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): **December 17, 2021**

Lineage Cell Therapeutics, Inc.
(Exact name of registrant as specified in charter)

California	**001-12830**	**94-3127919**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2173 Salk Avenue, Suite 200 **Carlsbad, California** (Address of principal executive offices)	**92008** (Zip Code)

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

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common shares, no par value	**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 a Material Definitive Agreement.

On December 17, 2021, Lineage Cell Therapeutics, Inc. and its subsidiary, Cell Cure Neurosciences Ltd. ("Cell Cure" and collectively, "Lineage") entered into a Collaboration and License Agreement (the "Agreement") with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively, "Roche"), wherein Lineage granted to Roche exclusive worldwide rights to develop and commercialize retinal pigment epithelium ("RPE cells") cell therapies, including its proprietary cell therapy known as OpRegen®, for the treatment of ocular disorders, including advanced dry age-related macular degeneration with geographic atrophy.

Under the terms of the Agreement, Roche will assume responsibility for further clinical development and commercialization of OpRegen®, which currently is being evaluated in a Phase 1/2a open-label, dose escalation clinical safety and efficacy study in patients with advanced dry age-related macular degeneration with geographic atrophy. Lineage will be responsible for completing activities related to the ongoing clinical study, for which enrollment is complete, and performing certain manufacturing and process development activities.

Roche will pay Lineage a $50 million upfront payment and Lineage is eligible to receive up to an additional $620 million in certain developmental, regulatory and commercialization milestone payments. Lineage is also eligible for tiered double-digit percentage royalties on net sales of OpRegen. All regulatory and commercial milestone payments, and royalty payments, are subject to the existence of certain intellectual property rights that cover OpRegen at the time such payments would otherwise become due, and the royalties on net sales of OpRegen are subject to financial offsets based on the existence of competing products.

The OpRegen program has been supported in part with contributions made by Hadasit Medical Research Services and Development Ltd. ("Hadasit"), the technology transfer company of Hadassah Medical Center, and the Israeli Innovation Authority (the "IIA"), an independent agency created to address the needs of global innovation ecosystems. A significant portion of early development on the OpRegen program occurred at Cell Cure, which is a 99%-owned subsidiary of Lineage. Cell Cure was established by the Hadassah Medical Center, where the intellectual property underlying the differentiation and manufacture of RPE cells originated. In addition, significant monetary support for the OpRegen program was provided by the IIA through a series of separate research grants, beginning in 2007. Each of these parties' contributions began when the OpRegen program was in its earliest stages of development. As a result, and subject to the terms of contracts among the applicable parties, Lineage is obligated to pay Hadasit and the IIA a portion of the upfront, milestone, and royalty payments which may be received from Roche under the Agreement. Lineage is obligated to pay approximately 24.3% of the upfront payment and any milestone payments, and 3% of all royalty payments it receives from Roche to the IIA, up to an aggregate cap on all payments to IIA of approximately $103 million.

In addition, pursuant to that certain Second Amended and Restated License Agreement, dated June 15, 2017, between Cell Cure and Hadasit, as amended, and a certain letter agreement entered into on December 17, 2021, by and between Cell Cure and Hadasit, Cell Cure is obligated to pay to Hadasit a maximum of 21.5% of the upfront payment (subject to certain reductions) and any milestone payments, and up to 50% of all royalty payments (subject to a maximum payment of 5% of net sales of products), Lineage receives from Roche. The letter agreement generally terminates upon the termination of the Agreement.

Unless earlier terminated by either party, the Agreement will expire on a product-by-product and country-by-country basis upon the expiration of all of Roche's payment obligations under the Agreement. Roche may terminate the Agreement in its entirety, or on a product-by-product or country-by-country basis, at any time with advance written notice. Either party may terminate the Agreement in its entirety with written notice for the other party's material breach if such party fails to cure the breach. Either party also may terminate the Agreement in its entirety upon certain insolvency events involving the other party.

