

**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): **August 12, 2021**

Lineage Cell Therapeutics, Inc.

(Exact name of registrant as specified in 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)

(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 stock	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 August 12, 2021, Lineage Cell Therapeutics, Inc. issued a press release announcing financial results for the quarter ended June 30, 2021, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued August 12, 2021

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 12, 2021

By: /s/ Brian M. Culley

Name: Brian M. Culley

Title: Chief Executive Officer



LINEAGE REPORTS SECOND QUARTER 2021 FINANCIAL RESULTS AND HIGHLIGHTS ADDITIONAL PROGRESS FROM CLINICAL CELL THERAPY PROGRAMS

- **OpRegen[®] Continued to Demonstrate Functional and Anatomical Improvements in Patients with Dry AMD**
- **Three Cases of Retinal Tissue Restoration Reported; Longest of Which Has Lasted 3 Years**
- **Company Added to Russell 3000[®] and Russell Microcap[®] Indexes**
- **License Agreement Announced with Immunomic Therapeutics Inc. to Develop New DC-Based Therapeutic**
- **New Chief Financial Officer Appointed**
- **Cash and Marketable Securities of \$68.7M Expected to Support Operations Well Into 2023**

CARLSBAD, CA – August 12, 2021 - 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 second quarter 2021. Lineage will host a conference call today at 4:30 p.m. Eastern Time to discuss its second quarter 2021 financial results and to provide a business update.

“Lineage continued to make significant operational and developmental progress during the second quarter, providing additional reports of clinically meaningful outcomes in patients with dry-AMD with geographic atrophy, advancing our OPC1 program for spinal cord injury, and reaching a paid milestone under our new VAC platform alliance,” stated Brian M. Culley, Lineage CEO. “OpRegen has generated the only known cases of retinal tissue restoration in previously confirmed atrophic areas in humans, and as importantly, has provided a durable functional benefit of improved visual acuity in the treated eyes of the majority of better vision, earlier-stage patients. We are excited that we soon will be returning OPC1 to clinical testing in a device safety study, which will include chronic spinal cord injury patients, and look forward to collaborating with the SCI community as part of our efforts to improve outcomes for individuals with this debilitating condition. We also believe being added to the Russell 3000[®] Index will improve awareness of the continued success of our cell transplant approach and that our current cash and cash equivalents provide funding to reach additional value-creating milestones in the months and years ahead.”

Some of the significant events and milestones achieved to date this year include:

- Reported a positive interim clinical update from the ongoing Phase 1/2a study of OpRegen for the treatment of dry-AMD with GA: 83% of all Cohort 4 patients exhibited stable or improved Best Corrected Visual Acuity at least 6 months post-treatment, while visual acuity declined in the majority of untreated eyes; notably, the first retinal restoration patient, with confirmed atrophy growth at baseline has had zero progression for almost three full years;
- Reported two additional cases of retinal tissue restoration in dry AMD patients treated with OpRegen; restoration has now been observed in three of four patients who received OpRegen RPE cells across a wide area of atrophy;
- Hosted a webinar with key therapeutic area experts to discuss the reported evidence of retinal tissue restoration findings in detail, including a review of anatomical improvements, functional activity, and additional results of treatment with OpRegen;
- Reported that the Company has been added to both the Russell 3000[®] as well as the Russell Microcap[®] Indexes;
- Reported that OPC1 will return to clinical testing; a Phase 1 clinical study will evaluate a novel delivery system in partnership with Neurgain Technologies and will include treatment of chronic spinal cord injury patients. The Phase 1 study is intended to validate the delivery system for use in a late-stage clinical study, expected to begin in 2022;
- Entered into a worldwide license agreement with Immunomic Therapeutics for an allogeneic cell-based cancer immunotherapy based on Lineage’s VAC platform with a total of \$2 million in upfront payments anticipated in the first year and the potential for \$67 million in development and commercial milestones;
- Announced an exclusive option agreement with Amasa Therapeutics for the supply and use of clinical-grade HyStem[®] for the development and commercialization of therapies for local treatment of solid tumors; and
- Announced the appointment of Kevin L. Cook as Chief Financial Officer. Mr. Cook brings broad expertise across a range of financial matters and has executed over \$30 billion of capital raising and corporate development transactions, approximately half of which involved life sciences companies.

