UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): **November 10, 2022**

Lineage Cell Therapeutics, Inc.
(Exact name of registrant as specified in 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** (Address of principal executive offices)	**92008** (Zip Code)

(442) 287-8990
Registrant's telephone number, including area code

(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 (*see* General Instruction A.2. below):

☐ 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**

Indicate by check mark whether the registrant is an emerging growth company as defined in 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 November 10, 2022, Lineage Cell Therapeutics, Inc. issued a press release announcing financial results for the quarter ended September 30, 2022, 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 November 10, 2022
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: November 10, 2022

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

Exhibit 99.1

LINEAGE CELL THERAPEUTICS REPORTS THIRD QUARTER 2022 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- **Appointed Jill Howe as Chief Financial Officer**
- **Established New R&D Facility and Expanded Existing cGMP Manufacturing Facility**
- **Received Notice of Allowance for Patent Applications Covering Directed Differentiation Methods for Retinal Pigmented Epithelium and Oligodendrocyte Progenitor Cells**
- **Cash, Cash Equivalents, and Marketable Securities of $66.4 Million as of September 30, 2022 Expected to Provide Capital Into Q3 2024**

CARLSBAD, CA – November 10, 2022 - Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today reported financial and operating results for the third quarter of 2022. Lineage management will host a conference call and webcast today at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time to discuss its third quarter 2022 financial and operating results and to provide a business update.

"A single administration of RG6501 (OpRegen®), a proprietary retinal pigment epithelial cell transplant, across an area of atrophy in advanced AMD patients has shown the potential to slow, stop, or reverse the progression of GA in our phase 1/2a clinical trial. To our knowledge, this is the first intervention that has reported anatomical changes of this magnitude in the field of GA, so we are pleased with the continued progress on RG6501 and the efforts which have been made to initiate its next clinical trial," stated Brian M. Culley, Lineage CEO. "Looking ahead, our focus turns increasingly to planned regulatory interactions for OPC1 and VAC2, from which we expect to inform and enable their next phases of clinical development in spinal cord injury and oncology, respectively. In parallel, we are advancing our newly launched cell transplant programs in photoreceptors for vision disorders and auditory neurons for hearing loss, with initial preclinical studies from our photoreceptor program currently ongoing and the start of preclinical testing of our auditory neuron program anticipated prior to year-end. We believe that completing these efforts while maintaining our commitment to disciplined spending will help Lineage create shareholder value in the coming year."

Recent milestones and activities included:

- **Announced appointment of Jill Howe as Chief Financial Officer effective November 14, 2022**
    - Ms. Howe brings more than 20 years of significant strategic, financial, and operational experience to Lineage, with an emphasis on capital strategy, corporate finance, treasury management, global infrastructure, and operational excellence. Ms. Howe has successfully built biotechnology organizations and implemented operational infrastructures alongside the execution of over $1.66 billion of capital raising transactions and will bring extensive strategic experience to the role.
- **Established new U.S. R&D facility and expanded current GMP manufacturing facility in Israel**
    - New Carlsbad facility will allow us to broaden R&D capabilities in the U.S. and facilitate the advancement of current and future allogeneic cell transplant programs and partnerships; the expansion of the Israel-based facility is expected to increase infrastructure, including development and optimization of larger-scale clinical manufacturing processes, and continued execution under the ongoing collaboration with Roche and Genentech for RG6501 (OpRegen).
- **Strengthened intellectual property portfolio**
    - Company announced notice of allowance of two patents covering processes for manufacturing allogeneic oligodendrocyte progenitor and retinal pigmented epithelium cells.
- **OPC1**
    - Completed verification and validation and preclinical testing activities for the novel parenchymal spinal delivery (PSD) system to support an upcoming regulatory submission.
- **VAC2**
    - Pre-Investigational New Drug (IND) application briefing package submitted to the U.S. Food and Drug Administration (FDA) to support U.S. clinical development for immuno-oncology.
- **ANP1 & PNC1**
    - Continued process development and activities in support of ongoing and planned preclinical testing.

