UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from_____ to _____

Commission file number 001-12830

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

California	**94-3127919**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2173 Salk Avenue, Suite 200
Carlsbad, California 92008
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code **(442) 287-8990**

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	**LCTX**	**NYSE American LLC**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	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 to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the registrant's common shares on the NYSE American on June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was $146.3 million.

The number of common shares outstanding as of March 4, 2025 was 228,356,290.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2025 annual meeting of shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

Lineage Cell Therapeutics, Inc.
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PART I

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. "Business," Part I, Item 1A. "Risk Factors," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this report. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. Forward-looking statements in this report include, but are not limited to, statements about:

- the potential to receive developmental, regulatory, and commercialization milestone and royalty payments under our Collaboration and License Agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc.;
- our plans to research, develop and commercialize our product candidates;
- the initiation, progress, success, cost and timing of our clinical trials and other product development activities;
- the therapeutic potential of our product candidates, and the indications for which we intend to develop our product candidates;
- our ability to successfully manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;
- the potential of our cell therapy platform;
- our ability to obtain additional capital to fund our operations;
- the potential that holders of outstanding warrants to purchase our common shares will exercise such warrants on a cash basis;
- our expectations and plans regarding existing and potential future collaborations with third parties such as pharmaceutical and biotechnology companies, government agencies, academic laboratories, and research institutes for the discovery, development, and/or commercialization of novel cell therapy products;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- the potential scope and value of our intellectual property rights; and
- the effects on our operations of the Israeli regional conflict and broader regional conflict, other geopolitical conflicts, political and economic instability, public health emergencies and macroeconomic conditions.

Forward-looking statements reflect our views and expectations as of the date of this report about future events and our future performance and condition, and involve known and unknown risks, uncertainties and other factors that may cause our actual activities, performance, results or condition to be materially different from those expressed or implied by the forward-looking statements. You should refer to Part I, Item 1A. "Risk Factors" of this report for a discussion of important factors that may cause our actual activities, performance, results and condition to differ materially from those expressed or implied by our forward-looking statements. As a result of a variety of factors, including those discussed in Part I, Item 1A. of this report, our forward-looking statements may prove to be inaccurate, and the inaccuracy may be material. Accordingly, you should not place undue reliance on any forward-looking statement. We anticipate that subsequent events and developments may cause our current views and expectations to change. However, while we may elect to update the forward-looking statements in this report at some point in the future, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date after the date of this report.

You should read this report and the documents that we reference in this report completely and with the understanding that our actual future performance, results and condition may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

This report also contains market data, industry forecasts and other data made by independent parties and by us relating to market size and growth and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

All brand names or trademarks appearing in this report are the property of their respective owners. Solely for convenience, the trademarks and trade names in this report may be referred to without the symbols ® and ™, but such references should not be construed as any indication that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

Unless otherwise stated or the context requires otherwise, references in this report to "Lineage," the "Company," "our company," "we," "us," and "our" refer collectively to Lineage Cell Therapeutics, Inc. and its consolidated subsidiaries.

RISK FACTOR SUMMARY

Below is a summary of the material factors that make an investment in our common shares speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" in Item 1A of Part I of this report and should be carefully considered, together with other information in this report and our other filings with the Securities and Exchange Commission (the "SEC") before making investment decisions regarding our common shares.

- We are dependent on our third-party collaboration with F. Hoffmann-La Roche Ltd and Genentech, Inc to develop and commercialize RG6501 (OpRegen®). If our collaborators are not successful in developing and commercializing OpRegen and/or they terminate the collaboration, we will lose a significant source of potential revenue, development and potential regulatory approval of OpRegen may be significantly delayed, and we may not be successful in establishing an alternative strategic collaboration or pursuing independent development and commercialization of OpRegen.
- Any failure or delay in the successful transfer of manufacturing process know-how by us to Roche or the inability of Roche to manufacture comparable cells could halt or delay the continued development of OpRegen.
- We have incurred operating losses since inception, and we do not know if or when we will attain profitability.
- Our investigational allogeneic cell therapies represent a novel approach to the treatment of serious medical conditions, which gives rise to significant challenges. Clinical development of our product candidates is a lengthy and expensive process with a high level of uncertainty as to timing and ultimate outcome. We may not be successful in identifying new product candidates and neither we nor our collaborators may succeed in developing or obtaining regulatory approval to market and sell any of our product candidates.
- We will continue to spend a substantial amount of our capital on research and development, but we might not succeed in developing products and technologies that are safe and effective for their target indications or commercially viable.
- We will need to raise substantial additional capital to complete the development and seek regulatory approval of our product candidates and to commercialize products approved for marketing, if any, and capital raising transactions may cause dilution to our existing shareholders, restrict our operations, or require us to relinquish rights to or dilute our economic interest in our product candidates or technology. If we are unable to obtain adequate capital, we may delay, reduce, limit the pace of, suspend or discontinue our product and technology development programs, which could significantly harm our business and prospects and cause the market price of our common shares to decline.
- We may expend our limited resources to identify or pursue particular product candidates and fail to identify other new product candidates or to capitalize on other product candidates that may be more profitable or for which there is a greater likelihood of success.
- If we fail to meet our obligations under our in-license agreements, we may lose our rights to key technologies on which our business depends.
- All of our manufacturing operations currently are conducted at our facility in Jerusalem, Israel, and any event or condition, such as political and economic conditions in Israel, war, terrorist attacks or other armed conflicts, that significantly disrupts our ordinary course of operations at our Jerusalem facility could harm our business and materially and adversely affect our financial condition and operating results. Further, our operations in Israel expose us to additional business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.
- Our subsidiary Cell Cure Neurosciences Ltd. has received Israeli government grants for certain of its research and development activities. The terms of these grants may require us to seek approvals and to satisfy specified conditions to manufacture products and transfer or license grant-supported technologies outside of Israel. In the context of such approvals, we will be required to pay penalties in addition to the repayment of the grants.
- We have relied on grant funding from CIRM (defined below) to support clinical development of OPC1 and we may not be able to obtain additional CIRM funding on a timely basis, or at all, which could adversely impact our ability to conduct and complete the DOSED clinical study of OPC1 (described below). In addition, our profits from the sale of products resulting from CIRM-funded development, if any, will be reduced by amounts that we are required to pay CIRM.
- Our business could be adversely affected if we lose the services of the key personnel upon whom we depend or if we fail to attract and retain senior management and key scientific personnel.
- Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

- Government-imposed bans or restrictions and religious, moral, and ethical concerns about the use of human embryonic stem cells could prevent us from developing and successfully marketing stem cell products.
- Some of our product candidates may be considered combination products by the U.S. Food and Drug Administration ("FDA") and other regulatory authorities, which could increase the complexity, cost and timeline for their development and regulatory approval.
- Considerable uncertainty exists regarding how federal government policy and budget decisions will unfold under the new U.S. presidential administration and legislation and legislative, executive and regulatory proposals and actions may adversely affect our business.
- Disruptions at the FDA and other government agencies, including due to a lack of funding, changes in leadership or significant personnel turnover, could delay or disrupt clinical and preclinical development and potential marketing approval of our product candidates and hinder our ability to raise additional capital.
- The FDA granted orphan drug designation to OPC1 for the treatment of acute spinal cord injuries, but there is no guarantee we will be able to maintain, or obtain the benefits associated with, such designation.
- The results of preclinical studies and early clinical trials are not necessarily predictive of future results.
- Interim, topline and preliminary data from clinical trials of our product candidates that we or our collaborators publicly disclose from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in final clinical data that is materially different and unfavorable.
- The manufacture of our cell therapy product candidates is complex, highly regulated and subject to a multitude of risks. We have limited experience manufacturing our product candidates on a clinical scale and no experience manufacturing on a commercial scale. Any failure to manufacture our product candidates in sufficient quantities in accordance with applicable quality standards and regulatory requirements and at acceptable costs may result in significant clinical development delays, or impair the ability to obtain approval for or commercialize our product candidates.
- Because developing cell therapy products is based on novel technologies that are unproven and may not result in approvable or marketable products, the lack of success, or perceived lack of success, of other companies developing or seeking to develop cell therapy products may adversely impact investor sentiment regarding our business and the market opportunities for our product candidates.
- Changes in or disruptions to the manufacturing operations and processes for our product candidates could significantly delay and increase the costs of clinical development and commercialization, if approved.
- The commercial success of any product candidate will depend upon the degree of market acceptance by physicians, patients and third-party payors.
- We face significant competition and the possibility that our competitors may develop therapies that are more effective, safer, more convenient, or less expensive than our product candidates. In addition, competitive products may be approved and successfully commercialized before ours, which may adversely affect our ability, or that of a strategic collaborator, to successfully commercialize our product candidates.
- We face potential product liability claims, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use or misuse of our products or product candidates harm patients or is perceived to harm patients, our regulatory approvals could be revoked, suspended or otherwise negatively affected, and our reputation could suffer.
- We currently have no marketing and sales force or distribution capabilities.
- Our intellectual property may be insufficient to protect our products and we may become subject to claims of infringement of the intellectual property of others.
- We rely on third parties, including strategic collaborators, clinical research organizations, medical institutions, clinical investigators, consultants, sole source suppliers of specialized materials and equipment, to advance the development of our product candidates and we may encounter significant challenges or delays as a result of our lack of control over those third parties, including increased costs and timelines for clinical trials of our product candidates.
- The market price of our common shares has been and may continue to be volatile.
- Insiders continue to have substantial influence over our company, which could limit your ability to influence the outcome of key transactions, including a change of control.
- There is no assurance that we will be able to maintain compliance with the NYSE American's continued listing standards, and failure to do so could result in the suspension of trading or delisting of our common shares, which could substantially impair our shareholders' ability to sell their shares and our ability to raise additional capital.

ITEM 1. BUSINESS

Overview

We are a clinical-stage biotechnology company developing novel allogeneic, or "off-the-shelf," cell therapies for serious neurological and ophthalmic conditions. Our programs are based on our proprietary, cell-based technology platform and associated development, formulation, delivery and manufacturing capabilities. From this platform, we design, develop, manufacture, and test specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. The cells we manufacture are produced by applying directed differentiation processes to established, well-characterized, and self-renewing pluripotent cell lines. These processes are based on specific developmental lineages and generated cells with desired characteristics. Functional cells developed from such lineages and which are relevant to the underlying condition are transplanted into patients in an effort to (a) *replace* or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and (b) *restore* or enhance the patient's functional activity.

Our business strategy is to efficiently leverage our technology platform and our development and manufacturing capabilities to advance our programs internally or in conjunction with strategic partners to further enhance their value and probability of success.

A significant area of focus is a collaboration we entered into with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively or individually, “Roche” or “Genentech”), under which our lead cell therapy program known as OpRegen®, is being developed for the treatment of ocular disorders, including geographic atrophy (“GA”) secondary to age-related macular degeneration (“AMD”). OpRegen (also known as RG6501) is a suspension of human allogeneic retinal pigmented epithelial (“RPE”) cells and is currently being evaluated in a Phase 2a multicenter clinical trial in patients with GA secondary to AMD which is referred to as the “GAlette Study”. OpRegen subretinal delivery has the potential to counteract RPE cell loss in areas of GA lesions by supporting retinal cell health and improving retinal structure and function. Under the terms of the Collaboration and License Agreement we entered into with Roche in December 2021 (the “Roche Agreement”), we received a $50.0 million upfront payment in January 2022 and are eligible to receive up to an additional $620.0 million in developmental, regulatory, and commercialization milestone payments. We also are eligible to receive tiered double-digit percentage royalties on net sales of OpRegen in the U.S. and other major markets. In May 2024, we entered into an additional agreement with Genentech (“Services Agreement”) pursuant to which we agreed to provide Genentech with supplemental clinical, technical, training, manufacturing, and procurement services that support the ongoing advancement of the OpRegen program in exchange for certain payments. In September 2024, Roche and Genentech announced receipt of Regenerative Medicine Advanced Therapy (“RMAT”) designation from the U.S. Food and Drug Administration (“FDA”) for OpRegen for the treatment of GA secondary to dry AMD.

Our most advanced internally owned product candidate is OPC1, an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury (“SCI”). Improved functional activity can lead to greater mobility and enhanced quality of life for patients and significant cost-savings for caregivers and payors. OPC1 also has an extensive long-term safety profile based on two clinical trials conducted to date: a five-patient Phase 1 safety trial in acute thoracic SCI, where all active subjects have been followed for at least 13 years, and a 25-patient Phase 1/2a multicenter dose-escalation trial in subacute cervical SCI, where all active subjects were evaluated for at least 7 years. Results from these studies have been published in the Journal of Neurosurgery Spine. OPC1 clinical development has been supported in part by a $14.3 million grant from the California Institute for Regenerative Medicine (“CIRM”). We plan to apply for additional funding from CIRM to support continued clinical development of OPC1 for the treatment of SCI when CIRM begins accepting new applications, which they have indicated they will do in Spring 2025. See “Grants from Government Entities – Grants from the California Institute for Regenerative Medicine,” below. In December 2023, we filed an Investigational New Drug (“IND”) amendment for OPC1 as it relates to our proposed DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical study, to evaluate the safety and utility of a novel spinal cord delivery device designed to administer OPC1 to the spinal parenchyma in subacute and chronic SCI patients. In March 2024, we received written correspondence from the FDA, advising us that due to their significant workload and conflicting PDUFA priorities at the agency, its review of our IND amendment and the DOSED study protocol was still ongoing, which remained so throughout 2024. On January 31, 2025, the FDA informed us that we could proceed with the DOSED study and shortly thereafter we announced that we were initiating the study. The study will enroll both subacute (between 21 to 42 days following injury) and chronic (between 1 to 5 years following injury) SCI patients. The DOSED study will be the first

study of OPC1 to include patients with a chronic injury, a condition which comprises the majority of SCI patients. We expect DOSED will enable subsequent studies aimed to demonstrate OPC1's ability to impact functional outcomes. UC San Diego Health, was named as the first participating site for the DOSED study. The DOSED study is expected to commence enrollment in the second quarter of 2025. See "Clinical Stage Cell Transplant Programs – OPC1," below for additional information.

Our complete pipeline of allogeneic, or "off-the-shelf", neurology and ophthalmic cell therapy programs currently available to us for development includes:

- *OpRegen (RG6501)*, an allogeneic RPE cell replacement therapy currently in a Phase 2a multicenter, open-label, single arm clinical trial, the GAlette Study, being conducted by Genentech, for the treatment of GA secondary to AMD.
- *OPC1*, an allogeneic oligodendrocyte progenitor cell therapy currently in a Phase 1b, multicenter, open -label safety trial, the DOSED study, which is designed to test the safety and utility of a novel spinal cord delivery device in subacute and chronic SCI patients. OPC1 continues to be evaluated in long-term follow-up from two completed Phase 1 and Phase 1/2a multicenter clinical trials in thoracic and subacute cervical SCI patients.
- ReSonance™ (ANP1), an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of sensorineural hearing loss.
- *PNC1*, an allogeneic photoreceptor cell transplant currently in preclinical development for the treatment of vision loss due to photoreceptor dysfunction or damage.
- *RND1,* a cell transplant program for an undisclosed indication, currently being developed through a gene editing collaboration with Factor Biosciences Limited.
- *A proprietary hypoimmune cell line,* which may have utility in additional central nervous system indications.

Other Programs and Technologies

Although we have to date focused on neurological and ophthalmic cell types, the pluripotent cells which our platform is based on are capable of becoming any of the cell types of the human body. We currently maintain a list of additional undisclosed product candidates which may be considered for development, or partnership in the future, and which altogether cover a range of therapeutic areas and conditions. Generally, these product candidates are based on the same platform technology and employ a similar guided cell differentiation and transplant approach as the product candidates detailed above, but in some cases may also include genetic modifications designed to enhance efficacy and/or safety profiles. We may elect not to develop or partner any of these product candidates.

In addition to seeking to create value for shareholders by developing product candidates through clinical development, we also may seek to create value from our intellectual property or related technologies and capabilities, through licensing collaborations and/or other strategic transactions.

Select Business Highlights

We and our partners have achieved numerous clinical, strategic and operational milestones.

- Ongoing execution of Lineage's contributions to our collaboration with Roche and Genentech for the development of OpRegen (RG6501) across multiple functional areas.
- Entered into a separate Services Agreement with Genentech to further support development of OpRegen (RG6501), including: (i) activities to support the ongoing Phase 1/2a study and currently enrolling Phase 2a GAlette study; and (ii) additional technical training and materials related to our cell therapy technology platform to support commercial manufacturing strategies.
- OpRegen (RG6501) Phase 1/2a clinical study 24-month visual acuity results featured at 2024 Retinal Cell & Gene Therapy Innovation Summit.

- Roche announced receipt of RMAT designation from the U.S. FDA for OpRegen, for the treatment of GA secondary to AMD.
- Submitted an IND amendment for OPC1 for the treatment of chronic and subacute spinal cord injury, and initiated activities to enroll SCI patients in the DOSED clinical study; currently targeting enrollment to commence in the second quarter of 2025.
- Closed two separate financings totaling $44 million in gross proceeds; potential to receive an additional $36 million in gross proceeds upon the full exercise in cash of OpRegen clinical milestone-linked warrants, which each have an exercise price of $0.91 per share.
- Created and hosted the 2nd Annual Spinal Cord Injury Investor Symposium in partnership with the Christopher & Dana Reeve Foundation with additional support from CIRM.
- ReSonance (ANP1) preclinical results presented at 59th Annual Inner Ear Biology Workshop: ReSonance manufactured by a proprietary process, developed in-house, at clinical scale, with relevant in-vitro functional activity; Immediate-use, thaw-and-inject formulation durably engrafted in preclinical hearing loss models.

Business Strategy

Our initial goal is to address serious neurological and ophthalmic disorders by developing and advancing allogeneic, or "off-the-shelf," treatments comprised of functional cells transplanted to the body. Our biological therapies are derived from the differentiation of pluripotent stem cells from established and self-renewing cell lines. We direct these pluripotent cells to become specific cell types, or combinations of the desired cell types, and use those differentiated cells as the treatment to restore diseased or diminished functions, such as impaired vision, loss of movement, sensation, or hearing.

To support the furtherance of our product candidates, we aim to generate or have generated in vitro and in vivo functional data to support human testing. In some cases, we may collaborate with strategic partners, external advisors, or consultants to support the development of our cell therapy technology.

A key area of focus is our continued execution under our collaboration with Roche and Genentech across multiple functional areas, including support for the ongoing Phase 2a multicenter clinical study of OpRegen in patients with GA secondary to AMD, as well as in the follow-up portion of our 24-patient Phase 1/2a multicenter clinical study of OpRegen, in patients with dry AMD.

We recently announced the initiation of the DOSED clinical study at our first contracted clinical site, UC San Diego Health, which will evaluate the safety and utility of a novel spinal cord delivery device to deliver OPC1, to the spinal parenchyma, in both subacute and chronic spinal cord injuries.

Our preclinical and research product candidates, ANP1 for hearing loss and PNC1 for vision loss due to photoreceptor dysfunction or damage, will continue to be evaluated for their scientific and commercial merit to determine the suitability of each program to advance into initial human testing.

Our efforts to broaden the application of our cell therapy platform and support long-term growth also include a strategic collaboration with Factor Biosciences for the development of a novel hypoimmune iPSC line, which will be evaluated for differentiation into cell transplant product candidates for CNS diseases and certain neurology indications. Through this collaboration we are developing a cell transplant therapy named RND1 for the treatment of an undisclosed indication. We believe this collaboration allows us to leverage our expertise to develop innovative cell transplant therapies by capitalizing on the convergence of directed cell differentiation and manufacturing with modern ex vivo gene editing technologies. Our former gene editing partner, Eterna Therapeutics, assigned this agreement to Factor in September 2024.

We have identified, and we may seek to develop, additional product candidates based on our cell replacement approach. We may elect to conduct these activities on our own or through various collaborative arrangements. We may utilize various types of pluripotent cell lines as starting material for our product candidates. Presently, our process

development and manufacturing activities, including our current good manufacturing practice ("cGMP") production of clinical trial material, are conducted at Cell Cure Neurosciences, Ltd., ("CCN"), our majority owned subsidiary.

Cell Therapy Technology Platform

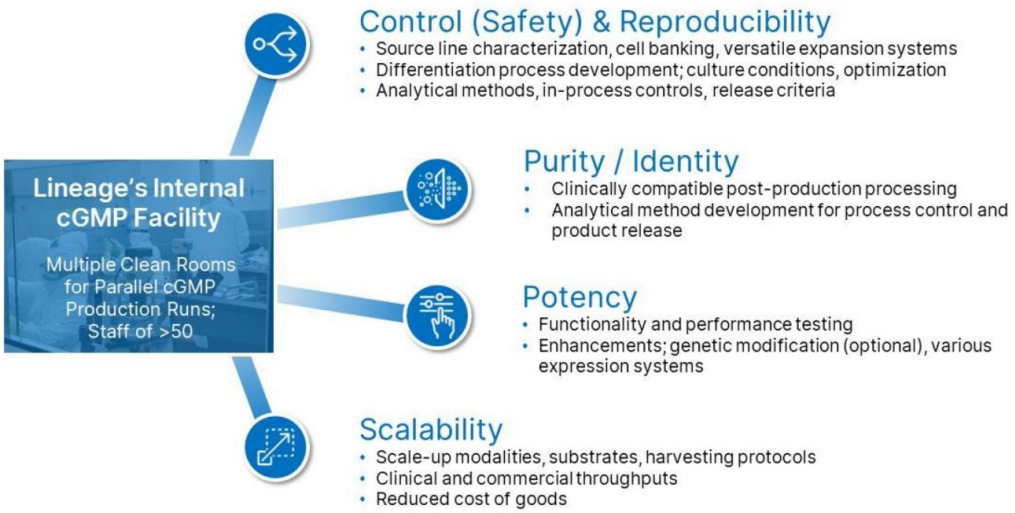
We believe we are one of the leading companies in pluripotent, cell-based non-oncology product development, as evidenced by our proprietary directed differentiation processes for multiple cellular lineages, cell manufacturing capabilities and stage of clinical development across multiple programs. Pluripotent cells, which are widely published as capable of becoming any human cell type, have potential applications in many areas of medicine with large unmet patient needs, including certain age-related degenerative diseases, degenerative conditions, or traumatic injury. Our programs are built on a proprietary, cell technology platform that integrates process development, manufacturing capabilities, formulation, and administration. Our product candidates consist of functional cells that may be able to replace faulty or absent cells, attenuate disease progression, or facilitate tissue repair. We are currently in clinical development with two pluripotent cell-derived product candidates (RPE cells and oligodendrocyte progenitor cells), and preclinical and research development for two additional candidates (auditory neurons and photoreceptor cells). In addition, we are investing in additional edited and non-edited pluripotent cell lines and are considering the differentiation of those pluripotent cells into additional cell types that may have therapeutic benefits in other areas of unmet medical need.

Cellular therapies are often aimed at regenerating or replacing affected cells or tissues and therefore may have more durable, broader, or more suitable applicability than certain traditional pharmaceutical products which seek to influence a single molecular target or a group of biological pathways. Small molecules and biologic therapies that require systemic delivery into the body can have unexpected side effects that can limit their usefulness. When cell replacement is locally administered to a specific anatomical compartment, systemic side effects can be well-tolerated. Lineage's cell therapy approach somewhat resembles transplant medicine, as it is focused on whether transplanted cells are retained or rejected by the body and whether the transplanted cells function as expected.

A key advantage of our approach is that it can provide us the opportunity to rapidly develop new programs without the extensive and costly steps traditionally required to develop a small molecule agonist or antagonist. Small molecule product development typically requires selection and validation of a drug target, followed by screening millions of molecules (e.g., a "library") to identify hits, followed by chemical modification to develop a hit into a potent lead. The process of developing a new cell therapy from pluripotent lines can be comparatively faster because the target cell type is already "validated", insofar as it is normally well-established in the literature as being the cell type which is dysfunctional or deficient in the patient and for which its' identity and disease-related functional properties can be imitated.

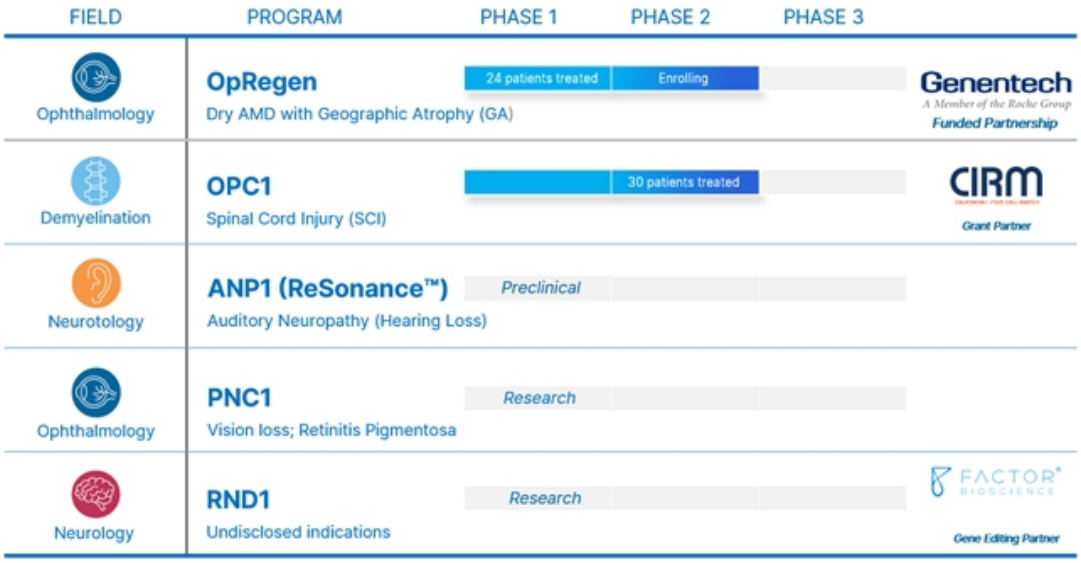
A significant challenge broadly facing the cell therapy field is the ability to create a stable source cell line and cell product with the purity control, reproducibility, potency and other vital manufacturing attributes, and to do so at the scale and cost needed to adequately and profitably supply the addressable market population with broad penetration. We believe these features are vital to creating a successful allogeneic cell transplant product. We believe one of our key advantages is the progress we have made toward demonstrating these capabilities in a GMP environment with actual production lots, a necessary milestone which to our knowledge has not been reduced to practice by any of our competitors.

Figure 1. Lineage's Internal cGMP Facility Capabilities



In addition to our corporate headquarters located in Carlsbad, California, we have a modern and innovative manufacturing facility in the Jerusalem Bio Park on the campus of the Hadassah University Hospital in Israel. That facility includes process development laboratories and a state-of-the-art, cGMP cell manufacturing facility. It is designed and equipped to run simultaneous cGMP processes as needed, and to produce a range of cell therapy products for human use in clinical trials as well as improve scalability for larger trials or potential commercialization (**Figure 1**). Currently, all of our cGMP manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, are conducted in this facility.

Figure 2. Neuroscience Focused Cell Therapy Pipeline



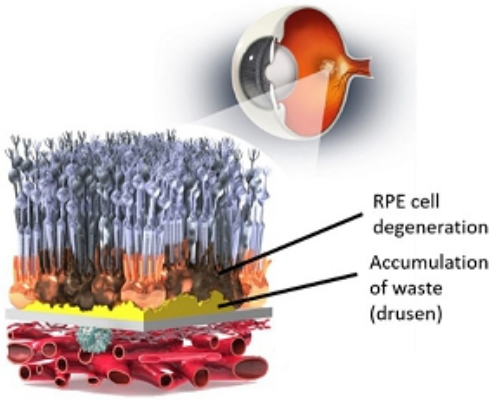
Clinical Stage Cell Transplant Programs

OpRegen® (RG6501)

OpRegen is a RPE cell therapy in Phase 2a development for the treatment of GA secondary to AMD. 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. See Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for discussion on the Roche Agreement.

OpRegen has been granted Fast Track and RMAT designations from the FDA, which includes an expedited regulatory path with the ability for increased interfacing with the FDA during the clinical development process.

AMD is a gradual, progressive, deterioration of the macula, the small sensitive area in the center of the retina that provides clear, high-definition central vision. It is a leading cause of vision loss in people over the age of 65 in the developed world. According to a 2022 report in JAMA Ophthalmology, 18.34 million individuals in the U.S. 40 years and older (11.64%) were living with early-stage AMD and 1.49 million (0.94%) were living with late-stage AMD in 2019. As the area of atrophy begins to include the fovea (the center of the macula), patients may lose their central vision, making facial recognition, reading, and driving difficult or impossible, and may ultimately become legally blind. The exact cause of GA secondary to AMD is unknown, but is thought to result from multiple factors, such as genetics, age, smoking history, and environmental effects. There are two clinical presentations of AMD, the dry form, and the wet, or neovascular form (growth of abnormal new blood vessels). Dry AMD typically advances slowly toward GA as RPE cells and photoreceptors become dysfunctional and deteriorate over time. RPE cells support and nourish the retina by metabolizing waste by-products and producing a number of components essential for photoreceptor health and function. If the metabolic waste products accumulate, lesions known as drusen may result. Approximately 85-90% of AMD patients suffer from the dry form of AMD, for which there are only two FDA approved therapeutic options at this time, pegcetacoplan injection (SYFOVRE®) and avacincaptad pegol intravitreal solution (IZERVAY™). Both of these approved products are complement inhibitors, administered either monthly or every other month, and neither has clinically demonstrated improved or restored vision to date, which means patients may still experience gradual vision decline while on treatment. Additionally, dry AMD may also lead to wet AMD, a condition for which FDA-approved treatments are administered to inhibit the growth of new blood vessels. Physicians often recommend a healthy diet, exercise and/or nutritional supplements for dry AMD, but nutritional supplements have shown limited efficacy in delaying the onset of more progressive disease in longer-term studies. The schematics in **Figures 3 and 4** show a representation of the process of drusen formation and the goal of cell replacement therapy.



