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 13, 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 7.01. Regulation FD Disclosure.

On November 30, 2021, Lineage Cell Therapeutics, Inc. ("Lineage" or the "Company") issued a press release, a copy of which 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, 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 made by Lineage, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01. Other Events.

On November 30, 2021, Lineage announced that restoration of retinal tissue was observed in a fourth patient enrolled in the Company's Phase 1/2a clinical study of its lead product candidate, OpRegen. Retinal tissue restoration and improved visual acuity has now been observed in all four better vision patients treated in Cohort 4 of the clinical study, where surgeons successfully covered the majority of the area of atrophy with a suspension of OpRegen cells. Outer retinal layer restoration, which was observed using clinical high-resolution optical coherence tomography ("OCT"), was evidenced by the presence of new areas of retinal pigment epithelium ("RPE") monolayer with overlying ellipsoid zone, external limiting membrane, and outer nuclear layer, which were not present at the time of baseline assessment. OpRegen is an allogeneic RPE cell transplant in development for the treatment of AMD with geographic atrophy ("GA"), or dry (atrophic) AMD.

OpRegen Phase 1/2a Interim Clinical Trial Results

- Retinal restoration, reported in four patients to date, persisted from over 12 months to greater than 3 years following treatment and continues to be followed.
- Restoration was evidenced by the presence of new areas of RPE monolayer with overlying ellipsoid zone, external limiting membrane, and outer nuclear layer, which were not present at the time of baseline assessment.
    - Reductions, or no progression for at least 1 year, was observed in the total area of GA in all four of these better vision Cohort 4 patients.
- Overall, using the Early Treatment Diabetic Retinopathy Study (ETDRS) assessment of best corrected visual acuity, 7/12 (58%) of each of Cohort 4 patients' treated eye were at baseline or better at 15 months or last time point, which extends beyond 3 years in some patients. In comparison, at the same time points, 8/12 (67%) were below baseline in those same patients' fellow untreated eyes.
    - All four retinal restoration patients reported improvements in their visual acuity, which has been maintained for at least 12 months in all four of those patients.
    - After including monitored data changes, the differences in visual acuity between treated and untreated eyes (mean change in Cohort 4 patient BCVA) continued to demonstrate statistical significance at Month 9 ($n = 12$, $p = 0.0280$) and Month 12 ($n = 12$, $p = 0.0411$), as determined via 2-sided Wilcoxon Signed Rank using NCSS, LLC statistical software, and at Month 15 ($n = 7$, $p = 0.0176$).
- Across the study, in patients with previously reported structural improvements in the retina, decreases in drusen density, and a trend toward slower GA progression in treated compared to untreated eyes continue to be present.
- Evidence of durable engraftment of OpRegen RPE cells has extended to more than 5 years in the earliest treated patients, supporting the potential for OpRegen to be a one-time treatment.

Overall, OpRegen has been well tolerated to date and there have been no new, unexpected ocular or systemic adverse events or serious adverse events that have not been previously reported.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release dated November 30, 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 13, 2021

By: */s/ George A. Samuel III*
Name: George A. Samuel III
Title: General Counsel and Corporate Secretary

Exhibit 99.1

LINEAGE REPORTS FOURTH CASE OF RETINAL TISSUE RESTORATION WITH OPREGEN®

- **Four Patients With Dry Age-Related Macular Degeneration Observed to Have Areas of Geographic Atrophy Which Diminished or Remained Unchanged Relative to Baseline for a Period of at Least 12 Months**
- **All Four Patients Exhibited Improvements in Visual Acuity at 12 Months**
- **Differences in Visual Acuity Between Treated and Untreated Eyes in all Cohort 4 Patients Remained Statistically Significant At 9, 12, and 15 Months**

CARLSBAD, CA– November 30, 2021 - Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, announced today that restoration of retinal tissue was observed in a fourth patient enrolled in the Company's Phase 1/2a clinical study of its lead product candidate, OpRegen®. Retinal tissue restoration and improved visual acuity has now been observed in all four better vision patients treated in Cohort 4, where surgeons successfully covered the majority of the area of atrophy with a suspension of OpRegen cells. Outer retinal layer restoration, which was observed using clinical high-resolution Optical Coherence Tomography (OCT), was evidenced by the presence of new areas of retinal pigment epithelium (RPE) monolayer with overlying ellipsoid zone, external limiting membrane, and outer nuclear layer, which were not present at the time of baseline assessment. These new and additive findings continue to support the Company's view that atrophic AMD is not an irreversible, degenerative condition and that some portion of diseased retinal tissue may be recoverable. OpRegen is an allogeneic RPE cell transplant in development for the treatment of age-related macular degeneration (AMD) with geographic atrophy (GA), or dry (atrophic) AMD.