The representations, warranties and covenants contained in the Agreement were made only for the purposes of the Agreement, were made as of specific dates, were made solely for the benefit of the parties to the Agreement and may not have been intended to be statements of fact, but rather, as a method of allocating risk and governing the rights and relationships among the parties to the Agreement. In addition, such representations, warranties and covenants may have been qualified by certain disclosures not reflected in the text of the Agreement and may apply standards of materiality and other qualifications and limitations in a way that is different from what may be viewed as material by Lineage's shareholders. In reviewing the representations, warranties and covenants contained in the Agreement, it is important to bear in mind that such representations, warranties and covenants were not intended by the parties to the Agreement to be characterizations of the actual state of facts or conditions of Lineage or OpRegen®. Moreover, information concerning the subject matter of the representations and warranties may change after the date of the Agreement, which subsequent information may or may not be fully reflected in public disclosures. For the foregoing reasons, the representations, warranties and covenants in the Agreement should not be read alone and should instead be read in conjunction with the other information contained in the reports, statements and filings that Lineage publicly files with the U.S. Securities and Exchange Commission.

Item 7.01. Regulation FD Disclosure.

On December 20, 2021, Lineage issued a press release announcing its entry into the Agreement. A copy of the press release is attached as Exhibit 99.1 to this report.

The information contained in this Item 7.01, including in Exhibit 99.1 to this report, is being "furnished" and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section or Sections 11 or 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in Exhibit 99.1 shall not be incorporated by reference into any filing with the Securities and Exchange Commission ("SEC") made by Lineage, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Cautionary Statement Regarding Forward-Looking Statements

Lineage cautions you that all statements, other than statements of historical facts, contained in this report, 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," "can," "plan," "potential," "predict," "seek," "should," "would," "contemplate," "project," "target," "suggest," or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to the further clinical development and commercialization of OpRegen®, Lineage's ability to complete its obligations under the Agreement, the potential future achievement of specified developmental, regulatory and commercialization milestones, and the potential future receipt of payments therefrom. 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 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated December 20, 2021.
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: December 20, 2021

By: */s/ George A. Samuel III*

Name: George A. Samuel III

Title: General Counsel and Corporate Secretary

Exhibit 99.1

LINEAGE ESTABLISHES EXCLUSIVE WORLDWIDE COLLABORATION WITH GENENTECH FOR THE DEVELOPMENT AND COMMERCIALIZATION OF OPREGEN® RPE CELL THERAPY FOR THE TREATMENT OF OCULAR DISORDERS

- **Genentech Will Pay Lineage $50 Million Upfront**
- **Eligible to Receive a Total of $670 Million in Upfront and Milestone Payments**
- **Conference Call to Discuss Collaboration Planned for 8 a.m. ET**

CARLSBAD, CA– December 20, 2021 - Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), today announced that Lineage and its subsidiary, Cell Cure Neurosciences Ltd., have entered into an exclusive worldwide collaboration and license agreement with Roche and Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), for the development and commercialization of a retinal pigment epithelium (RPE) cell therapy for the treatment of ocular disorders, including advanced dry age-related macular degeneration (dry AMD) with geographic atrophy (GA).

Genentech will assume responsibility for further clinical development and commercialization of Lineage's OpRegen program, which currently is being evaluated in a Phase 1/2a open-label, dose escalation clinical safety and efficacy study in patients with advanced dry AMD with GA. Under the terms of the collaboration agreement, Lineage will complete activities related to the ongoing clinical study, for which enrollment is complete, and perform certain manufacturing activities. Genentech will pay Lineage a $50 million upfront payment and Lineage is eligible to receive up to $620 million in additional development, approval and sales milestone payments, in addition to tiered double- digit royalties.

