

**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 12, 2022**

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 12, 2022, Lineage Cell Therapeutics, Inc. issued a press release announcing financial results for the quarter ended March 31, 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 May 12, 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: May 12, 2022

By: /s/ George A. Samuel III

Name: George A. Samuel III

Title: General Counsel and Corporate Secretary



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

- **Reported RG6501 (OpRegen®) Clinical Results at 2022 ARVO Meeting; Outer Retinal Structure Improvement Observed in Five Dry AMD Patients**
- **Expanded Pipeline with Two New Cell Therapy Development Programs; Auditory Neurons and Photoreceptors**
- **Announced Completion of Enrollment in VAC2 Phase 1 NSCLC Study by Cancer Research UK**
- **Cash and Cash Equivalents of \$78.1 Million as of March 31, 2022**

CARLSBAD, CA – May 12, 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 first 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 first quarter 2022 financial and operating results and to provide a business update.

“The first quarter of this year was highlighted by the rapid launch of new cell therapy programs in hearing loss and vision disorders and conducting tech transfer activities to support our alliance with Roche and Genentech for our dry AMD program,” stated Brian M. Culley, Lineage CEO. “Our broad strategic plan is to position Lineage as a leader in regenerative medicine through the transplant of specific cell types to treat significant unmet medical needs. As part of that plan, we have expanded our cell therapy pipeline to five distinct programs, each offering an opportunity to impact various diseases. We believe our ability to, in just a matter of months, advance from a product concept to generating new intellectual property to support the manufacture of specific cell types, is not only illustrative of the power and efficiency of our platform but also a competitive advantage compared to others in this field. Looking forward, our focus is on clinical and regulatory execution across our portfolio. We are working to advance OPC1 and VAC2 into their next phases of clinical testing, in spinal cord injury and oncology, respectively, as well as advancing our auditory neuron and photoreceptor programs through preclinical development and toward pre-IND meetings with FDA. We believe the combination of our disciplined use of capital and current balance sheet will support multiple years of progress, during which we anticipate reaching significant events with each of our clinical and preclinical programs.”

Recent milestones include:

- Reported RG6501 (OpRegen) Phase 1/2a clinical results at 2022 Association for Research in Vision and Ophthalmology, Inc. (ARVO) annual meeting: 12-month primary endpoint data support the potential for OpRegen to slow, stop or reverse disease progression in geographic atrophy (GA) secondary to age-related macular degeneration (AMD); outer retinal structure improvement observed in five dry AMD patients;
 - Announced expansion of pipeline with addition of new cell therapy program: allogeneic photoreceptor neural cell (PNC1) transplants for the treatment of diseases which may lead to blindness; dynamic culturing process offers path to clinical- and industrial-scale production of photoreceptors; data generated further demonstrated that a single cell suspension of photoreceptor precursor cells has the potential to survive and mature post-transplantation in a rodent model of retinal degeneration;
 - Announced completion of patient enrollment in Phase 1 clinical study of VAC2 for the treatment of non-small cell lung cancer (NSCLC) by Cancer Research UK; Lineage has now assumed responsibility for further clinical development of VAC2 and any future development opportunities derived from the VAC platform; and
 - Announced expansion of pipeline with addition of new cell therapy program: auditory neuronal cells (ANP1) for the treatment of hearing loss; intellectual property filed covering composition and methods for generating auditory neuronal progenitors.
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Some of the events and milestones anticipated by Lineage in the rest of 2022 include:

- Investigational New Drug (“IND”) amendment submission to enable clinical performance and safety testing of a novel parenchymal spinal delivery system for OPC1, in Q4 2022;
- FDA interaction to discuss recent manufacturing improvements made to OPC1, anticipated in Q4 2022;
- Clinical data update from the ongoing VAC2 Phase 1 non-small cell lung cancer study; anticipated from CRUK in 2H 2022;
- An IND submission for VAC2 to support US-based clinical testing in 2H 2022;
- Preclinical activities for both ANP1 and PNC1 programs; ongoing throughout 2022;
- Additional OPC1 publications, including full clinical study results from the SCiStar clinical study and an MRI findings paper; anticipated in 2H 2022;
- Continued development of a cell-based therapeutic for glioblastoma with our strategic partner, Immunomic Therapeutics; ongoing throughout 2022;
- Evaluation of opportunities for new VAC product candidates based on internally identified or partnered tumor antigens; ongoing throughout 2022;
- Evaluation of new funded partnership opportunities and/or expansion of existing collaborations; ongoing throughout 2022; and
- Continued participation in numerous investor and partnering meetings and medical and industry conferences to broaden awareness of our mission and accomplishments.