Some of the key upcoming milestones and activities anticipated by Lineage include:

- Planned Regenerative Medicine Advanced Therapy (RMAT) submission to FDA before year-end regarding an OPC1 IND amendment to enable clinical testing of a novel spinal cord delivery system.
- Response to a pre-IND regulatory submission which should provide clarity on a VAC2 CMC, nonclinical, and clinical information package to inform future U.S. clinical development, expected around year-end.
- Completion of an R&D manufacturing process sufficient to support initiation of preclinical testing and the initiation of such testing with ANP1 for the treatment of hearing loss, anticipated prior to year-end.
- An additional OPC1 manuscript from a Phase 1/2a clinical study in subacute cervical spinal cord injury.
- Submission of a grant application to California Institute for Regenerative Medicine (CIRM) for the continued support of the clinical development of OPC1.
- Clinical data update from the ongoing VAC2 Phase 1 non-small cell lung cancer (NSCLC) study, pending release from Cancer Research UK (CRUK).
- Evaluation of new partnership opportunities and/or expansion of existing collaborations.
- Continued participation in investor and partnering meetings and medical and industry conferences to broaden awareness of our mission, programs, and accomplishments.

Balance Sheet Highlights

Cash, cash equivalents, and marketable securities totaled $66.4 million as of September 30, 2022, which is expected to support planned operations into Q3 2024.

Third Quarter Operating Results

Revenues: Lineage's revenue is generated primarily from licensing fees, royalties, collaboration revenues, and research grants. Total revenues for the three months ended September 30, 2022 were approximately $3.0 million, a net increase of $0.7 million as compared to $2.3 million for the same period in 2021. The increase was driven by collaboration and licensing revenue recognized from deferred revenues from the Roche Agreement, partially offset by less royalty revenues.

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 September 30, 2022 were $8.0 million, a decrease of $0.1 million as compared to $8.1 million for the same period in 2021.

R&D Expenses: R&D expenses for the three months ended September 30, 2022 were $3.6 million, a net increase of $0.8 million as compared to $2.8 million for the same period in 2021. The net increase was primarily driven by higher OpRegen related expenses to support the Roche collaboration.

G&A Expenses: G&A expenses for the three months ended September 30, 2022 were $4.4 million, a net decrease of approximately $0.9 million as compared to $5.3 million for the same period in 2021. The decrease was primarily driven by $1.1 million in lower litigation and legal expenses and $0.3 million in lower investor relations expense, partially offset by a $0.5 million increase in payroll and related benefits expense.

Loss from Operations: Loss from operations for the three months ended September 30, 2022 was $5.2 million, a decrease of $1.6 million as compared to $6.8 million for the same period in 2021.

Other Expenses, Net: Other expenses, net for the three months ended September 30, 2022 reflected other expense, net of $0.3 million, compared to other expense, net of $2.0 million for the same period in 2021. The net change was primarily driven by a decrease in the value of marketable equity securities and 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 September 30, 2022 was $6.1 million, or $0.04 per share (basic and diluted), compared to a net loss attributable to Lineage of $7.8 million, or $0.05 per share (basic and diluted), for the same period in 2021.

Conference Call and Webcast

Interested parties may access today's conference call by dialing (800) 715-9871 from the U.S. and Canada and should request the "Lineage Cell Therapeutics Call" or provide conference ID number **5262180**. 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 November 17, 2022, by dialing (800) 770-2030 from the U.S. and Canada and entering conference ID number **5262180.**