"After reporting three previous cases of retinal restoration over the course of the last two years, we have been carefully examining the other Cohort 4 patients. We have put significant work into reviewing images from the remaining patient who had the majority of the area of atrophy covered by the OpRegen suspension at the time of surgical implant. I am pleased to report that at the scheduled Month 12 post-operative visit for this patient, although less prominent than the 3 previously reported cases due to a smaller area of atrophy at baseline, there is clear evidence of retinal restoration in some areas, and the total area of atrophy as calculated using square root transformation, or SQRT, is smaller than the size calculated at baseline," stated Jordi Monés, M.D., Ph.D., Director, Institut de la Màcula and Director, Principal Investigator and Founder, Barcelona Macula Foundation. "The finding of a fourth case of restoration further supports our goal of showing that atrophic age-related macular degeneration can be responsive to this type of cell therapy. Dry AMD is a progressive disease and halting or reversing an area of atrophy does not occur spontaneously, which we believe makes the durability and reproducibility of these changes unprecedented within the field. With 12 months of follow-up complete, I am eager to have these cases submitted for peer-reviewed publication."

"We have treated 24 patients with OpRegen, 12 of which were not legally blind at baseline and represent our intended treatment population. Among these 12 patients, four received thorough coverage of OpRegen cells across the majority of the atrophic area and experienced a cessation or reversal of their areas of atrophy at 12 months and continue to be followed. These patients also experienced increases in their visual acuity in their treated eye. We believe these four patients represent the only examples of an experimental treatment for dry AMD which can reduce an area of atrophy in humans, rather than simply slow its growth," added Brian M. Culley, Lineage CEO. "Restoration of retinal tissue using cell therapy represents a paradigm shift compared to conventional approaches, which to date have only shown an unremarkable slowing of progression. In addition to being well tolerated to date, the durability of changes to areas of atrophy and improvements in visual acuity support the continued and rapid clinical development of OpRegen. Alongside our advisors, we currently are preparing for multiple engagements with FDA to discuss aspects of OpRegen's designation, our manufacturing plans, and the design of a later-stage clinical trial to begin next year. We anticipate the first of these engagements will begin next month and continue in the first quarter of 2022."

OpRegen Phase 1/2a Interim Clinical Trial Results

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- Restoration was evidenced by the presence of new areas of RPE monolayer with overlying ellipsoid zone, external limiting membrane, and outer nuclear layer, which were not present at the time of baseline assessment.
    - Reductions, or no progression for at least 1 year, was observed in the total area of GA in all four of these better vision Cohort 4 patients.
- Overall, using the Early Treatment Diabetic Retinopathy Study (EDTRS) assessment of best corrected visual acuity (BCVA), 7/12 (58%) of each of Cohort 4 patients' treated eye were at baseline or better at 15 months or last time point, which extends beyond 3 years in some patients. In comparison, at the same time points, 8/12 (67%) were below baseline in those same patients' fellow untreated eyes.
    - All four retinal restoration patients reported improvements in their visual acuity, which has been maintained for at least 12 months in all four of those patients.
- Across the study, in patients with previously reported structural improvements in the retina, decreases in drusen density, and a trend toward slower GA progression in treated compared to untreated eyes continue to be present.
- Evidence of durable engraftment of OpRegen RPE cells has extended to more than 5 years in the earliest treated patients, supporting the potential for OpRegen to be a one-time treatment.

Overall, OpRegen has been well tolerated to date and there have been no new, unexpected ocular or systemic adverse events or serious adverse events that have not been previously reported.

About OpRegen

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 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 is 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 is a registered trademark of Cell Cure Neurosciences Ltd., a majority-owned subsidiary of Lineage Cell Therapeutics, Inc.

About Age-Related Macular Degeneration

Age-related macular degeneration (AMD) is an eye disease that can blur the sharp, central vision in patients and is the leading cause of vision loss in people over the age of 60. There are two forms of AMD: dry (atrophic) AMD and wet (neovascular) AMD. Dry (atrophic) AMD is the more common of the two forms, accounting for approximately 85-90% of all cases. In atrophic AMD, parts of the macula get thinner with age and accumulations of extracellular material between Bruch's membrane and the RPE, known as drusen, increase in number and volume, leading to a progressive loss of central vision, typically in both eyes. Global sales of the two leading wet AMD therapies were in excess of $10 billion in 2019. Nearly all cases of wet AMD eventually will develop the underlying atrophic AMD if the newly formed blood vessels are treated correctly. There are currently no U.S. Food and Drug Administration (FDA), or European Medicines Agency, approved treatment options available for patients with atrophic AMD.

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 immune-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," "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 potential benefits of treatment with OpRegen in dry AMD patients with GA, the significance of clinical data reported to date from the ongoing Phase 1/2a study of OpRegen, including the findings of retinal tissue restoration, Lineage's plans to meet with the FDA to discuss OpRegen's clinical development, the potential utilization of OCT imaging to measure efficacy in a pivotal clinical trial of OpRegen for the treatment of dry AMD with GA, and the potential for Lineage's investigational allogeneic cell therapies to provide safe and effective treatment for multiple, diverse serious or life threatening conditions. 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 treatment with OpRegen in dry AMD patients with GA may not provide the benefits anticipated, the risk that interim results from clinical trials may not be predictive of future results, including later clinical trial results, and that interim data from clinical trials may change as more patient data become available and are subject to audit and verification procedures, 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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