</u>
Loss from operations before income taxes	<u>(21,238)</u>	<u>(13,441)</u>	<u>(42,920)</u>	<u>(32,099)</u>
Income taxes	-	-	-	-
Net loss and comprehensive loss	<u>\$ (21,238)</u>	<u>\$ (13,441)</u>	<u>\$ (42,920)</u>	<u>\$ (32,099)</u>
Net loss per common share, basic and diluted	<u>\$ (0.64)</u>	<u>\$ (8.30)</u>	<u>\$ (1.41)</u>	<u>\$ (19.87)</u>
Weighted average number of shares outstanding used in computation of net loss per common share, basic and diluted	33,001,946	1,619,547	30,490,892	1,615,194

Condensed Balance Sheet Data

	June 30,	December 31,
	2024	2023
Cash and cash equivalents	\$ 174,981	\$ 121,466
Total assets	192,007	139,807
Total liabilities	27,059	26,272
Total stockholders' equity	164,948	113,535