Some of the events and milestones to look forward to include:

- OpRegen Program
 - o Presentation of additional interim data from the Phase 1/2a study, anticipated during the third and fourth quarters of 2021;
 - o Meeting with the U.S. Food and Drug Administration (FDA) to discuss further clinical development, anticipated in the fourth quarter of 2021.
- OPC1 Program
 - o Evaluation of the Neurgain Parenchymal Spinal Delivery (PSD) system in preclinical and clinical testing;
 - o GMP production of OPC1 via an improved manufacturing process and release testing to support a late-stage clinical trial;
 - o FDA interaction to discuss manufacturing improvements, anticipated around the end of 2021 or early 2022.
- VAC Program
 - o Completion of enrollment in the ongoing VAC2 Phase 1 non-small cell lung cancer study;
 - o Reporting results from the ongoing VAC2 Phase 1 study;
 - o Evaluation of opportunities for new VAC product candidates based on internally identified or partnered tumor antigens.
- Continued evaluation of partnership opportunities and expansion of existing external collaborations and identification of new collaborations.

Balance Sheet Highlights

Cash, cash equivalents and marketable securities totaled \$68.7 million as of June 30, 2021. Marketable securities of \$6.7 million as of June 30, 2021 include the Company's remaining ownership in OncoCyte and Hadasit Bio-Holdings Ltd.

Lineage added to its cash position during the second quarter of 2021 with approximately \$4.0 million in proceeds from the exercise of stock options, the majority of which were approaching expiration.

Second Quarter Operating Results

Revenues: Lineage's revenue is generated primarily from research grants, royalties, and licensing fees. Total revenues for the three months ended June 30, 2021 were approximately \$0.5 million, an increase of \$0.1 million as compared to \$0.4 million for the same period in 2020. The increase was primarily related to a \$0.2 million increase in licensing revenues in connection with the new collaborative agreement with Immunomic Therapeutics, and a \$0.1 million increase in royalties, partially offset by a \$0.2 million decrease in grant revenues, primarily driven by the completion of NIH grant-activities in the prior year.

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, 2021 were \$7.5 million, an increase of \$0.8 million as compared to \$6.7 million for the same period in 2020.

R&D Expenses: R&D expenses for the three months ended June 30, 2021 were \$2.9 million, an increase of approximately \$0.1 million as compared to \$2.8 million for the same period in 2020. The increase was primarily related to increases of \$0.3 million and \$0.2 million in OPC1 and VAC program expenses, respectively, partially offset by a net decrease of \$0.4 million in OpRegen and other ophthalmic application expenses, primarily driven by fluctuations in the timing of manufacturing activities.

G&A Expenses: G&A expenses for the three months ended June 30, 2021 were \$4.5 million, an increase of approximately \$0.6 million as compared to \$3.9 million for the same period in 2020. The increase was primarily attributable to increases of \$0.3 million in litigation and other expenses related to Lineage's merger with Asterias Biotherapeutics, Inc., \$0.3 million in investor and public relations expenses, and \$0.1 million in legal and patent expenses, partially offset by a \$0.1 million decrease in rent and utilities expenses.

Loss from Operations: Loss from operations for the three months ended June 30, 2021 was approximately \$7.1 million, an increase of \$0.7 million as compared to \$6.4 million for the same period in 2020.

Other Income/(Expenses), Net: Other income/(expenses), net for the three months ended June 30, 2021 reflected other income, net of \$2.1 million, compared to other expense, net of (\$0.1) million for the same period in 2020. The variance was primarily related to an increase in the value of Lineage's OncoCyte shares and the gain on extinguishment of debt from Lineage's Paycheck Protection Program loan forgiveness, partially offset by no sales of marketable equity securities as compared to the prior year's quarter, as well as 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 June 30, 2021 was \$4.8 million, or \$0.03 per share (basic and diluted), compared to a net loss attributable to Lineage of \$6.5 million, or \$0.04 per share (basic and diluted), for the same period in 2020.

