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): May 09, 2024

Lineage Cell Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

California	**001-12830**	**94-3127919**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
2173 Salk Avenue, Suite 200 Carlsbad, California		**92008**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (442) 287-8990

(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 shares	LCTX	NYSE American LLC

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 May 9, 2024, Lineage Cell Therapeutics, Inc. issued a press release announcing financial results for the quarter ended March 31, 2024, a copy of which is furnished as Exhibit 99.1.

The information under this Item 2.02 and in Exhibit 99.1 is being furnished and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), and is not to be incorporated by reference into any filing of the registrant under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in any such filing, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued May 9, 2024
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.

Lineage Cell Therapeutics, Inc.

Date: May 9, 2024

By: */s/ George A. Samuel III*
Name: George A. Samuel III
Title: General Counsel and Corporate Secretary

Exhibit 99.1

LINEAGE CELL THERAPEUTICS REPORTS FIRST QUARTER 2024 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- **Established New Services Agreement with Genentech to Support Ongoing Development of the OpRegen® Program**
- **Long-Term Visual Benefits from a Single Administration with OpRegen Reported at 2024 Retinal Cell & Gene Therapy Innovation Summit**
- **OpRegen Preclinical Results Presented at 2024 Association for Research in Vision and Ophthalmology Annual Meeting**
- **OPC1 Clinical Study Start Up Preparation Underway**
- **Received CIRM Grant to Support 2nd Annual SCI Investor Symposium**
- **Appointed Charlotte Hubbert, Ph.D., as Vice President of Corporate Development**

CARLSBAD, CA – May 9, 2024 - Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today reported its first quarter 2024 financial and operating results and will host a conference call at 4:30 p.m. Eastern Time to discuss these results and to provide a business update.

“The quarter was highlighted by significant milestones and data updates on our lead program,” stated Brian M. Culley, Lineage CEO. “A key area of attention for investors is our partnership with Roche and Genentech, and we are pleased to announce a new services agreement which reflects an additional commitment by Genentech for the benefit of the OpRegen program. We believe this agreement will enable our partners to take advantage of our cell transplant expertise to more fully investigate the promising potential of the OpRegen program and do so in a cost-effective manner. We also are planning to bring our second cell transplant program, OPC1, into the clinic this year for a condition with growing awareness of its unmet need and commercial opportunity. Lastly, we continue to build value through the advancement of our early-stage pipeline, which can help create value by capitalizing on the continued validation of our cell transplant approach.”

Recent Operational Highlights

- **RG6501 (OpRegen)**
  - Established new services agreement with Genentech, a member of the Roche Group, to support ongoing development of OpRegen. Under this new agreement, Lineage will provide additional clinical, technical, training and manufacturing services that further support the ongoing advancement and optimization of the OpRegen program. These additional services will be fully funded by Genentech and include: (i) activities to support the ongoing Phase 1/2a study and currently-enrolling Phase 2a study; and (ii) additional technical training and materials related to Lineage’s cell therapy technology platform to support commercial manufacturing strategies.
  - Continued execution under our collaboration with Roche and Genentech across multiple functional areas, including support for the ongoing Phase 2a clinical study in patients with GA secondary to AMD.
  - Positive clinical data from long-term follow-up of patients from the Phase 1/2a clinical study of OpRegen presented by David Telander, MD, PhD, Retinal Consultants Medical Group, at the 2024 Retinal Cell & Gene Therapy Innovation Summit.
    - Mean BCVA gain of 5.5 letters at 24 months in Cohort 4 patients (less advanced geographic atrophy)
    - Mean BCVA gains greater among patients with improvement in outer retinal structure (+7.4 letters)

        - Maintenance or increases in external limiting membrane (ELM) and retinal pigment epithelium (RPE) layers at 24 months observed in patients with extensive coverage of OpRegen across the areas of GA
        - Data suggests OpRegen may counteract RPE cell dysfunction and cell loss secondary to geographic atrophy by providing support to remaining retinal cells, with multi-year effects observed following a single administration
    - Preclinical results from a surgical development study of OpRegen presented by Rachel N. Andrews, DVM, PhD, DACVP, Genentech, a member of the Roche Group, at 2024 Association for Research in Vision and Ophthalmology Annual Meeting (2024 ARVO).

- **OPC1**
    - DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical study for the treatment of subacute and chronic spinal cord patient start-up activities underway.
    - Received an Education Conference II Grant from the California Institute for Regenerative Medicine (CIRM), to support the 2nd Annual Spinal Cord Injury Investor Symposium, hosted in partnership with the Christopher & Dana Reeve Foundation, to be held on June 26 and 27, 2024 at the Sanford Consortium for Regenerative Medicine in La Jolla, CA.

