

**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 6, 2020**

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 1.01. Entry into Material Definitive Agreement

On May 6, 2020, Lineage Cell Therapeutics, Inc. (“**Lineage**”) and its wholly owned subsidiary Asterias Biotherapeutics, Inc. (“**Asterias**”) entered into a Second Amendment to Clinical Trial and Option Agreement (the “**CTOA Amendment**”) with Cancer Research UK (“**CRUK**”) and Cancer Research Technology Limited (“**CRT**”), which amends the Clinical Trial and Option Agreement entered into between Asterias, CRUK and CRT dated September 8, 2014, as amended September 8, 2014. Pursuant to the CTOA Amendment, Lineage assumed all obligations of Asterias and exercised early its option to acquire data generated in the Phase 1 clinical trial of VAC2 in non-small cell lung cancer being conducted by CRUK. CRUK will continue conducting the VAC2 study.

Lineage and CRT effectuated the option by simultaneously entering into a license agreement (the “**License Agreement**”) pursuant to which Lineage agreed to pay the previously agreed signature fee of £1,250,000. In consideration of Lineage’s agreement to exercise the option prior to completion of the study, the parties agreed to defer the signature fee as follows: £500,000 in September 2020, £500,000 in January 2021 and £250,000 in April 2021. For the primary licensed product for the first indication, the License Agreement provides for milestone fees of up to £8,000,000 based upon initiation of a Phase 3 clinical trial and the filing for regulatory approval and up to £22,500,000 in sales-based milestones payments. Additional milestone fees and sales-based milestone payments would be payable for other products or indications, and mid-single-digit royalty payments are payable on sales of commercial products.

Either party may terminate the License Agreement for the uncured material breach of the other party. CRT may terminate the License Agreement in the case of Lineage’s insolvency or if Lineage ceases all development and commercialization of all products under the License Agreement.

Item 2.02. Results of Operations and Financial Condition.

On May 7, 2020, Lineage issued a press release announcing financial results for the quarter ended March 31, 2020, 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
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99.1	Press release issued May 7, 2020
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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 7, 2020

By: /s/ Brandi L. Roberts

Name: Brandi L. Roberts

Title: Chief Financial Officer



LINEAGE CELL THERAPEUTICS REPORTS FIRST QUARTER 2020 FINANCIAL RESULTS AND PROVIDES BUSINESS UPDATE

- **Presented Positive New Data from Phase 1/2a Clinical Study of OpRegen in Dry AMD at 2020 ARVO Virtual Meeting**
- **Announced Early Exercise of Option with Cancer Research UK for Immuno-Oncology Cell Therapy Program**
- **Initiated Process to Expand VAC Cell Therapy Platform to Develop Coronavirus Vaccine**
- **Maintained High Degree of Continuity of Global Operations During COVID-19 Pandemic**
- **Converted Portion of OncoCyte Shares into Net Proceeds of Approximately \$3.7 Million**

CARLSBAD, CA – May 7, 2020 - Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs, today reported financial and operating results for the first quarter ended March 31, 2020. Lineage management will host a conference call today at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time to discuss its first quarter 2020 financial and operating results and to provide a business update.

“Lineage has adapted quickly to an unprecedented business environment. We ensured the safety of our teams while maintaining the continuity of our global operations and advancing our programs with meaningful clinical data and contractual arrangements,” stated Brian M. Culley, Lineage CEO. “Looking ahead, we believe we are well positioned to achieve many of our 2020 objectives. Most notably, a clinical update recently presented at the ARVO meeting provided a more comprehensive picture of treatment with OpRegen, where certain patients were able to see better, have less growth to their area of geographic atrophy, and read faster, representing important enhancements to vision and quality of life metrics. We also are excited about exercising our option to regain control of the VAC platform for immuno-oncology and expand it to the development of a vaccine for coronaviruses such as SARS-CoV-2, the virus which causes COVID-19.”