Conference Call and Webcast

Lineage will host a [conference call and webcast](#) today, at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time to discuss its second quarter 2021 financial results and to provide a business update. Interested parties may access the conference call by dialing (866) 888-8633 from the U.S. and Canada and (636) 812-6629 from elsewhere outside 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 22, 2021, by dialing (855) 859-2056 from the U.S. and Canada and (404) 537-3406 from elsewhere outside the U.S. and Canada and entering conference ID number 4876810.

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 three allogeneic (“off-the-shelf”) clinical programs are in markets with billion dollar opportunities: (i) OpRegen[®], an investigational retinal pigment epithelium transplant therapy in Phase 1/2a development for the treatment of dry age-related macular degeneration, a leading cause of blindness in the developed world; (ii) OPC1, an investigational oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; and (iii) VAC, an allogeneic dendritic cell therapy platform for immuno-oncology and infectious disease, with investigational immunotherapy VAC2 currently in clinical development for the treatment of non-small cell lung cancer. 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,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would,” “contemplate,” “project,” “target,” “tend to,” “look forward to” or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to Lineage’s anticipated funding runway, data presentations, clinical trial advancement and the timing thereof, Lineage’s ability to achieve value-creating milestones, meetings and interactions with the FDA, evaluation of the Neurgain PSD system, manufacturing improvements, enrollment in the VAC2 Phase 1 study, announcement of clinical study results, payments under the license agreement with Immunomic Therapeutics, partnership evaluations and opportunities, and market opportunity and potential for its product candidates. 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 risks and uncertainties inherent in Lineage’s business and other risks discussed in Lineage’s filings with the Securities and Exchange Commission (the 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 filed with the SEC and Quarterly Report on Form 10-Q 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)

	June 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 62,001	\$ 32,585
Marketable equity securities	6,745	8,977
Trade accounts and grants receivable, net	326	4
Prepaid expenses and other current assets	2,505	2,433
Total current assets	71,577	43,999
NONCURRENT ASSETS		
Property and equipment, net	5,008	5,630
Deposits and other long-term assets	610	616
Goodwill	10,672	10,672
Intangible assets, net	46,887	47,032
TOTAL ASSETS	\$ 134,754	\$ 107,949
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 5,348	\$ 6,813
Lease liabilities, current portion	790	746
Financing lease, current portion	17	16
Deferred revenues	613	193
Liability classified warrants, current portion	-	1
Total current liabilities	6,768	7,769
LONG-TERM LIABILITIES		
Deferred tax liability	1,907	2,076
Lease liability, net of current portion	2,078	2,514
Financing lease, net of current portion	16	26
Liability classified warrants, net of current portion	384	437
TOTAL LIABILITIES	11,153	12,822
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of June 30, 2021 and December 31, 2020	-	-
Common shares, no par value, 250,000 shares authorized; 167,037 and 153,096 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	428,046	393,944
Accumulated other comprehensive loss	(3,051)	(3,667)
Accumulated deficit	(300,282)	(294,078)
Lineage Cell Therapeutics, Inc. shareholders' equity	124,713	96,199
Noncontrolling deficit	(1,112)	(1,072)
Total shareholders' equity	123,601	95,127
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 134,754	\$ 107,949

