



Lineage Cell Therapeutics Issues Letter to Stockholders

January 5, 2026

CARLSBAD, Calif.--(BUSINESS WIRE)--Jan. 5, 2026-- [Lineage Cell Therapeutics, Inc.](#) (NYSE American and TASE: LCTX), a clinical-stage biotechnology company developing novel allogeneic, or “off the shelf,” cell therapies for serious medical conditions, today published a letter to shareholders highlighting the company’s achievements throughout 2025 and its corporate outlook for 2026.

To Our Shareholders:

As we conclude a successful 2025, I want to extend my appreciation for your continued support of Lineage Cell Therapeutics and our mission to pioneer the emerging field of allogeneic cell therapy. I also wish to provide an outline for how we plan to continue our success in 2026.

The field of cell therapy has revolutionized oncology, saving lives and creating substantial shareholder value. But opportunities to build on success in that field appear increasingly difficult or marginal. We believe the next frontier of value-creation in cell therapy resides in *non-oncology* indications, such as neurology, ophthalmology, and metabolic diseases. We also believe Lineage is uniquely positioned to capitalize on this opportunity, mainly by applying our proprietary cell manufacturing technology to the production and transplantation of differentiated cell types.

Lineage is helping usher in this new branch of medicine by demonstrating the value of administering mature, differentiated cells, which are intended to replace the same type of cells which the patient lost to various conditions, such as dry age-related macular degeneration (dry-AMD), spinal cord injury, hearing loss, and Type 1 Diabetes. We prefer the term *cell transplant* to cell therapy because we don’t administer “stem cells” to patients. Instead, we create and deliver mature, differentiated and functionally active “replacement” cells that are substantially identical to the cells which an individual has lost due to disease or trauma. Those cells have been transplanted in a one-time procedure to treat conditions caused by the loss or dysfunction of a specific cell type. We summarize our unique approach to cell therapy as “replace and restore”. Each of our product candidates is allogeneic and utilizes a single, carefully selected and cultured cell line for the life of the product, which eliminates donor variability and reduces regulatory and clinical risk.

The OpRegen[®] cell therapy program is a suspension of allogeneic retinal pigment epithelial (RPE) cells designed to replace the RPE cells that have been lost to disease. OpRegen is being developed under a worldwide collaboration with [Roche](#) and [Genentech](#) for the treatment of geographic atrophy (GA) secondary to dry-AMD and is currently in a phase 2a trial. Our second clinical-stage program, OPC1, is an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury. Our preclinical program, ReSonance[™] (ANP1), is an allogeneic auditory neuron progenitor cell transplant for hearing loss and was recently partnered with a world-leading hearing healthcare company to advance preclinical development. We also recently launched a preclinical program in Type 1 Diabetes and have several additional indications planned for future development.

Our long-term goal is to build upon the continued success of OpRegen and create a pipeline of similar cell-based assets, some of which we might choose to develop internally and some which we might seek to partner, but all based on our core technology and platform, and which utilize our extensive expertise in the directed differentiation and scalable production of pluripotent cells into discrete cell types of the human body.

We reported many notable events in 2025, which helped broaden investor interest, including a funded research collaboration agreement for preclinical development of ReSonance, our first internally developed product candidate, and the launch of our new islet cell initiative. Alongside those accomplishments, two additional milestones were notable because they provided significant elevation in our confidence in the future of our company. The first was the continued progress made with the OpRegen cell therapy program. The second was progress made with our proprietary in-house manufacturing platform, named AlloSCOPE[™].

OpRegen

OpRegen is our most advanced program to date and serves as a critical case study for our approach to cell transplantation. Dry-AMD with GA is an increasingly established indication with an educated patient population, but suffers from underwhelming treatment options. Our initial reports from our Phase 1/2a clinical study of improved anatomy, halting of atrophic progression, and improved vision in patients with dry-AMD were unprecedented, but were viewed perhaps as too preliminary to be fully appreciated by the investment community. However, we believe that Roche and Genentech leadership saw potential in our approach and provided clinical, operational and financial support to enable the program’s further development. And from their subsequent reporting of our data, it has been shown that a single dose of OpRegen cells can provide visual improvement lasting for at least **3 years** among patients who receive the cells at the target location. This is an exceptionally promising finding because dry-AMD is a condition that does not self-resolve and only leads to worsening vision. Perhaps more importantly, three independent groups also pursuing RPE transplants reported similar exceptional outcomes during 2025, providing considerable evidence in support of this novel mechanism.