2020 Plans and Objectives:

- **Present new OpRegen data** from the ongoing Phase 1/2a clinical trial as available throughout the year.
 - **Complete patient enrollment** in the U.S. with the Gyroscope Orbit SDS and new thaw-and-inject formulation in the ongoing Phase 1/2a clinical trial of OpRegen for the treatment of dry AMD.
 - **Meet with the U.S. Food and Drug Administration (FDA)** to discuss the further clinical development of OpRegen.
 - **Evaluate partnership opportunities** for the OpRegen program and other development assets.
 - **Report VAC2 clinical data** from the initial patients treated in the ongoing Phase 1 trial in NSCLC (non-small cell lung cancer) run by Cancer Research UK.
 - **Enhance commercial utility of OPC1** program by introducing commercially enabling improvements to the manufacturing process in our GMP manufacturing facility.
 - **Continue engagement** with the investment and medical communities with virtual participation at medical and healthcare industry conferences, ongoing throughout 2020.
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- **Strengthen existing partnerships** with the National Institutes of Health, the Israel Innovation Authority, the California Institute for Regenerative Medicine and Cancer Research UK.
- **Seek non-dilutive support** for certain programs, as may be available, including for coronavirus vaccine development.

Balance Sheet and Cash Flow Highlights

Cash, cash equivalents, and marketable securities totaled \$25.8 million as of March 31, 2020. Marketable securities include our remaining ownership of unrestricted securities in OncoCyte Corporation (OncoCyte), AgeX Therapeutics, Inc. (AgeX) and Hadasit Bio-Holdings Ltd (Hadasit).

We have continued to fund our operations primarily by selling a portion of our marketable securities. On January 2, 2020, we sold 2,383,090 shares of OncoCyte stock for net proceeds of approximately \$5.0 million. On April 23, 2020, we sold an additional 1,672,689 shares of OncoCyte stock for net proceeds of approximately \$3.7 million. We continue to hold approximately 4.3 million shares of OncoCyte stock that are valued at \$11.3 million as of May 5, 2020, based on the closing price of its common stock on that date. All of our marketable securities are now in companies in which we hold less than 10% of the outstanding shares.

In conjunction with the sale of AgeX shares to Juvenescence Limited (Juvenescence) in 2018, we also hold a \$21.6 million promissory note bearing 7% annual interest that matures on August 30, 2020. As of March 31, 2020, the outstanding principal and accrued interest on the note was \$24.0 million. If, prior to August 30, 2020, Juvenescence completes an initial public offering resulting in gross proceeds of at least \$50.0 million, the promissory note automatically converts into the Juvenescence securities.

Net cash used in operating activities for the three months ended March 31, 2020 was approximately \$5.0 million, a decrease of \$4.3 million as compared to \$9.3 million in the same period of 2019. This level of quarterly activity was in line with our budgeted annual net operational spend of \$16 million for 2020. As a result of incremental expenses we anticipate incurring during the remainder of the year related to the early exercise of our option with Cancer Research UK, our plans for the development of a prophylactic vaccine against SARS-CoV-2 and other coronaviruses, and delays caused by COVID-19 to our OpRegen® clinical trial, we anticipate our net operational spend for 2020 will increase modestly.

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, 2020 were \$0.5 million, a decrease of \$0.4 million as compared to \$0.9 million for the same period in 2019. The decrease was primarily related to a \$0.4 million decrease in grant revenue due to the timing of grant related activities for OpRegen and other ophthalmic applications.

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, 2020 were approximately \$7.8 million, a decrease of \$5.8 million as compared to \$13.6 million for the same period in 2019.

R&D Expenses: R&D expenses for the three months ended March 31, 2020 were \$3.3 million, an approximate decrease of \$1.7 million as compared to \$5.0 million for the same period in 2019. The overall decrease was primarily related to decreases of \$1.8 million in OpRegen and other ophthalmic application expenses and \$0.4 million in Renevia® expenses, offset by an increase of approximately \$0.5 million in OPC1 expenses.

