

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 08, 2024

Lineage Cell Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

California
(State or Other Jurisdiction
of Incorporation)

001-12830
(Commission File Number)

94-3127919
(IRS Employer
Identification No.)

2173 Salk Avenue, Suite 200
Carlsbad, California
(Address of Principal Executive Offices)

92008
(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 August 8, 2024, Lineage Cell Therapeutics, Inc. issued a press release announcing financial results for the quarter ended June 30, 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 August 8, 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: August 8, 2024

By: /s/ George A. Samuel III

Name: George A. Samuel III

Title: General Counsel and Corporate Secretary



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

- **24 Month Visual Acuity Benefits from a Single Administration with OpRegen[®] Reported at 2024 Retinal Cell & Gene Therapy Innovation Summit**
- **Supported OpRegen for Geographic Atrophy in Phase 2a Study in Collaboration with Roche and Genentech**
- **Initiated Activities Under Recently Established Services Agreement with Genentech to Support Ongoing Development of OpRegen Program**
- **OPC1 Clinical Study Start Up Preparations Ongoing**
- **Hosted 2nd Annual Spinal Cord Injury Investor Symposium**

CARLSBAD, CA – August 8, 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 second quarter 2024 financial and operating results. The Company will host a conference call today at 4:30 p.m. Eastern Time to discuss these results and to provide a business update.

“The second quarter was highlighted by clinical and preclinical execution alongside expanded awareness and data updates on our lead program,” stated Brian M. Culley, Lineage CEO. “As the cell transplant field expands and continues to deliver exciting clinical outcomes, we are excited about our validating partnership and the collective expertise of the team at Roche and Genentech, as well as their ongoing leadership of the OpRegen program through presentations at scientific conferences and internal thought leader events, including Roche’s Virtual Ophthalmology Day, hosted just last month. We continue to support the ongoing Phase 2a clinical study and also have initiated activities under the recently established services agreement with Genentech, enabling our partners to take advantage of our cell transplant expertise to more fully investigate the potential of the OpRegen program. In parallel, we are focused on activities in support of returning our second cell transplant program, OPC1, into the clinic this year for the treatment of spinal cord injury, a condition with growing awareness of its unmet need and commercial opportunity.”

“Importantly, our continued inclusion within the Russell 3000[®] Index, can help our efforts to broaden investor awareness of, and support for, Lineage as a uniquely positioned cell transplant company, one with a pharma-validated lead program and a platform technology of internally-owned clinical and preclinical assets, which is focused on growing our internally-owned cGMP capabilities in support of process and intellectual property development,” added Mr. Culley.

Recent Operational Highlights

- **RG6501 (OpRegen)**
 - o Continued execution under our collaboration with Roche and Genentech, a member of the Roche Group, across multiple functional areas, including support for the ongoing Phase 2a clinical study in patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD).
 - o Initiated activities under recently established services agreement with Genentech to support ongoing development of OpRegen. Lineage is providing additional clinical, technical, training and manufacturing services, fully funded by Genentech, that further support the ongoing advancement and optimization of the OpRegen program and include: (i) activities to support the ongoing Phase 1/2a study and currently-enrolling Phase 2a study; and (ii) additional technical training and
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- materials related to Lineage's cell therapy technology platform to support commercial manufacturing strategies.
- o 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 best corrected visual acuity (BCVA) gain of 5.5 letters at 24 months (n=10) in Cohort 4 patients (less advanced GA)
 - Mean BCVA gains greater among patients with improvement in outer retinal structure (n=5, +7.4 letters)
 - Maintenance or increases in external limiting membrane (ELM) and retinal pigment epithelium (RPE) layer area at 24 months observed in patients with extensive coverage of OpRegen across the areas of GA (n=5)
 - Data suggest OpRegen may counteract RPE cell dysfunction and cell loss in patients with GA by providing support to remaining retinal cells, with multi-year effects observed following a single administration
- o 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**

- o 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 continue.
- o Hosted the 2nd Annual Spinal Cord Injury Investor Symposium, in partnership with the Christopher & Dana Reeve Foundation.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities of \$38.5 million as of June 30, 2024 is expected to support planned operations into Q4 2025.