Balance Sheet Highlights

Cash and cash equivalents totaled \$78.1 million as of March 31, 2022.

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, 2022 were \$5.2 million, an increase of \$4.8 million as compared to \$0.4 million for the same period in 2021. The increase was primarily related to licensing fees recognized from deferred revenues in connection with the \$50.0 million upfront licensing payment received in the first quarter of 2022 from 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 March 31, 2022 were \$11.5 million, an increase of \$4.2 million as compared to \$7.3 million for the same period in 2021, primarily attributable to a \$3.5 million non-recurring expense related to the potential settlement of the litigation concerning our 2019 acquisition of Asterias (“Asterias Litigation”).

R&D Expenses: R&D expenses for the three months ended March 31, 2022 were \$3.0 million, a decrease of \$0.4 million as compared to \$3.4 million for the same period in 2021. The decrease was driven by \$0.7 million in lower expenses for the OPC1 program, partially offset by \$0.2 million and \$0.1 million in higher expenses to support the VAC program and OpRegen related expenses to support the Roche Collaboration, respectively. Another \$0.1 million of the offsetting increase was related to initial costs to support the new auditory neuron cell therapy program.

G&A Expenses: G&A expenses for the three months ended March 31, 2022 were \$8.5 million, an increase of \$4.6 million as compared to \$3.9 million for the same period in 2021. The increase was primarily attributable to the \$3.5 million non-recurring expense related to the potential settlement of the Asterias Litigation, and \$0.5 million in share-based compensation.

Loss from Operations: Loss from operations for the three months ended March 31, 2022 was \$6.4 million, a decrease of \$0.7 million as compared to \$7.1 million for the same period in 2021.

Other Income/(Expenses), Net: Other income (expenses), net for the three months ended March 31, 2022 reflected other expense, net of (\$0.7) million, compared to other income, net of \$5.6 million for the same period in 2021. The net change of (\$6.3) million was primarily related to the gain on sale of marketable securities in the prior year.

Net Loss Attributable to Lineage: The net loss attributable to Lineage for the three months ended March 31, 2022 was \$7.1 million, or \$0.04 per share (basic and diluted), compared to a net loss attributable to Lineage of \$1.4 million, or \$0.01 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 (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 20, 2022, 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 1875641.

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 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 Phase 1/2a development for the treatment of geographic atrophy secondary to age-related macular degeneration, which 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 immunology 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 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: the collaboration and license agreement with Roche and Genentech, activities expected to occur thereunder, the potential to receive upfront, milestone and royalty consideration payable to Lineage thereunder; the potential benefits of treatment with OpRegen; the power and efficiency of Lineage’s platform and its competitive advantages; the ability of Lineage’s resources to support multiple years of progress; the potential future achievements of Lineage’s clinical and preclinical programs; the timing of potential FDA interactions, and of anticipated clinical trials and clinical data updates; and plans and expectations of Lineage’s products in development. 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 risk 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; the risk that competing alternative therapies may adversely impact the commercial potential of OpRegen; the risk that Roche and Genentech may not be successful in completing further clinical trials for OpRegen and/or obtaining regulatory approval for OpRegen in any particular jurisdiction; the risk that Lineage may not be able to manufacture sufficient clinical quantities of its product candidates in accordance with current good manufacturing practice; 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)