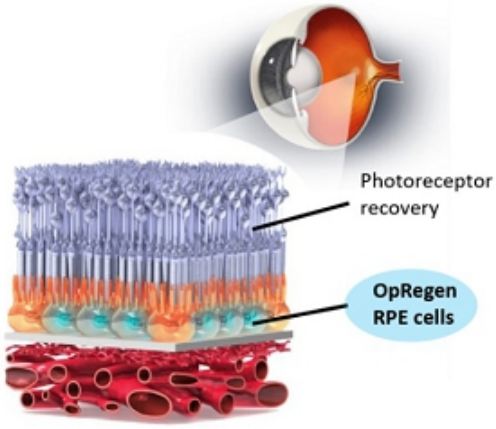


Figure 3. Dry AMD involves the loss of retina cells, creating an area of GA, which causes impaired vision and blindness	**Figure 4. OpRegen is an injection of RPE cells delivered to the retina, with the potential to replace lost retinal cells and/or preserve or restore vision**

We believe one of the most promising approaches to treat GA secondary to dry AMD is to replace the layer of damaged RPE cells with new, healthy, and functional RPE cells manufactured from a well-characterized, allogeneic cell line, transplanted to the subretinal space around the area of GA. OpRegen is a cell replacement therapy derived from our pluripotent cell technology in which our proprietary directed-differentiation methods convert pluripotent stem cells into nearly pure populations of RPE cells. Using this method, OpRegen is grown free of any animal products and consists of human RPE cells with high yield and purity that can be transplanted directly into the patient's eye, where the patient's own RPE cells are missing or dysfunctional. The goal of the OpRegen therapeutic approach is to slow or halt disease progression and to preserve and/or restore visual function.

OpRegen is intended to be an allogeneic, or "off-the-shelf," product provided to retinal surgeons, prepared in a ready-to-use "thaw-and-inject" form for transplantation. We believe OpRegen could have a lasting benefit from a single administration or may be administered every several years. This approach differs from other investigational agents, as well as from the two FDA-approved drugs for treatment of GA secondary to AMD, pegcetacoplan injection (SYFOVRE®) and avacincaptad pegol intravitreal solution (IZERVAY™), and approved agents currently marketed for wet AMD, such as ranibizumab (Lucentis®) and aflibercept (Eylea®). All of these approaches require repeated, frequent (monthly or every-other-month) intravitreal injections into the eye.

In a Phase 1/2a clinical trial, OpRegen has demonstrated the potential to slow, stop or reverse disease progression in GA secondary to AMD. In addition, results of imaging analyses demonstrated rapid improvement in outer retinal structure from patients enrolled in this study, suggesting that OpRegen RPE cells may provide direct support to the patients' remaining retinal cells within atrophic areas, improvements which can be detected within the first three months following a single administration. In this open-label, single-arm, multicenter, dose-escalation trial evaluating a single administration of OpRegen, the investigational product was delivered subretinally in patients with bilateral GA. Patient enrollment completed in November 2020, with twenty-four patients recruited into four cohorts. The first three 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 could be shipped directly to sites and used immediately upon thawing. 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 evaluated the preliminary activity of OpRegen treatment by assessing the changes in ophthalmological parameters measured by various methods of primary clinical relevance. Long-term follow-up of patients in this study is currently ongoing.

Results from the primary endpoint, the safety and tolerability at two years post OpRegen transplant suggest that OpRegen RPE cells were generally well-tolerated with an acceptable safety profile. Importantly, no unexpected ocular adverse events (AEs) were observed and those events that were observed were considered expected based on the surgical procedures involved in OpRegen administration, such as vitrectomy. Most AEs reported (Cohorts 1-3, 87%; Cohort 4, 93%) were mild in severity.

Phase 1/2a clinical study 24-month visual acuity results were presented at the 2024 Retinal Cell & Gene Therapy Innovation Summit in May 2024. Improvement in visual acuity and outer retinal structure in patients with extensive OpRegen bleb coverage of their GA area was present at 12 months (primary endpoint) and persisted through 24 months. BCVA gains in Cohort 4 patients (less advanced GA than in other cohorts) measured at 12 months were sustained at 24 months following a single subretinal administration of OpRegen. Mean change in BCVA among treated eyes for patients (n=10) completing 2-year follow up was +5.5 letters (Early Treatment Diabetic Retinopathy Study ("ETDRS") assessment). Effects were greater on average in the five (5) patients with extensive OpRegen coverage of atrophic areas at the time of surgical delivery. In these patients' treated eyes, the mean change in BCVA was +7.4 ETDRS letters for those completing 2-year follow-up (n=5). Maintenance or improvements in external limiting membrane ("ELM") and RPE drusen complex ("RPEDC") structure on OCT were observed in five patients in Cohort 4 with extensive OpRegen coverage of atrophic areas at the time of surgical delivery. Mean improvement of RPEDC area compared with baseline was maintained in treated eyes from 12 months (+2.6 mm2; n=5) to 24 months (+2.6 mm2; n=4). In comparison, mean change in RPEDC area decreased in untreated fellow eyes from 12 months (-1.1 mm2; n=5) to 24 months (-2.8 mm2; n=4). Mean change in ELM area increased in treated eyes from 12 months (+0.4 mm2; n=5) to 24 months (+0.8 mm2; n=4). In comparison, mean change in ELM area decreased in untreated fellow eyes from 12 months (-1.3 mm2; n=5) to 24 months (-1.9 mm2; n=4). Overall, these data suggest that OpRegen RPE cells may counteract RPE cell dysfunction and loss in GA by providing support to the remaining retinal cells within atrophic areas and such effects are durable through at least 24 months after a single administration.

36 months of follow-up in 10 of 12 patients with data available and treated as part of Cohort 4 (patients who had better baseline vision and smaller areas of GA at baseline than earlier cohorts who were legally blind), have recently been analyzed. Despite dry AMD being an irreversible and degenerative disease leading to progressive vision loss, visual acuity gains and retinal structure improvements observed in OpRegen-treated eyes in the Phase 1/2 clinical study continue to persist, suggesting that OpRegen RPE cells may provide durable support to patients' remaining retinal cells, including those near or within atrophic areas. Evidence of durable engraftment of OpRegen RPE cells has surpassed 5 years in the earliest-treated patients, supporting the potential for OpRegen to be a one-time treatment for patients with dry AMD. Overall, in the Phase 1/2a study (N=24), OpRegen continues to show an acceptable safety profile, which remains unchanged following inclusion of the recently-collected long-term follow-up safety data.

RG6501 (OpRegen) is currently being developed under an exclusive worldwide collaboration between us and Roche and Genentech. See "Collaborations—Roche Collaboration Agreement," below.

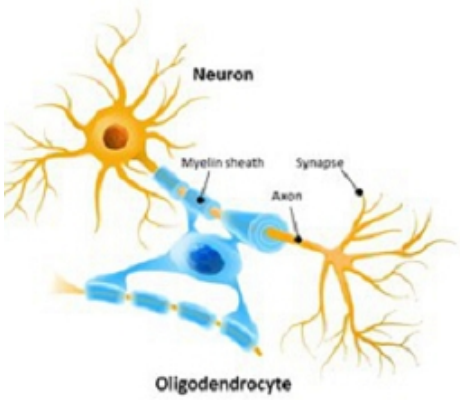
In November 2022, Genentech launched a Phase 2a, multicenter, open-label, single arm clinical study of RG6501 (OpRegen), the GAlette study with patient enrollment initiated in March 2023. The study is intended to optimize subretinal surgical delivery and evaluate biological activity of OpRegen in up to 60 patients with GA secondary to AMD. The primary objectives of the study are to evaluate (i) the success of subretinal surgical delivery of OpRegen as measured by the proportion of patients with subretinal surgical delivery of OpRegen to target regions under the retina, and (ii) the safety of subretinal surgical delivery of OpRegen as measured by the incidence and severity of procedure-related adverse events at 3 months following surgery. The secondary objective is to evaluate the biological activity of OpRegen measured by the proportion of patients with qualitative improvement in retinal structure, as determined by Optical Coherence Tomography (SD-OCT) imaging, within 3 months following surgery.

OPC1

OPC1 is an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute SCI. OPC1 has an extensive long-term safety profile and has been tested in two clinical trials to date: a five-patient Phase 1 safety trial in acute thoracic SCI, where all active subjects have been followed for at least 13 years; and a 25-patient Phase 1/2a multicenter dose-escalation trial in subacute cervical SCI, where all active subjects have been evaluated for at least 7 years. OPC1 is currently being tested in a phase 1 safety study of a novel delivery device, and in parallel, we are working on the design of a larger comparative clinical study. SCI occurs when the spinal cord is subjected to

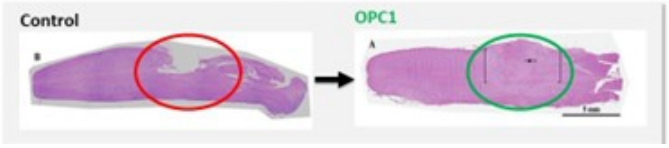
a severe crush or contusion injury, such as that caused by a car or motorcycle accident, and typically results in severe functional impairment, including limb paralysis, aberrant pain signaling, and loss of bladder and/or sexual function. There are approximately 18,000 new spinal cord injuries annually in the U.S. (NSCIC SCI Facts and Figures at a Glance (2023)), and there are currently no FDA-approved drugs specifically for the treatment of SCI, although methylprednisolone, a corticosteroid generally used as an anti-inflammatory drug, is sometimes prescribed on an off-label basis to reduce acute inflammation in the injured spinal cord immediately after injury. Approaches to treat this complex injury may include multiple mechanisms of action, such as biologics that preserve surviving neurons and stimulate new nerve axon outgrowth, suppression of lesion cavity formation at the injury site, generation of new blood vessels to repair the ischemic damage from injury, and myelination of the demyelinated and newly formed nerve axons. A potential therapeutic target in SCI is replacement of oligodendrocytes that are selectively lost at the injury site. As the sole source of the insulating protein myelin in the brain and spinal cord, oligodendrocytes wrap around nerve axons and allow the conduction of electrical impulses throughout the CNS, as shown in **Figure 5**.

Figure 5. Oligodendrocytes are the myelinating cells of the CNS and are critical for nerve signal conduction.



OPC1 is derived from our pluripotent cell technology under cGMP conditions using a directed differentiation method. These cells are stored frozen until ready for use and prepared for direct administration into the injured spinal cord. Based on preclinical studies, when OPC1 is transplanted into the injured spinal cord, the cells undergo further maturation to generate a replacement population of oligodendrocytes at the injury site that are capable of remyelinating denuded and newly formed nerve axons. Based on preclinical studies, prior to their maturation, the transplanted oligodendrocyte progenitor cells are believed to stimulate additional reparative processes, including promotion of neuron survival and nerve axon outgrowth, and induction of blood vessel formation in and around the injury site. In addition, OPC1 cells can migrate from the injection point to the injury site where they generate a supportive tissue matrix and suppress cavitation (Figure 6). Cavitation is a destructive process that occurs within the spinal cord following SCI, and typically results in permanent loss of motor and sensory function. A patient with cavitation can develop a condition known as syringomyelia, which results in additional neurological and functional damage to the patient and can result in chronic pain. Based on the multiple reparative properties associated with OPC1, we believe this candidate cell therapy product is ideally suited to treat neurological conditions such as SCI and other demyelination disorders of the CNS.

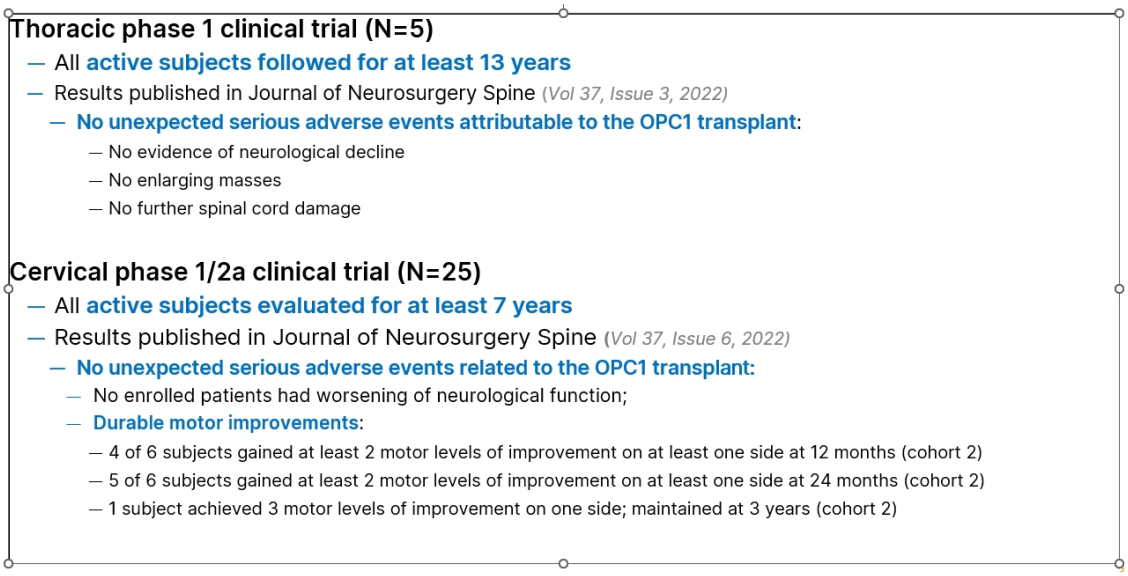
Figure 6. Suppression of spinal cavitation in a rat contusion model



The development of OPC1 has been supported by a $14.3 million clinical development grant from CIRM. We plan to apply for additional funding from CIRM to support continued clinical development of OPC1 for the treatment of SCI when CIRM begins accepting new applications. See "Grants from Government Entities – Grants from the California Institute for Regenerative Medicine," below.

To date, two clinical trials of OPC1 have been completed: a Phase 1 clinical safety trial in 5 patients with thoracic spinal cord injuries and a Phase 1/2a multicenter dose-escalation clinical trial in 25 patients with cervical spinal cord injuries. Results from both studies have been published in the *Journal of Neurosurgery Spine*. Key findings from these clinical studies are summarized in **Figure 7**.

Figure 7. OPC1 Thoracic & Cervical Clinical Trials Overview



The FDA designated OPC1 as a RMAT for the treatment of subacute SCI. RMAT designation allows for an accelerated development pathway and includes the ability for increased interfacing with the FDA during clinical development. The FDA has also granted OPC1 Orphan Drug Designation, providing a pathway to possible market exclusivity.

In 2019, we transferred all cGMP manufacturing processes, including the establishment of cell banks and the OPC1 process development and manufacturing for clinical studies, to CCN, our cell therapy manufacturing facility. Improvements to the manufacturing process were performed to create enhancements to the starting material, production process and scale and to achieve greater purity of OPC1. We also developed a ready-to-use thaw-and-inject formulation of OPC1 to simplify logistics and handling at the point of care and eliminate dose preparation at the clinical site. We have also manufactured clinical batches based on the improved process in a thaw-and-inject formulation in preparation for a larger-scale, late-stage clinical trial.

In February 2021, we announced an exclusive agreement with Neurgain Technologies, Inc. ("Neurgain"), to evaluate a novel delivery system for OPC1. Preliminary assessment of prototypes revealed promising compatibility with OPC1 product while simplifying the surgical procedure by providing surgeons with an instrument that is small, simple to use, and would not require stopping the patient's ventilator to perform the injection, allowing for flexibility with accurate delivery to the injury site. We continued to evaluate the Neurgain device throughout 2021 through 2023.

In June 2023, we launched a newly created forum to discuss the recent innovation, advancements and challenges in the treatment of SCI: the 1st Annual Spinal Cord Injury Investor Symposium. In addition to CIRM, the sponsors and collaborators for this inaugural event included the Christopher & Dana Reeve Foundation, the Sanford Stem Cell Institute at the University of California San Diego, and AbbVie. The event presented an opportunity for an open and collaborative dialogue among leading therapeutic area experts in SCI, researchers, representatives from companies working to develop various treatment approaches for SCI, persons with lived experience, caregivers, advocacy organizations, investors, healthcare analysts, and members of the public and media. In 2024, we hosted the 2nd Annual Spinal Cord Injury Investor Symposium.

On February 11, 2025 we announced the initiation of our DOSED clinical study, to evaluate the safety and utility of a novel delivery device to deliver OPC1 to the spinal cord of patients with an SCI and UC San Diego Health, a CIRM Alpha Clinic, was named as the first participating study site. DOSED is a Phase 1b, open label, multi-center, device safety study, in 3-5 subacute and 3-5 stable chronic subjects with complete (ASIA Impairment Scale A) or incomplete (ASIA Impairment Scale B), traumatic, focal SCI affecting either cervical (C4-C7) or thoracic (T1-T10) vertebrae. The primary objective of this study is to evaluate the safety of a novel Manual Inject Parenchymal Spinal Delivery System (MI PSD System) to administer OPC1 to the spinal parenchyma. The primary endpoint is frequency and severity of the MI PSD System or injection procedure related adverse events (AEs) through 30 days (1 month). Secondary endpoints are frequency and severity of AEs through 90 days. Exploratory endpoints include measurements of neurological impairment and function, changes from baseline.

We are actively working on expanding our existing and establishing new collaborations with SCI patient engagement and advocacy organizations, to enhance awareness of SCI and elevate the patient's voice in the treatment development process.

Preclinical and Research Cell Transplant Programs

Auditory Neurons

Our auditory neurons program, ANP1 was established in 2022 with the goal of advancing auditory neuron transplant therapy as a treatment option for hearing loss conditions. The initial focus of this program is on the treatment of auditory neuropathy spectrum disorders ("ANSD"), a group of conditions characterized by the loss of auditory neuron function where the sound is not transmitted properly from the cochlea (inner ear) to the brain. Based on our proprietary technology platform, we have developed a unique differentiation process for generating auditory neuron progenitor ("ANP") cells. In February 2023, we entered into a collaboration with the University of Michigan and Yehoash Raphael, Ph.D., The R. Jamison and Betty Williams Professor of Otolaryngology, Department of Otolaryngology-Head and Neck Surgery and Lab Director at the University of Michigan Kresge Hearing Research Institute, where preclinical testing of ANP1 has been ongoing. Initial preclinical results have been positive, with a demonstrated ability to deliver ANP cells into specific target areas utilizing standard surgical tools as well as to establish initial engraftment into certain anatomical destinations and survival after transplantation. ANP cells were confirmed to retain the expression of neuronal-specific markers post-transplantation and additionally demonstrated the ability to migrate. These results support the advancement of ANP1 into its new phase of preclinical development, the evaluation of the long-term engraftment of ANP cells and their functional assessment in hearing loss.

Photoreceptors

Our photoreceptor program, PNC1, is focused on a process of directing the differentiation of human pluripotent cells into clinical-grade transplantable photoreceptor precursors/cells and to show their further differentiation, integration, and function after transplantation into the subretinal space of animal models of photoreceptor degeneration. Photoreceptor degeneration is the hallmark of a variety of retinal diseases such as retinitis pigmentosa ("RP"). Currently, the only approved treatments for RP are gene therapies which treat specific genetic defects that lead to RP. Our PNC1 program is aimed to replace damaged photoreceptors regardless of the cause of degeneration.

Additional Research Programs

RND1

RND1 is a cell transplant candidate based on a novel hypoimmune iPSC cell line. RND1 is being developed in collaboration with our gene editing partner Factor Biosciences for the treatment of an undisclosed condition. We believe the hypoimmune iPSC cell line in development can provide a source of pluripotent cells for multiple product candidates in CNS diseases.

In February 2023, we entered into an option and license agreement with Factor (as assigned from Eterna) to develop engineered hypoimmune iPSC line that we will evaluate for differentiation into cell transplant product candidates for CNS diseases and certain indications, including RND1. We believe this collaboration allows us to leverage our expertise by capitalizing our directed cell differentiation and manufacturing capabilities with externally-sourced ex vivo gene editing technology. This is reflective of a portion of our corporate strategy which aims to capitalize on our process development capabilities by combining them with cell engineering and editing technologies to produce novel cell therapies with potentially superior product profiles compared to currently marketed therapies, if any.

In September 2023, we announced the initiation of certain development activities to generate a novel iPSC line under our agreement with Factor and our selection of specific gene edits for the initial product candidate to be developed by Factor. The edits include: the targeted deletion of the B2M gene, designed to reduce the immunogenicity of product candidates derived from the lines by inhibiting rejection by CD8+ T cells; the targeted insertion of the HLA-E gene, designed to overexpress HLA-E and prevent the allogeneic NK cell response; and a third undisclosed edit intended to confer clinical differentiation and a competitive advantage in the applicable indications. We expect that these edits may expand the edited cell lines' overall utility, including for non-immune privileged or non-human leukocyte antigen ("HLA") matched indications and may further differentiate the cell line from others currently in use by competitors.

Collaborations

To accelerate the discovery and advancement of transplanting specific cell types into the body, we have entered into, and intend to seek additional opportunities to form, collaborations with a diverse group of strategic partners. We have entered into collaborations with pharmaceutical and biotechnology companies, government agencies, academic laboratories, and research institutes with resources and expertise in diverse areas in an effort to advance our discovery and development platforms and will continue to evaluate such collaborations.

Roche Collaboration Agreement

On December 17, 2021, Lineage entered into the Roche Agreement, pursuant to which Lineage granted to Roche exclusive worldwide rights to develop and commercialize RPE cell therapies, including its proprietary cell therapy known as OpRegen, for the treatment of ocular disorders, including advanced dry AMD with GA.

Under the terms of the Roche Agreement, Roche assumed responsibility for further clinical development and commercialization of OpRegen and Lineage is responsible for completing activities related to the ongoing clinical study Phase 1/2a open-label, dose-escalation clinical safety and efficacy study in patients with advanced dry AMD with GA, for which enrollment is complete, and performing certain manufacturing and process development activities.

Roche paid Lineage a $50.0 million upfront payment (which was received in January 2022) and Lineage is eligible to receive up to an additional $620.0 million in developmental, regulatory and commercialization milestone payments. Lineage is also eligible for tiered double-digit percentage royalties on net sales of OpRegen. All milestone payments, and royalty payments, due under the Roche Agreement are subject to the existence of certain intellectual property rights that cover OpRegen at the time such payments would otherwise become due, and the royalties on net sales of OpRegen are subject to financial offsets based on the existence of competing products.

Unless earlier terminated by either party, the Roche Agreement will expire on a product-by-product and country-by-country basis upon the expiration of all of Roche's payment obligations under the Roche Agreement. Roche may

terminate the Roche Agreement in its entirety, or on a product-by-product or country-by-country basis, at any time with advanced written notice. Either party may terminate the Roche Agreement in its entirety with written notice for the other party's material breach if such party fails to cure the breach. Either party also may terminate the Roche Agreement in its entirety upon certain insolvency events involving the other party.

Based on the intercompany relationship between Lineage and CCN, Lineage is responsible for payment to the IIA (as defined below) approximately 24.1% of the upfront payment and of any future payments Lineage receives under the Roche Agreement, up to an aggregate cap on all payments to IIA, such cap growing over time via interest accrual until paid in full. As of December 31, 2024, the aggregate cap amount was $95.4 million. In addition, pursuant to the Second Amended and Restated License Agreement, dated June 15, 2017, CCN, and Hadasit Medical Research and Development Ltd. ("Hadasit"), as amended, and a letter agreement entered into between CCN and Hadasit on December 17, 2021, Lineage is responsible for payment to Hadasit (i) a maximum of 21.5% of the upfront payment (subject to certain reductions) and of any milestone payments Lineage receives from Roche under the Roche Agreement, and (ii) up to 50% of all royalty payments (subject to a maximum payment of 5% of net sales of products) Lineage receives from Roche under the Roche Agreement. In accordance with the foregoing obligations, from the $50.0 million upfront payment Lineage received from Roche in January 2022, Lineage paid $12.1 million to the IIA and $8.9 million to Hadasit. See "Grants from Government Entities," below, and Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information related to our obligations to the IIA and Hadasit.

In May 2024 we established a new Services Agreement with Genentech, a member of the Roche Group, to support ongoing development of OpRegen. Under this new agreement, Lineage agreed to provide additional clinical, technical, training and manufacturing services that further support the ongoing advancement and optimization of the OpRegen program. These additional services will be primarily funded by Genentech and include: (i) activities to support the ongoing Phase 1/2a study and currently-enrolling Phase 2a study; and (ii) additional technical training and materials related to Lineage's cell therapy technology platform to support commercial manufacturing strategies.

Grants from Government Entities

Grants from the Israeli Innovation Authority

Under the Israeli Encouragement of Research, Development and Industrial Initiative Technology Law, 5744-1984, as amended, and related regulations (collectively, the "Innovation Law"), research and development programs which meet specified criteria and are approved by the Israel Innovation Authority (the "IIA") are eligible for grants of up to 50% of the project's expenditure, as determined by the research committee, in exchange for the payment of royalties from the revenues generated from the sale of product candidates and related services developed, in whole or in part pursuant to, or as a result of, a research and development program funded by the IIA. The royalties are generally at a range of 3.0% to 5.0% of revenues until the entire IIA grant is repaid, together with an annual interest generally tied to an interest rate index.

Under the Innovation Law, the manufacture of product candidates developed with government grants is required to be performed in Israel. The transfer of manufacturing activity outside Israel may be subject to the prior approval of the IIA, and if approved, may increase the royalties payable to the IIA, in certain cases substantially. The amount of the increase in the royalties payable depends on the percentage of manufacturing activity that occurs outside Israel.

The know-how developed within the framework of the Innovation Law plan may not be transferred to third parties outside Israel without the prior approval of a governmental committee chartered under the Innovation Law. The IIA approval to transfer know-how created, in whole or in part, in connection with an IIA-funded project to a third party outside Israel where the transferring company remains an operating Israeli entity is subject to payment of a redemption fee to the IIA calculated according to a formula provided under the Innovation Law that is based, in general, on the ratio between the aggregate IIA grants to the company's aggregate investments in the project that was funded by these IIA grants, multiplied by the transaction consideration. The transfer of such know-how to a party outside Israel where the transferring company ceases to exist as an Israeli entity is subject to a redemption fee. The redemption fee in case of transfer of know-how to a party outside Israel is generally based on the ratio between the aggregate IIA grants received by the transferring company and the transferring company's aggregate research and development expenses, multiplied by the transaction consideration. The maximum amount payable to the IIA in case

of transfer of know-how outside Israel will not exceed six times the value of the grants received plus interest. In the event that the grant recipient ceases to be an Israeli corporation such payment shall not exceed six times the value of the grants received plus interest, with a possibility to reduce such payment to up to three times the value of the grants received plus interest if the research and development activity remains in Israel for a period of three years after payment to the IIA.

The restrictions under the Innovation Law, including restrictions on the sale, transfer or licensing to a non-Israeli entity of know-how developed as part of the programs under which the grants were given, continue to apply even after the repayment of royalties in full by the grant recipient.

Part of CCN's research and development efforts have been financed, partially, through grants that it has received from the IIA and when we acquired our holdings in CCN, we undertook in writing, vis-à-vis the IIA, to comply with, and to ensure the compliance by CCN with, the Innovation Law. We therefore must comply with the requirements of the Innovation Law and related regulations. To date, through a series of separate grants beginning in 2007, CCN received a total of $15.4 million from the IIA to support the OpRegen program. See Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information.

Grants from the California Institute for Regenerative Medicine

The clinical development of OPC1 has been supported by $14.3 million of funding from CIRM, a state agency established to fund stem cell research and development of new stem cell-based treatments. The terms of our grant award from CIRM require royalty payments to the California State General Fund based on net commercial revenue from the sale of any product, drug or service arising from CIRM-funded research as follows: 0.1% per $1.0 million of funds granted for the earlier of 10 years or nine times the award amount that has been paid. In addition, a 1% royalty will be owed on net commercial revenue in excess of $500 million per year until the last to expire patent covering a CIRM-funded invention, if any, contributed towards the commercialization of the product.

In February 2024, we applied for clinical program funding from CIRM to support the DOSED clinical study. Later in February 2024, CIRM's governing board determined to postpone acceptance of clinical funding applications submitted after January 31, 2024, in response to an unprecedented influx of applications and resulting review and budgetary issues. CIRM has announced that they anticipate opportunities for clinical funding to be re-opened in Spring 2025 and at that time we would plan to submit our grant applicant in support of our DOSED clinical study as part of that clinical funding program. However, no assurances can be given as to when CIRM will accept new clinical program funding applications or, if it does, that CIRM will accept our application for review or that it will award us any additional funding for the OPC1 program. See the risk factor titled, "We have relied on grant funding from CIRM to support clinical development of OPC1 and we may not be able to obtain additional CIRM funding, which could negatively impact our ability to advance clinical development of OPC1, as well as our operating results and financial condition. In addition, our profits from the sale of products resulting from CIRM-funded development, if any, will be reduced by amounts that we are required to pay CIRM," in Item 1A. Risk Factors of this report.

Other Programs

We may elect to enter into collaborations for additional product candidates currently in development and which cover a range of therapeutic areas. Generally, these product candidates are based on the same pluripotent platform technology and would employ a similar guided cell differentiation and transplant approach as our current clinical-stage products.

