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 11, 2022 (May 3, 2022)**

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 May 3, 2022, Lineage Cell Therapeutics, Inc. ("Lineage," "we," "us," "our," or the "Company") issued a press announcing results from the ongoing Phase 1/2a clinical study of RG6501 (OpRegen®), a retinal pigment epithelial cell therapy currently in development for the treatment of geographic atrophy ("GA") secondary to age-related macular degeneration ("AMD"), that were presented at the 2022 Association for Research in Vision and Ophthalmology Annual Meeting on May 2, 2022. A copy of the press release is attached as Exhibit 99.1 to this report.

The information provided under this Item 7.01, including the information 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 provided under this Item 7.01, including the information 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.

Item 8.01. Other Events.

On May 3, 2022, Lineage announced results from the ongoing Phase 1/2a clinical study of OpRegen that support the potential for OpRegen to slow, stop or reverse disease progression in GA secondary to AMD. Twelve-month primary endpoint data demonstrated that OpRegen was well tolerated in the study with an acceptable safety profile. We also reported preliminary evidence of visual function and outer retinal structure improvements observed in Cohort 4 patients with GA and impaired vision. The Phase 1/2a study is an open-label, single-arm, multi-center, dose-escalation trial evaluating a single administration of OpRegen delivered subretinally in patients with bilateral GA secondary to AMD. Twenty-four subjects were enrolled into four cohorts. In all subjects, the worse eye based on best corrected visual acuity ("BCVA") was selected for OpRegen subretinal delivery and the other eye was untreated. In Cohorts 1-3 (n=12), all patients were legally blind at the outset of the trial (BCVA: ≤20/200, with a study eye mean of 23.5 letters, or approximately 20/320 (standard deviation (SD): ±11.7; minimum-maximum: 0–39 letters)) and had significant progression of GA (study eye mean GA area: 12.7 mm^2 (SD: ±6.7; min-max: 6–30 mm^2)). Cohort 4 (n=12) enrolled patients with impaired vision (BCVA: ≥20/250 and ≤20/64, with a study eye mean of 44.8 letters, or approximately 20/125 (SD: ±7.5; min-max: 28–54 letters)) and smaller areas of GA (study eye mean GA area: 7.4 mm^2 (SD: ±2.9; min-max: 1.4–11 mm^2)). OpRegen was delivered subretinally via pars plana vitrectomy and retinotomy (n=17) or, in Cohort 4 only, via suprachoroidal cannula using the Gyroscope Therapeutics, Ltd. Orbit Subretinal Delivery System (n=7). We completed enrollment in Cohorts 1-3 in the middle of 2018 and in Cohort 4 in November 2020.

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 potential activity of OpRegen by assessing changes in visual function and retinal structure. The primary objective and the secondary objectives were assessed at 12 months following OpRegen subretinal delivery ("Month 12") and subjects are followed for up to five years.

Summary of Safety Results (data cutoff: January 18, 2022)

- All 24 treated patients reported at least one adverse event ("AE") and at least one ocular AE.
- The majority of AEs reported with OpRegen were mild (Cohorts 1-3, 87%; Cohort 4, 93%), and the immunosuppressive regimen was well tolerated.
- The ocular AEs reported with OpRegen were mainly related to the surgical procedures used for subretinal delivery, with the most common being conjunctival hemorrhage/hyperemia (n=17) and epiretinal membrane (n=16).
- One patient discontinued the study due to an AE that was determined unrelated to treatment.
- No cases of rejection following OpRegen subretinal delivery have been reported.
- No acute or delayed intraocular inflammation, or sustained intraocular pressure increase following OpRegen subretinal delivery has been observed.

Summary of Activity Results (data cutoff: January 18, 2022)

- Preliminary evidence of improvement in visual function using the Early Treatment Diabetic Retinopathy Study ("ETDRS") assessment of BCVA:

    - Cohort 4 subjects (n=12) had an average 7.6 letter gain in the study (treated) eye and an average 1.7 letter gain in the fellow (untreated) eye at Month 12 compared to baseline. Cohorts 1-3 subjects (n=11) had an average 4.7 letter gain in the study eye and an average 6.0 letter gain in the fellow eye at Month 12 compared to baseline.

