

**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): **May 13, 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 May 13, 2021, Lineage Cell Therapeutics, Inc. issued a press release announcing financial results for the quarter ended March 31, 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.

Exhibit No. Description

99.1	Press release issued May 13, 2021
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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 13, 2021

By: /s/ Brian M. Culley

Name: Brian M. Culley

Title: Chief Executive Officer



**LINEAGE REPORTS FIRST QUARTER 2021 FINANCIAL RESULTS AND HIGHLIGHTS
SIGNIFICANT PROGRESS WITH ALL THREE CLINICAL PROGRAMS**

- **OpRegen® Clinical Data Continued to Demonstrate Improvements in Dry Age-Related Macular Degeneration (AMD) with Geographic Atrophy (GA)**
- **Worldwide License Agreement Secured for a Cancer Immunotherapy Candidate Based on the Lineage VAC Platform**
- **Exclusive Agreement Secured to Evaluate a Novel System for Enhanced Delivery of OPC1**
- **Board of Directors Enhanced with Appointments of Healthcare Leaders, Drs. Anula Jayasuriya and Dipti Amin**
- **Current Cash and Marketable Securities Expected to Support Operations Well Into 2023**

CARLSBAD, CA – May 13, 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 first quarter 2021. Lineage will host a conference call today at 4:30 p.m. Eastern Time to discuss its first quarter 2021 financial results and to provide a business update.

“Lineage reported significant operational progress with each of its three clinical programs during the first quarter and beyond, delivering not only continued positive clinical results with OpRegen for the treatment of dry-AMD with GA, but also validating partnerships to support our OPC1 and VAC programs,” stated Brian M. Culley, Lineage CEO. “We remain encouraged by the totality of the OpRegen clinical data presented to date, which is suggestive of clinically meaningful benefits, especially in earlier stage disease dry-AMD patients. Moreover, the strategic collaborations we announced for OPC1 and VAC reflect our commitment to a comprehensive asset management approach and add external validation to the potential of our platform to create positive outcomes for patients. Additionally, the capital we brought in during the first quarter ensures that we not only are well funded to reach additional milestones, but also provide us with optionality with respect to partnership discussions.”

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

- Presented a positive interim clinical update from the ongoing Phase 1/2a study of OpRegen for the treatment of dry-AMD with GA at the 2021 Association for Research in Vision and Ophthalmology Meeting; 83% of all Cohort 4 patients exhibited stable or improved Best Corrected Visual Acuity (BCVA) while visual acuity declined in the majority of untreated eyes;
 - Reported that the first known finding of retinal tissue restoration in a patient who received a retinal pigment epithelium (RPE) cell transplant continues to demonstrate areas of retinal restoration as of their last assessment, approximately 3 years after treatment;
 - Treated a vitelliform maculopathy patient with OpRegen under named patient compassionate use: the delivery of OpRegen RPE cells via pars plana vitrectomy (PPV) was successful, with no complications arising during the procedure and the patient remains in follow-up;
 - 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;
 - Entered into an exclusive agreement with Neurgain Technologies to evaluate a novel delivery system for OPC1 for treatment of spinal cord injury;
 - Announced the appointment of Anula Jayasuriya, M.D., Ph.D., M.B.A., a successful healthcare private equity executive and venture capitalist with extensive clinical, industry, entrepreneurial, and investment experience, to the Company’s Board of Directors; and
 - Announced the appointment of Dr. Dipti Amin, MBBS, a medically trained senior executive with broad expertise in medicine, pharmacology, healthcare, research, and product development, to the Company’s Board of Directors.
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Some of the events and milestones to look forward to during the remainder of 2021 include:

- OpRegen Program
 - o Presentation of additional interim data from the Phase 1/2a study, anticipated during the second quarter of 2021;
 - o Meeting with the U.S. Food and Drug Administration (FDA) to discuss further clinical development, anticipated in the third quarter of 2021.
- OPC1 Program
 - o FDA Regenerative Medicine Advanced Therapy interaction to assess plans to evaluate the Neurgain Parenchymal Spinal Delivery (PSD) system, scheduled in June 2021;
 - o Evaluation of the Neurgain PSD system;
 - o Completion of improved manufacturing process, GMP production, and comparability testing to support a late-stage clinical trial;
 - o FDA interaction to discuss manufacturing improvements, anticipated around the end of 2021.
- VAC Program
 - o Completion of enrollment in the ongoing VAC2 Phase 1 non-small cell lung cancer study, anticipated in mid 2021;
 - o Introduction of manufacturing enhancements to the VAC platform;
 - o Reporting of results from the ongoing VAC2 Phase 1 study, anticipated in the fourth quarter of 2021;
 - 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 \$62.4 million as of March 31, 2021. Marketable securities of \$6.2 million as of March 31, 2021 include our remaining ownership of 1,122,401 shares of common stock in OncoCyte and 169,167 shares of common stock in Hadasit Bio-Holdings Ltd.

We added to our cash position in the first quarter of 2021 with net proceeds of \$19.3 million received from sales of our common shares under our ATM offering and net proceeds of \$10.1 million received from selling a portion of our marketable securities.

No sales were conducted under our ATM offering from March 6, 2021 through May 12, 2021.

First Quarter Operating Results

Revenues: Lineage's revenue is generated primarily from research grants, royalties, and licensing fees. Total revenues for the three months ended March 31, 2021 were approximately \$0.4 million, a decrease of \$0.1 million as compared to \$0.5 million for the same period in 2020. The decrease was primarily related to an approximate \$0.2 million decrease in grant income, which was primarily driven by the completion of SBIR grant-related activities, offset by a \$0.1 million increase in royalty-related 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 March 31, 2021 were \$7.3 million, a decrease of \$0.6 million as compared to \$7.9 million for the same period in 2020.

R&D Expenses: R&D expenses for the three months ended March 31, 2021 were \$3.4 million, an increase of approximately \$0.1 million as compared to \$3.3 million for the same period in 2020. The overall increase was primarily related to increases of \$0.5 million and \$0.4 million in VAC and OPC1 program expenses, respectively, and a net decrease of \$0.8 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 March 31, 2021 were \$3.9 million, a decrease of approximately \$0.6 million as compared to \$4.5 million for the same period in 2020. The decrease was primarily attributable to decreases of \$0.4 million in expenses related to our merger with Asterias Biotherapeutics, Inc., \$0.2 million in rent expense and utilities, \$0.1 million in legal and patent expenses, and \$0.1 million in compensation expense, offset by a \$0.2 million increase in investor and public relations expenses.

Loss from Operations: Loss from operations for the three months ended March 31, 2021 was approximately \$7.0 million, a decrease of \$0.4 million as compared to \$7.4 million for the same period in 2020.

Other Income/(Expenses), Net: Other income/(expenses), net for the three months ended March 31, 2021 reflected other income, net of \$5.6 million, compared to other expense, net of (\$1.0) million for the same period in 2020. The variance was primarily related to the gain on sale of marketable securities and changes in the value of marketable equity securities for the applicable periods, as well as exchange rate fluctuations related to Lineage's international subsidiaries. The increase in the value of Lineage's OncoCyte shares and subsequent sales during the first quarter 2021 contributed significantly to the overall net increase in other income.

Net loss attributable to Lineage: The net loss attributable to Lineage for the three months ended March 31, 2021 was \$1.4 million, or \$0.01 per share (basic and diluted), compared to a net loss attributable to Lineage of \$8.4 million, or \$0.06 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 first 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 May 21, 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 4996965.

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](https://twitter.com/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, 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 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)

	March 31, 2021 (Unaudited)	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 56,210	\$ 32,585
Marketable equity securities	6,154	8,977
Trade accounts and grants receivable, net	109	4
Prepaid expenses and other current assets	2,149	2,433
Total current assets	64,622	43,999
NONCURRENT ASSETS		
Property and equipment, net	5,114	5,630
Deposits and other long-term assets	601	616
Goodwill	10,672	10,672
Intangible assets, net	46,919	47,032
TOTAL ASSETS	\$ 127,928	\$ 107,949
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 5,733	\$ 6,813
Financing lease and right of use lease liabilities, current portion	786	762
Deferred revenues	101	193
Liability classified warrants, current portion	1	1
Total current liabilities	6,621	7,769
LONG-TERM LIABILITIES		
Deferred tax liability	2,076	2,076
Right-of-use lease liability, net of current portion	2,217	2,514
Financing lease, net of current portion	26	26
Liability classified warrants, net of current portion	418	437
TOTAL LIABILITIES	11,358	12,822
Commitments and contingencies		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of March 31, 2021 and December 31, 2020	-	-
Common shares, no par value, 250,000 shares authorized; 162,067 and 153,096 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	415,259	393,944
Accumulated other comprehensive loss	(2,091)	(3,667)
Accumulated deficit	(295,494)	(294,078)
Lineage Cell Therapeutics, Inc. shareholders' equity	117,674	96,199
Noncontrolling interest (deficit)	(1,104)	(1,072)
Total shareholders' equity	116,570	95,127
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 127,928	\$ 107,949