Intellectual Property

We seek to protect and rely on our proprietary cell-based therapy platform technologies and associated development and manufacturing capabilities and derived product candidates with intellectual property through a variety of measures, including seeking and maintaining patents intended to cover our products and compositions, their methods of use and processes for their manufacture, our platform technologies and any other inventions that are commercially important to the development of our business and, when appropriate, trade secret protection. We have sought, and intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the United States and internationally. We may also file

additional patent applications, when appropriate, to cover improvements on our manufacturing processes, clinical products, clinical product candidates, and related technologies. From time to time, we assess our patents and pending applications covering our products and product candidates. If we determine that any patents or patent applications no longer provide adequate or necessary protection, we may transfer or abandon such patents and patent applications to avoid incurring unnecessary costs.

To further protect our proprietary confidential information, know-how, and trade secrets, we require confidentiality agreements with our employees, consultants, vendors, collaborators and similar third parties. For example, we require our employees and consultants to execute confidentiality and invention assignment agreements upon accepting employment or entering into other relationships with us. We also implement internal policies and procedures to ensure protection of our proprietary confidential information including know-how and trade secrets through, for example, limited and restricted confidential access to this information.

There are no assurances that any of our intellectual property rights will guarantee complete or adequate protection or market exclusivity for our products and product candidates. We also enter into collaborative and other similar contractual arrangements with third parties, such as license agreements, to in-license and/or out-license intellectual property rights. Our financial success will be dependent, in part, on our ability to obtain rights to commercially valuable patents and other intellectual property, to protect and enforce our intellectual property rights and to operate without knowingly infringing any intellectual property rights of others.

We own or license, directly or through our subsidiaries, patent families that include several hundred U.S. and international patents and patent applications. We cannot be certain that issued patents will be enforceable or provide adequate protection or that pending applications will result in issued patents.

OpRegen®

We solely own and have rights to U.S. and international issued patents and pending patent applications relating to OpRegen, including those in-licensed from Hadasit. Our solely owned pending patent applications include those relating to a cryopreserved thaw-and-inject formulation which, if issued, will have estimated patent expiration dates in 2038. The issued patents and pending patent applications, if issued, have expiration dates ranging from 2028 to 2042. Pursuant to the Roche Agreement, we have licensed these patent rights to Roche to further develop and commercialize RPE cell therapies, including OpRegen (see "—Collaborations—Roche Collaboration Agreement" above).

OPC1

We own numerous U.S. and international issued patents and pending patent applications that are relevant to neural cells, such as oligodendrocyte progenitor cells, that are directed to the differentiation of pluripotent stem cells, including human embryonic stem ("hES") cells, into various neural cell types, as well as various culture and purification methods. These issued patents and pending patent applications include nine patent families directed to improved methods of producing oligodendrocyte progenitor cells, oligodendrocyte progenitor cell compositions, and methods of treatment of spinal cord injury using oligodendrocyte progenitor cells. These patent families include four U.S. patents directed to methods for producing oligodendrocyte progenitor cells, composition of oligogendrocyte progenitor cells and methods of treatment of spinal cord injury using oligodendrocyte progenitor cells. The estimated patent expiration dates of these nine patent families range from 2036 to 2046. The commercial success of OPC1 depends, in part, upon our ability to exclude competition for this product with the existing patent portfolio and new patent applications that may be filed, regulatory exclusivity, undisclosed know-how and/or trade secrets, or a combination of these exclusivity barriers to entry.

Auditory Neurons

We have ten pending patent applications for our ANP1 program which include two pending U.S. provisional patent applications and a pending U.S. utility patent application, six pending international patent applications and a PCT patent application. The pending U.S. utility application and the pending international applications if issued would have estimated patent expiration dates in 2043. It is anticipated that the pending provisional patent application will be converted to a PCT patent application in 2026. It is anticipated that the pending PCT patent application will be converted to a U.S. utility patent application and one or more international patent applications in 2026 and, if issued, would have estimated patent expiration dates in 2045.

Photoreceptors

We have rights to two patent families for our PNC1 program. These patent families include issued U.S. and international patents and pending patent applications. One of these patent families is owned by us and includes U.S. and international pending patent applications and issued patents with estimated patent expiration dates in 2036. The other patent family is jointly owned by us and Hadasit resulting from the collaborative efforts of Hadasit and CCN pursuant to the photoreceptor development program under the Second Amended and Restated License Agreement between Hadasit and CCN. This jointly owned patent family includes a pending U.S. utility patent applications and six international patent applications and, if issued, would have estimated patent expiration dates in 2043. We removed the photoreceptor development program from the scope of that license agreement in April 2024, and the pending U.S and international patent applications will continue to be jointly owned by us and Hadasit.

General Risks Related to Obtaining and Enforcing Patent Protection

Because patent applications are confidential until a patent application is published or a patent is issued, we may not know if our competitors have filed patent applications for technology covered by our pending applications or if we were the first to invent or first to file an application directed toward the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents or other proprietary rights that block or compete with our products. In addition, if competitors file patent applications covering our technology, we may have to participate in interference/derivation proceedings or litigation to determine the right to a patent. Litigation and interference/derivation proceedings are unpredictable and expensive, such that, even if we are ultimately successful, our results of operations may be adversely affected by such events. Accordingly, there is a risk that any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and be declared invalid in view of third-party patent applications and/or patents or through other proceedings before the U.S. Patent and Trademark Office such as post-grant reviews, reexaminations, and inter partes' reviews or oppositions and other comparable proceedings in foreign jurisdictions. Litigation, interferences, oppositions, inter partes' reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. We may also face challenges to our patent and regulatory protections covering our products by third parties, including manufacturers of generics and biosimilars that may choose to launch or attempt to launch their products before the expiration of our patent or regulatory exclusivity. Litigation, interference, oppositions, inter partes' reviews, administrative challenges or other similar types of proceedings are unpredictable and may be protracted, expensive and distracting to management. The outcome of such proceedings could adversely affect the validity and scope of our patent or other proprietary rights, hinder our ability to manufacture and market our products, require us to seek a license for the infringed product or technology or result in the assessment of significant monetary damages against us that may exceed any amounts that we may accrue on our financial statements as a reserve for contingent liabilities. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products. Furthermore, payments under any licenses that we are able to obtain would reduce our profits derived from the covered products and services.

The enforcement of patent rights often requires litigation against third-party infringers, and such litigation can be costly to pursue. Even if we succeed in having new patents issued or in defending any challenge to issued patents, there is no assurance that our patents will be comprehensive enough to provide us with meaningful patent protection against our competitors.

Employees

As of December 31, 2024, we had 77 employees, of which 24 were employed by Lineage and 53 were employed by CCN and work in Israel. Of the 77 employees, 70 were employed on a full-time basis and seven were employed on a part-time basis. Nine employees hold Ph.D. degrees in one or more fields of science or doctorates in medicine. None of our employees are covered by a collective bargaining agreement.

Manufacturing

Manufacturing of pluripotent-derived products is complex and requires the use of innovative technologies to handle living cells. Manufacturing these products requires facilities specifically designed for and validated for this purpose and specific quality assurance and quality control procedures are necessary. Currently, all of our cGMP manufacturing processes, including cell banking, staff training, and product manufacturing for our cell therapy product candidates, are conducted at our internally-controlled facility at CCN. The facility, which includes process development laboratories and a cGMP manufacturing facility, is designed and equipped to enable simultaneous cGMP processes and to produce a range of cell therapy products for human use in clinical trials as well as at a scale suitable for commercial launch.

Our process development and manufacturing are designed to address the complexity of manufacturing cell-based therapies with a specific focus on the reproducibility and scale of the manufacturing process. To this end each of our manufacturing processes contains predefined steps that are controlled by a specific set of control tests that allow us to follow up the progression of production according to the manufacturing plan. We implement a variety of 2-dimensional and 3-dimensional culture conditions to address the specific requirements of our pre-defined differentiation processes of the pluripotent cell into a functional cell product.

We obtain key materials required for the manufacture of our cell therapy product candidates from third-party manufacturers and suppliers, which include, in some instances, sole source manufacturers and suppliers. We do not currently have long-term commitments or supply agreements in place to obtain certain key materials used in the manufacture of our cell therapy product candidates.

Licensed Technology and Product Development Agreements

Lineage has obtained the right to use various technologies that we believe have great potential in our product development efforts, and that may be useful to other companies that are engaged in the research and development of products for human therapeutic and diagnostic use.

Second Amended and Restated License Agreement

In June 2017, CCN entered into a Second Amended and Restated License Agreement (the “Hadasit License Agreement”) with Hadasit, pursuant to which Hadasit granted CCN an exclusive, worldwide, royalty bearing license (with the right to grant sublicenses) in its intellectual property portfolio of materials and technology related to human stem cell derived (i) photoreceptor cells and (ii) retinal pigment epithelial cells (collectively, the “Licensed IP”), to use, commercialize and exploit any part thereof, in any manner whatsoever in the fields of the development and exploitation of (i) human stem cell derived photoreceptor cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders (the "Photoreceptor Field"), and (ii) human stem cell derived retinal pigment epithelial cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders. The development and exploitation of human stem cell derived photoreceptor cells (“PR Development Program”) is governed by a Research Agreement (“PR Research Agreement”) made part of and attached to the Hadasit License Agreement.

As consideration for the Licensed IP, CCN paid a one time lump sum payment and will pay a royalty in the low single digits of net sales from sales of Licensed IP by any invoicing entity, and a low double digit percent of sublicensing receipts. In addition, CCN pays Hadasit an annual minimal non-refundable royalty.

CCN further agreed to pay Hadasit non-refundable milestone payments upon the recruitment of the first patient for the first Phase IIB clinical trial, upon the enrollment of the first patient in the first Phase III clinical trials, upon delivery of the report for the first Phase III clinical trials, upon the receipt of an NDA or marketing approval in the European Union (“EU”), whichever is the first to occur, and upon the first commercial sale in the United States or EU, whichever is the first to occur.

The Hadasit License Agreement was amended on November 30, 2017 (“First Amendment”) to update the original list of patent applications and issued patents for Licensed IP, and provide for reimbursement of certain costs associated with a patent not originally listed in the Hadasit License Agreement to CCN. The Hadasit License

Agreement was amended on December 1, 2019 to replace PR Research Agreement with a new PR Research Agreement ("New PR Research Agreement") which included provisions with respect to the ownership of research results and intellectual property. The Hadasit License Agreement was further amended on December 17, 2021 by a letter agreement pursuant to which CCN is obligated to pay a maximum of 21.5% of any milestone payments Lineage receives under the Roche Agreement (subject to certain reductions, including for costs related to Lineage's performance obligations under the Roche Agreement) and up to 50% of all royalty payments (subject to a maximum payment of 5% of net sales of products), Lineage receives under the Roche Agreement. We removed the Photoreceptor Field from the scope of the Hadasit License Agreement, in April 2024.

The Hadasit License Agreement terminates upon the expiration of CCN's obligation to pay royalties for all licensed products, unless earlier terminated. In addition, the Hadasit License Agreement may be terminated by (i) Hadasit if, among other reasons, CCN fails to continue the clinical development of the Licensed IP or fails to take actions to commercialize or sell the Licensed IP over any consecutive 12 month period, and (ii) by either party for (a) a material breach which remains uncured following a cure period, or (b) the granting of a winding-up order in respect of the other party, or upon an order being granted against the other party for the appointment of a receiver or a liquidator in respect of a substantial portion of such other party's assets. The Hadasit License Agreement also contains mutual confidentiality obligations of CCN and Hadasit, and indemnification obligations of CCN.

WARF Agreements

We have rights to certain U.S. and international issued patents, pending patent applications, and stem cell lines with the Wisconsin Alumni Research Foundation ("WARF") under a Commercial License and Option Agreement entered into between Lineage and WARF in January 2008 (the "2008 WARF Agreement") and a Non-Exclusive License Agreement entered into between Asterias and WARF in October 2013 (the "2013 WARF Agreement").

Under the 2008 WARF Agreement and the 2013 WARF Agreement, we have a worldwide non-exclusive license under certain WARF patents and WARF-owned primate (including human) stem cell lines for use in internal research, and to make, use and sell products that are used as research tools and products that are discovered or developed through our internal research using such patents and stem cell lines. We paid upfront license fees and have agreed to additional payments upon the attainment of specified clinical development milestones, royalties on sales of commercialized products, and, subject to certain exclusions, a percentage of any payments that we may receive from any sublicenses that we may grant to use the licensed patents or stem cell lines.

The 2008 WARF Agreement will expire on the date of the last to expire licensed patent and the 2013 WARF Agreement will continue with respect to licensed cell lines unless terminated by a party. We may terminate either or both of the 2008 and 2013 WARF Agreements at any time with prior written notice, and WARF may terminate the WARF Agreements only upon our breach. We have agreed to indemnify WARF and certain other designated affiliated entities from liability arising out of or relating to the death or injury of any person or damage to property due to the sale, marketing, use or manufacture of products that are covered by the licensed patents, licensed stem cell lines or inventions or materials developed or derived from the licensed patents or stem cell lines.

Government Regulation

Government authorities at the federal, state and local level, and in other countries, extensively regulate among other things, the development, testing, manufacture, quality, approval, safety, efficacy, distribution, labeling, packaging, storage, record keeping, monitoring, reporting, marketing, import/export and promotion of drugs, biologics, and medical devices. Authorities also heavily regulate many of these activities for human cells, tissues, and cellular and tissue-based products ("HCT/Ps").

FDA and Foreign Regulation of Therapeutic Products

The FDA and foreign regulatory authorities will regulate our proposed products as drugs, biologics or medical devices, depending upon such factors as the use to which the product will be put, the chemical composition, and the interaction of the product with the human body. In the United States, the FDA regulates drugs, biologics and medical devices, among other products, under the Federal Food, Drug and Cosmetic Act ("FDCA"), the Public Health Service

Act (“PHSA”), and implementing regulations. Under this regulatory structure, establishments that manufacture HCT/Ps are subject to many regulations, including, but not limited to, registration and listing requirements and current good tissue practices. Certain proposed cell therapy products will be reviewed by the FDA staff in its Center for Biologics Evaluation and Research Office of Therapeutic Products.

Our human drug and biologic products will be subject to rigorous FDA review and approval procedures before they may be marketed in the United States. After testing in animals to evaluate the potential efficacy and safety of the product candidate, an IND submission must be made to the FDA to obtain authorization for human testing. Extensive clinical testing, which is generally done in three phases, must then be undertaken to demonstrate substantial evidence of safety and efficacy of each product in humans. Each clinical trial is conducted under the auspices of an independent Institutional Review Board (“IRB”). The IRB will consider, among other things, ethical factors, the safety of human subjects, and the possible liability of the institution.

Phase 1 clinical trials are conducted in a small number of healthy volunteers or volunteers with the target disease or condition to assess safety and dosage, and to identify adverse effects. Phase 2 clinical trials are conducted with groups of patients afflicted with the target disease or condition in order to determine preliminary efficacy, optimal dosages and expanded evidence of safety. In some cases, an initial trial is conducted in diseased patients to assess both preliminary safety and preliminary efficacy, in which case it is referred to as a Phase 1/2 clinical trial. Phase 3 clinical trials are large-scale, multicenter, comparative trials and are conducted with patients afflicted with the target disease or condition in order to monitor adverse effects and provide enough data to demonstrate the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend or terminate the clinical trial based upon the data which have been accumulated to that point and FDA's assessment of the risk/benefit ratio to the intended patient population. The clinical trial sponsor is required to report adverse events to the FDA and IRB in accordance with FDA laws and regulations. Monitoring of all aspects of the trial to minimize risks is a continuing process.

No action can be taken to market any therapeutic product in the U.S. until a New Drug Application (“NDA”) or Biologics License Application (“BLA”), as applicable, has been approved by the FDA. Submission of the application is not a guarantee that the FDA will find it complete and accept it for filing. If an application is accepted for filing, following the FDA’s review of safety and efficacy data compiled from clinical trials, the FDA may grant marketing approval, or deny the application by way of a complete response letter if it determines that the application does not provide an adequate basis for approval. FDA regulations also restrict the export of therapeutic products for clinical use prior to FDA approval. Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured or perform an establishment file review of the site. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with the requirements of current Good Manufacturing Practices (“cGMPs”) and adequate to assure consistent production of the product within required specifications including good tissue practices (“GTPs”) to the extent applicable. FDA's cGMP regulations detail minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. FDA's GTP regulations and guidance documents govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require when applicable, evaluation of donors through screening and testing. To maintain compliance with cGMPs, GTPs, and good clinical practices ("GCPs"), an applicant must incur significant expenditure of time, money and effort in areas including, but not limited to, training, record keeping, production, and quality control.

To date, although there are clinical trials of pluripotent stem cell-derived therapeutic products ongoing, we do not believe that the FDA has granted marketing approval to any pluripotent stem cell-based therapeutic products, and it is possible that the FDA or foreign regulatory agencies may subject our product candidates to additional or more stringent review than drugs or biologics derived from other technologies.

The FDA offers several programs to expedite development of products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments. A drug is eligible for designation as a Regenerative Medicine Advanced Therapy (“RMAT”) if: the drug is a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product or any combination product using such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act and part 1271 of Title 21, Code of Federal Regulations;; the drug is intended to treat,

modify, reverse or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or, if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and making available a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation is a separate process from seeking an NDA or BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product may be entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application fee. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Combination Products

Combination products are defined by the FDA to include products comprised of two or more regulated components or parts such as a biologic and a device. Combination products may be reviewed in a single application or in separate applications for the constituent parts. When regulated independently, drugs, biologics and devices each have their own regulatory requirements. However, the regulatory requirements for a combination product comprised of a biologic administered with a delivery device can be more complex because, in addition to the individual regulatory requirements for each component, additional combination product regulatory requirements may apply. The Office of Combination Products at the FDA coordinates the review of such products and determines the primary mode of action of a combination product. The definition and regulatory requirements for combination products may differ significantly among countries in which we may seek approval of our product candidates.

FDA Regulation of Manufacturing

The FDA regulates the manufacturing process of pharmaceutical products, HCT/Ps, and medical devices, requiring that they be produced in compliance with cGMP and GTP. See “Manufacturing", above. The FDA regulates and inspects equipment, facilities, laboratories and processes used in the manufacturing and testing of products prior to providing approval to market products. If, after receiving approval from the FDA, a material change is made to manufacturing equipment or to the location or manufacturing process, additional regulatory review may be required. The FDA also conducts regular, periodic visits to re-inspect the equipment, facilities, laboratories and processes of manufacturers following an initial approval. If, as a result of a post-approval inspection, the FDA determines that equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product approval, the FDA may seek civil, criminal or administrative sanctions and/or remedies against the manufacturer, including, but not limited to, suspension of manufacturing operations. Issues pertaining to manufacturing equipment, facilities or processes may also delay the approval of new products undergoing FDA review.

FDA Regulation of Advertising and Product Promotion

The FDA also regulates the content of advertisements used to market pharmaceutical and biologic products. Claims made in advertisements concerning the safety and efficacy of a product, or any advantages of a product over

another product, must be supported by clinical data filed as part of an NDA, a BLA, or an amendment to an NDA or a BLA, and must be consistent with the FDA-approved labeling and dosage information for that product. Additionally, the FDCA prohibits manufacturers of pharmaceutical and/or biologic products from making any claims, implicit or explicit, that are "false or misleading in any particular".

Pharmaceutical and biologic products may be promoted only for the approved indications in accordance with the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

Foreign Regulation

Sales of pharmaceutical products outside the U.S. are subject to foreign regulatory requirements that vary widely from country to country. Even if FDA approval has been obtained, approval of a product by comparable regulatory authorities of foreign countries must be obtained prior to the commencement of marketing the product in those countries. The time required to obtain such approval may be longer or shorter than that required for FDA approval.

Federal Funding and State Regulations

Effective July 7, 2009, the National Institute of Health ("NIH") adopted guidelines on the use of hES cells in federally funded research. The central focus of the guidelines is to assure that hES cells used in federally funded research are derived from human embryos that were created for reproductive purposes, are no longer needed for this purpose, and are voluntarily donated for research purposes with the informed written consent of the donors. hES cells that were not derived in compliance with the guidelines are not eligible for use in federally funded research.

The State of California has adopted legislation and regulations that require institutions that conduct stem cell research to notify, and in certain cases obtain approval from, a Stem Cell Research Oversight Committee ("SCRO Committee") before conducting the research. Under certain California regulations, all hES cell lines used in our research must be acceptably derived. California regulations further require certain records to be maintained with respect to stem cell research and the materials used. Lineage programs that involve the use of stem cells have been reviewed by a SCRO Committee to confirm compliance with federal and state guidelines.

The hES cell lines that we use are all on the NIH registry of lines that have been reviewed and meet standards for federal funding grants. All of our research programs utilize stem cells from established and well-characterized cell lines and which are capable of self-renewal and expansion through normal cellular division (mitosis). Our research programs do not require new tissue or cells from donors of any kind.

Health Insurance Portability and Accountability Act and Other Health Information Privacy and Security Laws

The Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose, access, or otherwise process individually identifiable protected health information, with respect to protecting the privacy, security, and transmission of protected health information. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for covered health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties. Additionally, HITECH created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, certain state and foreign laws also govern the privacy and security of health information in

some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Privacy and Data Security Laws

In the ordinary course of our business, we may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including data we collect about trial participants in connection with clinical trials. Accordingly, we are, or may become, subject to numerous data privacy and security requirements related to data privacy, security, and protection under federal, state, local, and foreign laws, regulations, guidance, and industry standards, many of which place restrictions on the Company's ability to transfer, access and use personal data across its business. Compliance with such requirements increases the cost and complexity of doing business and non-compliance may result in, among other penalties and sanctions, substantial monetary fines. The landscape of data privacy laws is evolving, with increasingly stringent regulatory frameworks related to personal data processing, which increase compliance obligations and exposure for noncompliance. In some jurisdictions violations may subject us to fines. For example, under the EU's General Data Protection Regulation 2016/679 ("EU GDPR"), government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of a company's annual global revenue, whichever is greater. Further, some laws allow individuals to initiate litigation related to processing of their personal data.

The laws to which we may be subject include privacy-specific laws at a state level such as the California Consumer Privacy Act of 2018 ("CCPA"). Other countries in which we operate also have general privacy obligations, including Israel's Protection of Privacy Law 5741-1981, the EU GDPR, and the UK's similar privacy law ("UK GDPR"). These non-US laws apply to processing of personal data of residents, and may apply to some of our activities. Some of our uses of personal information may be subject to specific privacy laws, such as the Telephone Consumer Protection Act or the CAN-SPAM Act. Obligations under these privacy laws may include data minimization, notification, consent, contractual provisions with third parties, restrictions on transfers from one country to another (such as restrictions under EU GDPR and UK GDPR of transfers of personal data to the US unless certain provisions have been met), and record keeping obligations. We are also subject to a complex patchwork of data security and breach notification laws, which exist at a state level in the US (in addition to obligations under HIPAA, discussed above), and also in laws outside of the US, such as GDPR and UK GDPR. Obligations under these laws may include notification in the event of a data breach; limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; implementing and maintaining technical and organizational safeguards for personal data. In addition to privacy and data security specific legislation, there are also enforcements brought under unfair and deceptive trade practice laws, such as Section V of the FTC Act. Regulators often issue guidance to assist companies, which guidance is frequently updated, and these guidance are relied on by enforcement bodies and courts.

There is a growing trend towards required public disclosure of clinical trial data in the EU which adds to the complexity of obligations relating to processing health data from clinical trials. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against the Company, harm to its reputation, and adversely impact its business and operating results. The uncertainty regarding the interplay between different regulatory frameworks further adds to the complexity that the Company faces with regard to data protection regulation. In addition, Israel's Protection of Privacy Law 5741-1981 and the regulations promulgated thereunder impose certain obligations with respect to the manner personal data is processed, and government regulators may issue fines or sanctions for non-compliance.

In certain circumstances we may transfer personal information of EU individuals to the US. Often we rely on standard contractual clauses. These have been questioned by privacy advocates, which scrutiny has grown under the new US presidential administration, and their sufficiency be subject to legal review. In addition, Switzerland and the UK similarly restrict personal data transfers outside of those jurisdictions to countries, such as the United States, that do not provide an adequate level of personal data protection, and certain countries outside Europe (e.g., Israel) have also passed or are considering laws requiring local data residency or otherwise impeding the transfer of personal data across borders.

In addition, business practices in the healthcare industry have come under increased scrutiny, particularly in the U.S., by government agencies (e.g., the U.S. Federal Trade Commission (the "FTC") and the U.S. Department of

Health and Human Services ("HHS")) and state attorneys general, which continue to stress the intersection of health and privacy as a compliance and enforcement priority. Resulting investigations and prosecutions carry the risk of significant civil and criminal penalties. Of note is the increased enforcement activity by data protection authorities in various jurisdictions, particularly in the EU, where significant fines have been levied on companies for data breaches, violations of privacy requirements, and unlawful cross-border data transfers. In the U.S., the FTC has stepped up enforcement of data privacy with several significant settlements (including settlements concerning the downstream sharing of personal information and use and disclosure of personal health data) and there have been a material increase in class-action lawsuits linked to the collection and use of biometric data and use of tracking technologies.

Federal and State Fraud and Abuse Laws

A variety of federal and state laws prohibit fraud and abuse. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including the Centers for Medicare & Medicaid Services ("CMS"), the Department of Justice, the Office of Inspector General for the HHS, and various state agencies. In addition, the Medicare and Medicaid programs increasingly use a variety of contractors to review claims data and to identify improper payments as well as fraud and abuse. These contractors include Recovery Audit Contractors, Medicaid Integrity Contractors and Zone Program Integrity Contractors. In addition, CMS conducts Comprehensive Error Rate Testing audits, the purpose of which is to detect improper Medicare payments. Any overpayments identified must be repaid unless a favorable decision is obtained on appeal. In some cases, these overpayments can be used as the basis for an extrapolation, by which the error rate is applied to a larger universe of claims, and which can result in even higher repayments.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, to induce or in return for either the referral of an individual, or the furnishing, recommending, or arranging for the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under a federal healthcare program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, ownership interests and providing anything at less than its fair market value. Recognizing that the federal Anti- Kickback Statute is broad and may prohibit certain common activities within the healthcare industry, the Office of Inspector General for HHS has issued a series of statutory exceptions and regulatory "safe harbors." However, these exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection from prosecution under the federal Anti-Kickback Statute. Although payment and business practices that meet the requirements of a safe harbor are not treated as offenses under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued. However, conduct and business arrangements that do not fully satisfy all requirements of an applicable safe harbor may result in increased scrutiny by government enforcement authorities and would be evaluated on a case-by-case basis based on a cumulative review of their facts and circumstances. Additionally, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act (collectively, the "ACA") codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

The federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced by private citizens on behalf of the government, through civil whistleblower or qui tam actions, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent. Pharmaceutical and other healthcare companies have been prosecuted under these laws for alleged off-label promotion of drugs, purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes, and allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims.

HIPAA also created new federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare

benefit program, including private third-party payers. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

Many states have laws similar to the federal laws described above and the state laws may be broader in scope and may apply regardless of payor, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or that apply regardless of payor, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, state laws that require the reporting of information related to drug pricing, and state and local laws requiring the registration of pharmaceutical sales representatives.

Additionally, the U.S. Foreign Corrupt Practices Act ("FCPA") prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

If our operations are found to be in violation of any of the laws described above, or any other governmental regulations that apply to us, we may be subject to significant civil, criminal and administrative penalties, including sanctions, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations.

Coverage and Reimbursement

Patients generally rely on third-party payors to reimburse part or all of the costs associated with medical products. Accordingly, market acceptance of medical products can depend on the extent to which third-party coverage and reimbursement is available from government health administration authorities, private healthcare insurers and other healthcare funding organizations. No uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Pharmaceutical companies may be required to provide specified rebates or discounts on the products it sells to certain government funded programs, including Medicare and Medicaid, and those rebates or discounts have increased over time. The ACA increased many of these mandatory discounts and rebates required and imposed a new branded prescription pharmaceutical manufacturers and importers fee payable each year by certain pharmaceutical companies and manufacturers.

Outside of the United States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU

provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of reform proposals to change the healthcare system. There is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by federal and state legislative initiatives, including those designed to limit the pricing, coverage, and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded healthcare programs, and increased governmental control of drug pricing.

In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Since its enactment, there have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA. For example, legislation enacted in 2017, informally known as the Tax Cuts and Jobs Act (the "2017 Tax Act"), among other things, removes penalties for not complying with ACA's individual mandate to carry health insurance. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Thus, the ACA will remain in effect in its current form. In January 2025, the new U.S. presidential administration issued Executive Order 14148, which revoked Executed Order 14009 issued by the prior U.S. presidential administration in January 2021, which had initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. Considerable uncertainty exists regarding how federal government policy and budget decisions will unfold with respect to healthcare reform under the new U.S. presidential administration. It is possible that the ACA will be subject to judicial or Congressional challenges in the future.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Congress is considering additional health reform measures.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the HHS finalized a regulation removing safe harbor protection

for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule was delayed until 2032 by the Inflation Reduction Act of 2022. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. The Most Favored Nation regulations mandate participation by identified Medicare Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021 CMS published a final rule that rescinds the Most Favored Nation model interim final rule. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to President Biden's executive order, on September 9, 2021, the HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles and considerable uncertainty exists regarding how federal government policy and budget decisions will unfold with respect to drug pricing under the new U.S. presidential administration.

In August 2022, the Inflation Reduction Act of 2022 was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the Inflation Reduction Act of 2022 requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The Inflation Reduction Act of 2022 permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Major Sources of Revenues

The following table shows our major sources of revenues, as a percentage of total revenues, that were recognized during the years ended December 31, 2024 and 2023:

	Year ended December 31,	
Sources of Revenues	**2024**	**2023**
Collaboration revenues	85.8%	84.8%
Royalties, license and other revenues	14.2%	15.2%

Our collaboration revenues for the years ended December 31, 2024 and 2023 are related primarily to the $50.0 million upfront payment from Roche under the Roche Agreement. Our royalties, license and other revenues for the years ended December 31, 2024 and 2023 represent cash flows generated under patent families that Asterias acquired from Geron and the Services Agreement with Genentech. See Note 3 (Revenue) and Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information.