"Genentech is a clear global leader in ophthalmology and has demonstrated a longstanding commitment to patients, innovative research and successful product development," said Brian M. Culley, Lineage's CEO. "Their desire to combine our cell therapy technology with their ophthalmology expertise and capabilities will help advance the OpRegen program more rapidly and we believe successfully to patients with serious ocular disorders, such as dry age-related macular degeneration. Lineage's objective is to pioneer a new branch of regenerative medicine, based on transplanting whole cells into the body to restore activity lost to aging, injury or disease. We believe the results we have demonstrated to date with OpRegen represent a paradigm change many did not believe possible with cell therapy, by restoring retinal tissue and potentially halting or reversing the expansion of geographic atrophy. I am incredibly proud of what the Lineage team has accomplished with the OpRegen program and look forward to joining forces with the Genentech team as they work to take this program to the next level and potentially to patients in need of treatment."

Mr. Culley continued, "Looking ahead, Lineage will remain focused on advancing our spinal cord injury and oncology programs as well as announcing new disease settings where we plan to deploy our technology, either on our own or through strategic alliances. All of us at Lineage are immensely proud to have the opportunity and responsibility to advance a new and exciting branch of medicine, and our aim is to make a profound impact on the patients who serve as our inspiration."

"Genentech has a longstanding commitment to discovering and developing novel drugs for the treatment of serious eye disorders such as with advanced dry AMD with GA, which is one of our focus areas within ophthalmology," said James Sabry, M.D., Ph.D., global head of Pharma Partnering, Roche. "We are excited to partner with Lineage Cell Therapeutics to advance potential new therapies in an area of high unmet medical need."

Conference Call Information

Lineage will host a live conference call and webcast today beginning at 8 a.m. ET to discuss the collaboration with the Roche Group and Genentech. 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 December 27, 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 5174206.

About OpRegen

OpRegen has been developed in part through contributions and financial grants made by Hadasit Medical Research Services and Development Ltd. ("Hadasit") and the Israeli Innovation Authority (the "IIA"). Lineage is obligated to pay a portion of upfront, milestone and royalty payments it receives to Hadasit and the IIA. OpRegen is currently being evaluated in a Phase 1/2a open-label, dose escalation safety and efficacy study of a single injection of human retinal pigment epithelium cells derived from an established pluripotent cell line and transplanted subretinally in patients with advanced dry AMD with GA. The study enrolled 24 patients into 4 cohorts. The first 3 cohorts enrolled only legally blind patients with a best corrected visual acuity (BCVA) of 20/200 or worse. The fourth cohort enrolled 12 better vision patients (BCVA from 20/65 to 20/250 with smaller mean areas of GA). Cohort 4 also included patients treated with a new "thaw-and-inject" formulation of OpRegen, which can be shipped directly to sites and used immediately upon thawing, removing the complications and logistics of having to use a dose preparation facility. The primary objective of the study was to evaluate the safety and tolerability of OpRegen as assessed by the incidence and frequency of treatment emergent adverse events. Secondary objectives are to evaluate the preliminary efficacy of OpRegen treatment by assessing the changes in ophthalmological parameters measured by various methods of primary clinical relevance. OpRegen has been well tolerated to date and there have been no new, unexpected ocular or systemic adverse events or serious adverse events related to OpRegen or study procedures that have not been previously reported.

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, an allogeneic dendritic cell therapy produced from Lineage's VAC technology platform for immuno-oncology and infectious disease, currently in Phase 1 clinical development for the treatment of non-small cell lung cancer. 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 and activities expected to occur under the collaboration and license agreement, the upfront, milestone and royalty consideration payable to Lineage, the potential benefits of treatment with OpRegen, and Lineage's plans to advance its spinal cord injury and oncology programs and announce new disease settings where it plans to deploy its technology. 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 the risk that competing alternative therapies may adversely impact the commercial potential of OpRegen, which could materially adversely affect the milestone and royalty payments payable to Lineage under the collaboration and license agreement, 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, and risks and uncertainties inherent in Lineage's business and other risks 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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