    - Three subjects in Cohort 4, or 25% of Cohort 4, and one subject in Cohorts 1-3 had a 15 letter or greater gain in the study eye at Month 12 compared to baseline. None of the fellow (untreated) eyes had a 15 letter or greater gain.

- Five Cohort 4 subjects with OpRegen delivered to most or all of the GA area, including the fovea, had greater gains in visual function at Month 12 (average 12.8 letter gain) as compared with subjects who did not receive OpRegen in a similar manner to most or all of the GA area, with evidence for regions of apparent improvement of outer retinal structure as assessed by spectral domain optical coherence tomography ("SD-OCT").

- SD-OCT imaging analysis of all subjects is ongoing.

These data support the potential for OpRegen to slow, stop, or reverse disease progression in GA. Further assessment of the optimal disease stage for intervention, surgical procedure for subretinal delivery, and target delivery location of OpRegen in a larger, controlled clinical study is needed to confirm these preliminary findings.

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," "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 patients with GA, the significance of clinical data reported to date, including the findings of evidence of visual function and outer retinal structure improvements, from the ongoing Phase 1/2a study of OpRegen. 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 report, including, but not limited to, the risk that positive findings in early clinical and/or nonclinical studies of a product candidate may not be predictive of success in subsequent clinical and/or nonclinical studies of that candidate; the risk that competing alternative therapies may adversely impact the commercial potential of OpRegen; 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; the risk that Lineage may not be able to manufacture sufficient clinical quantities of its product candidates in accordance with current good manufacturing practice; risks and uncertainties inherent in Lineage's business and other risks discussed 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 May 3, 2022
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: May 11, 2022

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

Exhibit 99.1

RG6501 (OPREGEN®) PHASE 1/2A CLINICAL RESULTS SUPPORT THE POTENTIAL FOR OPREGEN TO SLOW, STOP OR REVERSE DISEASE PROGRESSION IN GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION

- **12-Month Primary Endpoint Data Suggest OpRegen is Well Tolerated with an Acceptable Safety Profile**
- **Preliminary Evidence of Visual Function and Outer Retinal Structure Improvements Observed in Cohort 4 Patients with GA and Impaired Vision**
- **Data Reported at 2022 ARVO Meeting by Allen C. Ho, M.D., FACS**

CARLSBAD, CA – May 3, 2022 - Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing allogeneic cell therapies for unmet medical needs, today announced that results from the primary endpoint, safety and tolerability 1 year post-transplant, in the ongoing Phase 1/2a clinical study of RG6501 (OpRegen), a retinal pigment epithelial cell therapy currently in development for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD), were presented yesterday at the 2022 Association for Research in Vision and Ophthalmology Annual Meeting (ARVO 2022). The presentation, *"Safety and Efficacy of a Phase 1/2a Clinical Trial of Transplanted Allogeneic Retinal Pigmented Epithelium (RPE, OpRegen) Cells in Advanced Dry Age-Related Macular Degeneration (AMD)"* was featured as part of the Retinal Prostheses and Transplantation Session, by Allen C. Ho, M.D., FACS, Wills Eye Hospital Attending Surgeon and Director of Retina Research, Professor of Ophthalmology, Thomas Jefferson University, Mid Atlantic Retina and President, The Retina Society (abstract number 3714956). RG6501 (OpRegen) is currently being developed under an exclusive worldwide collaboration between Lineage, Roche and Genentech, a member of the Roche Group.

"These data, though uncontrolled, offer the promising demonstration that OpRegen may be able to impact GA disease progression in a clinically meaningful manner, particularly when delivered on-target and in earlier disease, in patients afflicted with what was previously thought to be an inevitably progressive disease," stated Dr. Ho. "Obviously, larger, controlled studies are required, but spontaneous disease regression does not occur in GA so these results suggest that OpRegen may be a potentially transformational therapy and strongly support further development."