None of our revenue for the years ended December 31, 2024 or 2023 were generated outside of the United States.

Marketing

We do not have established marketing, sales or distribution infrastructure or capabilities. In order to commercialize any of our product candidates if approved for commercial sale, we must either establish a sales and marketing organization with technical expertise and supporting distribution and compliance capabilities or collaborate with third-parties that have sales and marketing experience. As we move our product candidates through development toward regulatory approval, we intend to evaluate options for each product candidate's commercialization strategy. These options include building our own sales force and other commercial infrastructure, entering into strategic marketing collaborations with third parties, out-licensing the product to other pharmaceutical or biotechnology companies, and combinations of these strategies.

Competition

The cell therapy industry is characterized by rapid innovation, intense and dynamic competition with a strong emphasis on proprietary products. While we believe that our technology, manufacturing capabilities, scientific knowledge, and experience in the field of cell therapy provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceutical and biotechnology companies with substantially greater financial and other resources than we have, academic institutions and governmental agencies and public and private research institutions, as well as standard-of-care treatments, new products undergoing development and combinations of existing and new therapies. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies, including combinations thereof, that may become available in the future.

As mentioned above, some of our competitors have substantially greater financial and other resources than we have, such as larger research and development staff and well-established marketing and salesforces, or may operate in jurisdictions with lower standards of evidence to bring products to market. For example, we are aware that some of our competitors, including Abbvie, Novo Nordisk A/S, Bayer AG, Regeneron Pharmaceuticals, Santen Pharmaceuticals, Sana Biotechnology Inc., jCyte, Inc., Astellas Pharma Inc., and Apellis Pharmaceuticals Inc., may be conducting clinical trials for therapies that could compete with our cell therapy programs.

Corporate Information

Lineage was incorporated on November 30, 1990 in the State of California. Our common shares trade on the NYSE American and the Tel Aviv Stock Exchange under the symbol "LCTX." Our principal executive offices are at 2173 Salk Avenue, Suite 200, Carlsbad, CA 92008, USA, and our phone number at that address is (442) 287-8990. Our website address is www.lineagecell.com. The information on, or that can be accessed through our website, is not part of this report. We routinely use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. We also make available, free of charge through our website, our most recent annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports as soon as reasonably practicable after the reports are electronically filed with or furnished to the SEC.

ITEM 1A. RISK FACTORS

An investment in our common shares involves a high degree of risk. You should carefully consider all the risk factors described below, as well as the other information in this report, when evaluating our business and before deciding whether to purchase, hold or sell our common shares. Each of these risk factors, as well as additional risks not presently known to us or that we currently consider immaterial, could harm our business, financial condition, results of operations and/or growth prospects, as well as adversely affect the market price of our common shares, in which case you may lose all or part of your investment.

Risks Related to Our Business Operations and Capital Requirements

We are dependent on our third-party collaboration with Roche to develop and commercialize OpRegen. If Roche is not successful in developing and commercializing OpRegen and/or Roche terminates the collaboration, we will lose a significant source of potential revenue.

We currently have a collaboration and license agreement with Roche, pursuant to which we license to Roche rights to develop and commercialize our retinal pigment epithelium cell therapies, including OpRegen (the "Licensed Products"), for the treatment of ocular disorders, including age-related macular degeneration with geographic atrophy. Roche is obligated to pay us milestone payments upon the achievement of specified developmental, regulatory and commercialization milestones. In addition, Roche is obligated to pay us royalties upon sales of the Licensed Products, if any. All regulatory and commercial milestone payments and royalty payments are subject to the existence of certain intellectual property rights that cover OpRegen at the time such payments would otherwise become due, and the royalties on net sales of OpRegen are subject to financial offsets based on the existence of competing products.

We are exposed to numerous risks associated with the Roche agreement, including Roche having sole control over the clinical development and commercialization of any Licensed Products developed under the agreement. The Roche agreement also prevents us from developing or commercializing retinal pigment epithelium cell therapies for the treatment of ocular disorders on our own or with any third party. Our collaboration with Roche involves risks that are different from the risks associated with independently advancing product candidates, including that Roche may have or develop economic or business interests that are inconsistent with ours; take actions contrary to our requests or objectives; take actions that reduce our return on investment for this collaboration; or take actions that harm our reputation.

Roche's degree of control of the collaboration, clinical development and commercialization efforts may impact the payment amounts that we receive under the Roche agreement. For example, Roche may suspend development of OpRegen or other product candidates covered by the Roche agreement or decide not to pursue commercialization of OpRegen or such other product candidates at all, or it may agree to pay royalties to third parties or adopt a pricing model that reduces the amount of royalties we might otherwise expect. For example, in 2024, Roche announced that it decided to halt the development of some of its programs on the basis that such programs did not provide sufficient grounds for Roche to continue investing in the candidate.

We are expecting Roche to develop and commercialize the Licensed Products, and if Roche is not able to develop and commercialize the Licensed Products, determines not to continue to pursue development and commercialization of the Licensed Products, or determines to terminate the collaboration at any time in its sole discretion, which it has the right to do, we will not receive any future milestone or royalty payments under the agreement which would harm our business, business prospects, financial condition and results of operations. Even if Roche develops and commercializes the Licensed Products, Roche may not do so on the timelines we expect and the Licensed Products may not be commercially successful, each of which could harm our business, business prospects, financial condition and results of operations.

Roche may determine not to pursue development and commercialization and/or to terminate the collaboration, in its sole discretion, for many reasons, including:

- delays in development, manufacture or clinical supply of OpRegen (see the risk factor titled, "The manufacture of our cell therapy product candidates is complex, highly regulated and subject to a multitude of risks. We have limited experience manufacturing our product candidates on a clinical scale and no experience manufacturing on a commercial scale. Any failure to manufacture our product candidates in sufficient quantities in accordance with applicable quality standards and regulatory requirements and at acceptable costs, may result in significant

clinical development delays or impair our ability, or that of a strategic collaborator, to obtain approval for or commercialize our product candidates," below);

- Roche may conclude that clinical supply of OpRegen does not meet its internal standards;
- Roche may believe that data generated in clinical trials for OpRegen may be negative, inconclusive, or do not otherwise demonstrate adequate safety, efficacy or clinical benefit to warrant further development or commercialization;
- Roche may conclude that the commercial landscape in GA secondary to AMD has significantly changed with the FDA's approval in 2023 of Apellis Pharmaceuticals, Inc.'s Syfovre® (pegcetacoplan injection) and Iveric bio, Inc.'s IZERVAY™ (avacincaptad pegol intravitreal solution);
- Roche may not dedicate the resources necessary to carry OpRegen through clinical development, regulatory approval, or commercialization;
- Roche may conclude that the commercial potential of OpRegen does not meet its internal thresholds or yield a timely return on its investment in OpRegen;
- Roche may choose not to develop and commercialize OpRegen in certain, or any, markets or for one or more indications, if at all;
- Roche may change the focus of its development or commercialization efforts or prioritize other programs and, accordingly, reduce the efforts and resources allocated to OpRegen;
- Roche may be unable to obtain regulatory clearances or approvals to continue clinical development or commercialization of OpRegen in a timely manner, or at all;
- the failure to develop a formulation and/or manufacturing process for OpRegen that Roche believes is commercially viable in a timely manner, or at all; or
- the loss or impairment of intellectual property rights related to OpRegen.

If Roche terminates the collaboration:

- we would no longer have the right to receive any milestone payments or royalties thereunder;
- further development of OpRegen, if any, would be significantly delayed or terminated;
- we would bear all risks and costs related to any further clinical development, manufacturing, regulatory approval and commercialization OpRegen, if any;
- we might determine that the commercial potential of OpRegen does not warrant further development of OpRegen;
- we would need to raise additional capital if we were to choose to pursue OpRegen development on our own, or we would need to establish alternative collaborations with third parties, which might not be possible in a timely manner, or at all;
- if we were to choose to pursue OpRegen development independently, we would need to work collaboratively with Roche to transfer the OpRegen program back to us, and such a transfer might take significant amounts of time, would be resource intensive and costly, and might not be feasible; and
- it may adversely affect the interest of other third parties in pursuing strategic collaborations relating to our product candidates, including OpRegen, or technology or the terms of any such potential collaboration.

Any loss or termination of rights under the collaboration will cause us to lose a significant source of potential revenue and could significantly delay or result in the discontinuation of development of OpRegen or significantly diminish the commercial potential of OpRegen, which would have a material and adverse effect on our company, financial condition and results of operations and could cause the market price of our common shares to decline.

In addition, we are required under the Roche agreement to transfer certain manufacturing process know-how to Roche to facilitate manufacture of OpRegen and other potential Licensed Products for clinical trials and

commercialization. Transferring manufacturing testing and processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. We have never completed such transfer and we can give no assurances that we will be successful in doing so. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We and Roche will need to conduct significant development work to transfer these processes. In addition, we may be required to demonstrate the comparability of the cells generated by Roche with cells previously produced and used in testing. Any failure or delay in the successful transfer of manufacturing process know-how to Roche or the inability of Roche to manufacture comparable cells could halt or delay the continued development of OpRegen and other potential Licensed Products.

We have incurred operating losses since inception, and we do not know if or when we will attain profitability.

Our total operating losses for the fiscal years ended December 31, 2024 and 2023 were $21.5 million and $24.7 million, respectively, and we had an accumulated deficit of $403.5 million as of December 31, 2024. Since inception, we have incurred significant operating losses and we expect to continue to incur significant operating losses for the foreseeable future. Unless and until we or a third-party collaborator succeed in developing, obtaining regulatory approval for, and generating substantial revenue from sales of one or more of our product candidates, we do not expect to become profitable. All of our product candidates will require substantial additional development time and resources before we or any collaborator would be able to apply for or receive any regulatory approval to market and sell a product, and the timeline for and outcome of these development efforts is highly uncertain. We anticipate our operating losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize our product candidates and seek to identify, assess, acquire, in-license or develop additional product candidates. We may never achieve profitability.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us and our collaborators to be successful in a range of challenging activities, including completing clinical and nonclinical studies of our product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing, and selling any approved products, and satisfying any post-marketing regulatory requirements. We are attempting to develop new technology and therapeutic products. Cell therapy is a nascent field with limited regulatory approval precedent, which makes it difficult to predict the time and cost of product candidate development and seeking regulatory approval. The regulatory pathway with the FDA and comparable foreign regulatory authorities may be more complex, time-consuming, and unpredictable relative to more well-known therapeutic approaches. We and our collaborators may never succeed in these activities and, even if we do, may never generate revenues that are significant enough for us to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

Our investigational allogeneic cell therapies represent a novel approach to the treatment of serious medical conditions, which gives rise to significant challenges. We or our collaborators may not succeed in developing any of our product candidates.

We are developing a pipeline of allogeneic cell therapy product candidates with cells that we create by applying proprietary differentiation protocols to established pluripotent cell lines and which must be transplanted into patients to replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury. While there are over 200 cell types in the human body, not all of these cell types will represent product candidates. Allogeneic cell therapy is still an emerging area of therapeutic medical intervention, and as such, it is difficult to accurately predict the type and scope of challenges we and our collaborators may face during the identification and development of our product candidates. We and our collaborators face significant challenges and uncertainties associated with the identification, manufacture, preclinical and clinical development, regulatory approval pathway, and third-party payor coverage and reimbursement of our product candidates required for successful commercialization, including:

- successfully identifying potential product candidates;
- manufacturing our product candidates to our internal standards and those of our collaborators, as applicable, as well as to applicable regulatory specifications, in a timely manner, and on the scale necessary to support larger-scale clinical trials, and, if approved, commercialization;

- understanding and addressing variability in our cell manufacturing processes, which could affect our ability, or the ability of our collaborators, as applicable, to produce clinical trial material and, if approved, commercial product in a reliable and consistent manner;
- designing and completing clinical trials of our product candidates that will demonstrate their safe and effective use to treat the targeted disease or other medical condition;
- sourcing clinical and, if approved, commercial supplies of key components required for the manufacture of our product candidates;
- developing formulations of our cells that reduce or eliminate dose preparation or other complexities of handling and administration of our product candidates at the point of care;
- identifying, developing and validating delivery systems and methods for successful surgical transplantation of our cells;
- obtaining regulatory approval, as the regulatory frameworks for approval of potential allogeneic cell therapies in and outside of the U.S. are evolving;
- establishing sales, marketing, and compliance capabilities to gain acceptance of a novel therapy, if approved;
- obtaining sufficient product coverage and reimbursement from third-party payors such as government healthcare administration authorities and private healthcare insurers for any approved product to enable the product to compete in the marketplace and become commercially profitable; and
- obtaining and maintaining intellectual property protection for our product candidates, the operations used to manufacture them and the methods for using them in order to prevent third parties from making, using, selling, offering to sell or importing our product candidates or otherwise exploiting our cell manufacturing processes.

If we are not successful in addressing key challenges in development and commercialization of our cell therapy product candidates, or if our product candidates and technologies do not prove to be safe or effective for the indications for which they are being developed, our business prospects and revenue opportunities will be materially limited.

We will continue to spend a substantial amount of our capital on research and development, but we might not succeed in identifying or developing product candidates that are safe and effective for their target indications or commercially viable.

Our research and development activities are costly, time consuming, and their results are uncertain. We incurred research and development expenses amounting to approximately $12.5 million and $15.7 million during the fiscal years ended December 31, 2024 and 2023, respectively, and we expect to continue to incur substantial research and development expenses. If we successfully identify and develop a new technology or product candidates, refinement of the new technology or product and definition of the practical applications and limitations of the technology or product may take years and require large sums of money. Clinical trials of new therapeutic products, particularly those products that are regulated as biologics, drugs, or devices, such as our product candidates, are very expensive and take years to complete. Only a small percentage of therapeutic product candidates that enter the development process ever receive marketing approval. Even with substantial spending on research and development of our product candidates, they might not prove to be safe or efficacious in the human medical applications for which they are being developed, or they may prove too expensive to manufacture or otherwise fail to gain sufficient market acceptance to be commercially viable.

We will need to obtain substantial additional funding to complete the development and seek regulatory approval of our product candidates and to commercialize products approved for marketing, if any. If we are unable to obtain adequate capital when needed, we may delay, reduce, limit the pace of, suspend or discontinue our product and technology development programs or other operations, which could significantly harm our business and prospects and cause the market price of our common shares to decline.

We believe that our cash, cash equivalents and marketable securities as of December 31, 2024 will be sufficient to fund our planned operations for at least twelve months after the issuance date of our consolidated financial statements included elsewhere in this report; however, these resources will not be sufficient to fund our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and seek regulatory approval of our product candidates and to commercialize products approved for

marketing, if any. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our planned operations.

Until such time as we are able to generate sufficient revenues from product sales, royalties or license fees, if ever, we expect to fund our operations through equity offerings, debt financings or other third-party capital sources, including potentially new grants from governmental entities or strategic alliances, collaborations, licenses or other similar arrangements. However, additional capital may not be available to us when needed, on favorable terms, or at all, and any additional capital raised may not be sufficient to enable us to complete development or obtain regulatory approval of our product candidates or commercialize approved products, if any. Our past success in raising capital through equity offerings, strategic collaborations and grants from governmental entities should not provide any assurance that we will be successful in raising additional capital through any of those means when needed, or at all. We expect our ability to raise additional capital will depend not only on progress we and our collaborators make in developing our technologies and product candidates, but also on factors outside of our control that affect access to capital and conditions in the capital markets. A low trading volume, share price and market capitalization together with limited revenue and net losses, may make it difficult and expensive for us to raise additional capital through equity or debt financings. Our ability to obtain additional funds and the amount and type of financing available to us may be adversely impacted by unstable and unfavorable market conditions. Due to our significant operations in Israel, the ongoing Israeli regional conflict may also, directly or indirectly, adversely impact our ability to raise additional capital. An economic downturn, recession or recessionary concerns, potential for or actual U.S. government shutdowns, inflation, relatively high interest rates, public health emergencies, pandemics, geopolitical conflicts, terrorist attacks, global supply chain disruptions, natural or environmental disasters, strained relations between the U.S. and various other countries, social and political discord and unrest in the U.S. and various other countries can be expected to negatively impact financial markets. Volatility and deterioration in the financial markets and relatively high interest rates may make equity or debt financings more difficult, more costly or more dilutive and may increase competition for, or limit the availability of, funding from other third-party sources such as from strategic collaborations and grants from governmental and other entities. Our ability to obtain additional funds and the amount, type and terms of any potential financing may also be adversely affected by the performance of other companies perceived as comparable to us. For example, development setbacks or failures in cell therapies being developed by third parties could have a negative effect on potential investor or strategic collaborator sentiment for our technologies and product candidates.

As discussed elsewhere in this report, we issued warrants to purchase an aggregate of up to 41,447,372 of our common shares in connection with our November 2024 registered direct offering. Warrants to purchase up to 39,473,688 of our common shares have an exercise price of $0.91 per share and warrants to purchase up to 1,973,684 of our common shares have an exercise price of $0.95 per share, in each case, subject to customary adjustments. If the warrants are exercised in full on a cash basis, we would receive $37.8 million in gross proceeds. As of the filing date of this report, the trading price of our common shares is below the exercise prices of the warrants, and no assurances can be given that all or any portion of such warrants will be exercised, or if exercised, that they will be exercised on a cash basis. See also the risk factor below titled “The issuance of common shares upon exercise of warrants will cause immediate and substantial dilution to existing shareholders.”

If we are unable to raise capital when needed or on attractive terms, we may be forced to significantly delay, reduce, limit the pace of, suspend or discontinue some or all aspects of our product and technology development programs or other operations, fail to meet obligations under our in-license agreements and relinquish important rights, and forego opportunities to expand our pipeline, in which case, our ability to achieve our operational goals could be materially and adversely affected. In addition, if we do not have adequate capital, we may seek strategic alliances for research and development programs at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available, or relinquish or license on unfavorable terms, our rights to technologies or future product candidates that we otherwise would seek to develop or commercialize ourselves, which could have a material adverse effect on our business and prospects.

Our forecast of the period of time through which our financial resources will support our planned operations is based on a number of assumptions that may prove to be wrong or require adjustment as a result of business decisions, the risks, uncertainties other factors discussed elsewhere in this Risk Factors section or factors not presently known or material to us, and we may use our available financial resources sooner than we currently expect. Our future funding requirements will depend on many factors, including:

- scope, progress and results of our ongoing and planned preclinical studies, clinical trials, and nonclinical activities for our product candidates;
- unanticipated serious safety concerns related to the use of our product candidates;
- timing of licensing payments we may be required to make based on the development of our product candidates;
- the number and development requirements of product candidates that we may pursue;
- the timing and outcome of regulatory review of our product candidates;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial and manufacturing requirements for approval;
- our decisions to initiate additional clinical trials, not to initiate any clinical trial or to terminate an existing clinical trial;
- the cost of obtaining and the availability of materials, equipment and devices that are necessary for the production or administration of our product candidates;
- our ability to maintain existing development and commercialization collaborations and whether we decide to enter into new third-party collaborations for development or commercialization of our product candidates and the terms of any such collaboration;
- the cost and timing of establishing and validating new manufacturing processes or facilities for our product candidates and any approved products or of transferring manufacturing responsibilities to a collaborator; and
- additions or departures of key management or scientific personnel.

If we cannot conduct our planned operations or otherwise capitalize on business opportunities due to a lack of capital, our business, financial condition, and results of operations could be adversely affected and the market price of our common shares may decline.

Raising additional capital may cause dilution to our existing shareholders, restrict our operations, or require us to relinquish rights to or dilute our economic interest in our product candidates or technology on terms unfavorable to us.

We may seek additional capital through a variety of means, including equity offerings, debt financings or other third-party funding, including grants or new strategic alliances and licensing or collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Any debt capital financing may involve covenants that restrict our operations, including limitations on additional borrowing and on the use of our assets and may also include equity components, such as warrants, which could cause your ownership interests to be diluted. If we raise capital through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates and technology or grant licenses on terms that are not favorable to us compared to if we developed and commercialized a product candidate without a strategic collaboration. Any such arrangements may be dilutive to our ownership or economic interest in the products we develop, and we might have to accept royalty payments on product sales rather than receiving the gross revenues from product sales. See, for example, the terms of our agreement with Roche to develop and commercialize OpRegen. Grants from third parties may involve covenants that restrict our operations, require us to relinquish valuable rights in our products, technology and other intellectual property and may be dilutive to our economic interest in products and technologies we develop with such funding. For example, as discussed in Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report, pursuant to the terms of grants received by Cell Cure Neuroscience Ltd. (“CCN”) from the Israeli government, there are limitations on our ability to manufacture products and transfer or license technologies outside of Israel and considerable contingent financial obligations to the IIA with respect to products, technologies and intellectual property developed with the support of IIA grant funding, which includes the OpRegen program, and, as discussed below in this Risk Factors section, pursuant to the terms of a grant we received from CIRM in support of clinical development of OPC1, we have royalty payment obligations to CIRM based on net sales of products developed with the support of CIRM funding, if any.

Our ability to raise capital through equity or convertible debt financings may be limited by applicable rules of the SEC and NYSE American.

Our ability to raise capital through the sale of equity securities may be limited by various rules and regulations, including rules of the SEC, the NYSE American or any other securities exchange on which our common shares are listed, which place limits on the amount of securities that we may sell in certain circumstances or require shareholder approval to sell securities in excess of certain amounts. For example, we were required to obtain shareholder approval to sell our securities to Broadwood Capital in our November 2024 registered direct offering. Although such shareholder approval was obtained in this instance, no assurance can be given that our shareholders would approve any future capital raising transaction that requires their approval. We may have to forego opportunities to raise capital on favorable terms if we are limited by applicable rules and regulations, which may include requiring us to obtain shareholder approval.

Obtaining shareholder approval may be a costly and time-consuming process, and seeking shareholder approval could delay our ability to secure otherwise available capital, or cause us to miss such opportunities entirely, which may harm our business and prospects, and there is no guarantee our shareholders ultimately would approve a proposed transaction. We could face difficulties in soliciting a sufficient number of proxies from our shareholders to achieve a quorum at a shareholder meeting, particularly if the majority of our outstanding shares continues to be held by a large number of individual, retail investors, and may have to adjourn or postpone a shareholder meeting, which would further increase the time and expense of obtaining shareholder approval. If our shareholders do not approve a proposed offering and sale involving our equity securities, our ability to raise additional capital may be materially and adversely impacted, as well as our ability to pursue business opportunities where our common shares may be used as consideration, such as strategic transactions to expand our product pipeline, and to retain and recruit key personnel and other employees.

We may expend our limited resources to pursue particular product candidates and fail to capitalize on other product candidates that may be more profitable or for which there is a greater likelihood of success.

We have multiple cell therapy programs in development and limited resources. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates may not yield any commercially viable products. If we do not accurately evaluate the clinical or commercial potential or target market for a particular product candidate, we may focus our resources on product candidates that do not demonstrate successful clinical results or commercial viability at the expense of other programs that may have had greater success, or relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we fail to meet our obligations under our in-license agreements, we may lose our rights to key technologies on which our business depends.

Our business depends on several critical technologies that are based in part on technology licensed from third parties. Those third-party license agreements impose obligations on us, including payment obligations and obligations to pursue development of commercial products under the licensed patents or technology. If a licensor believes that we have failed to meet our obligations under a license agreement, the licensor could seek to limit or terminate our license rights, which could lead to costly and time-consuming litigation and, potentially, a loss of the licensed rights. During the period of any such litigation, our ability to carry out the development and commercialization of potential products, and our ability to raise any capital that we might then need, could be significantly and negatively affected. If our license rights were restricted or ultimately lost, we would not be able to continue to use the licensed technology in our business. Our license agreements are discussed in more detail under “Licensed Technology and Product Development Agreements” in Item 1. “Business” above.

We may acquire or acquire rights to new technologies, product candidates and other assets or businesses, which could fail to result in a commercial product or net sales, divert our management’s attention, result in additional dilution to our shareholders or otherwise disrupt our business and adversely affect our results of operations.

We evaluate and consider strategic opportunities on an ongoing basis that we believe could complement or expand our portfolio, enhance our technical capabilities or otherwise offer growth opportunities. We may in the future acquire or acquire rights to develop and commercialize new technologies, product candidates and other assets or businesses or pursue joint ventures or investments in complementary businesses. However, we may not be able to successfully complete any in-license, acquisition or other strategic transaction we choose to pursue, and we may not successfully integrate any acquired or licensed technology, development program or business in a cost-effective and non-disruptive manner. The pursuit of these potential transactions may divert the attention of management and cause us to incur significant costs and expenses in identifying, investigating and pursuing suitable opportunities and transactions, even if we do not complete the transaction. We may not be able to identify desirable targets or be successful in entering into an agreement with any particular target. Furthermore, the anticipated benefits of any strategic transaction may not materialize.

In addition, we may not be able to successfully integrate any acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. We also face risk of shareholder lawsuits in connection with acquisitions that can divert management's focus from operating our business and result in significant legal and other expenses, which could harm our operating results and financial condition. For example, in 2023, we settled a putative shareholder class action lawsuit relating to our acquisition of Asterias after more than three years of litigation. See Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report. In addition, if an acquired technology, product candidate or other asset or business fails to meet our expectations, our business, financial condition and results of operations may be negatively affected. Additional risks we may face in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition and integration challenges;
- integration of cGMP manufacturing operations from an acquired business or company;
- retention of key employees from an acquired business or company;
- changes in relationships with other collaborators as a result of new program or product acquisitions or strategic positioning resulting from the acquisition;
- the need to implement or improve controls, procedures, and policies at the acquired business or company;
- financial reporting, revenue recognition or other financial or control deficiencies of an acquired company that we don't adequately address and that cause our reported results to be incorrect;
- liability for activities of an acquired company before the acquisition, including intellectual property infringement claims, misappropriation or other violation, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with an acquired company, including claims from terminated employees, vendors, former shareholders or other third parties.

Our failure to address these risks or other problems encountered in connection with acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities, and harm our business generally.

All of our manufacturing operations currently are conducted at our facility in Jerusalem, Israel. Accordingly, political and economic conditions in Israel and war, cyberattacks, terrorist attacks or other armed conflicts involving Israel and the broader region could directly affect our business. Any event or condition that significantly disrupts our ordinary course of operations at our Jerusalem facility could harm our business and materially and adversely affect our financial condition and operating results.

We or our collaborators, suppliers, CROs, other service providers, or other third parties on which we rely may experience interruptions to our operations, including the conduct of our research and development programs, clinical

trials, and manufacturing operations, due to natural disasters, public health emergencies, geopolitical conflicts, political and economic instability, acts of terrorism, or hardware, software, telecommunication or electrical failures, which could significantly disrupt or harm our business.

Currently, all of our cGMP manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, are conducted by our subsidiary, CCN, at its facility in Jerusalem, Israel, and more than two-thirds of our workforce are CCN employees who are based in the same facility. Accordingly, political and economic conditions in Israel and terrorist attacks, cyberattacks, war or other armed conflicts involving Israel could directly affect our business.

As a result of safety concerns and in response to government-imposed restrictions on movement and travel and other precautions taken to address the Israeli regional conflict, our operations at our CCN facility in Jerusalem have been impacted. Further, a number of our CCN employees in Israel are members of the military reserves and subject to call-up in response to regional instability. Male Israeli citizens are obligated to perform several days, and in some cases more, of annual military reserve duty each year until they reach the age of 40 (or older, for reservists who are military officers or who have certain occupations) and, in the event of a military conflict, may be called to active duty. A number of employees in Israel, including CCN's chief executive officer, have been activated for military duty in the past and additional employees may also be activated, which could disrupt our operations. In addition, the general impact on employees operating in a region subject to instability could adversely impact our operations. Although we have business continuity plans in place to address medium- or long-term disruptions that could result from regional instability, those plans are limited and do not account for every possible scenario, and in addition, any long-term closure of our CCN facility, or if that facility were damaged, or if hostilities otherwise disrupt the ongoing operation of our facility or if a meaningful number of employees are unable to work for significant portions of time, our operations would be materially and adversely impacted. It is currently not possible to predict the scope, duration or severity of present or future regional instability or its effects on our operations, financial condition or operating results. Instability in the region can rapidly evolve, and could materially adversely impact our business and operations, as well as the overall economy in Israel and the value of the New Israeli Shekel.

Our operations are vulnerable to significant disruption if a natural disaster, public health emergency, terrorist attack, cyber attack, war or other armed conflict, power outage or any other sudden, unforeseen and severe event or condition damages, destroys or otherwise prevents us from using, or disrupts normal operations at, our CCN facility. For example, a natural disaster, explosion, cyber attack, fire or prolonged power outage could result in damage to or destruction of materials and equipment that are critical for our research and manufacturing operations, including our cell banks, or otherwise prevent us from conducting product testing or manufacturing sufficient clinical supplies, which would delay the advancement of our programs and materially harm our business, operating results, prospects, or financial condition. Our cell therapy product candidates are manufactured by starting with cells which are stored in the form of a master cell bank. While we have taken precautions to safeguard our cell banks from catastrophic events and we take precautions when transporting our cell banks, it is possible that we could lose one or more master cell banks and have our manufacturing severely impacted by the need to replace a cell bank. The disaster recovery and business continuity plans we currently have in place are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. Any natural or man-made disaster affecting our CCN facility or employees could materially harm our business.

Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners, or a significant downturn in the economic or financial condition of Israel, could adversely affect our operations. Ongoing and revived hostilities or other Israeli regional political or economic factors could harm our operations, product candidate development and results of operations. Although Israel has entered into various agreements with Egypt, Jordan, the Palestinian Authority and with various states in the Persian Gulf, there has been a continuous unrest and terrorist activity with varying levels of severity. In addition, Israel faces threats from more distant neighbors, in particular, Iran and Iran-backed militia groups, which have heightened since the October 2023 attacks on Israel. Our insurance policies do not cover us for the damages incurred in connection with these conflicts or for any resulting disruption in our operations. The Israeli government, as a matter of law, provides coverage for the reinstatement value of direct damages that are caused by terrorist attacks or acts of war; however, the government may cease providing such coverage or the coverage might not be enough to cover potential damages. In the event that hostilities disrupt the ongoing operation of our Jerusalem facility, our operations may be materially adversely affected.

Several countries, principally in the Middle East, still restrict doing business with Israel and Israeli companies, such as CCN. Several other countries have suspended relations with Israel and additional countries may impose restrictions on doing business with Israel and Israeli companies, whether as a result of ongoing instability or hostilities in the region or otherwise. In addition, there have been increased efforts by activists to cause companies, research institutions and consumers to boycott Israeli goods and cooperation with Israeli-related entities based on Israel's military operations including in Gaza and Israeli government policies. Such actions, particularly if they become more widespread, may adversely impact our ability to obtain supplies necessary to our manufacturing operations, cooperate with research institutions and collaborate with other third parties. Any hostilities involving Israel, any interruption or curtailment of trade or scientific cooperation between Israel and its present partners, or a significant downturn in the economic or financial condition of Israel could adversely affect our business, financial condition and results of operations. We may also be targeted by cyber terrorists specifically because CCN is an Israeli-related company. See also the discussion in this Risk Factors section under "If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences."

CCN has received Israeli government grants for certain of its research and development activities. The terms of these grants may require us to seek approvals and to satisfy specified conditions to manufacture products and transfer or license grant-supported technologies outside of Israel. In the context of such approvals, we will be required to pay penalties in addition to the repayment of the grants.

CCN has received Israeli government grants for certain of its research and development activities, including grants under the Innovation Law. The terms of these grants require prior approval and the satisfaction of specified conditions to manufacture products and transfer or license technologies outside of Israel. See "Item 1. Business—Grants from Government Entities," above. For example, the OpRegen program has been supported in part by the IIA through a series of separate research grants, beginning in 2007. As a result, and subject to the requirements of the Innovation Law, we paid the IIA approximately 24.1% of the upfront payment we received under the Roche Agreement, or approximately $12.1 million, and we are obligated to pay to the IIA approximately 24.1% of any milestone and royalty payments we may receive under the Roche Agreement, up to an aggregate cap on all payments to IIA, such cap growing over time via interest accrual until paid in full. As of December 31, 2024, the aggregate cap amount was approximately $95.4 million.

The restrictions under the Innovation Law may impair our ability to enter into any future agreements which involve IIA-funded products or know-how without the approval of IIA, or limit the economic benefit that we might derive under such agreements. We cannot be certain that any approval of IIA will be obtained on terms that are acceptable to us, or at all. We may not receive the required approvals should we wish to transfer or license IIA-funded know-how, manufacturing and/or development outside of Israel in the future. Furthermore, in the event that we undertake a transaction involving the transfer to a non-Israeli entity of know-how developed with IIA-funding pursuant to a merger or similar transaction, the consideration available to our shareholders may be significantly reduced by the amounts we are required to pay to the IIA. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with the requirements under the Innovation Law may subject CCN to mandatory repayment of grants received by it (together with interest and penalties), as well as expose its directors and management to criminal proceedings. In addition, the IIA may from time-to-time conduct royalty audits.

We have relied on grant funding from CIRM to support clinical development of OPC1 and we may not be able to obtain additional CIRM funding, which could negatively impact our ability to advance clinical development of OPC1, as well as our operating results and financial condition. In addition, our profits from the sale of products resulting from CIRM-funded development, if any, will be reduced by amounts that we are required to pay CIRM.

The clinical development of OPC1 has been supported by $14.3 million of funding from CIRM, a state agency established to fund stem cell research and development of new stem cell-based treatments. In February 2024, CIRM announced that it was postponing acceptance of clinical program funding applications submitted after January 31, 2024. As of the filing date of this report, CIRM is still not accepting applications for clinical program funding opportunities. CIRM paused accepting new applications while it refines its processes and procedures to ensure that new applications align with the Strategic Allocation Framework approved by the CIRM Governing Board. CIRM

anticipates resuming new application reviews by the Spring of 2025. We would plan to apply for additional funding from CIRM to support continued clinical development of OPC1 for the treatment of SCI when CIRM lifts the pause on accepting new clinical program funding applications. However, no assurances can be given as to when CIRM will accept new clinical program funding applications, if at all; or, if it does, that CIRM will accept our application for review or that it will award us any additional funding for the OPC1 program. Moreover, we expect that any CIRM funding will only be applicable to expenses we incur after the date of receipt of an appliable grant and that expenses incurred by us prior to the receipt of any such grant will not be eligible for CIRM funding. If we are unable to timely obtain another CIRM grant or if the amount of grant funding we receive from CIRM, if any, is insufficient to support the DOSED clinical study, the timeline for the conduct of the study may be adversely affected and we may be unable to complete the study or we may need to raise funds through other means to continue clinical development of OPC1, which could have a higher cost of capital, cause dilution to our shareholders, restrict our operations or require us to relinquish rights on unfavorable terms.

In addition, the terms of our grant award from CIRM require, and we expect the terms of any future grant from CIRM, if any, will require, royalty payments to CIRM based on sales of products developed with CIRM funding, if any, which will reduce our profits on sales of such products. See Item 1. "Business—Grants from Government Entities," above for additional information.

Our international business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

CCN is our 94% owned subsidiary located in Jerusalem, Israel. Currently, all of our cGMP manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, are conducted by CCN at its Jerusalem facility. A portion of our OpRegen Phase 1/2a clinical trial has been conducted at sites in Israel. Conducting operations internationally involves a number of risks, including:

- difficulty in staffing and managing foreign operations;
- failure by us to obtain the appropriate regulatory approvals;
- logistics and regulations associated with shipping drug product or patient samples, including infrastructure conditions and transportation delays;
- financial risks, such as longer payment cycles and exposure to foreign currency exchange rate fluctuations;
- subject to tax on Global Intangible Low Tax Income earned by foreign subsidiaries;
- political and economic instability, including wars, terrorism, cyber attacks, and political unrest, inter-governmental disputes, outbreak of disease, boycotts, curtailment of trade and other business restrictions;
- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, tariffs, labor and employment laws, data and privacy laws, regulatory requirements and other governmental approvals, permits and licenses; and
- regulatory and compliance risks that may fall within the purview of the U.S. Foreign Corrupt Practices Act, UK Bribery Act, anti-boycott laws and other anti-corruption laws.

Any of these factors could significantly harm our international operations and, consequently, our results of operations. In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our clinical trial activities. Further, the ongoing Israeli regional conflict may have the effect of heightening many of the risks and uncertainties of conducting significant aspects of our operations outside of the United States and, in particular, in Israel.

Our success internationally will depend, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks, particularly in Israel. Failure to manage these and other risks may have a material adverse effect on our operations in Israel and on our business as a whole.

Our business could be materially and adversely affected in the future by the effects of a public health crisis.

Disease outbreaks, epidemics and pandemics, particularly in regions where our product candidates are manufactured or where clinical trial sites or other business operations are concentrated, could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of third parties upon whom we rely, including strategic collaborators, clinical trial sites, CROs, suppliers and other vendors. A public health crisis may have negative impacts on our ability, or that of a strategic collaborator, to initiate new clinical trial sites, enroll new patients and to maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delay in our ability, or that of a strategic collaborator, to obtain regulatory approvals of our product candidates, if at all. For example, the COVID-19 pandemic and actions taken to reduce its spread disrupted our normal course of business operations and delayed patient enrollment in our OpRegen Phase 1/2a clinical trial. Additionally, some enrolled patients in that trial decided not to participate in follow-up visits on schedule or at all.

The extent to which a future public health crisis may impact our business, results of operations and financial condition is highly uncertain, cannot be predicted with confidence and will depend on, among other factors, the duration and severity of the disease outbreak, epidemic or pandemic and government actions taken in response. Potential disruptions might include, but are not limited to:

- delays or difficulties in clinical trial site initiation, including difficulties in recruiting clinical site investigators and staff,
- delays or difficulties in enrolling patients or conducting follow-up visits with patients in clinical trials of our product candidates, particularly patients who may be at higher risk of complications from the infection or other health condition;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting the infection or other health conditions or being forced to quarantine;
- diversion of healthcare resources away from the conduct of clinical trials, including at hospitals or other facilities serving as our clinical trial sites;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel;
- limitations on employee or other resources that would otherwise be focused on the conduct of clinical trials of our product candidates and preclinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, school closures or mass transit disruptions;
- manufacturing delays and difficulties for us and our suppliers of raw materials caused by business closures, operational restrictions or labor shortages;
- delays in clinical trial sites receiving the supplies and materials needed to conduct clinical trials of our product candidates, including interruption in global shipping that may affect the transport of clinical trial materials and supplies;
- changes in local regulations as part of a response to public health crisis which may require us or a strategic collaborator to change the ways in which clinical trials of our product candidates are conducted, which may result in unexpected costs, or cause us or our collaborators to discontinue the clinical trials altogether;
- interruption or delays in the operations of the FDA or other regulatory authorities, including with respect to their manufacturing or clinical trial site inspections, which may impact their ability to timely review and process any submissions we or our collaborators file;
- risk that participants enrolled in our clinical trials will contract the infection or other health conditions while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

In addition, to the extent any disease outbreak, epidemic or pandemic adversely affects our business, financial condition or results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this ‘‘Risk Factors’’ section.

Our business could be adversely affected if we lose the services of the key personnel upon whom we depend or if we fail to attract and retain senior management and key scientific personnel.

We believe that our continued success depends to a significant extent upon our efforts and ability to retain highly qualified personnel. All of our officers and other employees, including CCN employees, are at-will employees and may terminate their employment with us at any time with no advance notice. The loss of the services of key personnel could have a material adverse effect on us. Further, the replacement of any of key personnel would likely involve significant time and costs and may significantly delay or prevent the achievement of our business and clinical objectives and would harm our business.

In addition, we could experience difficulties attracting qualified employees in the future. For example, competition for qualified personnel in the biotechnology and medical device field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our business, including our clinical development activities. We may not be able to attract quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information or that their former employers own their research output.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances to which we are subject in the U.S. or Israel could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances to which we are subject in the U.S. or Israel could be interpreted, changed, modified or applied adversely to us. For example, it is currently unclear exactly what actions the new U.S. presidential administration will implement relating to existing U.S. tax laws, statutes, rules, regulations or ordinances, and if implemented, how such actions may impact our business operations and financial performance. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. or Israeli tax expense.

Political uncertainty may have an adverse impact on our operating performance and results of operations.

Considerable uncertainty exists regarding how federal government policy and budget decisions will unfold under the new U.S. presidential administration. Such uncertainty and, depending on how federal government policy and budget decisions unfold, may have an adverse impact on our operating performance and results of operations. In particular, the U.S. continues to experience significant political events that cast uncertainty on global financial and economic markets, especially following the recent presidential election. Furthermore, the imposition of tariffs, trade protection measures, import or export licensing requirements, trade sanctions or similar restrictions could negatively impact our business and operations. Any actions taken by the new presidential administration, including the many recent executive orders, may have a negative impact on the U.S. economy and on our business, financial condition, and results of operations. See also the risk factor below titled “Disruptions at the FDA, SEC and other government agencies, including due to a lack of funding, changes in leadership or significant personnel turnover, could delay or disrupt clinical and preclinical development and potential marketing approval of our product candidates and hinder our ability to raise additional capital.”

Our ability to use net operating losses and other tax attributes to offset future taxable income or taxes may be subject to limitations.

As of December 31, 2024, we had substantial net operating loss (“NOL”) carryforwards for U.S. federal and state tax purposes and other tax attributes to offset future taxable income. However, our federal NOL carryforwards and other tax attributes may not be available to offset future taxable income because of restrictions under U.S. tax law and similar limitations that may apply under state tax laws. A portion of our federal and state NOL carryforwards will begin to expire, if not utilized, in varying amounts between 2030 and 2044. Our federal research and development tax

credit carryforwards expire in varying amounts between 2024 and 2044, the California research and development tax credit carryforwards have no expiration date. See Note 12 (Income Taxes) to our consolidated financial statements included in this report for additional information. NOL carryforwards and research and development and other tax credits that expire unused will be unavailable to offset future income tax liabilities. Under federal income tax law, federal NOL carryforwards generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income. It is uncertain if and to what extent various states that we may operate in will conform to the federal tax law. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, our ability to use our pre-change NOL carryforwards and tax credits to offset post-change taxable income, if any, could be subject to significant limitations. Similar provisions of state tax law may also apply. In addition, the state of California suspended the use of the NOL deduction for tax years 2024 through 2026 if their California taxable income is greater than or equal to $1 million. Accordingly, the Company may not be able to offset taxable income with their NOL carryforwards during these years. The state of California also limited the use of their research and development credits to $5 million for tax years 2024 through 2026, which could accelerate or permanently increase state taxes owed. As a result of limitations on our ability to use our NOL carryforwards and tax credits, we may be unable to gain the benefit of a material portion of our NOL carryforwards and tax credits, which could harm our future operating results by effectively increasing our future income tax obligations. . There is also considerable uncertainty regarding how federal tax policy will unfold under the new U.S. presidential administration and we cannot predict the effect of any potential change in federal tax policy on our business or financial position.

Taxing authorities could reallocate our taxable income among our subsidiaries, which could increase our overall tax liability.

We are organized in the United States, and have subsidiaries in Israel and Singapore. If we succeed in growing our business, we may conduct increased operations through subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that such arrangements be priced the same as those between unrelated companies dealing at arm's length and that appropriate documentation is maintained to support the value of such arrangements. Our transfer pricing policies were formulated with the assistance of third-party experts; however, tax authorities in any country may disagree with our transfer pricing policies and procedures and we are subject to more tax audits as a result of having subsidiaries in foreign countries. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, particularly in relation to our subsidiary CCN, it would increase our tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Because a portion of our expenses are incurred in currencies other than the U.S. Dollar, our results of operations may be harmed by currency fluctuations.

Our reporting and functional currency is the United States Dollar, but a material portion of our research and development and other operating expenses are incurred in Israeli New Shekels through our subsidiary CCN. As a result, we are exposed to some currency fluctuation risks. We do not currently manage our foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. For example, we do not engage in any active hedging techniques, and we do not employ any derivative instruments. Unfavorable fluctuations in the exchange rate between Israeli New Shekels and U.S. dollar may adversely affect our comprehensive loss and cash flows.

Disruptions at the FDA, SEC and other government agencies, including due to a lack of funding, changes in leadership or significant personnel turnover, could delay or disrupt clinical and preclinical development and potential marketing approval of our product candidates and hinder our ability to raise additional capital.

Twice in the past decade, the previous appropriations legislation deadline was reached and Congress failed to pass a new appropriations bill or continuing resolution to temporarily extend funding, resulting in U.S. government shutdowns that caused federal agencies to halt non-essential operations. The federal government came very close to another shutdown in late 2023. Political polarization among lawmakers may lead to a higher frequency and longer duration of government shutdowns in the future. A federal government shutdown could prevent or delay staff at federal agencies from performing key functions that may adversely affect our business.

In addition, considerable uncertainty exists regarding how federal government policy and budget decisions will unfold, including the regulatory and spending priorities of the new U.S. presidential administration and Congress, and what challenges potential policy changes and budget reductions will present for us and our industry generally. Government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. The new U.S. presidential administration may institute significant changes to certain federal regulatory agencies including the FDA and SEC, including reductions in funding levels or restructuring of such agencies that could adversely impact us. For example, the ability of the FDA to review and approve new product applications or take action with respect to other regulatory matters can be affected by a variety of factors, including funding levels, ability to accept the payment of user fees, ability to hire and retain key personnel, and statutory, regulatory and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. For example, as a result of the COVID-19 pandemic, the FDA's inspectional activities were interrupted and restarted on a risk-based basis, which had the effect of delaying review and potential approval of product candidate marketing applications. Disruptions at the FDA may delay meetings and other communications with agency staff necessary to progress development of our product candidates and may slow the time necessary for acceptance, review and approval of applications to commence clinical studies or to market a new product in the U.S. In addition, disruptions at the SEC could prevent or delay SEC staff from performing key functions, including, for example, granting acceleration requests for registration statements, declaring registration statements or amendments thereto effective and providing interpretive guidance or no-action letters. For example, if a federal government shutdown halts non-essential SEC operations for an extended period, it may negatively impact our ability to raise additional capital through registered offerings of our securities in the future. If a prolonged U.S. government shutdown or other event or condition occurs that prevents or significantly delays the FDA, SEC or other regulatory agencies from hiring and retaining personnel and conducting their regular activities, or if an agency is restructured or experiences significant reduction in funding, leadership changes or employee turnover, it could significantly impact the ability of these agencies to timely review and process our regulatory submissions and may impede our access to additional capital needed to maintain or expand our operations or to complete important acquisitions or other transactions, which could have a material adverse effect on our business.

Risks Related to Government Regulation

If we or our strategic collaborators do not receive regulatory approvals, our product candidates may not be marketed or sold.

Our investigational cell therapies cannot be marketed or sold until the FDA and corresponding foreign regulatory authorities approve the products for the human medical applications for which they are being developed. In addition, the regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. The need to obtain regulatory approval to market a new product means that:

- We or our collaborators will have to conduct expensive and time-consuming clinical trials of new products. The full cost of conducting and completing clinical trials necessary to obtain FDA and foreign regulatory approval of a new product cannot be presently determined but could exceed our current financial resources.

- Clinical trials and the regulatory approval process for a pharmaceutical or cell-based product can take several years to complete. As a result, we or our collaborators will incur the expense and delay inherent in seeking FDA and foreign regulatory approval of new products, even if the results of clinical trials are favorable.
- Data obtained from preclinical and clinical studies is susceptible to varying interpretations and regulatory changes that could delay, limit, or prevent regulatory agency approvals.
- Because our cell therapy candidates involve the application of new technologies and approaches to medicine, the FDA or foreign regulatory agencies may subject those products to additional or more stringent review than drugs or biologics derived from other technologies.
- A product that is approved may be subject to restrictions on use.
- The FDA can recall or withdraw approval of a product, if it deems necessary.
- We or our collaborators will face similar regulatory issues in foreign countries.

Government-imposed bans or restrictions and religious, moral, and ethical concerns about the use of hES cells could prevent us from developing and successfully marketing stem cell products.

Government-imposed bans or restrictions on the use of embryos or hES cells in research and development in the United States and abroad could generally constrain stem cell research, thereby limiting the market and demand for our products. During March 2009, the federal government, pursuant to a presidential executive order, lifted certain restrictions on federal funding of research involving the use of hES cells, and in accordance with the executive order, the NIH has adopted guidelines for determining the eligibility of hES cell lines for use in federally funded research. The central focus of the guidelines is to assure that hES cells used in federally funded research were derived from human embryos that were created for reproductive purposes, were no longer needed for this purpose, and were voluntarily donated for research purposes with the informed written consent of the donors. The hES cells that were derived from embryos created for research purposes rather than reproductive purposes, and other hES cells that were not derived in compliance with the guidelines, are not eligible for use in federally funded research. California law requires that stem cell research be conducted under the oversight of a SCRO Committee. Many kinds of stem cell research, including the derivation of new hES cell lines, may only be conducted in California with the prior written approval of the SCRO Committee. A SCRO Committee could prohibit or impose restrictions on the research that we plan to do. The use of hES cells may give rise to religious, moral, and ethical issues. These considerations could lead to more restrictive government regulations or could generally constrain stem cell research, thereby limiting the market and demand for our products.

Some of our product candidates, may be considered combination products by the FDA and other regulatory authorities, which could increase the complexity, cost and timeline for their development and regulatory approval.

To the extent our product candidates meet the FDA's or other regulatory authority's definition of a combination product, the regulatory approval requirements can be more complex because in addition to the individual regulatory requirements for each component, e.g., a biologic and a medical device, additional combination product regulatory requirements may apply. The cost and timeline for development of any of our cell therapy product candidates determined to be a combination product may be substantially greater than that of other product candidates. In addition, even if the FDA does not determine that our product candidates are combination products, we may nevertheless be required to obtain approval from more than one Center of the FDA because a device will need to deliver our product candidates to patients. For example, we had to obtain approval from two Centers of the FDA (the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health) before the FDA would allow us to proceed with the DOSED clinical study. Having to obtain approval from more than one center of the FDA increases the chances of not receiving approval and adds complexity, time and cost.

We expect that the commercial opportunity for some of our products may depend on our ability, or that of a commercial collaborator, to obtain and maintain reimbursement and continued coverage from various payors, including government agencies and insurance companies.

If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

For example, in the United States, healthcare providers are reimbursed for covered services and products they deliver through Medicare, Medicaid and other government healthcare programs, as well as through private payers. No uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Decisions regarding whether to cover any of our product candidates, if approved, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. We may be required to provide specified rebates or discounts on the products we sell to certain government funded programs, including Medicare and Medicaid, and those rebates or discounts have increased over time. The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act (collectively, the "ACA"), enacted in 2010, increased many of the mandatory discounts and rebates and imposed a new branded prescription pharmaceutical manufacturers and importers fee payable each year by certain manufacturers.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Further, coverage policies and third-party payor reimbursement rates may change at any time. Therefore, even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

We face similar issues outside of the United States. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

In addition, we are subject to the risk that a negative perception of the future pharmaceutical pricing environment by potential collaborators and investors could negatively impact their financial models and their decision to invest in, or enter into a collaboration, with us. If investors have a negative view on the future pharmaceutical pricing environment, this could cause us to raise capital at higher cost and our stockholders could suffer greater dilution. If potential collaborators have such a view, this could make it more challenging for us to enter into collaborations on acceptable terms or at all, which could require us to fund clinical trials on our own, which we currently do not have the capital to do. See the risk factor above titled "Raising additional capital may cause dilution to our existing shareholders, restrict our operations, or require us to relinquish rights to or dilute our economic interest in our product candidates or technology on terms unfavorable to us."

Legislation and legislative, executive and regulatory proposals intended to contain health care costs may adversely affect our business.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. As an example, in August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Further, the Biden administration released an additional executive order on October 14, 2022, the U.S. Department of Health & Human Services to submit a report within 90 days on how the Center for Medicare and Medicaid Innovation can be further leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries. It is unclear whether this executive order or similar policy initiatives will be implemented in the future. Further, on December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act of 1980. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights, which would allow the U.S. government to share a company's drug patents developed with federal funds with other companies. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. The impact of these legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented on the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures, including the prescription drug provisions under the Inflation Reduction Act, as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

Disruptions at the FDA and other government agencies caused by funding shortages or other events or conditions outside of their control could negatively impact our business.

The ability of the FDA to review and approve proposed clinical trials or new product candidates can be affected by a variety of factors, including, but not limited to, government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, as a result of the COVID-19 pandemic, the FDA's inspectional activities were interrupted and restarted on a risk-based basis, which had the effect of delaying review and potential approval of product candidate marketing applications. In addition, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop various activities.

The ACA and future changes to that law may adversely affect our business.

As a result of the adoption of the ACA, in the United States, substantial changes have been made to the system for paying for healthcare in the United States. Among the ACA's provisions of importance to our industry are that it:

- created the branded prescription pharmaceutical manufacturers and importers annual fee;
- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price. However, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024;

- created new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded the entities eligible for discounts under the Public Health program;
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- created a licensure framework for follow on biologic products.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties for not complying with the ACA's individual mandate to carry health insurance, and eliminating the implementation of certain ACA-mandated fees. In June 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Moreover, prior to the United States Supreme Court ruling, in January 2021, President Biden issued an executive order that, among other things, instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, other litigation, and the healthcare reform measures of the Biden administration will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In 2024, CMS built upon the then U.S. presidential administration's goals of advancing health equity by expanding access to quality, affordable health coverage and care by increasing access to health care services, simplifying choice and improving the plan selection process. Considerable uncertainty exists regarding the nature and scope of healthcare reform measures under the new U.S. presidential administration.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in 2020 the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further,

in November 2020, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed until 2032 by the Inflation Reduction Act of 2022. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which has been delayed until 2032 by the Inflation Reduction Act of 2022. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. The Most Favored Nation regulations mandate participation by identified Medicare Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. As a result of litigation challenging the Most Favored Nation model, in December 2021, CMS published a final rule that rescinds the Most Favored Nation model interim final rule. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to President Biden's executive order, in September 2021, the HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In January 2025, the new U.S. presidential administration issued Executive Order 14148, which rescinded the prior U.S. presidential administration Executive Order 14087, which had built upon a July 2021 Executive Order by setting out the policy to have the HHS Secretary test healthcare payment and delivery models to lower drug costs. Considerable uncertainty exists regarding how the new U.S. presidential administration will reform the Inflation Reduction Act and other drug pricing policies.

If we fail to comply with the extensive legal and regulatory requirements affecting the healthcare industry, we could face increased costs, penalties and loss of business.

Our activities, and the activities of our collaborators, distributors and other third-party providers, are subject to extensive government regulation and oversight both in the U.S. and in foreign jurisdictions. The FDA and comparable agencies in other jurisdictions will directly regulate many of our most critical business activities, including the conduct of preclinical and clinical studies, product manufacturing, future advertising and promotion, product distribution, adverse event reporting and product risk management. Our current and future interactions in the U.S. or abroad with physicians and other healthcare providers that may prescribe or purchase our products once commercialized are also subject to government regulation designed to prevent fraud and abuse in the sale and use of the products and place greater restrictions on the marketing practices of healthcare companies. Healthcare companies are facing heightened scrutiny of their relationships with healthcare providers from anti-corruption enforcement officials. In addition, healthcare companies have been the target of lawsuits and investigations alleging violations of government regulation, including claims asserting submission of incorrect pricing information, impermissible off-label promotion of pharmaceutical products, payments intended to influence the referral of healthcare business, submission of false claims for government reimbursement, antitrust violations or violations related to environmental matters. Risks relating to compliance with laws and regulations may be heightened as we bring products to the market globally.

Regulations governing the healthcare industry are subject to change, with possibly retroactive effect, including:

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, pricing or marketing practices, compliance with wage and hour laws and other employment practices, method of delivery, payment for healthcare products and services, compliance with health information and data privacy and security laws and regulations, tracking and reporting payments and other transfers of value made to physicians and teaching hospitals, extensive anti-bribery and anti-corruption prohibitions, product serialization and labeling requirements and used product take-back requirements;
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;

- as a result of the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language, which has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays or changes;
- requirements that provide for increased transparency of clinical trial results and quality data, such as the EMA's clinical transparency policy, which could impact our ability to protect trade secrets and competitively sensitive information contained in approval applications or could be misinterpreted leading to reputational damage, misperception or legal action which could harm our business;
- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products; and
- changes the new U.S. presidential administration may institute to federal regulatory agencies including the FDA, including reductions in funding levels or restructuring of such agencies.

Additionally, conditions and regulations governing the health care industry in the U.S. are subject to greater risk of change and uncertainty as a result of changes in legislative and regulatory priorities and personnel.

Violations of governmental regulation may be punishable by criminal and civil sanctions against us, including fines and civil monetary penalties and exclusion from participation in government programs, including Medicare and Medicaid, as well as against executives overseeing our business. In addition to penalties for violation of laws and regulations, we could be required to repay amounts we received from government payors or pay additional rebates and interest if we are found to have miscalculated the pricing information we have submitted to the government. We cannot ensure that our compliance controls, policies and procedures will in every instance protect us from acts committed by our employees, collaborators, partners or third-party providers that would violate the laws or regulations of the jurisdictions in which we operate. Whether or not we have complied with the law, an investigation into alleged unlawful conduct could increase our expenses, damage our reputation, divert management time and attention and adversely affect our business.

Even if we receive approval to market a product candidate, we may be subject to extensive post-approval regulatory obligations that may have a significant adverse effect on our business, results of operations, financial condition and reputation.

Even after initial FDA or foreign regulatory agency approval has been obtained, further studies may be required to provide additional data on safety or to gain approval for the use of a product as a treatment for clinical indications other than those initially targeted. Use of a product during testing and after marketing could reveal side effects that could delay, impede, or prevent marketing approval, result in a regulatory agency-ordered product recall, or in regulatory agency-imposed limitations on permissible uses or in withdrawal of approval. For example, if the FDA or foreign regulatory agency becomes aware of new safety information after approval of a product, it may require us to conduct further clinical trials to assess a known or potential serious risk and to assure that the benefit of the product outweigh the risks. If we are required to conduct such a post-approval study, periodic status reports must be submitted to the FDA or foreign regulatory agency. Failure to conduct such post-approval studies in a timely manner may result in substantial civil or criminal penalties. Data resulting from these clinical trials may result in expansions or restrictions to the labeled indications for which a product has already been approved. Any of these requirements or actions may negatively impact our business or operations.

The FDA has granted orphan drug designation to OPC1 for the treatment of acute SCIs. However, there is no guarantee we will be able to maintain this designation, receive this designation for any other product candidate, or obtain the benefits associated with such designation, including marketing exclusivity.

We have orphan drug designation from the FDA for OPC1 for the treatment of acute SCIs and we may seek orphan drug designation for other product candidates. As discussed in more detail in Item 1. "Business—Government Regulation—FDA and Foreign Regulation of Therapeutic Products," above, generally, if a biologic with orphan drug designation from the FDA subsequently receives the first marketing approval for the indication for which it has such

designation, the product is entitled to seven years of marketing exclusivity in the United States. Other benefits of an orphan drug designation may include a waiver of the marketing application fee. However, the orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

We may not obtain any future orphan drug designations that we apply for. Orphan drug designations do not guarantee that we will be able to successfully develop our product candidates, and there is no guarantee that we will be able to maintain any orphan drug designations that we receive. For instance, orphan drug designations may be revoked if the FDA determines that our request for orphan drug designation was materially defective, if the FDA determines that the product candidate was not eligible for designation at the time of the submission of the request, or if we are unable to assure sufficient quantities of the commercial product for which the designation was granted to meet the needs of patients.