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs. Lineage's programs are based on its robust proprietary cell-based therapy platform and associated in-house development and manufacturing capabilities. With this platform Lineage develops and manufactures specialized, terminally differentiated human cells from its pluripotent and progenitor cell starting materials. These differentiated cells are developed to either replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury or administered as a means of helping the body mount an effective immune response to cancer. Lineage's clinical and preclinical programs are in markets with billion dollar opportunities and include five allogeneic ("off-the-shelf") product candidates: (i) OpRegen, a retinal pigment epithelial cell therapy in development for the treatment of geographic atrophy secondary to age-related macular degeneration, is being developed under a worldwide collaboration with Roche and Genentech, a member of the Roche Group; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; (iii) VAC2, a dendritic cell therapy produced from Lineage's VAC technology platform for immuno-oncology and infectious disease, currently in Phase 1 clinical development for the treatment of non-small cell lung cancer; (iv) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy; and (v) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage. For more information, please visit www.lineagecell.com or follow the company on 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. Such statements include, but are not limited to, statements relating to: our ability to support our planned operations into the third quarter of 2024 with our existing cash, cash equivalents and marketable securities; Ms. Howe’s employment with Lineage and the anticipated or implied benefits thereof to Lineage and Lineage’s continued growth and ability to exhibit greater productivity in the future; plans and expectations regarding our products in development and our ability to advance our product candidates into their next phases of clinical or preclinical testing; our ability to create shareholder value in the future; the potential benefits to us and our operations of our new and expanded facilities, including the broadening of our R&D capabilities, advancing our programs and partnerships, and increasing our infrastructure; our ability to support multiple years of progress and achieve important milestones; our collaboration and license agreement with Roche and Genentech and the potential to receive milestone and other consideration thereunder; the potential benefits of treatment with OpRegen; the potential future achievements of our clinical and preclinical programs; the timing of anticipated FDA interactions, preclinical activities, clinical trials, and clinical data updates related to our programs, and the submission of a grant application to the CIRM; plans and expectations regarding publications relating to our programs; plans and expectations regarding potential new partnership opportunities and existing collaborations; and our ability to broaden awareness of our mission and accomplishments. 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 more quickly than expected; that potential benefits of the new and expanded facilities to the Company and its operations may not be realized as quickly as expected or at all; that potential benefits of newly developed intellectual property to the Company may not be realized as quickly as expected or at all; 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 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 we may not establish new partnerships or expand existing collaborations; that we do not successfully broaden awareness of our mission or accomplishments; that we 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). Lineage’s forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. 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 and Quarterly Report on Form 10-Q 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.

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Tables to follow

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

	September 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 24,752	$ 55,742
Marketable securities	41,603	2,616
Accounts and grants receivable, net	434	50,840
Prepaid expenses and other current assets	1,720	2,351
Total current assets	68,509	111,549
NONCURRENT ASSETS		
Property and equipment, net	4,652	4,872
Deposits and other long-term assets	591	630
Goodwill	10,672	10,672
Intangible assets, net	46,724	46,822
TOTAL ASSETS	$ 131,148	$ 174,545
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 9,807	$ 27,969
Lease liabilities, current portion	543	801
Financing lease, current portion	25	30
Deferred revenues	12,364	18,119
Liability classified warrants, current portion	-	197
Total current liabilities	22,739	47,116
LONG-TERM LIABILITIES		
Deferred tax liability	2,076	2,076
Deferred revenues, net of current portion	26,544	32,454
Lease liability, net of current portion	2,216	1,941
Financing lease, net of current portion	16	30
Liability classified warrants and other long-term liabilities	4	30
TOTAL LIABILITIES	53,595	83,647
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of September 30, 2022 and December 31, 2021	-	-
Common shares, no par value, 250,000 shares authorized; 169,886 and 169,477 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	439,148	434,529
Accumulated other comprehensive loss	(3,184)	(5,211)
Accumulated deficit	(357,016)	(337,097)
Lineage Cell Therapeutics, Inc. shareholders' equity	78,948	92,221
Noncontrolling (deficit)	(1,395)	(1,323)
Total shareholders' equity	77,553	90,898
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 131,148	$ 174,545