	<u>March 31, 2022</u>	<u>December 31, 2021</u>
	<u>(Unaudited)</u>	
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 78,062	\$ 55,742
Marketable equity securities	1,882	2,616
Accounts and grants receivable, net	515	50,840
Prepaid expenses and other current assets	1,413	2,351
Total current assets	81,872	111,549
NONCURRENT ASSETS		
Property and equipment, net	4,548	4,872
Deposits and other long-term assets	639	630
Goodwill	10,672	10,672
Intangible assets, net	46,789	46,822
TOTAL ASSETS	\$ 144,520	\$ 174,545
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 8,957	\$ 27,969
Lease liabilities, current portion	719	801
Financing lease, current portion	31	30
Deferred revenues	14,885	18,119
Liability classified warrants, current portion	1	197
Total current liabilities	24,593	47,116
LONG-TERM LIABILITIES		
Deferred tax liability	2,076	2,076
Deferred revenues, net of current portion	30,821	32,454
Lease liability, net of current portion	1,781	1,941
Financing lease, net of current portion	26	30
Liability classified warrants and other long-term liabilities	5	30
TOTAL LIABILITIES	59,302	83,647
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of March 31, 2022 and December 31, 2021	-	-
Common shares, no par value, 250,000 shares authorized; 169,727 and 169,477 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	435,818	434,529
Accumulated other comprehensive loss	(5,087)	(5,211)
Accumulated deficit	(344,184)	(337,097)
Lineage Cell Therapeutics, Inc. shareholders' equity	86,547	92,221
Noncontrolling (deficit)	(1,329)	(1,323)
Total shareholders' equity	85,218	90,898
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 144,520	\$ 174,545

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

	Three Months Ended March 31,	
	2022	2021
REVENUES:		
Collaboration revenues	\$ 4,865	\$ -
Royalties	372	293
Grant revenues	-	98
Total revenues	<u>5,237</u>	<u>391</u>
Cost of sales	<u>(176)</u>	<u>(112)</u>
Gross profit	<u>5,061</u>	<u>279</u>
OPERATING EXPENSES:		
Research and development	2,988	3,394
General and administrative	8,469	3,935
Total operating expenses	<u>11,457</u>	<u>7,329</u>
Loss from operations	<u>(6,396)</u>	<u>(7,050)</u>
OTHER INCOME/(EXPENSES):		
Interest income, net	1	2
Gain on sale of marketable securities	-	6,024
Unrealized (loss) gain on marketable equity securities	(735)	1,239
Unrealized gain on warrant liability	221	18
Other (expenses), net	(184)	(1,681)
Total other income (expenses), net	<u>(697)</u>	<u>5,602</u>
LOSS BEFORE INCOME TAXES	<u>(7,093)</u>	<u>(1,448)</u>
Deferred income tax benefit	<u>-</u>	<u>-</u>
NET LOSS	<u>(7,093)</u>	<u>(1,448)</u>
Net loss attributable to noncontrolling interest	<u>6</u>	<u>32</u>
NET LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	<u>\$ (7,087)</u>	<u>\$ (1,416)</u>
NET LOSS PER COMMON SHARE:		
BASIC	<u>\$ (0.04)</u>	<u>\$ (0.01)</u>
DILUTED	<u>\$ (0.04)</u>	<u>\$ (0.01)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		
BASIC	<u>169,647</u>	<u>158,725</u>
DILUTED	<u>169,647</u>	<u>158,725</u>

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

	Three Months Ended	
	March 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	\$ (7,087)	\$ (1,416)
Net loss allocable to noncontrolling interest	(6)	(32)
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)
Unrealized loss/(gain) on marketable equity securities	735	(1,239)
Depreciation expense, including amortization of leasehold improvements	150	174
Amortization of right-of-use asset	(4)	10
Amortization of intangible assets	32	112
Stock-based compensation	1,106	539
Common stock issued for services	-	102
Change in unrealized gain on warrant liability	(221)	(18)
Foreign currency remeasurement and other gain	75	1,712
Changes in operating assets and liabilities:		
Accounts and grants receivable	50,321	(135)
Prepaid expenses and other current assets	573	(92)
Accounts payable and accrued liabilities	(18,905)	(1,031)
Deferred revenue and other liabilities	(4,865)	(86)
Net cash provided by (used in) operating activities	<u>21,904</u>	<u>(7,424)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of OncoCyte common shares	-	10,064
Proceeds from the sale of HBL common shares	-	21
Purchase of equipment and other assets	(46)	(11)
Net cash (used in) provided by investing activities	<u>(46)</u>	<u>10,074</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	379	1,717
Common shares received and retired for employee taxes paid	(8)	(13)
Proceeds from exercise of subsidiary warrants	2	-
Proceeds from sale of common shares	148	19,873
Payments for offering costs	-	(614)
Repayment of lease liability	(8)	-
Net cash provided by financing activities	<u>513</u>	<u>20,963</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	<u>(42)</u>	<u>(80)</u>
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	22,329	23,533
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	56,277	33,183
At end of the period	<u>\$ 78,606</u>	<u>\$ 56,716</u>

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