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): **October 14, 2019**

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

California	**1-12830**	**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 October 14, 2019, Lineage Cell Therapeutics, Inc. issued a press release announcing interim data from its ongoing Phase I/IIa 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 October 14, 2019

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: October 15, 2019

By: */s/ Brian M. Culley*
Name: Brian M. Culley
Title: Chief Executive Officer

LINEAGE CELL THERAPEUTICS PRESENTS NEW OPREGEN® DATA AT AMERICAN ACADEMY OF OPHTHALMOLOGY ANNUAL MEETING

Treatment with OpRegen Continues to be Well Tolerated with Increased Visual Acuity Observed in Cohort 4 Patients

CARLSBAD, CA – October 14, 2019 - Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs, today announced positive additional results from an ongoing Phase I/IIa study of its lead product candidate, OpRegen®, a retinal pigment epithelium cell transplant therapy currently in development for the treatment of dry age-related macular degeneration (dry AMD). The results were presented at the 2019 American Academy of Ophthalmology Annual Meeting (AAO 2019) in San Francisco, CA on October 14 th, 2019. Data from the study demonstrate that treatment with OpRegen continues to be well tolerated and, at the furthest time point collected, all four Cohort 4 patients treated to date have better visual acuity on an Early Treatment Diabetic Retinopathy Scale (ETDRS) in the treated eye (range +8 to +19 letters) than in the untreated eye (range -2 to +7 letters). The largest increase recorded at any single timepoint in a Cohort 4 patient was +22 letters. Cohort 4 patients have better baseline vision and less advanced disease than Cohorts 1-3 patients, who were legally blind at baseline. Previously reported structural improvements in the retina and decreases in drusen density observed in some patients have been maintained and there is evidence of the continued presence of transplanted OpRegen cells in patients treated in the first 3 cohorts, some over 3 years following administration. Of note, the first patient successfully dosed using the Orbit Subretinal Delivery System (Orbit SDS) as well as a new Thaw-and-Inject (TAI) formulation of OpRegen is also demonstrating signs of improved visual acuity having gained 13 letters in the 3 months following administration as assessed by ETDRS. Overall, OpRegen appears well tolerated with preliminary evidence of improved structural changes and potential improvement in visual acuity following treatment in some patients.

“We are encouraged by the interim data we have obtained so far from our clinical trial of OpRegen for dry AMD. We intend to collect longer time points and enroll additional Cohort 4 patients, but the anatomical changes to the retina, tolerability profile, and early Best Corrected Visual Acuity and geographic atrophy measurements we have collected are directionally promising, especially for a condition for which there are no FDA-approved options,” stated Brian Culley, CEO of Lineage. “Our near-term efforts will be to accelerate enrollment in the current study, which will increase our database of information and guide next steps for the development of OpRegen as a potential new treatment for dry AMD.”

Data presented at AAO showed that OpRegen, as well as both surgical procedures used to deliver OpRegen to the subretinal space via (i) pars plana vitrectomy (PPV) with retinotomy and (ii) the Orbit SDS, have been well tolerated. Notably, asymmetrical, reduced directional growth of the area of geographic atrophy (GA) in the treated area receiving OpRegen was observed in 3 patients. This finding will require additional long-term follow-up since GA expansion is a progressive but slow process. Imaging of several Cohort 1-3 patients, and of particular interest, those from the better vision Cohort 4, continue to demonstrate structural improvement within the retina and evidence of the continued presence of the transplanted OpRegen cells. Within the area of the OpRegen cell transplant, signs of a reduction and change in drusen material as well as improvements or possible restorations of the ellipsoid zone and retinal pigment epithelium (RPE) layers have persisted. The photoreceptor layer and ellipsoid zone assumed a more regular structural appearance in areas of the transition zone where OpRegen was administered, suggesting potential structural restoration of the retina in areas receiving the RPE cells. This is of particular importance because in dry AMD the structure of the retina can be impacted by the formation of excess drusen and ultimately death of RPE cells and photoreceptors, which are critical to sight. Other changes observed following OpRegen treatment persisted through the last time point examined (>3 years in some patients), included subretinal pigmentation and hyper-reflective areas seen on optical coherence tomography (OCT).

The Best Corrected Visual Acuity (BCVA) in eyes receiving OpRegen have not deteriorated more rapidly than expected and areas of GA have not progressed faster than historical averages. Taken together, there are early positive trends for both when compared with the untreated fellow eye. Importantly, the visual acuity of the first 4 Cohort 4 patients have all seen improvements from baseline levels and will be followed for longer periods of time. The next 5 Cohort 4 patients with less severe disease (i.e. smaller areas of GA and visual acuity of between 20/64 and 20/250), which is actively recruiting, will receive OpRegen via the Orbit SDS.

There have been no unexpected adverse events (AEs) or treatment-related systemic serious AEs reported in the first sixteen patients enrolled into this Phase I/IIa safety and tolerability study. 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, all occurring in patients receiving OpRegen via the PPV route of administration. The Orbit SDS is an alternative to the PPV route and is designed to avoid ERM formation. The next 5 patients treated are expected to receive OpRegen via the Orbit SDS rather than the PPV route of administration.

The abstract presentation, entitled, *"Phase 1/2a Study of Subretinally Transplanted Human Embryonic Stem Cell-Derived RPE Cells in Advanced Dry-Form AMD Patients"* was presented as part of the OP07 Retina, Vitreous Original Paper Session on Monday, October 14th, 2019 by Eyal Banin, M.D., Ph.D., Professor of Ophthalmology, Director, Center for Retinal and Macular Degenerations, Department of Ophthalmology at Hadassah-Hebrew University Medical Center (abstract number PA039).

The American Academy of Ophthalmology is the world's largest association of eye physicians and surgeons. A global community of 32,000 medical doctors, the AAO protects sight and empowers lives by setting the standards for ophthalmic education and advocating for our patients and the public. AAO innovates to advance our profession and to ensure the delivery of the highest-quality eye care. For more information, please visit www.aao.org or follow the academy on Twitter @AAO.

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 proprietary cell-based therapy platform and associated 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 either to 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 assets include (i) OpRegen®, a retinal pigment epithelium transplant therapy in Phase I/IIa 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 I/IIa development for the treatment of acute spinal cord injuries; and (iii) VAC2, an allogeneic cancer immunotherapy of antigen-presenting dendritic cells currently in Phase I development for the treatment of non-small cell lung cancer. Lineage is also evaluating potential partnership opportunities for Renevia®, a facial aesthetics product that was recently granted a Conformité Européenne (CE) Mark. 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 enrollment and development of Lineage's OpRegen Program. 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 described 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 filed with the SEC, including Lineage's Annual Report on Form 10-K filed with the SEC on March 14, 2019 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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