Although data from Roche and Genentech’s ongoing phase 2a GAlette trial of OpRegen in approximately 60 patients remains forthcoming, it is notable that during 2025, Genentech opened 9 additional clinical sites, and previously acquired novel and proprietary surgical delivery devices from a competitor, in addition to seeking and receiving RMAT designation for OpRegen. Late last year, Lineage also received its first cash milestone from among the up to \$620 million of additional development and commercial milestones we are eligible for under our collaboration. Overall, we believe there is growing evidence of a commitment by our partners to OpRegen in the ongoing open-label study, so we therefore remain eager for future program updates.

The AlloSCOPE[™] (Allogeneic, Scalable, Consistent, Off-the-shelf, Pluripotent Cell Engineering) Platform

A second important achievement during 2025 was the success we demonstrated with our proprietary AlloSCOPE manufacturing platform. AlloSCOPE is a term we’re using to distinguish our methods and capabilities from our competitors. AlloSCOPE stands for Allogeneic, Scalable, Consistent,

Off-the-shelf, Pluripotent Cell Engineering, which highlights the key attributes of our in-house technology and which we believe includes the “table stakes” necessary to create a commercially successful allogeneic cell therapy. From our proprietary AlloSCOPE platform, we twice successfully completed a current Good Manufacturing Practice (“cGMP”) production run from a custom, two-tiered cell banking system, featuring a genetically-stable master cell bank (MCB) created from a single, well-characterized pluripotent cell line, which generated a working cell bank (WCB), which then provided the source material for a final cell-based product candidate that for one of our programs, was released and used in the clinic last year. This achievement is notable because we do not need to rely on hopeful speculation regarding our ability to scale pluripotent cells with the purity, potency, and regulatory quality required for clinical use: we have *reduced these steps to practice*, a standard which we believe sits beyond the reach of many of our competitors and which can become a valuable differentiator for our company.

The AlloSCOPE platform describes a differentiation and production modality from which we can manufacture millions of doses of an allogeneic, cell-based product derived from a single initial cell line, conferring consistent, cost-effective, and scalable cell-based production. Importantly, AlloSCOPE can be applied across multiple programs; and this is why we recently began to evaluate it as a solution to the massive production scale required for a commercially-viable islet cell therapy for the treatment of Type 1 Diabetes.

Together, progress with OpRegen and the AlloSCOPE platform have elevated our confidence in a successful future. With confidence in our future success as a tailwind, we have been investing further in our technology. Because our prior investments can be applied in some cases across different cell types, our cost to launch a new program can be very manageable. As a result, we now have two additional undisclosed cell types receiving initial Research & Development and/or Business Development investment, and we plan to share updates on those new initiatives during 2026.

One aspect of this expansion strategy is to help attract additional collaborations, as we demonstrated successfully with Roche/Genentech for OpRegen and [William Demant Invest A/S](#) for ReSonance. Collaborative models are central to our business, sharing development risk while maintaining disciplined capital allocation. We intend to remain selective in this regard, pursuing partnerships that amplify our advantages.

Another aspect of our strategy is pipeline diversification and expansion, which we are pursuing in a rigorous and selective way, intended to maximize the *per share* value of the company. That means striking a balance between capital raising and investing, and striking a second balance between partnered and internally owned assets. Our overall goal with this strategy is to pair our innovation with operational excellence in a disciplined and step-wise way, with the overall objective of enabling high-quality and effective cell therapy products to be made from our innovative platform at commercial scale for patients around the world.

To conclude, our work is grounded in the conviction that replacing lost or dysfunctional cells can restore function and fundamentally reshape many treatment paradigms. However, those cells need to be offered in a commercially viable (e.g. scalable, and off-the-shelf) format. This year, we made meaningful progress in strengthening our scientific, operational, and strategic foundations to support that vision, including:

- Advancing our clinical and preclinical pipeline
- Strengthening our proprietary AlloSCOPE platform and manufacturing capabilities
- Maintaining cash runway, financial discipline, and organizational focus

The year ahead will be exciting as we continue advancing our therapeutic candidates and pursue opportunities that broaden our platform. The biotech sector has struggled for years, but recent forecasts from trusted investment leaders suggest that clinical-stage companies with data readouts and other major events should find enhanced interest with institutional healthcare and generalist investors in 2026. To that end, we expect continued updates this year on our lead partnered program, OpRegen, based on Roche/Genentech’s public actions to date; we have a second program, OPC1, in clinical testing; we have two externally funded development collaborations; and we have demonstrated the capability to launch brand new, in-house programs in an economically efficient way.