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
REVENUES:				
Collaboration revenues	$ 2,592	$ 293	$ 11,605	$ 506
Royalties	406	1,909	1,183	2,430
Grant revenues	-	68	-	237
Total revenues	2,998	2,270	12,788	3,173
Cost of sales	(235)	(985)	(626)	(1,222)
Gross profit	2,763	1,285	12,162	1,951
OPERATING EXPENSES:				
Research and development	3,592	2,811	9,883	9,136
General and administrative	4,422	5,317	18,160	13,788
Total operating expenses	8,014	8,128	28,043	22,924
Loss from operations	(5,251)	(6,843)	(15,881)	(20,973)
OTHER INCOME/(EXPENSES):				
Interest income (expense), net	384	1	435	(1)
Gain on sale of marketable securities	-	-	-	6,024
Unrealized loss on marketable equity securities	(233)	(2,450)	(1,677)	(621)
Gain on extinguishment of debt	-	-	-	523
Gain on revaluation of warrant liability	-	53	223	105
Other income (expense), net	(475)	393	(2,550)	(318)
Total other income/(expense), net	(324)	(2,003)	(3,569)	5,712
LOSS BEFORE INCOME TAXES	(5,575)	(8,846)	(19,450)	(15,261)
Income tax (expense)/benefit	(541)	1,012	(541)	1,181
NET LOSS	(6,116)	(7,834)	(19,991)	(14,080)
Net loss attributable to noncontrolling interest	47	11	72	51
NET LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	$ (6,069)	$ (7,823)	$ (19,919)	$ (14,029)
NET LOSS PER COMMON SHARE:				
BASIC	$ (0.04)	$ (0.05)	$ (0.12)	$ (0.09)
DILUTED	$ (0.04)	$ (0.05)	$ (0.12)	$ (0.09)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
BASIC	169,786	167,624	169,722	163,120
DILUTED	169,786	167,624	169,722	163,120

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

	Nine Months Ended September 30,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	$ (19,919)	$ (14,029)
Net loss allocable to noncontrolling interest	(72)	(51)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash provided by (used in) operating activities:		
Gain on sale of marketable securities	-	(6,024)
Unrealized loss gain on marketable equity securities	1,67 7	621
Gain on extinguishment of debt	-	(523)
Depreciation expense, including amortization of leasehold improvements	441	504
Change in right-of-use assets and liabilities	(24)	19
Amortization of intangible assets	113	178
Accretion of income on marketable debt securities	(186)	-
Stock-based compensation	3,328	2,601
Common stock issued for services	-	202
Gain on revaluation of warrant liability	(223)	(105)
Deferred tax benefit	-	(1,181)
Foreign currency remeasurement and other gain	2,668	295
Changes in operating assets and liabilities:		
Accounts and grants receivable	50,206	(104)
Prepaid expenses and other current assets	517	(1,229)
Accounts payable and accrued liabilities	(17,573)	354
Deferred revenue and other liabilities	(11,591)	784
Net cash provided by (used in) operating activities	9,362	(17,688)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable debt securities	(40,628)	-
Proceeds from the sale of OncoCyte common shares	-	10,064
Proceeds from the sale of HBL common shares	-	21
Purchase of equipment	(429)	(194)
Net cash (used in) provided by investing activities	(41,057)	9,891
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	506	6,269
Common shares received and retired for employee taxes paid	(17)	(41)
Proceeds from exercise of subsidiary warrants, net	991	-
Proceeds from sale of common shares	148	30,741
Payments for offering costs	(95)	(980)
Repayment of lease liability	(23)	(13)
Net cash provided by financing activities	1,510	35,976
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(795)	(34)
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(30,980)	28,145
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	56,277	33,183
At end of the period	$ 25,297	$ 61,328
SUPPLEMENTAL DISCLOSURES		
Cash paid for interest $	13	$ 12