Second Quarter Operating Results

Revenues: Lineage's revenue is generated primarily from collaboration revenues and royalties. Total revenues for the three months ended June 30, 2024 were \$1.4 million, a net decrease of \$1.8 million as compared to approximately \$3.2 million for the same period in 2023. The decrease was primarily driven by less collaboration and licensing revenue recognized from deferred revenues under the collaboration and license agreement with Roche.

Operating Expenses: Operating expenses are comprised of research and development (R&D) expenses and general and administrative (G&A) expenses. Total operating expenses for the three months ended June 30, 2024 were \$7.3 million, a decrease of \$0.9 million as compared to \$8.2 million for the same period in 2023.

R&D Expenses: R&D expenses for the three months ended June 30, 2024 were \$2.9 million, a net decrease of \$1.0 million as compared to \$3.9 million for the same period in 2023. The net decrease was primarily driven by \$0.6 million for our OPC1 program and \$0.3 million for our preclinical programs.

G&A Expenses: G&A expenses for the three months ended June 30, 2024 were approximately \$4.3 million, a net increase of approximately \$0.1 million as compared to \$4.2 million for the same period in 2023. The increase was primarily driven by stock-based compensation expense and personnel costs.

Loss from Operations: Loss from operations for the three months ended June 30, 2024 were \$5.9 million, an increase of \$0.9 million as compared to \$5.0 million for the same period in 2023.

Other Income/(Expenses): Other income (expenses) for the three months ended June 30, 2024 reflected other income of \$0.1 million, compared to other expenses of (\$0.2) million for the same period in 2023. The change was

primarily driven by exchange rate fluctuations related to Lineage's international subsidiaries, fair market value changes in marketable equity securities, and interest income earned within our money market accounts.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended June 30, 2024 was \$5.8 million, or \$0.03 per share (basic and diluted), compared to a net loss attributable to Lineage of \$5.2 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 August 8th, 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 August 15th, 2024, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number 6024260.

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 with 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 fourth quarter of 2025; the impacts to Lineage of our continued inclusion within the Russell 3000 Index; and the potential of our platform technology and/or manufacturing capabilities 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)
(UNAUDITED)

	June 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 29,622	\$ 35,442
Marketable securities	8,874	50
Accounts receivable, net	235	745
Prepaid expenses and other current assets	1,659	2,204
Total current assets	40,390	38,441
NONCURRENT ASSETS		
Property and equipment, net	2,018	2,245
Operating lease right-of-use assets	2,584	2,522
Deposits and other long-term assets	598	577
Goodwill	10,672	10,672
Intangible assets, net	46,540	46,562
TOTAL ASSETS	\$ 102,802	\$ 101,019
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 5,018	\$ 6,270
Operating lease liabilities, current portion	1,069	830
Finance lease liabilities, current portion	46	52
Deferred revenues, current portion	9,142	10,808
Total current liabilities	15,275	17,960
LONG-TERM LIABILITIES		
Deferred tax liability	273	273
Deferred revenues, net of current portion	18,543	18,693
Operating lease liabilities, net of current portion	1,768	1,979
Finance lease liabilities, net of current portion	68	91
TOTAL LIABILITIES	35,927	38,996
Commitments and contingencies		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Common shares, no par value, 450,000 shares authorized as of June 30, 2024 and December 31, 2023; 188,824 and 174,987 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	467,928	451,343
Accumulated other comprehensive loss	(2,470)	(3,068)
Accumulated deficit	(397,158)	(384,856)
Lineage's shareholders' equity	68,300	63,419
Noncontrolling deficit	(1,425)	(1,396)
Total shareholders' equity	66,875	62,023
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 102,802	\$ 101,019