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,	
	2021	2020	2021	2020
REVENUES:				
Grant revenue	\$ 71	\$ 287	\$ 169	\$ 635
Royalties from product sales and license fees	228	99	521	265
Collaboration revenues	213	-	213	-
Total revenues	<u>512</u>	<u>386</u>	<u>903</u>	<u>900</u>
Cost of sales	<u>(125)</u>	<u>(75)</u>	<u>(237)</u>	<u>(169)</u>
Gross profit	<u>387</u>	<u>311</u>	<u>666</u>	<u>731</u>
OPERATING EXPENSES:				
Research and development	2,931	2,805	6,325	6,144
General and administrative	4,536	3,908	8,471	8,427
Total operating expenses	<u>7,467</u>	<u>6,713</u>	<u>14,796</u>	<u>14,571</u>
Loss from operations	<u>(7,080)</u>	<u>(6,402)</u>	<u>(14,130)</u>	<u>(13,840)</u>
OTHER INCOME/(EXPENSES):				
Interest income (expense), net	(3)	380	(1)	785
Gain on sale of marketable securities	-	2,470	6,024	3,728
Unrealized gain (loss) on marketable equity securities	590	(4,146)	1,830	(5,484)
Gain on extinguishment of debt	523	-	523	-
Unrealized gain (loss) on warrant liability	35	(6)	52	29
Other income (expense), net	970	1,174	(711)	(176)
Total other income/(expense), net	<u>2,115</u>	<u>(128)</u>	<u>7,717</u>	<u>(1,118)</u>
LOSS BEFORE INCOME TAXES	<u>(4,965)</u>	<u>(6,530)</u>	<u>(6,413)</u>	<u>(14,958)</u>
Deferred income tax benefit	<u>169</u>	<u>-</u>	<u>169</u>	<u>-</u>
NET LOSS	<u>(4,796)</u>	<u>(6,530)</u>	<u>(6,244)</u>	<u>(14,958)</u>
Net loss attributable to noncontrolling interest	<u>8</u>	<u>8</u>	<u>40</u>	<u>37</u>
NET LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	<u>\$ (4,788)</u>	<u>\$ (6,522)</u>	<u>\$ (6,204)</u>	<u>\$ (14,921)</u>
NET LOSS PER COMMON SHARE:				
BASIC	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>	<u>\$ (0.04)</u>	<u>\$ (0.10)</u>
DILUTED	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>	<u>\$ (0.04)</u>	<u>\$ (0.10)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
BASIC	<u>162,914</u>	<u>149,821</u>	<u>160,831</u>	<u>149,814</u>
DILUTED	<u>162,914</u>	<u>149,821</u>	<u>160,831</u>	<u>149,814</u>

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

	Six Months Ended June 30,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	\$ (6,204)	\$ (14,921)
Net loss allocable to noncontrolling interest	(40)	(37)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities:		
Gain on sale of marketable securities	(6,024)	(3,728)
Unrealized (gain)/loss on marketable equity securities	(1,830)	5,484
Gain on extinguishment of debt	(523)	-
Depreciation expense, including amortization of leasehold improvements	338	423
Amortization of right-of-use asset	20	18
Amortization of intangible assets	145	831
Stock-based compensation	1,458	1,232
Common stock issued for services	202	-
Change in unrealized gain on warrant liability	(53)	(29)
Write-off of security deposit	-	150
Deferred tax benefit	(169)	-
Foreign currency remeasurement and other gain	692	236
Changes in operating assets and liabilities:		
Accounts and grants receivable, net	(353)	125
Accrued interest receivable	-	(756)
Prepaid expenses and other current assets	34	1,442
Accounts payable and accrued liabilities	(955)	214
Deferred revenue and other liabilities	422	51
Net cash used in operating activities	<u>(12,840)</u>	<u>(9,265)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of OncoCyte common shares	10,064	10,941
Proceeds from the sale of AgeX common shares	-	985
Proceeds from the sale of Hadasit common shares	21	-
Purchase of equipment and other assets	(140)	(16)
Proceeds from the sale of equipment and other assets	14	-
Other deposits	-	48
Net cash provided by investing activities	<u>9,959</u>	<u>11,958</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	5,348	-
Common shares received and retired for employee taxes paid	(27)	(13)
Repayment of financing lease liabilities	-	(17)
Proceeds from Paycheck Protection Program ("PPP") Loan	-	523
Proceeds from sale of common shares	27,813	-
Payments for offering costs	(877)	-
Net cash provided by financing activities	<u>32,257</u>	<u>493</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(43)	(38)
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	29,333	3,148
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	33,183	10,096
At end of the period	<u>\$ 62,516</u>	<u>\$ 13,244</u>