Moreover, even if we are able to receive and maintain orphan drug designations, we may ultimately not receive any period of regulatory exclusivity if our product candidates are approved. For instance, we may not receive orphan product regulatory exclusivity if the indication for which we receive FDA approval is broader than the orphan drug designation. Orphan exclusivity may also be lost for the same reasons that orphan drug designation may be lost. Orphan exclusivity may further be lost if we are unable to assure a sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan exclusivity for any of our current or future product candidates, that exclusivity may not effectively protect the product from competition as different products can be approved for the same condition or products that are the same as ours can be approved for different conditions. Even after an orphan product is approved, the FDA can also subsequently approve a product containing the same principal molecular features for the same condition if the FDA concludes that the later product is clinically superior. The FDA may further grant orphan drug designation to multiple sponsors for the same compound or active molecule and for the same indication. If another sponsor receives FDA approval for such product before we do, we would be prevented from launching our product in the United States for the orphan indication for a period of at least seven years, unless we can demonstrate clinical superiority. Moreover, third-party payors may reimburse for products off-label even if not indicated for the orphan condition.

Regenerative Medicine Advanced Therapy designation may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that a product candidate will receive marketing approval.

We received RMAT designation from the FDA for both OPC1 for the treatment of subacute SCIs as well as OpRegen for the treatment of GA secondary to AMD, and we may seek RMAT designation for other product candidates. There is no assurance that we will obtain RMAT designation for any other current or future product candidates. RMAT designation does not change the FDA's standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, including anti-kickback and false claims laws, transparency laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our current and future operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and healthcare professional transparency laws and regulations. These laws may impact, among other things, our research activities and our proposed sales, marketing, and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws, including the federal False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- HIPAA, which created new federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH and their implementing regulations, which imposes certain requirements on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose, access, or otherwise process individually identifiable protected health information, relating to the privacy, security, and transmission of individually identifiable health information;
- The Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS, information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payors, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare reform legislation has strengthened these laws.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply, we may be subject to significant penalties, including administrative, civil and criminal penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, imprisonment, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Our Clinical Development and Commercial Operations

Clinical development of new therapeutic products is a lengthy and expensive process with a high level of uncertainty as to timing and ultimate outcome.

Clinical and nonclinical development of new therapeutic products is expensive and can take many years to complete, and its outcome and timing are inherently uncertain. Clinical trials of our product candidates may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the development process. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials, and cell therapy is a relatively new field, which may heighten the risk of failure. Events that may prevent successful or timely completion of clinical development of our product candidates include, but are not limited to:

- inability to generate satisfactory preclinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical studies necessary for product approval;
- delays in identifying, developing or securing rights to use, and testing delivery systems or other methods for administration of our potential cell therapies;

- delays in securing clinical investigators and agreeing on acceptable terms with contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among CROs and clinical trial sites;
- delays in obtaining required institutional review board ("IRB") or ethics committee ("EC") approval at each clinical trial site;
- failure of IRB to follow FDA protocol;
- failure obtaining permission from regulatory authorities to conduct a clinical trial after review of an IND or equivalent foreign application or amendment;
- slower than anticipated rates of patient recruitment and enrollment or failure to reach the targeted number of study participants due to competition from other clinical trials or available treatment options (some potentially newly approved and marketed), or patients dropping out of our clinical studies once enrolled;
- failure by clinical sites or our CROs or other third parties to adhere to clinical trial requirements or report complete findings;
- failure to perform the clinical studies in accordance with the FDA's good clinical practices requirements or applicable foreign regulatory guidelines;
- occurrence of serious adverse events ("SAEs") or adverse events ("AEs") associated with our product candidates or with product candidates of third parties that may have characteristics similar to or perceived to be similar to our product candidates;
- negative or inconclusive results from clinical trials of our product candidates or clinical trials of product candidates with characteristics similar to or perceived as similar to our product candidates, which may result in decisions by us or our collaborators, or requirements imposed by regulators, to conduct additional clinical studies or to curtail or abandon development programs for a product candidate;
- inadequate effectiveness or unacceptable side effects, possibly resulting in the FDA or other regulatory authorities denying approval of our product candidates;
- approval and introduction of new therapies or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;
- inability to monitor patients adequately during or after treatment or problems with patient compliance with the clinical trial protocols;
- inability or unwillingness of medical investigators to follow our clinical trial protocols;
- inadequate supply or quality of clinical trial materials or other supplies necessary for the conduct of our clinical trials;
- delayed or unfavorable FDA or other regulatory agency inspection and review of a clinical trial site or a manufacturing facility;
- inability to use clinical trial results from foreign jurisdictions to support U.S. regulatory approval;
- changes in regulatory requirements and guidance that require amending clinical trial protocols or conducting additional clinical or nonclinical studies; and
- greater than anticipated cost of clinical studies of our product candidates.

If patients drop out of our clinical trials, miss scheduled doses or follow-up visits or otherwise fail to follow clinical trial protocols, or if our clinical trials are otherwise disrupted due to unforeseen events, such as previously occurred as a result of the COVID-19 pandemic as discussed elsewhere in this Risk Factors section, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program. In addition, the risks and uncertainties discussed herein with respect to clinical development we conduct or control, similarly apply to clinical development of our product candidates by a strategic collaborator.

Delays or any inability to successfully complete clinical development and obtain regulatory approval could result in additional costs to us, impair our ability to generate revenue and harm our financial condition. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow competitors to develop and bring products to market before we do and may harm our prospects and results of operations.

The results of preclinical studies and early clinical trials of our product candidates are not necessarily predictive of future results. Our product candidates may not have favorable results in later clinical trials despite positive results in preclinical and early clinical studies, which may have a material and adverse effect on our business and financial condition.

All of our product candidates will require substantial additional development, and no assurances can be given that the development of any of our product candidates will ultimately be successful, whether development activities are conducted by us or a strategic collaborator. Results from preclinical testing and clinical studies of our product candidates, may support continued development and we or a collaborator may spend significant time and resources on development of a potential product based on results of such early studies, but product candidates in later stages of development may fail to demonstrate safety and efficacy results necessary for regulatory approval or commercial viability. Many companies in our industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products. A failure of one or more clinical studies can occur at any stage of development, including in a post-approval study.

In later clinical studies, our product candidates may not demonstrate the efficacy, durability of efficacy, or safety achieved in preclinical and earlier clinical studies for a variety of reasons, including:

- our efforts to improve, standardize, and scale up the manufacture of our clinical product candidates, including OpRegen and OPC1, and any resulting changes to the product candidates, may adversely affect the safety, purity, potency or efficacy of such product candidates;
- differences in delivery systems or other methods of transplant or administration of our cell formulations;
- differences in trial design, including number of subjects, controls (type and number), eligibility criteria, patient populations, and endpoints;
- the complexity of our product candidates;
- advancements in the standard of care, including newly approved and/or marketed products, may affect our ability or that of a collaborator to demonstrate efficacy or achieve trial endpoints in current or future clinical trials of our product candidates; and
- variability in interpretation and analysis of study data.

For example, based on data analyzed to date, in our Phase 1/2a open-label trial for OpRegen, OpRegen has been well tolerated and demonstrated an acceptable safety profile, with no unexpected adverse events, while having qualifiable and quantifiable therapeutic potential in patients with geographic atrophy secondary to age-related macular degeneration. However, positive data from the Phase 1/2a trial are not necessarily predictive of results that may be seen from the ongoing Phase 2a clinical trial of RG6501 (OpRegen) being conducted by Roche. We do not know how OpRegen will perform in that Phase 2a trial or future clinical trials.

Additional clinical trials of our product candidates, which may include registrational trials, trials in additional patient populations or under different treatment conditions, and trials using different manufacturing protocols, processes, materials or facilities or under different manufacturing conditions, will be necessary before we or our collaborators are able to seek approvals for our product candidates from the FDA and regulatory authorities outside the United States to market and sell these product candidates. Our failure, or that of our collaborators, to meet the requirements to support marketing approval for our product candidates in ongoing and future clinical trials would substantially harm our business and prospects. If clinical trials of our product candidates are not successful, our business, financial condition and results of operations could be materially harmed, and the price of our common shares may decline significantly following announcement of an unsuccessful clinical trial.

Interim, topline and preliminary data from clinical trials of our product candidates that we or our collaborators publicly disclose from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in final clinical data that is materially different and unfavorable.

From time to time, we or collaborators conducting clinical trials of our product candidates may publicly disclose interim, preliminary or topline data from those clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, preliminary and topline results reported for clinical trials of our product candidates may differ from final results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Such data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously disclosed by us or a collaborator. As a result, preliminary and topline data should be viewed with reservation until the final data are available. From time to time, we or a collaborator may also disclose interim data from clinical trials of our product candidates. Interim data from clinical trials of our product candidates are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary, topline or interim data and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or those of our collaborators, or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we or a collaborator chooses to publicly disclose regarding a particular trial is based on what is typically extensive information, and you or others may not agree with what we or the collaborator determines is the material or otherwise appropriate information to include in the public disclosure, and any information we or the collaborator determines not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the topline data reported by us or a collaborator differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability, or that of a collaborator, to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

The manufacture of our cell therapy product candidates is complex, highly regulated and subject to a multitude of risks. We have limited experience manufacturing our product candidates on a clinical scale and no experience manufacturing on a commercial scale. Any failure to manufacture our product candidates in sufficient quantities in accordance with applicable quality standards and regulatory requirements and at acceptable costs, may result in significant clinical development delays or impair our ability, or that of a strategic collaborator, to obtain approval for or commercialize our product candidates.

The manufacture and supply of our cell therapy product candidates involve novel processes that are generally more complex than those required for small molecule drugs and accordingly present significant challenges and are subject to multiple risks. These complex processes involve the expansion and differentiating of pluripotent or embryonic stem cells to produce a master cell bank from which an indefinitely renewable working cell bank can be obtained in order to produce the desired cell product candidate. Reprograming pluripotent cells or establishing a line of cells from embryonic stem cells that can proliferate without differentiating and remain well characterized, including being free of potentially deleterious genetic mutations, is challenging and requires a significant amount of time and resources. The process requires significant expertise and capital investment, including in the development and validation of advanced manufacturing techniques and specific quality assurance and quality control procedures. As a result of the complexities involved, the cost to manufacture human cell-based biologics is generally higher than for traditional therapies and the manufacturing process is less reliable and more difficult to reproduce. In addition, our cost of goods development is at an early stage. The actual cost to manufacture and supply our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates. Excessive manufacturing costs could make our product candidates too expensive to compete with alternative products or therapies, or might result in third-party payors declining to cover our products or setting coverage levels too low for us or a strategic collaborator to earn a profit from the commercialization of one or more of our products.

We will need to scale up our manufacturing operations to produce sufficient quantities of our cell therapy product candidates for later-stage clinical trials and potential commercialization, as we do not currently have the infrastructure or capability to manufacture sufficient quantities of each of our product candidates to support large clinical trials or commercialization, if approved. Currently, as described elsewhere in this Risk Factors section, we are entirely dependent on our subsidiary, CCN, and its manufacturing facility located in Israel for the manufacture and supply of our cell therapy product candidates. While that facility is designed and equipped to enable simultaneous cGMP processes and to produce a range of human cell therapy products for use in clinical trials, as well as at a scale suitable for commercial launch, gene and cell therapy product manufacturers often encounter difficulties in production, particularly in scaling up, validating initial production, ensuring the absence of contamination, and ensuring process robustness after initial production. These include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, and shortages of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. We are subject to those challenges. As a result of the complexities involved in manufacturing, the cost to manufacture our product candidates is generally higher than traditional small molecule chemical compounds and the manufacturing process is less reliable and more difficult to reproduce.

In addition, we will need greater manufacturing capacity to support commercial development of all our product candidates. If we do not have sufficient capital to increase our internal manufacturing capabilities, we may need to rely on third-parties to manufacture and supply any products we develop and there is no assurance that we would be able to identify third parties capable of manufacturing our product candidates on acceptable terms or at all.

We are still developing optimized and reproducible manufacturing processes for clinical and commercial-scale manufacturing of our product candidates. To date, we have not scaled the manufacturing processes with respect to any of our product candidates for commercialization. None of our manufacturing processes have been validated for commercial production of our product candidates. We may face multiple challenges as we scale up our manufacturing operations or transfer manufacturing operations to a strategic collaborator or other third-party manufacturer and, ultimately, we or such third party may not be successful as to one or more of our product candidates. These challenges include, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability and purity issues, compliance with cGMP and cGTP, lot consistency and timely availability and quality of acceptable reagents and raw materials. In addition, we are continuing to optimize our protocols for the supply and transport of our product candidates for distribution to clinical trial sites. Although we are working to develop reproducible and commercially viable manufacturing processes for our product candidates, and effective protocols for the supply and transport of our product candidates, doing so is a difficult and uncertain task. If we or a strategic collaborator or other third-party manufacturer are unable to scale production to the level required for commercialization, we or they may not be able to meet the requirements for the potential commercial launch or to meet potential future demand if any product candidates are approved for commercialization, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

The manufacturing processes for any products that we may develop and the facilities used to manufacture our product candidates are subject to FDA and foreign regulatory authority approval requirements, and we will need to meet, and any third party manufacturers we may rely on the future will need to meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. We cannot provide assurance that the manufacturing processes we use or that any future third-party manufacturer uses, or the technologies incorporated into these processes, will result in viable or scalable yields of our product candidates that will have safety, purity, potency, and efficacy profiles acceptable to us, our partners or collaborators, including Roche, or regulatory authorities, or meet market demand. We may be required to identify alternative protocols, processes, raw materials, or facilities for the manufacture of any of our product candidates in compliance with applicable regulatory requirements. In addition, we may be required to increase our safety testing protocols for our product candidates. Any modifications to our manufacturing and supply protocols, processes, safety testing, materials or facilities, including as a result of transferring manufacturing operations to a strategic collaborator or other third-party manufacturer, and any delays in, or inability to, establish acceptable manufacturing and supply operations for our product candidates could require us to incur substantial additional development costs or result in significant delays to clinical development or regulatory approval of our product candidates. If we or any future third-party manufacturer is unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we or a collaborator may not obtain or maintain the regulatory approvals needed to commercialize our product candidates. Even if we or a collaborator obtains regulatory approval for any product candidates, there is no assurance that either we or any future third-party manufacturer will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities and on the requisite timelines to meet the requirements for the potential launch of the product,

or to meet potential future demand. Additionally, changes in regulatory requirements may require us or a third-party manufacturer to perform additional studies or to modify protocols, processes, materials or facilities for the manufacture of our product candidates or any components thereof. Any of these challenges could delay initiation or completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase the cost of goods, and have an adverse effect on our business, financial condition, results of operations and prospects.

In addition, because developing cell therapy products is based on novel technologies that are unproven and may not result in approvable or marketable products, the lack of success, or perceived lack of success, of other companies developing or seeking to develop cell therapy products may adversely impact investor sentiment regarding our business and the market opportunities for our product candidates.

Changes in or disruptions to our manufacturing operations could materially and adversely affect our business.

We may have to make changes to the manufacturing operations or processes for our product candidates at various points during development, before or after commercialization, for various reasons, such as to control costs, achieve scale, decrease processing time, increase manufacturing success rate, or for other reasons, such as to transfer manufacturing responsibilities to a collaborator. Such changes, even seemingly minor changes, carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of any then-ongoing clinical trials or future clinical trials, or the performance of the product. In certain circumstances, if changes are made to the manufacturing operations or process for a product candidate, the FDA or foreign regulatory authorities may require comparability studies to be performed and additional preclinical or clinical data to be collected prior to undertaking additional clinical trials or obtaining marketing approval for the product candidate, or if already on the market, prior to supplying any product produced with such modified process. For instance, if changes are made to the manufacturing process for a product candidate during the course of clinical development, regulatory authorities may require us or our collaborator to show the comparability of the product used in earlier clinical phases or earlier portions of a trial to the product used in later clinical phases or later portions of the trial. We or our collaborator may be unable to successfully generate comparability data, and even if such data is generated and provided, regulatory authorities may determine that the data are insufficient to support a determination of comparability which would result in additional testing, and could result in manufacturing delays and affect our ability, or that of our collaborator, to timely commence or complete clinical trials of our product candidate, which could delay further development or commercialization of such product candidate and may increase our development costs substantially and/or delay payments to us from a collaborator.

Currently, as described elsewhere in this Risk Factors section, we are entirely dependent on our subsidiary CCN and its manufacturing facility located in Israel for the manufacture and supply of our cell therapy product candidates, and events or conditions that disrupt operations at that facility could materially and adversely affect our business. In 2022, we announced the opening of a new research and development facility in Carlsbad, California to support the development of current and future allogeneic cell transplant programs. Utilization of this new facility for cGMP manufacturing of our product candidates will require significant additional investment, including hiring and retaining additional experienced scientific, quality control, quality assurance, and manufacturing personnel, which may be difficult given the intense competition for qualified personnel in our industry as described elsewhere in this Risk Factors section. Even if we have sufficient capital to complete the build-out and staffing of the Carlsbad facility, we will need to conduct significant development work to transfer our manufacturing processes to enable manufacturing of any product candidate in our Carlsbad facility. Transferring manufacturing testing and processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. If, in the future we were to transfer manufacturing responsibilities to a collaborator, as we expect to do with OpRegen, or engage a third-party manufacturer to conduct any of the cGMP manufacturing for our product candidates, or any product, we would face similar and significant challenges in transferring manufacturing processes and know-how, which may delay the manufacture of clinical trial or commercial supplies and disrupt or delay clinical development of our product candidates. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We or our collaborator may be required to demonstrate the comparability of clinical material generated at any new facility with material previously produced and used in clinical testing. Any inability to manufacture comparable material by us, a collaborator, or any third-party manufacturer we may engage could delay the development and commercialization of our product candidates and may increase our development costs substantially.

Our product candidates are susceptible to product loss or reduced manufacturing success rates at various points during the manufacturing process, including quality issues due to contamination, equipment damage or failure, including during shipment or storage, failure of equipment to operate as expected, improper installation or operation of equipment, operator error, damage to, variability of, or improper use of raw materials or consumables necessary for the manufacturing process, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Any of these issues, and even minor deviations from normal manufacturing processes, could result in reduced production yields, product defects, and other supply disruptions and delays. If any contaminants are discovered in a product candidate during production or clinical testing this could lead to the withdrawal of the product from clinical trials. Moreover, if the FDA or comparable foreign regulatory authorities determine that we or any future third-party manufacturer is not in compliance with applicable laws and regulations, including cGMPs and cGTPs, the FDA or comparable foreign regulatory authority may not approve a marketing application until the deficiencies are corrected or we or a collaborator replace the manufacturer in our application with a manufacturer that is in compliance, which may not be feasible on a timely basis at a reasonable cost, or at all. If we or any future third-party manufacturer fails to comply with applicable regulatory requirements, we or a collaborator may ultimately be unable to manufacture the product candidate. Any such failure could be the basis for the FDA to issue a warning letter or an untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of supplies of the product candidate, total or partial suspension of production, suspension of then-ongoing clinical trials, refusal to approve then-pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties. The occurrence of any of these issues could result in product liability claims, delay or failure to commence or complete clinical development, obtain regulatory approval of or commercialize our product candidates.

Our manufacturing operations, and those of any third-party manufacturer on which we may rely, are also susceptible to disruption due to resource constraints, labor shortages, supply chain failures, public health emergencies, geopolitical conflict, war, acts of terrorism, political or economic instability or crises, natural disasters, and other reasons. Any adverse developments affecting manufacturing operations for any of our product candidates may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other supply interruptions that could negatively impact the conduct of clinical trials or the commercialization of any product candidates for which we or a collaborator may obtain regulatory approval. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications as a result of defects or storage over an extended period of time, undertake costly remediation efforts, or seek more costly manufacturing alternatives, which may not be available on a timely basis, or at all.

The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance by physicians, patients, third-party payors, other healthcare providers and others in the medical community.

Even if a product candidate obtains regulatory approval, its commercial success will depend in part on physicians, patients, third-party payors, other healthcare providers and others in the medical community accepting our product candidates as medically useful, cost-effective, and safe. Any product candidate we or a collaborator brings to the market may not gain market acceptance by such parties. The degree of market acceptance of any of our product candidates will depend on several factors, including without limitation:

- the efficacy of the product as demonstrated in clinical trials and potential advantages over competing treatments;
- the prevalence and severity of any side effects;
- the clinical indications for which approval is granted, including any limitations or warnings contained in a product's approved labeling;
- the convenience and ease of administration, including compared to alternative treatments;
- the cost of treatment, including in relation to alternative treatments;
- the willingness of the patients and physicians to accept and use these therapies;
- the marketing, sales and distribution support for the products;
- the publicity concerning our products or competing products and treatments; and

- the pricing and availability of coverage and adequate reimbursement by third-party payors and government agencies

Even if a product displays a favorable efficacy and safety profile upon approval, market acceptance of the product will be uncertain. Efforts to educate the medical community and third-party payors on the benefits of the products may require significant investment and resources and may never succeed. If our product candidates fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, other healthcare providers and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

If the market opportunities for our product candidates prove to be significantly smaller than we estimate, our business prospects may suffer.

Our projections of addressable patient populations within any particular disease state or condition that may benefit from treatment with our product candidates are based on our beliefs and estimates. Market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates. Our estimates have been derived from a variety of sources, including market research and publications and scientific literature estimating the total number of potential patients and currently approved or used therapies. Our estimates are also based on assumptions regarding the potential size of the market assuming broad regulatory approval or potential usage by physicians beyond the approved label. Any of our estimates may prove to be incorrect. The scope of approval and potential use of any product candidate may be significantly narrower, and the number of patients may turn out to be lower than expected. Competitive products or approaches may be approved or come into use and achieve market penetration earlier than our products candidates. The potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to. If any of our estimates proves to be inaccurate, the market opportunity for any of our product candidates could be significantly diminished, which would have an adverse material impact on our business.

We face significant competition and the possibility that our competitors may develop therapies that are more effective, safer, more convenient, or less expensive than our product candidates. In addition, competitive products may be approved and successfully commercialized before ours, which may adversely affect our ability, or that of a strategic collaborator, to successfully commercialize our product candidates.

The biotechnology and pharmaceutical industries, including the still emerging area of cell therapies, is intensely competitive and characterized by rapid and significant innovation. Any of our product candidates that obtains regulatory approval will face substantial competition based on many different factors, including its relative safety and efficacy, ease of administration for healthcare providers, convenience of use for patients, as well as the timing and scope of regulatory approvals for our product, the cost of manufacturing and whether sufficient quantities can be produced to meet demand, our marketing and sales capabilities or those of our collaborators, pricing, reimbursement coverage levels, and patent positions. Competing products could present superior treatment alternatives, including by being more effective, safer or easier or more convenient to administer, or may be less expensive for third-party payors or patients or marketed and sold more effectively than any products we may develop.

Our competitors include a variety of major pharmaceutical and biopharmaceutical companies and specialty pharmaceutical and biotechnology companies, as well as technology and therapeutics being developed at academic institutions and other public and private research institutions. Many of our competitors have greater financial and other resources, such as larger research and development staff, more experienced manufacturing organizations and facilities, and established sales and marketing organizations. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources, including intellectual property that may be necessary or useful for the development and commercialization of our product candidates, being concentrated in our competitors and becoming unavailable to us on reasonable commercial terms or at all. Third parties are commercializing, have developed, are developing or may develop product candidates, platform technologies and processes that will compete with ours. Competitive therapeutic treatments may include those that have already been approved and accepted by the medical community and considered standard-of-care treatments, as well as novel treatments recently approved or that are currently in preclinical or clinical development and may obtain market penetration earlier than our products do. For example, in 2023, the FDA approved two therapies for the treatment of GA secondary to AMD, Apellis Pharmaceuticals, Inc.'s SYFOVRE® (pegcetacoplan injection) and IVERIC bio, Inc.'s IZERVAY™ (avacincaptad

pegol intravitreal solution), and these treatments became available to patients in the U.S. One or both of those products may obtain significant market penetration before OpRegen completes clinical development. Regulatory approval and/or the achievement of clinical or commercial success of one or more competing products or product candidates may reduce or eliminate the market for our product candidates. For additional information regarding our competition, see "Business—Competition" in Item 1 above. In addition, if one or more competing products fail to obtain regulatory approval or achieve clinical or commercial success and are perceived by regulators, healthcare providers, third-party payors or potential patients as comparable to our product candidates, our regulatory strategy could be impaired, our ability, or that of a collaborator, to obtain regulatory approval for our product candidates could be delayed or prevented, or the market for our product candidates may be reduced or eliminated.

Competitive products may make any product we develop obsolete or noncompetitive before we recover the expense of developing and commercializing the product. If we or our collaborators are unable to compete effectively, the products we may develop independently or in collaboration with a third party, if approved, may never achieve significant market share or generate significant revenue, which could adversely affect our business, prospects and financial condition.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs. If the use or misuse of our products or product candidates harm patients or is perceived to harm patients even when such harm is unrelated to our products or product candidates, our regulatory approvals could be revoked, suspended or otherwise negatively affected, our reputation could suffer, and we could be subject to costly and damaging product liability claims.

We face the risk of incurring liabilities to clinical trial patients if they are injured as a result of their participation in clinical trials of our product candidates or products. We also face potential product liability for use or misuse of our products that obtain regulatory approval and are commercialized. In 2023, we settled a product liability lawsuit, which we determined was not material, relating to the use in a clinical trial of a product candidate that we are no longer developing and have no plans to pursue, and that is not related to the cell therapy candidates we currently are developing. See Note 13 (Commitments and Contingencies) to our consolidated financial statements included this report for additional information. We may not successfully defend any product liability claims made against us in the future. Product liability claims could delay or prevent completion of our clinical development programs. Such claims could result in FDA or other regulatory authority investigations of the safety of our product candidates or products, our manufacturing processes and facilities or our marketing programs. If any claims are made and if liability can be established, the amount of any liability we or our affiliates may incur, could exceed any insurance coverage in effect, and the amount of the liability could be material to our financial condition and operating results. In addition, even if we successfully defend against product liability claims, we could incur substantial costs in defending against claims and suffer significant reputational harm that negatively impacts our business.

The use or misuse of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by those who use our product candidates in clinical trials, consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates or future products may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. Legal proceedings are inherently uncertain and unpredictable and proceedings believed to be immaterial could prove to have a material adverse effect on our business, operating results and financial condition. Regardless of merit or eventual outcome, product liability claims may result in:

- reputational harm;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- substantial costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to complete development of or commercialize our product candidates;

- product recalls, withdrawals or labeling, marketing or promotional restrictions; and
- decreased demand for any marketed products.

We may not be able to maintain appropriate product liability insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to product liability claims. If and when we obtain marketing approval for a product candidate and prior to commercial launch, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain appropriate product liability insurance on commercially reasonable terms or in adequate amounts. Significant damages have been awarded in class action lawsuits based on drugs or medical treatments that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause the price of our common shares to decline and, if the amount of damages exceeds our insurance coverage, could adversely affect our results of operations and business.

We currently have no marketing and sales force or distribution capabilities. If we are unable to establish effective internal capabilities or effectively collaborate with third parties to market and sell our product candidates, if approved, our ability to generate product revenue will suffer.

We currently have no marketing, sales, or distribution capabilities because all of our cell therapy product candidates are in preclinical or early clinical development, or in OpRegen's case, we have entered into an agreement whereby Roche has commercialization responsibility for the product, if approved. We will need to build on a territory-by-territory basis marketing, sales, distribution and supporting capabilities to commercialize any other product candidate that obtains regulatory approval, or selectively seek to enter into similar strategic collaborations or otherwise outsource these functions to one or more third parties such as contract sales organizations and distributors. There are significant risks involved if we decide to establish our own sales and marketing capabilities or enter into arrangements with third parties to perform these functions. To the extent that we enter into collaboration agreements with respect to marketing, sales, or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would subject us to a number of risks, including that we may not be able to control the amount or timing of resources that a commercialization collaborator devotes to our products or that a collaborator's willingness or ability to complete its obligations may be adversely affected by business combinations or significant changes in the collaborator's business strategy. If we are unable to enter into these arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. Building our own sales and marketing team with technical expertise and supporting distribution capabilities, would require a significant capital investment and require significant attention of our senior management team to manage, and any failure or delay in the development of those internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our product candidates that obtain approval. If we are unable to develop adequate marketing and sales capabilities on our own or effectively partner with third parties, our ability to generate product revenue will suffer and we may incur significant additional losses, which would have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to our Intellectual Property

Our intellectual property may be insufficient to protect our products.

Our patents and patent applications are directed to compositions of matter, formulations, methods of use and/or methods of manufacturing, as appropriate. In addition to patenting our own technology and that of our subsidiaries, we have licensed patents and patent applications for certain stem cell technologies, human pluripotent stem cells, and hES cell lines, and other technologies from other companies. We own or license, directly or through our subsidiaries, patent families that include several hundred U.S. and international patents and patent applications. We cannot be certain that issued patents will be enforceable or provide adequate protection or that pending applications will result in issued patents. In addition to the loss of patent protection due to expiration, from time to time, we assess our patents and pending applications covering our products and product candidates and if we determine that any patents or patent applications no longer provide adequate or necessary protection, we abandon such patents and patent applications to avoid incurring unnecessary costs.