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

	Three Months Ended March 31,	
	2021	2020
REVENUES:		
Grant revenue	\$ 98	\$ 348
Royalties from product sales and license fees	293	166
Total revenues	<u>391</u>	<u>514</u>
Cost of sales	<u>(112)</u>	<u>(94)</u>
Gross profit	<u>279</u>	<u>420</u>
OPERATING EXPENSES:		
Research and development	3,394	3,339
General and administrative	3,935	4,519
Total operating expenses	<u>7,329</u>	<u>7,858</u>
Loss from operations	<u>(7,050)</u>	<u>(7,438)</u>
OTHER INCOME/(EXPENSES):		
Interest income, net	2	405
Gain on sale of marketable securities	6,024	1,258
Unrealized gain (loss) on marketable equity securities	1,239	(1,338)
Unrealized gain on warrant liability	18	35
Other expenses, net	(1,681)	(1,350)
Total other income (expenses), net	<u>5,602</u>	<u>(90)</u>
LOSS BEFORE INCOME TAXES	<u>(1,448)</u>	<u>(8,428)</u>
Deferred income tax benefit	<u>-</u>	<u>-</u>
NET LOSS	<u>(1,448)</u>	<u>(8,428)</u>
Net loss attributable to noncontrolling interest	<u>32</u>	<u>29</u>
NET LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	<u>\$ (1,416)</u>	<u>\$ (8,399)</u>
NET LOSS PER COMMON SHARE:		
BASIC	<u>\$ (0.01)</u>	<u>\$ (0.06)</u>
DILUTED	<u>\$ (0.01)</u>	<u>\$ (0.06)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		
BASIC	<u>158,725</u>	<u>149,807</u>
DILUTED	<u>158,725</u>	<u>149,807</u>

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

	Three Months Ended March 31,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	\$ (1,416)	\$ (8,399)
Net loss allocable to noncontrolling interest	(32)	(29)
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)	(1,258)
Unrealized (gain)/loss on marketable equity securities	(1,239)	1,338
Depreciation expense, including amortization of leasehold improvements	174	212
Amortization of right-of-use asset	10	9
Amortization of intangible assets	112	498
Stock-based compensation	539	626
Common stock issued for services	102	-
Change in unrealized gain on warrant liability	(18)	(35)
Foreign currency remeasurement and other gain	1,712	1,424
Changes in operating assets and liabilities:		
Accounts and grants receivable, net	(135)	66
Accrued interest receivable	-	(378)
Receivables from OncoCyte and AgeX, net of payables	-	(40)
Prepaid expenses and other current assets	(92)	911
Accounts payable and accrued liabilities	(1,031)	(138)
Deferred revenue and other liabilities	(86)	167
Net cash used in operating activities	<u>(7,424)</u>	<u>(5,026)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of OncoCyte common shares	10,064	4,963
Proceeds from the sale of AgeX common shares	-	258
Proceeds from the sale of Hadasit common shares	21	-
Purchase of equipment and other assets	(11)	(10)
Other deposits	-	45
Net cash provided by investing activities	<u>10,074</u>	<u>5,256</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	1,717	-
Common shares received and retired for employee taxes paid	(13)	(2)
Repayment of financing lease liabilities	-	(8)
Proceeds from sale of common shares	19,873	-
Payments for offering costs	(614)	-
Net cash provided by (used in) financing activities	<u>20,963</u>	<u>(10)</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(80)	73
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	23,533	293
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	33,183	10,096
At end of the period	<u>\$ 56,716</u>	<u>\$ 10,389</u>