G&A Expenses: G&A expenses for the three months ended March 31, 2020 were \$4.5 million, a decrease of \$4.1 million as compared to approximately \$8.6 million for the same period in 2019. The decrease was primarily attributable to a \$3.3 million reduction in expenses related to our merger with Asterias Biotherapeutics, Inc. (Asterias), a \$0.9 million decrease in salaries, benefits and severance costs primarily related to terminated personnel, a \$0.4 million reduction in accounting expenses, a \$0.1 million reduction in rent expenses and a \$0.1 million reduction in consulting expenses, offset by a \$0.5 million increase in legal and patent expenses and a \$0.2 million increase related to the cessation of shared services reimbursements.

Loss from Operations: Loss from operations for the three months ended March 31, 2020 was \$7.4 million, an approximate decrease of \$5.4 million as compared to \$12.8 million for the same period in 2019.

Other (Expense) Income, Net: Other income/(expenses), net for the three months ended March 31, 2020 reflected other expense, net of (\$1.0) million, compared to other income, net of \$47.7 million for the same period in 2019. The variance was primarily related to changes in the value of equity method investments and marketable equity securities for the applicable periods, as well as foreign currency translation adjustments related to Lineage's international subsidiaries. The value of Lineage's OncoCyte shares increased by \$37.7 million in the three months ended March 31, 2019, which contributed greatly to the overall balance in other income, net for that period.

Net loss attributable to Lineage: The net loss attributable to Lineage for the three months ended March 31, 2020 was \$8.4 million, or \$0.06 per share (basic and diluted), compared to a net income attributable to Lineage of \$39.3 million, or \$0.30 per share (basic and diluted), for the same period in 2019.

Conference Call and Webcast

Lineage will host a conference call and webcast today, at 1:30 pm PT/4:30 pm ET to discuss its first quarter 2020 financial results and to provide a business update. A live webcast of the conference call will be available online in the Investors section of Lineage's website. Interested parties may also 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 14, 2020, 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 7948501.

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 three allogeneic ("off-the-shelf") product candidates: (i) OpRegen[®], a 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 oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; and (iii) VAC2, a cancer immunotherapy of antigen-presenting dendritic cells in Phase 1 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,” or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to Lineage’s manufacturing plans, enrollment activities, data presentations, clinical trial advancement, proposed expansion of the VAC platform to address coronaviruses, expected net operational spend, planned meetings with the FDA and partnership evaluations. 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 Annual Report on Form 10-K filed with the SEC on March 12, 2020 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.

Lineage Cell Therapeutics, Inc. IR

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Tables to follow

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

	March 31, 2020 (Unaudited)	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 9,832	\$ 9,497
Marketable equity securities	15,933	21,219
Promissory note from Juvenescence	23,994	23,616
Trade accounts and grants receivable, net	253	317
Receivables from affiliates, net	47	7
Prepaid expenses and other current assets	2,225	2,863
Total current assets	52,284	57,519
NONCURRENT ASSETS		
Property and equipment, net	7,539	8,175
Deposits and other long-term assets	637	864
Goodwill	10,672	10,672
Intangible assets, net	47,750	48,248
TOTAL ASSETS	\$ 118,882	\$ 125,478
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 5,321	\$ 5,226
Financing lease and right of use lease liabilities, current portion	1,240	1,223
Deferred revenues	200	-
Deferred grant revenue	208	45
Total current liabilities	6,969	6,494
LONG-TERM LIABILITIES		
Deferred tax liability	3,315	3,315
Deferred revenues	-	200
Right-of-use lease liability, net of current portion	3,527	3,868
Financing lease, net of current portion	66	77
Liability classified warrants, net of current portion, and other long-term liabilities	247	277
TOTAL LIABILITIES	14,124	14,231
Commitments and contingencies		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of March 31, 2020 and December 31, 2019	-	-
Common shares, no par value, 250,000 shares authorized; 149,818 shares issued and outstanding as of March 31, 2020 and 149,804 shares issued and outstanding as of December 31, 2019	387,686	387,062
Accumulated other comprehensive income (loss)	634	(681)
Accumulated deficit	(281,821)	(273,422)
Lineage Cell Therapeutics, Inc. shareholders' equity	106,499	112,959
Noncontrolling interest (deficit)	(1,741)	(1,712)
Total shareholders' equity	104,758	111,247
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 118,882	\$ 125,478