- **Corporate Updates**
    - Appointed veteran industry executive Dr. Charlotte Hubbert as Vice President of Corporate Development. Dr. Hubbert previously served as Partner and Head of Gates Foundation Venture Capital, an initiative at the Bill and Melinda Gates Foundation Strategic Investment Fund, and most recently served in the leadership team at NanoString Technologies. She currently serves on the Board of Directors of the Beckman Research Institute at the City of Hope and is a Strategic Director at Madrona Venture Group.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities of $43.6 million as of March 31, 2024, is expected to support planned operations into Q3 2025.

First Quarter Operating Results

Revenues: Lineage's revenue is generated primarily from collaboration revenues and royalties. Total revenues for the three months ended March 31, 2024 were approximately $1.4 million, a net decrease of $1.0 million as compared to $2.4 million for the same period in 2023. The decrease was primarily driven by lower collaboration and licensing revenue recognized from deferred revenues under the collaboration and license agreement with Roche.

Operating Expenses: Operating expenses are primarily comprised of research and development ("R&D") expenses and general and administrative ("G&A") expenses. Total operating expenses for the three months ended March 31, 2024 were $8.1 million, a decrease of $0.9 million as compared to $9.0 million for the same period in 2023.

R&D Expenses: R&D expenses for the three months ended March 31, 2024 were $3.0 million, a net decrease of $1.2 million as compared to $4.2 million for the same period in 2023. The net decrease was primarily driven by $0.4 million for our OPC1 program, $0.3 million for our preclinical programs, and $0.2 million for our OpRegen program. Another $0.3 million of the decrease was attributable to other research and development expenses, primarily related to reduced manufacturing activities.

G&A Expenses: G&A expenses for the three months ended March 31, 2024 were $5.0 million, a net increase of $0.3 million as compared to approximately $4.7 million for the same period in 2023. The increase was primarily driven by $0.2 million in stock-based compensation expenses, and an overall increase in costs incurred for consulting services.

Loss from Operations: Loss from operations for the three months ended March 31, 2024 were $6.7 million, an increase of $0.1 million as compared to $6.6 million for the same period in 2023.

Other Income/(Expenses), Net: Other income (expenses), net for the three months ended March 31, 2024 was comprised of other income of $0.1 million, compared to other income of $0.4 million for the same period in 2023. The net decrease was primarily driven by the employee retention credit recognized in the prior year, partially offset by exchange rate fluctuations related to Lineage's international subsidiaries.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended March 31, 2024 was $6.5 million, or $0.04 per share (basic and diluted), compared to a net loss attributable to Lineage of $4.4 million, or $0.03 per share (basic and diluted), for the same period in 2023.

Conference Call and Webcast

Interested parties may access the conference call on May 9th, 2024, by dialing (800) 715-9871 from the U.S. and Canada and should request the "Lineage Cell Therapeutics Call". A live webcast of the conference call will be available online in the Investors section of Lineage's website. A replay of the webcast will be available on Lineage's website for 30 days and a telephone replay will be available through May 15th, 2024, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 1330332.

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel or "off-the-shelf," cell therapies to address unmet medical needs. Lineage's programs are based on its proprietary cell-based technology platform and associated development and manufacturing capabilities. From this platform, Lineage designs, develops, manufactures, and tests specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. These cells are created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages. Cells derived from such lineages are transplanted into patients in an effort to replace or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and to restore or augment the patient's functional activity. Lineage's neuroscience focused pipeline currently includes: (i) OpRegen, a retinal pigment epithelial cell therapy in Phase 2a development under a worldwide collaboration with Roche and Genentech, a member of the Roche Group, for the treatment of geographic atrophy secondary to age-related macular degeneration; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of spinal cord injuries; (iii) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; (iv) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage; and (v) RND1, a novel hypoimmune induced pluripotent stem cell line being developed in collaboration with Eterna Therapeutics Inc. For more information, please visit www.lineagecell.com or follow the company on X/Twitter @LineageCell.

Forward-Looking Statements

Lineage cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as "believe," "aim," "may," "will," "estimate," "continue," "anticipate," "design," "intend," "expect," "could," "can," "plan," "potential," "predict," "seek," "should," "would," "contemplate," "project," "target," "tend to," or the negative version of these words and similar expressions. Lineage's forward-looking statements are based upon its current expectations and beliefs and involve assumptions that may never materialize or may prove to be incorrect. Such statements include, but are not limited to, statements relating to: the benefits of our new services agreement Genentech and its impact on advancing the OpRegen program; the commencement of the DOSED clinical study for OPC1; that our cash, cash equivalents and marketable securities is sufficient to support our planned operations into the third quarter of 2025; and the potential of our early-stage pipeline to create value. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Lineage's actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in this press release, including, but not limited to, the following risks: that we may need to allocate our cash to unexpected events and expenses causing us to use our

cash, cash equivalents and marketable securities more quickly than expected; that clinical trials of our product candidates may not commence, progress or be completed as expected due to many factors within and outside of our control; that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; that OpRegen may never be proven to provide durable anatomical functional improvements in dry-AMD patients, that competing alternative therapies may adversely impact the commercial potential of OpRegen; that Roche and Genentech may not successfully advance OpRegen or be successful in completing further clinical trials for OpRegen and/or obtaining regulatory approval for OpRegen in any particular jurisdiction; that the ongoing Israel-Hamas war may materially and adversely impact our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, all of which are conducted by our subsidiary in Jerusalem, Israel; that Lineage may not be able to manufacture sufficient clinical quantities of its product candidates in accordance with current good manufacturing practice; and those risks and uncertainties inherent in Lineage's business and other risks discussed in Lineage's filings with the Securities and Exchange Commission (SEC). Further information regarding these and other risks is included under the heading "Risk Factors" in Lineage's periodic reports with the SEC, including Lineage's most recent Annual Report on Form 10-K filed with the SEC and its other reports, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Lineage undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law. All forward-looking statements are expressly qualified in their entirety by these cautionary statements.