The patent positions of pharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal and factual questions. Our business could be negatively affected by any of the following:

- the claims of any patents that are issued may not provide meaningful protection, may not provide a basis for commercially viable products or may not provide us with any competitive advantages;
- the validity of our patents may be challenged by third parties;
- others may have patents of which we are not aware that relate to our technology or business that may prevent us from marketing our product candidates unless we are able to obtain a license to those patents;
- our pending patent applications and the pending patent applications to which we have rights may not result in issued patents;
- we may have to participate in interference/derivation proceedings or litigation to determine the right to a patent.
- our patents may have claims that are inadequate to protect our competitive position on our products; and
- we may not be successful in developing additional proprietary technologies that are patentable.

In addition, others may independently develop similar or alternative technologies, duplicate any of our technologies and, if patents are licensed or issued to us, design around the patented technologies licensed to or developed by us. Moreover, we could incur substantial costs in litigation if we have to defend ourselves in patent lawsuits brought by third parties or if we initiate such lawsuits and in other proceedings relating to the validity of our patents.

Confidentiality agreements with employees and third parties may not prevent disclosure of trade secrets and other proprietary information.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, subject matter for which patents are difficult to enforce, and other elements of our product candidates, technology, and product discovery and development processes that involve proprietary know-how, information, or technology that we do not cover through patent protection. Any disclosure, either intentional or inadvertent, by our current or former employees, consultants, collaborators, or those of third parties, including consultants and vendors that we engage to perform research, clinical trials, or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary or confidential information could enable competitors to duplicate or surpass our technological achievements and erode our competitive position in our market. Because we collaborate and expect to continue to collaborate with third parties in the development and manufacture of our product candidates, we may, at times, share trade secrets with them, which increases the possibility that our trade secrets will be misappropriated or disclosed.

Trade secrets and confidential information can be difficult to protect. We seek to protect our trade secrets, know-how, and confidential information, in part, by entering into confidentiality agreements with our employees, consultants, vendors, collaborators and other third parties. For example, we require our employees and consultants to execute confidentiality and invention assignment agreements upon accepting employment or entering into other relationships with us. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary or confidential information, including our technology and processes. We also implement internal policies and procedures to ensure protection of our proprietary confidential information including know-how and trade secrets through, for example, limited and restricted confidential access to this information. Although we use reasonable efforts and employ reasonable means to protect our trade secrets and confidential information, our employees, consultants, vendors, collaborators and other third parties might intentionally or inadvertently disclose such information to competitors or other third parties in breach of our agreements with such parties, and adequate remedies for such breaches may be unavailable. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, we may be required to disclose trade secrets and other confidential information to governmental authorities, including in connection with regulatory filings related to our product candidates, and such authorities may make certain documentation or information contained therein available to the public. If we are unable to or otherwise fail to take

advantage of any opportunity to protect trade secrets or other confidential information, our competitors could use such information to compete with us, which would significantly harm our business.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition.

If we are unable to obtain and enforce patents and to protect our trade secrets, others could use our technology to compete with us, which could limit opportunities for us to generate revenues by licensing our technology and selling products.

Our success will depend in part on our ability to obtain and enforce patents and maintain trade secrets in the United States and in other countries. If we are unsuccessful at obtaining and enforcing patents or maintaining trade secrets, our competitors could use our unpatented technology or trade secrets and create products that compete with our products, without paying license fees or royalties to us. The preparation, filing, prosecution and maintenance of patent applications and patents can be costly and time consuming. Our limited financial resources may not permit us to pursue patent protection of all of our technology and products in all key markets. Even if we are able to obtain issued patents covering our technology or products, we may have to incur substantial legal fees and other expenses to enforce our patent rights to protect our technology and products against infringers.

We may not have the financial resources to finance the litigation required to preserve our patent and trade secret rights. Litigation, interferences, oppositions, inter partes reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. This means that patents owned or licensed by us, or our trade secrets, may be lost if the outcome of a proceeding is unfavorable to us.

There is no certainty that our pending or future patent applications will result in the issuance of patents.

Our success depends in part on our ability to obtain, protect and defend patent and other intellectual property rights such as trade secrets that are important to the commercialization of our products and product candidates. The degree of patent protection and trade secret protection that will be afforded to our products and processes in the U.S. and in other important markets remains uncertain and is dependent upon the scope of protection decided upon by the patent offices, courts, administrative bodies and lawmakers in these countries. We can provide no assurance that we will successfully obtain or preserve patent protection or trade secret protection for the technologies incorporated into our products and processes, or that the protection obtained will be of sufficient breadth and degree to protect our commercial interests in all countries where we conduct business. If we cannot prevent others from exploiting our inventions, patented technologies and trade secrets, we will not derive the benefit from them that we currently expect. Furthermore, we can provide no assurance that our products will not infringe patents or other intellectual property rights held by third parties.

In Europe, there is uncertainty about the eligibility of hES cell subject matter for patent protection. The European Patent Convention prohibits the granting of European patents for inventions that concern “uses of human embryos for industrial or commercial purposes.” A recent decision at the Court of Justice of the EU interpreted parthenogenetically produced hES cells as patentable subject matter. Consequently, the European Patent Office now recognizes that human pluripotent stem cells (including human ES cells) can be created without a destructive use of human embryos as of June 5, 2003, and patent applications relating to hES cell subject matter with a filing and priority date after this date are no longer automatically excluded from patentability under Article 53 (a) EPC and Rule 28(c) EPC.

Intellectual property we may develop using grants received from governmental entities are subject to rights maintained by those governments.

Research and development we perform that is funded by grants from governmental entities and any intellectual property that we create using those grants may be subject to certain rights of the governmental entities to require that we license or grant rights to the intellectual property developed using that funding in certain circumstances.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

We enter into agreements with our employees pursuant to which they agree that any inventions created in the scope of their employment are assigned to us or owned exclusively by us, without the employee retaining any rights. A significant portion of our intellectual property has been developed by our employees and CCN's employees in the course of their employment. Under the Israeli Patent Law, 5727-1967 (the "Patent Law"), inventions conceived by an employee during the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his or her inventions. Previous decisions by the Israeli Compensation and Royalties Committee have created uncertainty in this area regarding whether the right to receive remuneration for service inventions can be voluntarily waived by an employee and whether such waiver is enforceable. In addition, the Committee determined that even if such right to receive compensation and royalties for service inventions may be waived, the waiver should be specific. Subsequent court cases have not provided significant clarity on these matters.

The Israeli Supreme Court noted (in an obiter dictum) in 2012, without making any decisive ruling, that an employee who contributes to an invention during his employment could be allowed to seek compensation for it from their employer, even if the employee's contract of employment specifically states otherwise and the employee has transferred all intellectual property rights to the employer. The Israeli Supreme Court considered the possibility that a contract that revokes the employee's right for royalties and compensation may not necessarily foreclose the right of the employee to claim a right for royalties. As a result, even if we believe that none of our employees has any rights in any of our intellectual property, or to receive royalties, it is unclear if, and to what extent, our employees may be able to claim compensation with respect to our future revenue. As a result, we may receive less revenue from future products if such claims are successful, or incur additional royalty expenses, which in turn could impact our future profitability.

There is no certainty that we will be able to obtain licenses to intellectual property rights owned by third parties.

There are no assurances that any of our intellectual property rights will guarantee protection or market exclusivity for our products and product candidates. In such cases, we may need to obtain enabling licenses from third parties to protect our products and product candidates, try to secure market exclusivity or avoid infringing on the intellectual property rights of third parties. If we are unable to fully protect our product candidates or achieve market exclusivity for our products and product candidates, our financial success will be dependent, in part, on our ability to protect and enforce our intellectual property rights, and to operate without infringing upon the proprietary rights of others by obtaining enabling licenses.

As an example, Astellas' patent portfolio with respect to the manufacture of its RPE products could adversely impact our rights to manufacture or commercialize OpRegen. Moreover, we could incur substantial costs in litigation if we have to defend ourselves in patent lawsuits brought by third parties or if we initiate such lawsuits. We may also face competition from companies that have filed patent applications or have obtained patents relating to the propagation and differentiation of stem cells. Those companies include Ocata, which in 2015 had certain U.S. patents issue with claims directed to methods of producing RPE cells and isolating and purifying such cells. We may be required to seek licenses from these competitors in order to commercialize certain products proposed by us, and such licenses may not be granted.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. We cannot be certain that our platform technologies, product candidates, and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. The legal and administrative landscape related to infringement of the patents and proprietary rights of third parties is fluid as there is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents. These include interference, derivation, inter partes review, post-grant review, and reexamination proceedings before the U.S. Patent and Trademark Office or oppositions and other comparable proceedings in foreign jurisdictions. Litigation and other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and, even if resolved in our favor, are likely to divert significant resources from our core business and distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to enter into or compete in the marketplace.

Risks Related to our Dependence on Third Parties

We may become dependent on possible future collaborations to develop and commercialize many of our product candidates and to provide the regulatory compliance, sales, marketing and distribution capabilities required for the success of our business.

We may enter into various kinds of collaborative research and development and product marketing agreements to develop and commercialize our product candidates. The expected future milestone payments and cost reimbursements from collaboration agreements could provide an important source of financing for our research and development programs, thereby facilitating the application of our technology to the development and commercialization of our products, but there are risks associated with entering into collaboration arrangements.

As described elsewhere in this Risk Factors section, we are dependent on our collaboration with Roche to develop and commercialize OpRegen, and we could become dependent upon one or more possible future collaborative arrangements. A collaborative arrangement upon which we might depend might be terminated by our collaboration partner or a partner might determine not to actively pursue the development or commercialization of our products. Termination of a collaboration agreement by a collaboration partner could dissuade other organizations from collaborating with us and negatively impact our ability to enter into new collaborations or achieve favorable collaboration terms. A collaboration partner also may not be precluded from independently pursuing competing products and drug delivery approaches or technologies.

There is a risk that a collaboration partner might fail to perform its obligations under the collaborative arrangements or may be slow in performing its obligations, or that we have a dispute that harms our working relationship and requires significant resources to resolve, or that we are unable to resolve on our own, resulting in costly legal proceedings. In addition, a collaboration partner may experience financial difficulties at any time that could prevent it from having available funds to contribute to the collaboration. If a collaboration partner fails to conduct its product development, commercialization, regulatory compliance, sales and marketing or distribution activities successfully and in a timely manner, or if it terminates or materially modifies its agreements with us, the development and commercialization of one or more product candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue such development and commercialization on our own.

We do not have the ability to independently conduct clinical trials required to obtain regulatory approvals for our product candidates and we rely on third parties over whom we have limited control to perform important clinical and preclinical development activities for us.

We currently rely, and plan to continue to rely, on third parties such as CROs, data management companies, contract clinical research associates, medical institutions, clinical investigators and contract laboratories to assist with

preclinical development and conduct clinical trials of our product candidates and we may encounter challenges or delays in our development programs as a result of this reliance. Because these third parties are not our employees, we have limited control over whether or not they devote sufficient time and resources on our programs. Due to our reliance on these third parties, we may not directly control the timing, conduct and expense of our clinical trials. Changing or adding additional CROs involves additional cost and requires management time and attention. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur that could negatively impact our ability to meet our anticipated clinical development timelines. If the third parties we engage fail to perform their contractual duties or regulatory obligations or fail to meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to failing to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not obtain regulatory approval for or successfully commercialize our product candidates.

We obtain reagents and specialized materials and equipment required for the manufacture of our cell therapy product candidates from third-party manufacturers and suppliers, which include, in some instances, sole source manufacturers and suppliers. The loss of these suppliers, or their failure to provide us with sufficient key materials or equipment on a timely basis at an acceptable cost, or at all, could materially and adversely affect our business.

The development and manufacture of our cell-based product candidates depends on the availability of reagents and specialized materials and equipment which are required to be acceptable to the FDA and applicable foreign regulatory authorities, and such reagents, materials, and equipment may not be available to us on acceptable terms or at all. We rely on third-party suppliers for key components required for the manufacture of our product candidates, including in some cases, sole source manufacturers and suppliers, and we currently do not have long-term commitments or supply agreements to obtain certain of these components.

We use reagents in our manufacturing processes, some of which are manufactured or supplied by small companies with limited resources and experience with respect to supporting clinical or commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support manufacturing of products under cGMP or may otherwise be ill-equipped to support our needs, particularly as we scale up our manufacturing processes. Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured process and possibly into product candidates, which may contribute to variable patient outcomes and possible adverse events. We do not have long-term commitments or supply agreements with many of these suppliers and may not be able to enter into supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support our clinical, and ultimately commercial, manufacturing operations.

For some of the reagents, materials, and equipment we require, we currently rely and may in the future rely on sole source suppliers or a limited number of suppliers. We may be unable to continue to source reagents, materials, or equipment from any of these suppliers for various reasons, including due to regulatory actions or requirements affecting a supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands from other customers and supply limitations, or quality issues. We cannot be sure that these suppliers will remain in business, or that they will not be purchased by one of our competitors or another company that is not interested in continuing to supply us with these materials in sufficient quantities, on acceptable terms, or at all. The lead time needed to establish a relationship with a new supplier who has access to the required raw materials can be lengthy. The time and effort to identify and qualify a new supplier could result in additional costs, diversion of resources, or reduced manufacturing yields, any of which may negatively impact our business. Additionally, due to global geopolitical, economic, and other factors beyond our control, there has been, and there may continue to be, a shortage of key materials and equipment that are necessary to manufacture our product candidates, including certain consumables such as bags, flasks, and pipette tips, which has affected and may continue to affect our ability to obtain the materials and equipment necessary to manufacture our product candidates and increased our research and development costs. Failures or difficulties faced at any level of our supply chain could delay or impede the development and commercialization of our product candidates and adversely affect our business, financial condition and results of operations. In light of the unpredictable nature of the current economic climate, it may be increasingly difficult for us to predict and control our future expenses for the reagents, materials, and

equipment we require to manufacture our product candidates. If any of the foregoing events were to occur, we may experience significant delays in manufacturing our product candidates, and in turn, in the commencement and completion of preclinical development and testing or clinical trials and potential regulatory approval of our product candidates, which could harm our business.

If we are required to change suppliers, or modify the components, equipment, materials or disposables used for the manufacture of our product candidates, we may be required to change our manufacturing operations or clinical trial protocols or to provide additional data to regulatory authorities in order to use any alternative components, equipment, materials or disposables, any of which could set back, delay, or increase the costs required to complete our clinical development and commercialization of our product candidates. Additionally, any such change or modification may adversely affect the safety, efficacy, stability, or potency of our product candidates, and could adversely affect clinical development of our product candidates and harm our business.

In some cases, specialized delivery systems or devices may be used to administer our cell therapy product candidates, and we may rely on third parties to manufacture and supply those systems or devices and provide us with intellectual property rights to develop and commercialize them with our cell therapies, if approved. If we are not able to obtain those systems or devices in quantities needed in accordance with our quality standards and regulatory requirements and at acceptable costs, or at all, or those systems or devices fail to perform as expected, clinical development and possible regulatory approval of our product candidates may be significantly delayed and more expensive than anticipated and our business may suffer.

The administration of certain of our cell therapy product candidates requires invasive surgical procedures. We may seek to improve the accuracy or reduce the complexity, risk and variability of administering of our cells to the targeted site in the human body by integrating into the surgical procedures specialized delivery systems or devices developed, manufactured and supplied by third parties. For example, we believe a novel parenchymal spinal delivery system developed by a third party could improve usability and precision in administering OPC1 to the injury site in the spinal cord, hence we entered into an exclusive option and license agreement with that third party, Neurgain, to collaborate on the clinical testing of the device for OPC1 and will evaluate the safety and utility of the device to deliver OPC1 in the DOSED clinical study. To the extent we collaborate with third parties for specialized delivery systems or devices for administration of our product candidates, we may become dependent on those third parties and their contract manufacturers and suppliers not only for rights to use those systems or devices, but also for the manufacture and supply of those systems or devices in sufficient quantities and at acceptable quality levels and costs for our clinical trials, and ultimately to potentially market and sell them with our product candidates, if approved. Our dependence on such third parties is subject to a multitude of risks, including these risks:

- They or their third-party manufacturers might not manufacture in a timely manner the device, systems or components in the quantity or quality required to meet our clinical trial needs and, if approved, commercial needs.
- They or their third-party manufacturers may not perform as agreed, may terminate their agreements, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute on a commercial scale, if approved.
- They or their third-party manufacturers may not produce the systems or devices in accordance with applicable regulatory requirements, and their processes or facilities may fail inspection by the FDA or corresponding state or foreign regulatory agencies. We will not have control over their compliance with applicable laws and regulations.
- They or their third-party manufacturers may not obtain or maintain intellectual property rights necessary for the development, manufacture and, if approved, commercialization of the systems or devices.
- They or their third-party manufacturers may experience manufacturing difficulties as a result of resource constraints, labor shortages, supply chain failures, public health emergencies, cyberattacks, geopolitical conflict, wars, acts of terrorism, political or economic instability or crises, natural disasters, or other events outside of their control or the control of their third-party manufacturers. This may result in business closures that adversely affect our ability to obtain clinical or commercial supplies as needed.
- We may be subject to product liability exposure arising out of use of the systems or devices to administer our product candidates in clinical trials or, if approved, for commercial use, and our insurance may not cover all potential claims.

If any such third-party collaborator or their contract manufacturers or suppliers were to encounter any of these difficulties, our ability to commence and conduct clinical trials of certain of our cell therapy product candidates on communicated timelines, or at all, could be jeopardized. These third-party collaborators and their contract manufacturers and suppliers would also be subject to many of the same risks we face in developing our own manufacturing capabilities, as described elsewhere in these Risk Factors. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, could require us to either conduct additional clinical trials at additional expense or terminate clinical trials completely. Each risk could delay our clinical trials, any potential approval of our product candidates by the FDA, or the commercialization of our product candidates, and could result in higher costs or deprive us of potential product revenue.

Risks Pertaining to Our Common Shares

The market price of our common shares has been and may continue to be volatile, and you could lose all or part of your investment.

The trading price of our common shares has been and is likely to continue to be highly volatile. The stock market in general, and biotechnology companies in particular, especially small cap and microcap companies, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to their operating performance. Broad market and industry factors may negatively affect the market price of our common shares, regardless of our actual operating performance, financial condition or progress in development of our product candidates. The market price for our common stock may be influenced by a variety of factors, some of which are beyond our control, including:

- delays in progress or completion of clinical trials of our product candidates, OpRegen in particular, as to which Roche has sole discretion and control over its clinical development, or other changes in the development status of or anticipated development timeline for our product candidates;
- results of clinical and nonclinical studies of our product candidates;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial and manufacturing requirements for regulatory approvals;
- developments concerning the manufacture or supply of our product candidates;
- unanticipated serious safety concerns related to the use of our product candidates or third-party product candidates perceived to be similar;
- delays in regulatory submissions related to our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse regulatory decisions relating to our product candidates or third-party product candidates perceived to be similar or competitive to ours;
- our inability to establish or maintain important collaborations and license agreements, including any material disputes or amendments;
- announcements of strategic collaborations or significant licenses, acquisitions or dispositions, joint ventures or capital commitments by us or companies perceived to be comparable to us;
- additions or departures of key personnel;
- our cash position and the level of expenses related to development of our product candidates;
- announcements or expectations of additional financing efforts;
- sales of our common shares by us, our insiders or other shareholders;
- trading volume of our common shares;
- changes in the market valuation of companies perceived to be comparable to us;

- actual or anticipated variations in our operating results;
- changes in accounting policies and practices or material weakness or ineffectiveness of our internal controls or disclosure controls;
- disagreements with our auditor or termination of an auditor engagement;
- disputes or other developments relating to proprietary rights, including patents and trade secrets, or other avenues of market exclusivity for our product candidates or products and product candidates perceived to be competitive to ours;
- changes in the structure of healthcare payment systems;
- significant lawsuits, including intellectual property, product liability or shareholder litigation;
- publication of research reports about us or our industry, or cell therapies in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- actual or potential suspension of trading or delisting of our common shares by stock exchanges.
- inclusion or exclusion of our common shares in or from stock indices such as the Russell 3000® Index;
- significant business disruptions caused by natural or man-made disasters, prolonged public health emergencies, wars and other armed conflicts, and regional instability, including in and around Ukraine and Israel;
- market conditions in the biotechnology sector and general political and economic conditions; and
- other factors described in this Risk Factors section.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of their shares. This type of litigation, if instituted against us, could result in substantial costs and a diversion of our management's attention and resources, which could materially and adversely affect our business and financial condition.

Because we do not intend to pay cash dividends, our common shares may not be a suitable investment for anyone who needs to earn dividend income.

We do not pay cash dividends on our common shares. For the foreseeable future, we anticipate that any earnings generated in our business will be used to finance the growth of our business and will not be paid out as dividends to holders of our common shares. This means that any return to our shareholders will be limited to the appreciation of their shares and, therefore, our common shares may not be a suitable investment for anyone who needs to earn dividend income from their investments.

Insiders continue to have substantial influence over our company, which could limit your ability to influence the outcome of key transactions, including a change of control.

Our directors, executive officers and their affiliates, in the aggregate, owned approximately 19.3% of our outstanding common shares as of December 31, 2024 and approximately 22.1% of our outstanding common shares as of March 4, 2025 as a result of the purchase by Broadwood Partners in our registered direct offering we announced in November 2024. As a result, these shareholders, if acting together, will be able to heavily influence or control matters requiring approval by our shareholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree, and which may be averse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deter certain public investors from purchasing our common shares and might ultimately affect the market price of our common shares.

If we or our subsidiaries issue additional common shares or preferred shares, investors in our common shares may experience dilution of their ownership interests.

We and our subsidiaries may issue additional common shares or other securities convertible into or exercisable for common shares to raise additional capital or to hire or retain employees or consultants, or in connection with future acquisitions of companies or licenses to technology or rights, in settlement of lawsuits, or for other business purposes. The issuance of additional securities may be dilutive to our shareholders and may create downward pressure on the trading price of our common shares. For example, in November 2024 we announced a registered direct offering of 39,473,688 of our common shares and accompanying warrants to purchase an aggregate of up to 39,473,688 of our common shares. That offering closed in two tranches: one in November 2024 and another in January 2025.

Our articles of incorporation, as amended, authorize us to issue an aggregate of 452,000,000 shares of capital stock consisting of 450,000,000 common shares and 2,000,000 "blank check" preferred shares, which means we may issue, without shareholder approval, one or more series of preferred shares having such designation, powers, privileges, preferences, including preferences over our common shares respecting dividends and distributions, terms of redemption and relative participation, optional, or other rights, if any, of the shares of each such series of preferred shares and any qualifications, limitations or restrictions thereof, as our board of directors may determine. The terms of one or more series of preferred shares could dilute the voting power or reduce the value of our common shares. Any preferred shares may also be convertible into common shares on terms that would be dilutive to holders of common shares. Our subsidiaries may also issue their own preferred shares with a similar impact on our ownership of the subsidiaries.

As of December 31, 2024, we had 26,725,294 common shares reserved for issuance upon the exercise of outstanding options and 501,032 common shares reserved for issuance upon the vesting and settlement of restricted stock units awarded under our equity incentive plans. The exercise of outstanding options and vesting and settlement of outstanding restricted stock units would be dilutive to our existing shareholders.

We have used "at the market" ("ATM") offerings of our common shares to raise substantial capital. For information regarding such sales of our common shares see "At the Market ('ATM') Offering" in Note 10 (Shareholders' Equity) to our consolidated financial statements included in this report. We may continue to use ATM offerings to fund our operations. As of March 4, 2025, $39.97 million was available for sale under our ATM offering program. Additional sales of our common shares in our ATM offering may result in substantial dilution to our existing shareholders and such sales, or the anticipation of such sales, may cause the market price of our common shares to decline.

The operation of some of our subsidiaries has been financed in part through the sale of shares of capital stock and warrants to purchase securities of those subsidiaries to private investors. Future sales of such securities by our subsidiaries could reduce our ownership interest in the applicable subsidiary, and correspondingly dilute our shareholders' ownership interests in our consolidated enterprise.

The issuance of common shares upon exercise of warrants would cause immediate and substantial dilution to existing shareholders.

As discussed elsewhere in this report, we issued warrants to purchase an aggregate of up to 41,447,372 of our common shares in connection with our November 2024 registered direct offering. Warrants to purchase up to 39,473,688 of our common shares have an exercise price of $0.91 per share and warrants to purchase up to 1,973,684 of our common shares have an exercise price of $0.95 per share, in each case, subject to customary adjustments. The warrants become exercisable beginning May 21, 2025 and will expire on the earlier of (a) May 21, 2028 and (b) the 90th day following the date of the public disclosure of the intent to advance OpRegen® (also known as RG6501) into a multi-center phase 2 or 3 clinical trial which includes a control or comparator arm, or if the date of such public disclosure occurs prior to May 21, 2025, the 90th day following May 21, 2025, with each such 90-day period subject to extension if certain conditions, including equity conditions, some of which are outside of our control, are not satisfied. The warrants also provide for cashless exercise in certain circumstances, including if the shares issuable upon exercise thereof are not covered by an effective registration statement.

The issuance of common shares upon exercise of these warrants will result in dilution to the ownership interests of other shareholders. Although warrants to purchase up to 33,552,635 of our common shares have a beneficial ownership limitation provision providing that the holder may not exercise any portion of its warrant if the holder,

together with its affiliates, would beneficially own in excess of 4.99% (or 9.99% if the holder so elected prior to the issuance of the warrant) of the number of our common shares outstanding immediately after giving effect to such exercise, this provision does not prevent such holder from exercising a portion of their warrants, selling those shares, and then exercising additional portions of their warrants, while still staying below the beneficial ownership cap percentage. By doing so, the holder could sell more of our common shares than the beneficial ownership cap percentage. In addition, upon 61 days' prior notice to us, the warrant holder may increase or decrease the beneficial ownership cap percentage, provided that the beneficial ownership limitation percentage may not exceed 9.99%. Furthermore, the operation of the beneficial ownership limitation provision may not allow a warrant to be exercised in full at a time when it would otherwise required to be exercised in full.

The availability for public resale of our common shares issued upon exercise of the warrants, the perception that such sales could occur, or any actual resales of such shares could adversely affect the market price of our common shares. We cannot predict the extent to which the warrants will be exercised or the effect, if any, that future issuances and sales of our common shares may have on the market price of our common shares.

In addition, the common shares issuable upon exercise of the warrants represent overhang that may adversely affect the market price of our common shares. Overhang occurs when there is a greater supply of a company's stock in the market than there is demand for that stock. When this happens the price of the stock may decrease, and any additional shares which shareholders attempt to sell in the market may only further decrease the market price of the shares. In addition, if the trading volume of our common shares cannot absorb shares sold by holders of the warrants, then the market price of our common shares may also decrease.

There is no assurance that we will be able to maintain compliance with the NYSE American's continued listing standards, and failure to do so could result in the suspension of trading or delisting of our common shares, which could substantially impair our shareholders' ability to sell their shares and our ability to raise additional capital.

Our common shares are listed on the NYSE American. To maintain our listing, we must satisfy several continued listing standards, including financial condition and/or operating results standards, market value and distribution standards, a low selling price standard, and corporate governance standards. For example, for as long as we have net losses for our five most recent fiscal years, the exchange may consider delisting our common shares if our shareholders' equity is less than $6 million, and under the low selling price standard, if the exchange determines our common shares have been selling at levels viewed to be abnormally low, which we believe is a trading price below $0.10, the exchange can commence delisting proceedings and immediately suspend trading in our common shares. In addition, any developments which substantially reduce the size of our company, the nature and scope of our operations, the value or amount of our securities available for the market, or the number of shareholders, may occasion a review of continued listing by the exchange. We cannot assure you that we will be able to continue to meet the NYSE American's continued listing requirements.

The suspension or delisting of our common shares, or the commencement of delisting proceedings, for whatever reason could, among other things, substantially impair our ability to raise additional capital; result in the loss of interest from institutional investors, result in restrictions or prohibitions on brokers from trading in our common shares, result in the loss of confidence in our company by shareholders, collaborators and employees, and result in fewer financing, strategic and business development opportunities. The suspension or delisting of our common shares, or the commencement of delisting proceedings for whatever reason may materially impair our shareholders' ability to buy and sell shares of our common shares and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common shares. In addition, our common shares have been included in the Russell 3000® Index from time to time. In the short term, inclusion in the index may favorably impact the price, trading volume, and liquidity of our common shares, in part, because holders attempting to track the composition of that index may have been required to buy our common shares, which could cause a material increase in the price at which our common shares trades. As of the filing date of this report, the trading price of our common shares is below the minimum required for inclusion in the Russell 3000® Index. If our common shares are removed from the index because they do not meet the criteria for continued inclusion, including due to too low of a trading price, index funds, institutional investors, or other holders attempting to track the composition of that index may be required to sell our common shares, which would adversely impact the price and frequency at which our common shares trade.

Our business could be negatively affected as a result of actions of activist shareholders, and such activism could affect the trading value of our securities.

Shareholders may, from time to time, engage in proxy solicitations or advance shareholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management, and the SEC's "universal proxy" rules could significantly lower the cost and increase the ease and likelihood of shareholder activism. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and collaboration partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our current business strategy. We may choose to initiate, or may become subject to, litigation as a result of a proxy contest or matters arising from a proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in the price of our common shares based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business. Furthermore, the trading value of and demand for our common shares could be adversely affected by allegations made or reports issued by short sellers, analysts, activists or others regarding our business, further influencing volatility in the market price of our common shares.

Securities analysts may not initiate coverage or continue to cover our common shares, and this may have a negative impact on the market price of our common shares.

