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): **November 16, 2020**

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 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 8.01. Other Events.

On November 16, 2020, Lineage Cell Therapeutics, Inc. issued a press release announcing interim data from its ongoing Phase 1/2a study of OpRegen®. A copy of the press release is filed as an exhibit to this report and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated November 16, 2020
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: November 16, 2020

By: */s/ Chase C. Leavitt*
Name: Chase C. Leavitt
Title: General Counsel and Corporate Secretary

LINEAGE CELL THERAPEUTICS PRESENTS NEW OPREGEN® DATA FOR DRY AMD WITH GA AT 2020 AMERICAN ACADEMY OF OPHTHALMOLOGY ANNUAL MEETING

- **Improved Visual Acuity Continues to be Observed in Cohort 4 Patients**
- **First Known Clinical Report of Retinal Tissue Regeneration Persisted to 23 Months with Further Improvement in Visual Acuity**
- **Patient Enrollment Recently Completed**
- **Therapeutic Expert Call with Principal Investigator Christopher D. Riemann, M.D. Scheduled for November 17, 2020 at 4:00 pm Eastern Time**

CARLSBAD, CA – November 16, 2020 - Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing three novel cell therapies for serious medical conditions, today announced positive interim results from the ongoing 24-patient Phase 1/2a clinical study of Lineage's lead product candidate, OpRegen®. OpRegen is an investigational cell therapy consisting of allogeneic retinal pigment epithelium (RPE) cells administered to the subretinal space for the treatment of dry age-related macular degeneration (AMD) with geographic atrophy (GA). At AAO, new data were presented on 20 patients, including 8 patients treated in Cohort 4, which feature better baseline vision and smaller areas of GA. All 8 of these patients were treated with a new "thaw-and-inject" formulation of OpRegen and 4 were treated using the Gyroscope Orbit Subretinal Delivery System (Gyroscope SDS). Data presented at AAO showed improvements in visual acuity in Cohort 4 patients, with treated versus fellow eye comparisons reaching statistical significance at 9 and 12 months following OpRegen administration. These improvements were maintained for up to 24 months in some patients. A trend towards slower GA growth was observed in the first 6 Cohort 4 patients, a trend maintained for as long as 24 months in patients with 24-month data available. Previously reported structural improvements in the retina and decreases in drusen density have continued with evidence of durable engraftment of OpRegen cells in treated patients, some more than 4 years following administration, with no immunosuppression utilized beyond the perioperative period. Overall, OpRegen appears to be well-tolerated in all patients treated to date. The final four patients in the study were treated during November and will provide additional visual acuity data in the coming months.

"These new data increasingly suggest to us that treatment with OpRegen can provide clinically meaningful outcomes in dry AMD patients with GA, particularly for those with earlier-stage disease," stated Brian M. Culley, Lineage CEO. "According to a recent survey published in Investigative Ophthalmology & Visual Science, only 27% percent of retinal specialists believed patients with visual acuity of 20/200 or worse could benefit from treatment with an agent which slows the growth of GA, while 93-99% of them believed patients with visual acuity of 20/200 or better could benefit from this approach. This is consistent with our belief that recent data from our Cohort 4 patients, which have less advanced disease and better baseline vision, are more exciting and provide a better surrogate for the potential clinical and commercial opportunity for OpRegen."

Mr. Culley added, "In addition to reporting the first known finding of anatomical restoration of retinal tissue, which has persisted below baseline for 23 months and counting, treatment with OpRegen continues to demonstrate other benefits in some patients, including increases in visual acuity, reductions in the growth rate of GA and increases in reading speed. These are additive to the improvements we previously reported in retinal architecture and drusen reduction. Further, the multi-year durability of transplants without rejection is notable for our allogeneic cell therapy approach, especially as patients did not require long-term immunosuppression. With enrollment recently completed, our focus turns next toward collecting safety and efficacy data on the most recently treated patients, advancing partnership and investor discussions we've been having, exploring our options for later-stage clinical development, and speaking with the FDA about next steps. Our objective is to position the OpRegen program as a front-runner in the race to address an unmet need in what is widely expected to be a multi-billion-dollar dry AMD therapeutic market and to drive Lineage forward as the pre-eminent allogeneic cell therapy company."