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Tables to follow

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	March 31, 2024 (Unaudited)	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 43,576	$ 35,442
Marketable securities	45	50
Accounts receivable, net	77	745
Prepaid expenses and other current assets	2,018	2,204
Total current assets	45,716	38,441
NONCURRENT ASSETS		
Property and equipment, net	2,104	2,245
Operating lease right-of-use assets	2,855	2,522
Deposits and other long-term assets	596	577
Goodwill	10,672	10,672
Intangible assets, net	46,540	46,562
TOTAL ASSETS	$ 108,483	$ 101,019
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 5,683	$ 6,270
Operating lease liabilities, current portion	1,052	830
Finance lease liabilities, current portion	49	52
Deferred revenues, current portion	10,106	10,808
Total current liabilities	16,890	17,960
LONG-TERM LIABILITIES		
Deferred tax liability	273	273
Deferred revenues, net of current portion	18,177	18,693
Operating lease liabilities, net of current portion	2,074	1,979
Finance lease liabilities, net of current portion	79	91
TOTAL LIABILITIES	37,493	38,996
Commitments and contingencies (Note 13)		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common shares, no par value, 450,000 shares authorized as of March 31, 2024 and December 31, 2023; 188,754 and 174,987 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	466,571	451,343
Accumulated other comprehensive loss	(2,771)	(3,068)
Accumulated deficit	(391,398)	(384,856)
Lineage's shareholders' equity	72,402	63,419
Noncontrolling deficit	(1,412)	(1,396)
Total shareholders' equity	70,990	62,023
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 108,483	$ 101,019

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)
(UNAUDITED)

	Three Months Ended March 31,	
	2024	2023
REVENUES:		
Collaboration revenues	$ 1,187	$ 2,121
Royalties, license and other revenues	257	265
Total revenues	1,444	2,386
OPERATING EXPENSES:		
Cost of sales	98	119
Research and development	3,010	4,185
General and administrative	4,997	4,724
Total operating expenses	8,105	9,028
Loss from operations	(6,661)	(6,642)
OTHER INCOME (EXPENSES):		
Interest income, net	462	410
(Loss) gain on marketable equity securities, net	(5)	40
Foreign currency transaction gain/(loss), net	(354)	(472)
Other income	—	457
Total other income (expenses), net	103	435
LOSS BEFORE INCOME TAXES	(6,558)	(6,207)
Provision for income tax benefit	—	1,803
NET LOSS	(6,558)	(4,404)
Net loss attributable to noncontrolling interest	16	32
NET LOSS ATTRIBUTABLE TO LINEAGE	$ (6,542)	$ (4,372)
Net loss per common share attributable to Lineage basic and diluted	$ (0.04)	$ (0.03)
Weighted-average common shares used to compute basic and diluted net loss per common share	182,909	170,127

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(UNAUDITED)

	Three Months Ended March 31,	
	2024	**2023**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	$ (6,542)	$ (4,372)
Net loss attributable to noncontrolling interest	(16)	(32)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities:		
Loss (gain) on marketable equity securities, net	5	(40)
Accretion of income on marketable debt securities	—	(326)
Depreciation and amortization expense	153	138
Change in right-of-use assets and liabilities	(10)	—
Amortization of intangible assets	22	33
Stock-based compensation	1,163	1,031
Deferred income tax benefit	—	(1,803)
Foreign currency remeasurement and other loss	371	465
Changes in operating assets and liabilities:		
Accounts receivable	668	95
Prepaid expenses and other current assets	195	(847)
Accounts payable and accrued liabilities	(574)	(3,463)
Deferred revenue	(1,218)	(2,121)
Net cash used in operating activities	(5,783)	(11,242)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable debt securities	—	(7,718)
Maturities of marketable debt securities	—	23,332
Purchase of equipment	(38)	(188)
Net cash (used in) provided by investing activities	(38)	15,426
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	132	51
Common shares received and retired for employee taxes paid	(23)	(37)
Proceeds from sale of common shares	14,037	—
Payments for offering costs	(112)	—
Repayment of finance lease liabilities	(13)	(13)
Net cash provided by financing activities	14,021	1
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(70)	(100)
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	8,130	4,085
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	35,992	11,936
At end of the period	$ 44,122	$ 16,021