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

	Three Months Ended March 31,	
	2020	2019
REVENUES:		
Grant revenue	\$ 348	\$ 749
Royalties from product sales and license fees	166	86
Sale of research products and services	-	93
Total revenues	<u>514</u>	<u>928</u>
Cost of sales	<u>(94)</u>	<u>(68)</u>
Gross profit	<u>420</u>	<u>860</u>
OPERATING EXPENSES:		
Research and development	3,339	4,961
General and administrative	4,519	8,660
Total operating expenses	<u>7,858</u>	<u>13,621</u>
Loss from operations	<u>(7,438)</u>	<u>(12,761)</u>
OTHER INCOME/(EXPENSES):		
Interest income, net	405	442
Gain on sale of marketable equity securities	1,258	-
Unrealized (loss) gain on marketable equity securities	(1,338)	1,931
Gain on equity method investment in OncoCyte at fair value	-	37,713
Gain on equity method investment in Asterias at fair value	-	6,744
Unrealized gain on warrant liability	35	37
Other (expense) income, net	(1,350)	806
Total other (expense) income, net	<u>(990)</u>	<u>47,673</u>
(LOSS)/INCOME BEFORE INCOME TAXES	<u>(8,428)</u>	<u>34,912</u>
Deferred income tax benefit	<u>-</u>	<u>4,384</u>
NET (LOSS)/INCOME	<u>(8,428)</u>	<u>39,296</u>
Net loss attributable to noncontrolling interest	<u>29</u>	<u>14</u>
NET (LOSS)/INCOME ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	<u>\$ (8,399)</u>	<u>\$ 39,310</u>
NET (LOSS)/INCOME PER COMMON SHARE:		
BASIC	<u>\$ (0.06)</u>	<u>\$ 0.30</u>
DILUTED	<u>\$ (0.06)</u>	<u>\$ 0.30</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		
BASIC	<u>149,807</u>	<u>132,865</u>
DILUTED	<u>149,807</u>	<u>132,869</u>

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

	Three Months Ended March 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss) income attributable to Lineage Cell Therapeutics, Inc.	\$ (8,399)	\$ 39,310
Net loss allocable to noncontrolling interest	(29)	(14)
Adjustments to reconcile net (loss) income attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities:		
Unrealized gain on equity method investment in OncoCyte at fair value	-	(37,713)
Unrealized gain on equity method investment in Asterias at fair value	-	(6,744)
Gain on sale of marketable securities	(1,258)	-
Unrealized loss (gain) on marketable equity securities	1,338	(1,931)
Deferred income tax benefit	-	(4,384)
Depreciation expense, including amortization of leasehold improvements	212	269
Amortization of right-of-use asset	9	14
Amortization of intangible assets	498	485
Stock-based compensation	626	1,440
Change in unrealized gain on warrant liability	(35)	(37)
Foreign currency remeasurement and other (gain) loss	1,424	(839)
Changes in operating assets and liabilities:		
Accounts and grants receivable, net	66	(614)
Accrued interest receivable	(378)	(378)
Receivables from OncoCyte and AgeX, net of payables	(40)	2,129
Prepaid expenses and other current assets	911	(66)
Accounts payable and accrued liabilities	(138)	(241)
Deferred revenue and other liabilities	167	-
Net cash used in operating activities	<u>(5,026)</u>	<u>(9,314)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of OncoCyte common shares	4,963	-
Proceeds from the sale of AgeX common shares	258	-
Cash and cash equivalents acquired in the Asterias Merger	-	3,117
Purchase of equipment and other assets	(10)	(169)
Security deposit paid and other	45	(2)
Net cash provided by investing activities	<u>5,256</u>	<u>2,946</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Common shares received and retired for employee taxes paid	(2)	(74)
Reimbursement from landlord on tenant improvements	-	738
Repayment of financing lease liabilities	(8)	(6)
Repayment of principal portion of promissory notes	-	(52)
Net cash (used by) provided by financing activities	<u>(10)</u>	<u>606</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	73	53
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	293	(5,709)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	10,096	24,399
At end of the period	<u>\$ 10,389</u>	<u>\$ 18,690</u>