OpRegen Data Update & Highlights from the AAO Presentation (data presented on 20 patients, dosed through October 5, 2020):

- **Continued progressive functional improvement.**
  - In Cohort 4, 6 out of 7 (86%) of patients' treated eyes measured above their baseline vision (Best Corrected Visual Acuity, or BCVA) at 12 months, a clinically relevant timeframe, or as of the longest available timepoint less than 12 months (data collection continues for more recently-treated patients).
  - Data to date demonstrate a localized slowing of GA progression in the treated areas with a trend towards slower GA growth in treated versus fellow eyes in pooled analyses.
- **Long-term engraftment** is supported with imaging observations up to more than 4 years, even with a short immunosuppression regimen.
  - In all Cohort 4 patients receiving OpRegen TAI formulation, per protocol, immunosuppressants have been discontinued as scheduled, typically within 90 days post-operatively, and no cases of acute or delayed rejection or inflammation have been reported.
  - One Cohort 4 patient was treated only with mycophenolate mofetil and received no tacrolimus for immunosuppression.
- **Anatomical restoration of retinal tissue.**
  - A Cohort 4 patient with evidence of retinal restoration and confirmed history of GA growth, which was first reported at 9 months, continues at month 23 to have an area of GA smaller than at baseline.
  - This patient also experienced additional improvement in BCVA from 9 to 23 months post-treatment, while the untreated eye has experienced further reduction in visual acuity.
  - Long-term monitoring on this patient is expected to continue
- **Treatment overview.**
  - As of October 5, 2020, 16 patients were treated via pars planar vitrectomy (PPV), while 4 were treated with the Gyroscope SDS.
  - As of November 10, 2020, 17 patients were treated via PPV, while 7 were treated with the Gyroscope SDS.
  - Enrollment in the phase 1/2a study is complete; follow-up continues for safety and efficacy.
- **Safety and tolerability.**
  - The primary objective of the study is to evaluate the safety and tolerability of OpRegen at 12 months, and in patients which have reached this time point OpRegen appears well tolerated.
  - There have been no unexpected adverse events (AEs) or treatment-related systemic serious AEs reported in enrolled patients.
  - The most common and expected ocular AEs were the formation or exacerbation of mild to moderate epiretinal membranes (ERMs) and a single report of a retinal detachment, with cause unknown (all occurring in patients receiving OpRegen via the PPV route of administration).
  - The Gyroscope SDS is an alternative to the PPV route and is designed to avoid ERM formation.
    - Through October 2020, 16 patients were treated via PPV while 4 were treated with the Gyroscope SDS. ERMs were observed in 13 PPV patients.
    - One patient treated with the Gyroscope SDS developed a mild choroidal neovascularization (CNV) at the site of needle penetration 6 months post-treatment which was successfully treated with a single dose of an approved anti-VEGF agent. The cause was unknown.
    - One patient treated via PPV developed a mild CNV at > 24 months post-treatment.
  - Other changes observed following OpRegen treatment persisted through the last time point examined (> 4 years in some patients), including subretinal pigmentation and hyper-reflective areas seen on optical coherence tomography (OCT).

The results were presented at the 2020 American Academy of Ophthalmology Annual Meeting (AAO 2020). The presentation, *"Phase 1/2a Study of Subretinally Transplanted hESC-Derived RPE Cells in Advanced Dry-Form AMD Patients"* was featured as part of the Original Paper Session, OP02V Retina, Vitreous Original Papers on November 15, 2020 and was presented by Christopher Riemann, M.D.

KOL Call and Webcast

Lineage will host a therapeutic area expert call with Christopher D. Riemann, M.D., Vitreoretinal Surgeon and Fellowship Director, Cincinnati Eye Institute and University of Cincinnati School of Medicine, to discuss the interim results on November 17, 2020 at 4:00 pm Eastern Time / 1:00 p.m. Pacific Time. Interested parties can access the event on the Events and Presentations section of Lineage's website.

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 (vision from 20/65 to 20/250 with smaller 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. In total, 17 patients were treated via PPV, while 7 were treated with the Gyroscope SDS. 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. Additionally, for the patients in Cohort 4 that receive subretinal delivery of OpRegen utilizing the Gyroscope SDS, objectives will include the evaluation of the safety of delivery of OpRegen using the Gyroscope SDS.

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

About Dry AMD

Dry age-related macular degeneration (AMD) is a leading cause of adult blindness in the developed world. There are two forms of AMD: wet AMD and dry AMD. Dry AMD is the more common of the two types, accounting for approximately 85-90% of cases. Wet AMD is the less common of the two types, accounting for approximately 10-15% of cases. Global sales of the two leading wet AMD therapies were in excess of $10 billion in 2019. Nearly all cases of wet AMD begin as dry AMD. Dry AMD typically affects both eyes. There are currently no U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA) approved treatment options available for patients with dry 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) VAC, an allogeneic dendritic cell therapy platform for immuno-oncology and infectious disease, 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.

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 the development plans for OpRegen and post-enrollment timing expectations. 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.

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