2022 ARVO Presentation Highlights

Summary of Safety Results

- All 24 treated patients reported at least one adverse event (AE) and at least one ocular AE
- The majority of AEs reported with OpRegen were mild (Cohort 1-3, 87%; Cohort 4, 93%), and the immunosuppressive regimen was well tolerated
- Ocular AEs observed with OpRegen were mainly related to the surgical procedures used for subretinal delivery, with the most common being conjunctival hemorrhage/hyperemia (n=17) and epiretinal membrane (n=16)
- One patient discontinued the study due to an AE that was unrelated to treatment
- No cases of rejection, acute or delayed intraocular inflammation, or sustained increases in intraocular pressure following OpRegen subretinal delivery have been reported

Summary of Activity Results

- Preliminary evidence of improvement in visual function was observed in patients with GA and impaired vision at baseline (Cohort 4 [n=12])
    - Patients in Cohort 4 had an average 7.6 letter gain in visual acuity at 12 months in the study eye
    - Three patients in Cohort 4 (25%) had a 15 letter or greater gain in visual acuity at 12 months in the study eye
- Five patients in Cohort 4 with OpRegen delivered to most or all of the GA area, including the fovea, had greater gains in visual function (average 12.8 letter gain), with evidence for regions of apparent improvement of outer retinal structure as assessed by SD-OCT
    - The SD-OCT imaging analysis is ongoing

These data support the potential for OpRegen to slow, stop or reverse disease progression in GA. Further assessment of the optimal disease stage for intervention, surgical procedure for subretinal delivery and target delivery location of OpRegen in a larger, controlled clinical study is needed to confirm these findings.

Dr. Ho's presentation is available on the Events and Presentations section of Lineage's website.

The Association for Research in Vision and Ophthalmology, Inc. (ARVO) was founded in 1928 in Washington, DC by a group of 73 ophthalmologists. ARVO is the largest and most respected eye and vision research organization in the world. ARVO members include nearly 11,000 researchers from over 75 countries. ARVO advances research worldwide into understanding the visual system and preventing, treating and curing its disorders. For more information, please visit https://www.arvo.org/ or follow the association on Twitter @ARVOInfo.

About OpRegen

OpRegen® is a retinal pigment epithelial cell therapy in development for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration. Following subretinal delivery, OpRegen has the potential to counteract RPE cell loss in areas of GA lesions by supporting retinal structure and function. OpRegen is being developed under a worldwide collaboration between Lineage, Roche and Genentech, a member of the Roche Group.

About the Phase 1/2a Study

The Phase 1/2a study is an open-label, single-arm, multi-center, dose-escalation trial evaluating a single administration of OpRegen delivered subretinally in patients with bilateral GA. Twenty-four patients were enrolled 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 patients with impaired vision (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 activity of OpRegen treatment by assessing the changes in ophthalmological parameters measured by various methods of primary clinical relevance.

About Geographic Atrophy

Geographic atrophy (GA) is an advanced form of age-related macular degeneration (AMD) characterized by severe loss of visual function. GA is a leading cause of adult blindness in the developed world, affecting at least 5 million people globally. There are two forms of advanced AMD: neovascular AMD and GA. GA and neovascular AMD can occur simultaneously in the same eye, and patients treated for neovascular AMD may still go on to develop GA. GA 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 GA.

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 five allogeneic ("off-the-shelf") product candidates: (i) OpRegen, a retinal pigment epithelial cell therapy in Phase 1/2a development for the treatment of geographic atrophy secondary to age-related macular degeneration; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; (iii) VAC2, a 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 (iv) ANP1, an auditory neuronal progenitor cell therapy for the potential treatment of auditory neuropathy, and (v) PNC1, a photoreceptor neural cell therapy for the treatment of vision loss due to photoreceptor dysfunction or damage. For more information, please visit www.lineagecell.com or follow the company on Twitter @LineageCell.

Forward-Looking Statements

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