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
REVENUES:				
Collaboration revenues	\$ 1,098	\$ 2,871	\$ 2,285	\$ 4,992
Royalties, license and other revenues	310	354	567	619
Total revenues	<u>1,408</u>	<u>3,225</u>	<u>2,852</u>	<u>5,611</u>
OPERATING EXPENSES:				
Cost of sales	44	127	142	246
Research and development	2,868	3,873	5,878	8,058
General and administrative	4,363	4,249	9,360	8,973
Total operating expenses	<u>7,275</u>	<u>8,249</u>	<u>15,380</u>	<u>17,277</u>
Loss from operations	<u>(5,867)</u>	<u>(5,024)</u>	<u>(12,528)</u>	<u>(11,666)</u>
OTHER INCOME (EXPENSES):				
Interest income	463	382	925	792
Loss on marketable equity securities, net	(10)	(150)	(15)	(110)
Foreign currency transaction loss, net	(378)	(497)	(732)	(969)
Other income	19	86	19	543
Total other income (expenses)	<u>94</u>	<u>(179)</u>	<u>197</u>	<u>256</u>
LOSS BEFORE INCOME TAXES	<u>(5,773)</u>	<u>(5,203)</u>	<u>(12,331)</u>	<u>(11,410)</u>
Provision for income tax benefit	<u>—</u>	<u>—</u>	<u>—</u>	<u>1,803</u>
NET LOSS	<u>(5,773)</u>	<u>(5,203)</u>	<u>(12,331)</u>	<u>(9,607)</u>
Net (income) loss attributable to noncontrolling interest	<u>13</u>	<u>(26)</u>	<u>29</u>	<u>6</u>
NET LOSS ATTRIBUTABLE TO LINEAGE	<u>\$ (5,760)</u>	<u>\$ (5,229)</u>	<u>\$ (12,302)</u>	<u>\$ (9,601)</u>
Net loss per common share attributable to Lineage basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.07)</u>	<u>\$ (0.06)</u>
Weighted-average common shares used to compute basic and diluted net loss per common share	<u>188,813</u>	<u>170,592</u>	<u>185,861</u>	<u>170,361</u>

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

	Six Months Ended June 30,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	\$ (12,302)	\$ (9,601)
Net loss attributable to noncontrolling interest	(29)	(6)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities:		
Loss on marketable equity securities, net	15	110
Accretion of income on marketable debt securities	(102)	(516)
Depreciation and amortization expense	295	276
Change in right-of-use assets and liabilities	(20)	81
Amortization of intangible assets	22	65
Stock-based compensation	2,432	2,311
Deferred income tax benefit	—	(1,803)
Foreign currency remeasurement and other loss	767	1,011
Changes in operating assets and liabilities:		
Accounts receivable	508	(147)
Prepaid expenses and other current assets	516	(270)
Accounts payable and accrued liabilities	(1,245)	(3,941)
Deferred revenue	(1,816)	(5,080)
Net cash used in operating activities	<u>(10,959)</u>	<u>(17,510)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of marketable equity securities	18	—
Purchases of marketable debt securities	(8,761)	(12,635)
Maturities of marketable debt securities	—	47,664
Purchase of equipment	(88)	(444)
Net cash (used in) provided by investing activities	<u>(8,831)</u>	<u>34,585</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	219	80
Common shares received and retired for employee taxes paid	(23)	(37)
Proceeds from sale of common shares	14,070	5,789
Payments for offering costs	(113)	(174)
Repayment of finance lease liabilities	(27)	(29)
Net cash provided by financing activities	<u>14,126</u>	<u>5,629</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(158)	(192)
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	<u>(5,822)</u>	<u>22,512</u>
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	35,992	11,936
At end of the period	<u>\$ 30,170</u>	<u>\$ 34,448</u>