Our priorities in 2026 will include achieving key clinical and financial milestones, expanding our manufacturing capability, and maintaining the organizational focus necessary to execute with consistency.

Our progress is the result of the commitment and expertise of our employees, the collaboration of our partners, and the confidence of our shareholders. We remain dedicated to delivering long-term value through scientific innovation and disciplined execution, and we look forward to updating you on our achievements in the coming year.

Thank you for your continued support of Lineage Cell Therapeutics.

Sincerely,

Brian Culley
Chief Executive Officer
Lineage Cell Therapeutics

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel allogeneic, or “off the shelf,” cell therapies for serious medical conditions. Lineage’s programs are based on its proprietary cell-based technology platform and associated development and manufacturing capabilities. From this platform, Lineage designs, develops, manufactures, and tests specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. These cells are created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages. Cells derived from such lineages are transplanted into patients in an effort to replace or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and to restore or augment the patient’s functional activity. Lineage’s pipeline currently includes: (i) OpRegen[®] cell therapy, a retinal pigment epithelial cell therapy in Phase 2a development under a worldwide collaboration with Roche and Genentech, a member of the Roche Group, 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 spinal cord injuries; (iii) ReSonance[™] (ANP1), an auditory neuronal progenitor cell therapy in development under a collaboration with William Demant Invest A/S for the potential treatment of auditory neuropathy; (iv) PNC1, a photoreceptor neural cell therapy for the potential treatment of vision loss due to photoreceptor dysfunction or damage; (v) RND1, a novel hypimmune induced pluripotent stem cell line being developed under a gene editing

partnership; and (vi) ILT1, a cell therapy initiative focused on islet cell transplants for the treatment of Type 1 Diabetes. For more information, please visit www.lineagecell.com or follow the company on X/Twitter [@LineageCell](https://twitter.com/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. In some cases, forward-looking statements 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,” “goal,” “suggest,” or the negative version of these words and similar expressions. Such forward-looking statements include, but are not limited to, statements relating to: Lineage’s ability to develop additional product candidates, including two undisclosed cell types currently under development, in an economically efficient way, and that such development will capitalize on any potential opportunities for non-oncology indications, create value, or maximize the per share value of the company; the broad potential for Lineage’s regenerative medicine platform to restore function and fundamentally reshape many treatment paradigms; Lineage’s ability to enter into additional partnerships and/or collaboration agreements to support development of current or potential future product candidates; the potential therapeutic benefits of OpRegen cell therapy in patients with GA secondary to AMD and the significance of the Phase 1/2a clinical study data reported to date; Roche and Genentech’s plans regarding further development of OpRegen, including their evaluation of proprietary surgical delivery devices, their commitment to the ongoing open-label study and our beliefs and expectations regarding Roche and Genentech’s provision of clinical, operational and financial support for the OpRegen program and any updates that may occur therefor; the potential of the AlloSCOPE platform and its ability to manufacture millions of doses of an allogeneic, cell-based product, including islets cells, derived from a single initial cell line, conferring consistent, cost-effective, and scalable cell-based production, across multiple programs, and the extent to which such ability will remain beyond the reach of many competitors; that the planned funding under the research collaboration agreement with WDI will fund all currently planned preclinical development of ReSonance (ANP1); and the plans and expectations with respect to OPC1. 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, but not limited to, the following risks: that development activities, preclinical activities, and clinical trials of our current or potential future product candidates may not commence, progress or be completed as expected due to many factors within and outside of our control; 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; that Roche and Genentech may not successfully advance OpRegen cell therapy or be successful in completing further clinical trials for OpRegen cell therapy and/or obtaining regulatory approval for OpRegen cell therapy in any particular jurisdiction; that competing alternative therapies, including by any independent groups also pursuing RPE transplants, may adversely impact the commercial potential of OpRegen cell therapy; that OPC1 clinical trials may not be successful; that the ongoing Israeli regional conflict may materially and adversely impact our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, all of which are conducted by our subsidiary in Jerusalem, Israel; that Lineage may not be able to manufacture sufficient clinical quantities of its product candidates in accordance with current good manufacturing practice; and those risks and uncertainties inherent in Lineage’s business and other risks discussed 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. 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 filed with the SEC and its other subsequent reports, which are available on the SEC’s website at www.sec.gov. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. Lineage undertakes no obligation to update any forward-looking statement 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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