The trading market for our common shares depends, in part, on the research and reports that securities analysts publish about our business and our common shares. We do not have any control over these analysts. Although certain securities analysts currently cover us and our common shares, there is no guarantee that such analysts will continue to provide such coverage or that other analysts will initiate such coverage. If securities analysts do not cover us and our common shares and/or fail to publish regular reports on our business, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. If securities analysts do cover us and our common shares, they could issue reports or recommendations that are unfavorable to the price of our common shares, and they could downgrade a previously favorable report or recommendation, and in either case our share price could decline as a result of the report.

General Risk Factors

We are subject to stringent and changing obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including data we collect about trial participants in connection with clinical trials. As a result, we are, or may become, subject to numerous data privacy and security requirements related to data privacy, security, protection and transfer under federal, state, local, and foreign laws, regulations, guidance, and industry standards. See Item 1. "Business—Government Regulation—Privacy and Data Security Laws," above. These requirements may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these requirements requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

If we, or our personnel or third parties upon whom rely, fail, or are perceived to have failed, to address or comply with applicable data privacy, security, protection and transfer requirements, we could face significant consequences.

These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. In the United States, privacy and security obligations are often enforced under deceptive and unfair trade practice laws, using theories that a company's activities were either misleading or unfair.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; and other adverse consequences.

We are dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we may process confidential, and sensitive, including personal data (such as health-related data), intellectual property, and proprietary business information (collectively, sensitive information). We have also outsourced some of our operations (including parts of our information technology infrastructure) to a number of third-party service providers who may have, or could gain, access to sensitive information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties.

Cyberattacks, malicious internet-based activity, and online and offline fraud are increasing in frequency, persistence, sophistication and intensity. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors engage and are expected to continue to engage in cyberattacks, including, without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. In particular, the Israeli regional conflict may increase the risk that state-sponsored parties or their supporters launch cyberattacks or carry out other geopolitically motivated retaliatory actions that adversely disrupt our operations in Israel. We and the third parties upon which we rely may be subject to a variety of evolving threats, including, but not limited to, malware (including as a result of persistent threat intrusions), malicious code (such as viruses and worms), ransomware attacks, denial-of-service attacks (such as credential stuffing), social engineering attacks (including phishing attacks), personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other technology assets, adware, telecommunication failures, earthquakes, fires, floods, and other similar threats. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. These vulnerabilities may be heightened as a result of flexible work arrangements, including hybrid or remote work policies implemented by us and our third-party service providers, that were first adopted in response to the COVID-19 pandemic and have continued by many businesses. Similarly, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support us and our services. Moreover, the prevalent use of mobile devices by our employees and third-party service providers to access confidential information increases the risk to our information technology systems and data. Future or past business transactions (such as acquisitions or integrations) could also expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our proprietary or sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to conduct our business operations and divert significant resources. Though we have insurance that may cover some of the costs and fees resulting from a cyberattack, data security incident, or data breach, that insurance may not cover, or be sufficient to cover, all of the costs, losses, damages, fines, and penalties that may arising from a data security incident or to mitigate liabilities arising therefrom. In addition, such insurance may not continue to be available on commercially reasonable terms or at all.

We may expend significant resources or modify our business activities to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures and tools, industry-standard or reasonable security measures to protect our information technology systems and proprietary and sensitive information.

While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent cyberthreats, cyberattacks, security incidents, data breaches, malware, ransomware attacks and other disruptions that could adversely affect our business. We may be unable in the future to detect vulnerabilities in our information technology systems because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. Despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. In addition, failure to maintain effective internal accounting controls related to security incidents and cybersecurity in general could impact our ability to produce timely and accurate financial statements and subject us to regulatory scrutiny.

Applicable data privacy and security obligations, including data breach notification laws in the US and elsewhere, may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); financial obligations to third parties, indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause interruptions in our operations and could result in a material disruption of our programs. For example, the loss of clinical trial or nonclinical study data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs due to additional time and resources necessary to recover and verify or potentially reproduce the data.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations.

Failure of our internal control over financial reporting could harm our business and financial results.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected. Our growth and entry into new products, technologies and markets will place significant additional pressure on our system of internal control over financial reporting. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud. Having CCN located in a foreign country also adds to the complexity of our internal control over financial reporting and adds to the risk of a system failure, an undetected improper use or expenditure of funds or other resources by a subsidiary, or a failure to properly report a transaction or financial results of a subsidiary. We allocate certain expenses among Lineage itself and one or more of our subsidiaries, which creates a risk that the allocations we make may not accurately reflect

the benefit of an expenditure or use of financial or other resources by Lineage as the parent company and the subsidiaries among which the allocations are made. An inaccurate allocation may impact our consolidated financial results, particularly in the case of subsidiaries that we do not wholly own since our financial statements include adjustments to reflect the minority ownership interests in our subsidiaries held by others.

If we identify material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or assert that our internal control over financial reporting is effective, or, when required, if our independent registered public accounting firm is unable to express an opinion or expresses a qualified or adverse opinion about the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common shares could be negatively affected. In addition, we could become subject to investigations by the NYSE American, the SEC, and other regulatory authorities, which could require additional financial and management resources.

Unfavorable macroeconomic conditions and wars or armed conflicts could have an adverse impact on our business, financial condition and results of operations, including our clinical trials.

Our results of operations are affected by prevailing economic and political conditions and other factors beyond our control, such as the rate of inflation, fluctuations in costs, particularly due to changes in labor costs and material costs, levels of business confidence, and wars or armed conflicts.

The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, supply shortages, increased costs of labor, components, manufacturing and shipping, as well as weakening exchange rates and other similar effects. As a result of inflation, we may experience cost increases. Changes in other economic conditions, including rising interest rates, lower consumer confidence, and volatile equity capital markets, may also affect our business. Although we may take measures to mitigate the effects of economic conditions, if these measures are not effective, our business, financial condition, results of operations and liquidity could be materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when the benefits of such measures and the effects of such conditions impact our results of operations. Given these economic considerations, among other potential consequences, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations sooner than expected, which may not be available in sufficient amounts or on reasonable terms, if at all. See also the discussion in this Risk Factors section under "We will need to obtain substantial additional funding to complete the development and seek regulatory approval of our product candidates and to commercialize products approved for marketing, if any. If we are unable to obtain adequate capital when needed, we may delay, reduce, limit the pace of, suspend or discontinue our product and technology development programs or other operations, which could significantly harm our business and prospects and cause the market price of our common shares to decline." In addition, if the risks described in this paragraph materialize, the possibility of other risks described herein materializing and/or the impact of those risks may increase.

Regional instability in and around Israel and Ukraine, and the uncertain nature, magnitude, and duration of those conflicts and the potential effect of sanctions and other measures being imposed in response thereto have contributed to increased levels of economic and political uncertainty, which could have an adverse impact on macroeconomic factors that affect the financial markets, the global economy and our business and operations. See also the risk titled, "All of our manufacturing operations currently are conducted at our facility in Jerusalem, Israel. Accordingly, political and economic conditions in Israel and war, cyberattacks, terrorist attacks or other armed conflicts involving Israel and the broader region could directly affect our business. Any event or condition that significantly disrupts our ordinary course of operations at our Jerusalem facility could harm our business and materially and adversely affect our financial condition and operating results." above. Additionally, the ongoing wars may disrupt the ability of third parties on which we rely to perform in accordance with our expectations, including CROs to conduct clinical trials. Moreover, enrollment and retention of clinical trial participants may be adversely affected. We cannot be certain what the overall impact of ongoing wars will be on our ability to conduct and complete our clinical trials on schedule. However, interruptions of our clinical trials could significantly delay our clinical development plans and potential authorization or approval of our product candidates, which could increase our costs and jeopardize our ability to successfully commercialize our product candidates.

Adverse litigation judgments or settlements resulting from legal proceedings in which we may be involved could expose us to monetary damages or limit our ability to operate our business.

In 2023 we settled a putative shareholder class action lawsuit and a product liability lawsuit, and may in the future become involved in other class actions, derivative actions, private actions, collective actions, investigations, and various other legal proceedings by shareholders, collaborators, clinical trial participants, employees, suppliers and other vendors, service providers, competitors, government agencies, or others. The results of any such litigation, investigations, and other legal proceedings are inherently unpredictable and expensive. Although some of the costs and expenses of such claims may be covered by insurance, any claims against us, whether meritorious or not, could be time consuming, result in costly litigation, damage our reputation, require significant amounts of management time, and divert significant resources. Additionally, a dramatic increase in the cost of directors' and officers' liability insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover significant defense costs, settlements, and damages awarded to plaintiffs. If any of these legal proceedings were to be determined adversely to us, or we were to enter into a settlement arrangement, we could be exposed to monetary damages or limits on our ability to operate our business, which could have an adverse effect on our business, financial condition, results of operations and prospects. In addition, the uncertainty associated with material litigation could lead to increased volatility in our stock price.

Our business could be negatively impacted by environmental, social and corporate governance ("ESG") matters or our reporting of such matters.

Certain investors, employees, collaborators, and other stakeholders are focused on ESG matters. Moreover, certain governmental authorities have proposed or adopted, and may continue to propose or adopt, certain mandated ESG reporting requirements, which, to the extent adopted, could significantly increase our compliance and reporting costs. At the same time, anti-ESG sentiment has gained momentum across the United States, with several states having enacted or proposed "anti-ESG" policies or legislation. We may be perceived to be not acting responsibly in connection with these matters or, on the other hand, we may be criticized or perceived as not prioritizing returns to our shareholders by those who criticize a company's focus on ESG matters, either of which could negatively impact us and adversely affect the price of our common shares.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

We have certain processes and policies in place to assess, identify and manage material cybersecurity risks. We also periodically monitor and test our information systems for potential vulnerabilities. We use various tools designed to help identify, investigate and resolve cybersecurity incidents, and to help recover from them in a timely manner. These processes, policies and tools comprise our cybersecurity risk program, and are integrated into our overall risk management program.

We have an Information Technology Policy that sets parameters for the use, privacy, security, retention, and disposal of our information and other assets. We also have an Incident Response Policy which sets forth the steps for assessment, containment, and disclosure of cybersecurity threats. These policies were prepared using relevant guidance and technology standards and are reviewed periodically.

We collaborate with third parties to assess the effectiveness of our cybersecurity risk program and have assessed it against the National Institute of Standards and Technology ("NIST") cybersecurity framework. In addition, we consider the internal risk oversight programs of third-party service providers with whom we engage in order to help protect us from any related cybersecurity vulnerabilities.

Under our cybersecurity risk program, we provide all of our employees with periodic cybersecurity training, which covers timely and relevant topics, including social engineering, phishing, password protection, confidential data protection, asset use and mobile security, and educates employees on the importance of reporting all incidents immediately.

Although we are subject to cybersecurity risks, to date, none have materially affected our company, including our business strategy, results of operations, or financial condition. Notwithstanding our cybersecurity risk program, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on our company. See Item 1A. "Risk Factors" for a discussion of cybersecurity risks.

Governance

Our board of directors oversees our risk management process directly and through its committees. The audit committee of our board of directors has the power and responsibility to coordinate our board's oversight over our risk management procedures and to discuss with our management our policies with respect to risk assessment and risk management. Our board of directors has delegated to its audit committee oversight authority of our information security (including cybersecurity) risk management.

Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with our management. Our Senior Director, Human Resources & Infrastructure, who together with our Chief Financial Officer and General Counsel, work in close partnership with our outside information technology and cybersecurity consulting firm, and collectively, comprise the core team members of our Rapid Response Team under our Incident Response Policy. The Rapid Response Team is made up of a broad range of participants with relevant education, skills, and experience to investigate cybersecurity threats and assess the materiality thereof to determine internal reporting to our audit committee and board of directors, as well as external reporting or disclosure requirements. Management provides at least quarterly updates to the audit committee, and in turn management and the audit committee provide periodic updates to our board of directors, regarding ongoing cybersecurity risk assessments and related activities.

ITEM 2. PROPERTIES

General

We lease all the properties from which we operate our business. In general, we believe that our properties are well-maintained, adequate and suitable for our current operations and for our operations in the foreseeable future. See Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information regarding the properties we lease.

Lineage Facilities

Our corporate headquarters are in an office park in Carlsbad, California. We also lease industrial space adjacent to our corporate headquarters.

CCN Facilities

Under various leases, CCN leases office and laboratory space in the Bio Park on the campus of the Hadassah University Hospital in Jerusalem, Israel.

ITEM 3. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings. From time-to-time we may be involved in a variety of legal proceedings. Such proceedings may initially be viewed as immaterial but could later prove to be material. Legal proceedings are inherently unpredictable and excessive verdicts do occur. Given the inherent uncertainties in litigation, even when we can reasonably estimate the amount of possible loss or range of loss and reasonably estimable loss contingencies, the actual outcome may change in the future due to new developments or changes in approach. In addition, legal proceedings could involve significant expense and diversion of management's attention and resources from other matters. For a discussion of legal proceedings in which we are involved, see Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common shares are listed on the NYSE American and on the Tel Aviv Stock Exchange under the ticker symbol LCTX.

Holders

As of March 4, 2025, there were approximately 351 record holders of our common shares. The number of beneficial owners of our common shares is substantially greater than the number of record holders because a large portion of our common shares is held of record through brokerage firms in "street name".

Dividend Policy

We have not paid cash dividends on our common shares and we do not anticipate paying cash dividends on our common shares in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our board of directors, subject to applicable laws and contractual limitations, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Securities

Except as previously reported in our quarterly reports on Form 10-Q and current reports on Form 8-K filed with the SEC, during the year ended December 31, 2024, there were no unregistered sales of equity securities by us during the year ended December 31, 2024.

Issuer Purchases of Equity Securities

None.

ITEM 6. RESERVED

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our audited consolidated financial statements for the two-year period ended December 31, 2024, and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. In particular, the discussion is intended to provide an analysis of significant trends and material changes in our financial position and the operating results of our business during the year ended December 31, 2024 as compared to the year ended December 31, 2023. This discussion should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this report. These historical financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks described throughout this report, particularly in "Item 1A. Risk Factors."

Company and Business Overview

We are a clinical-stage biotechnology company developing novel allogeneic, or "off-the-shelf," cell therapies for serious neurological and ophthalmic conditions. Our programs are based on our proprietary, cell-based technology platform and associated development, formulation, delivery and manufacturing capabilities. From this platform, we design, develop, manufacture, and test specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. The cells we manufacture are produced by applying directed differentiation processes to established, well-characterized, and self-renewing pluripotent cell lines. These processes are based on specific developmental lineages and generated cells with desired characteristics. Functional cells developed from such lineages and which are relevant to the underlying condition are transplanted into patients in an effort to (a) *replace* or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and (b) *restore* or enhance the patient's functional activity.

Our business strategy is to efficiently leverage our technology platform and our development and manufacturing capabilities to advance our programs internally or in conjunction with strategic partners to further enhance their value and probability of success.

A significant area of focus is a collaboration we entered into with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively or individually, "Roche" or "Genentech"), under which our lead cell therapy program known as OpRegen®, is being developed for the treatment of ocular disorders, including geographic atrophy ("GA") secondary to age-related macular degeneration ("AMD"). OpRegen (also known as RG6501) is a suspension of human allogeneic retinal pigmented epithelial ("RPE") cells and is currently being evaluated in a Phase 2a multicenter clinical trial in patients with GA secondary to AMD which is referred to as the "GAlette Study". OpRegen subretinal delivery has the potential to counteract RPE cell loss in areas of GA lesions by supporting retinal cell health and improving retinal structure and function. Under the terms of the Collaboration and License Agreement we entered into with Roche in December 2021 (the "Roche Agreement"), we received a $50.0 million upfront payment in January 2022 and are eligible to receive up to an additional $620.0 million in developmental, regulatory, and commercialization milestone payments. We also are eligible to receive tiered double-digit percentage royalties on net sales of OpRegen in the U.S. and other major markets. In May 2024, we entered into an additional agreement with Genentech ("Services Agreement") pursuant to which we agreed to provide Genentech with supplemental clinical, technical, training, manufacturing, and procurement services that support the ongoing advancement of the OpRegen program in exchange for certain payments. In September 2024, Roche and Genentech announced receipt of Regenerative Medicine Advanced Therapy ("RMAT") designation from the U.S. Food and Drug Administration ("FDA") for OpRegen for the treatment of GA secondary to dry AMD.

Our most advanced internally owned product candidate is OPC1, an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury ("SCI"). Improved functional activity can lead to greater mobility and enhanced quality of life for patients and significant cost-savings for caregivers and payors. OPC1 also has an extensive long-term safety profile based on two clinical trials conducted to date: a five-patient Phase 1 safety trial in acute thoracic SCI, where all active subjects have been followed for at least 13 years, and a 25-patient Phase 1/2a multicenter dose-escalation trial in subacute cervical SCI, where all active subjects were evaluated for at

least 7 years. Results from these studies have been published in the Journal of Neurosurgery Spine. OPC1 clinical development has been supported in part by a $14.3 million grant from the California Institute for Regenerative Medicine ("CIRM"). We plan to apply for additional funding from CIRM to support continued clinical development of OPC1 for the treatment of SCI when CIRM begins accepting new applications, which they have indicated they will do in Spring 2025. See "Grants from Government Entities – Grants from the California Institute for Regenerative Medicine," below. In December 2023, we filed an Investigational New Drug ("IND") amendment for OPC1 as it relates to our proposed DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical study, to evaluate the safety and utility of a novel spinal cord delivery device designed to administer OPC1 to the spinal parenchyma in subacute and chronic SCI patients. In March 2024, we received written correspondence from the FDA, advising us that due to their significant workload and conflicting PDUFA priorities at the agency, its review of our IND amendment and the DOSED study protocol was still ongoing, which remained so throughout 2024. On January 31, 2025, the FDA informed us that we could proceed with the DOSED study and shortly thereafter we announced that we were initiating the study. The study will enroll both subacute (between 21 to 42 days following injury) and chronic (between 1 to 5 years following injury) SCI patients. The DOSED study will be the first study of OPC1 to include patients with a chronic injury, a condition which comprises the majority of SCI patients. We expect DOSED will enable subsequent studies aimed to demonstrate OPC1's ability to impact functional outcomes. UC San Diego Health, was named as the first participating site for the DOSED study. The DOSED study is expected to commence enrollment in the second quarter of 2025. See "Clinical Stage Cell Transplant Programs – OPC1," below for additional information

Our complete pipeline of allogeneic, or "off-the-shelf", neurology and ophthalmic cell therapy programs currently available to us for development includes:

- *OpRegen (RG6501)*, an allogeneic RPE cell replacement therapy currently in a Phase 2a multicenter, open-label, single arm clinical trial, the GAlette Study, being conducted by Genentech, for the treatment of GA secondary to AMD.
- *OPC1*, an allogeneic oligodendrocyte progenitor cell therapy currently in a Phase 1b, multicenter, open -label safety trial, the DOSED study, which is designed to test the safety and utility of a novel spinal cord delivery device in subacute and chronic SCI patients. OPC1 continues to be evaluated in long-term follow-up from two completed Phase 1 and Phase 1/2a multicenter clinical trials in thoracic and subacute cervical SCI patients.
- ReSonance™ (ANP1), an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of sensorineural hearing loss.
- *PNC1*, an allogeneic photoreceptor cell transplant currently in preclinical development for the treatment of vision loss due to photoreceptor dysfunction or damage.
- *RND1,* a cell transplant program for an undisclosed indication, currently being developed through a gene editing collaboration with Factor Biosciences Limited.
- *A proprietary hypoimmune cell line,* which may have utility in additional central nervous system indications.

Other Programs and Technologies

Although we have to date focused on neurological and ophthalmic cell types, the pluripotent cells which our platform is based on are capable of becoming any of the cell types of the human body. We currently maintain a list of additional undisclosed product candidates which may be considered for development, or partnership in the future, and which altogether cover a range of therapeutic areas and conditions. Generally, these product candidates are based on the same platform technology and employ a similar guided cell differentiation and transplant approach as the product candidates detailed above, but in some cases may also include genetic modifications designed to enhance efficacy and/or safety profiles. We may elect not to develop or partner any of these product candidates.

In addition to seeking to create value for shareholders by developing product candidates through clinical development, we also may seek to create value from our intellectual property or related technologies and capabilities, through licensing collaborations and/or other strategic transactions.

Israeli Regional Conflict

All of our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, are conducted by our subsidiary, CCN, at its facility in Jerusalem, Israel, and more than two-thirds of our workforce are CCN employees who are based in the same facility. As of the date of the filing of this report, our operations have not been materially or adversely impacted as a result of the Israeli regional conflict that began in October 2023 nor the broader regional conflict that has developed since.

As a result of safety concerns and in response to government-imposed restrictions on movement and travel and other precautions taken at the outset of the conflict, our operations at our facilities in Israel were temporarily impacted. Further, a number of the employees in Israel are members of the military reserves and subject to immediate call-up in response to ongoing regional conflict. In addition, the general impact on employees operating in a region of conflict could adversely impact our operations. Although we have business continuity plans in place to address medium- or long-term disruptions that could result from regional instability, any long-term closure of our facilities in Israel, or if those facilities were damaged, or if hostilities otherwise disrupt the ongoing operation of our facilities, or if a meaningful number of employees are unable to work for significant portions of time, our operations would be materially and adversely impacted.

It is currently not possible to predict the scope, duration or severity of the ongoing war or its effects on our operations, financial condition or operating results. The ongoing war is rapidly evolving, and could materially adversely impact our business and operations, including our ability to raise capital, as well as the overall economy in Israel and the value of the New Israeli Shekel. See the risk factor in Item 1A. Risk Factors in this report titled, "All of our manufacturing operations currently are conducted at our facility in Jerusalem, Israel. Accordingly, political and economic conditions in Israel and war, cyberattacks, terrorist attacks or other armed conflicts involving Israel and the broader region could directly affect our business. Any event or condition that significantly disrupts our ordinary course of operations at our Jerusalem facility could harm our business and materially and adversely affect our financial condition and operating results. "

Our commercial insurance may not cover losses that may occur as a result of events associated with war and terrorism. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure that this government coverage will be maintained or that it will sufficiently cover our potential damages. Any losses or damages incurred by us could have a material adverse effect on our business.

Critical Accounting Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the reported amounts in our consolidated financial statements and related notes. We have identified below our critical accounting policies and estimates that we believe require the greatest amount of judgment. On an ongoing basis, we evaluate estimates which are subject to significant judgment, including those related to revenue recognition under collaborative agreements, impairment of intangible assets, deferred income taxes and tax reserves, and judgments used to determine whether warrants, at the time of their issuance, should be classified as liabilities or equity. Actual results could differ materially from those estimates.

On an ongoing basis, we evaluate our estimates compared to historical experience and trends which form the basis for making judgments about the carrying value of assets and liabilities. To the extent that there are material differences between our estimates and our actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

We believe the assumptions and estimates associated with the following have the greatest potential impact on our consolidated financial statements. For information on all of our significant accounting policies, see Note 2 (Significant Accounting Policies) in the accompanying notes to the consolidated financial statements included in this report.

Revenue Recognition Under Collaborative Agreements

We review collaborative agreements to determine if the accounting treatment falls under Accounting Standards Codification ("ASC"), Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), or ASC *Topic 808, Collaborative Arrangements* ("ASC 808"). For agreements that may be within the scope of ASC 808, we may analogize to ASC 606 for some aspects of the agreements. If elements of the collaboration reflect a vendor-customer relationship, then those elements are within the scope ASC 606. The classification of transactions under our arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants.

We determine revenue recognition for arrangements within the scope of Topic 606 by performing the following five steps: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when (or as) the customer obtains control of the product or service. We consider the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard. We apply the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances. As part of the accounting treatment for these contracts, we must develop estimates and assumptions that require judgment, including estimated collaboration costs, to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. After the transaction price is allocated to the performance obligation, an input method of costs incurred over total estimated costs to be incurred is used to measure progress toward completion of the performance obligation and to calculate the corresponding revenue to recognize each period. This input method requires significant judgment by management to estimate total costs to complete and to measure the progress toward completion of the performance obligation. We believe the input methodology represents the most appropriate measure of progress towards satisfaction of the identified performance obligations. For further information, see Note 3 (Revenue) in the accompanying notes to the consolidated financial statements included in this report.

Impairment of Intangible Assets

Our intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. If an impairment indicator is present, we evaluate recoverability by a comparison of the carrying amount of the assets to future undiscounted net cash flows expected to be generated by the assets. If the assets are impaired, the impairment recognized is measured by the amount by which the carrying amount exceeds the estimated fair value of the assets.

Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the values assigned to the assets acquired and liabilities assumed in the acquisition transaction. Goodwill is tested for impairment in accordance with Accounting Standards Update ("ASU") 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. In-process research and development ("IPR&D") assets are indefinite-lived intangible assets until the completion or abandonment of the associated research and development ("R&D") efforts. Once the R&D efforts are completed or abandoned, the IPR&D will either be amortized over the asset's estimated life as a finite-lived intangible asset or be impaired, respectively, in accordance with ASC Topic 350, *Intangibles – Goodwill and Other* ("ASC 350"). In accordance with ASC 350, goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment at least annually and between annual tests if we become aware of an event or a change in circumstances that would indicate the asset may be impaired. For further information, see Note 6 (Goodwill and Intangible Assets, Net) in the accompanying notes to the consolidated financial statements included in this report.

Income Taxes

Lineage accounts for income taxes in accordance with ASC Topic 740, *Income Taxes* ("ASC 740"), which prescribes the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. ASC 740 guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For

benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. Lineage files a U.S. federal income tax return as well as California combined and foreign income tax returns. Lineage's judgments regarding future taxable income may change over time due to changes in market conditions, changes in tax laws, tax planning strategies or other factors. If Lineage assumptions, and consequently the estimates, change in the future with respect to Lineage's own deferred tax assets and liabilities, the valuation allowance may be increased or decreased, which may have a material impact on Lineage's consolidated financial statements. Lineage recognizes accrued interest and penalties related to unrecognized tax benefits, if any, as income tax expense; however, no amounts were accrued for the payment of interest and penalties as of December 31, 2024 and 2023. We provided a reserve against our federal and California research and development credits generated. The carryforward amounts for these credits have been reported net of these reserves. Accordingly, no accrued interest and penalties related to unrecognized tax benefits have been recorded as of December 31, 2024 and 2023. For further information, see Note 12 (Income Taxes) in the accompanying notes to the consolidated financial statements included in this report.

Warrants

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in FASB ASC Topic 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC Topic 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's common shares, whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance. Liability and equity-classified warrants are valued using a Black-Scholes option pricing model at issuance, and for liability-classified warrants, at each reporting period end date while the warrants are outstanding. Changes in fair value of liability-classified warrants are recorded in the consolidated statements of operations.

Results of Operations

Comparison of Years Ended December 31, 2024 and 2023

Revenues

The following table shows our revenues for the years ended December 31, 2024 and 2023 (amounts in thousands except percentages).

	Year Ended December 31,		Dollar Increase (Decrease)	Percent Increase (Decrease)
	2024	2023		
Collaboration revenues	$ 8,149	$ 7,588	$ 561	7%
Royalties, license and other revenues	1,350	1,357	(7)	(1)%
Total revenues	$ 9,499	$ 8,945	$ 554	6%

For the twelve months ended December 31, 2024, the $0.6 million increase in total revenues was primarily due to collaboration revenues recognized under the Roche Agreement resulting from continued progress toward completion of the performance obligations and from updates in the total estimated costs to be incurred under the Roche Agreement. Under the Roche Agreement, delivery is determined to be over time and revenue is recognized utilizing an input method of costs incurred over total estimated costs to complete the performance obligation.

Collaboration revenues may fluctuate from period to period based on changes in estimated costs to support the performance obligations. The collaboration revenue was included within deferred revenue at the beginning of each reporting period. See Note 3 (Revenue) to our condensed consolidated financial statements included in this report for additional information.

Operating Expenses

Our operating expenses consist of cost of sales, research and development expenses, and general and administrative expenses.

Cost of sales. These expenses consist of costs associated with royalty revenue which has resulted from product sales by our sublicensees.

Research and development expenses. These expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct expenses and indirect research-related overhead expenses including compensation and related benefits, stock-based compensation, consulting fees, research and laboratory fees, rent of research facilities, amortization of intangible assets, and license fees paid to third parties to acquire patents or licenses to use patents and other technology. Research and development costs with no future benefit or alternative use are expensed as incurred. Research and development expenses incurred and reimbursed by grants from third parties approximate the grant income recognized in our consolidated statements of operations. Royalties and sublicensing fees are recorded as research and development expenses, unless they are associated with royalties from product sales, which we classify as cost of sales in our consolidated statements of operations. We expect our total research and development expenses to fluctuate each reporting period based on several factors including (i) the stage of development for each cell therapy program, (ii) the availability of resources to work on each program, and (iii) the timing of contractual obligations.

General and administrative expenses. These expenses consist of employee and director compensation and related benefits, including stock-based compensation, for executive and corporate personnel, professional and consulting fees, and allocated overhead such as facilities rent and equipment rent and maintenance, insurance costs allocated to general and administrative expenses, costs of patent applications, prosecution and maintenance, stock exchange-related costs, depreciation expense, marketing costs, legal and accounting costs, and other miscellaneous expenses.

The following table shows our operating expenses for the years ended December 31, 2024 and 2023 (amounts in thousands, except percentages).

	Year Ended December 31,		Dollar Increase (Decrease)	Percent Increase (Decrease)
	2024	2023		
Cost of sales	$ 334	$ 671	$ (337)	(50)%
Research and development	12,472	15,705	(3,233)	(21)%
General and administrative	18,171	17,302	869	5%
Total operating expenses	$ 30,977	$ 33,678	$ (2,701)	(8)%

The following table shows the amount of our total research and development expenses allocated to our primary research and development projects for the periods presented (amounts in thousands, except percentages).

	Year Ended December 31,			
	Amount		Percent of Total	
	2024	2023	2024	2023
OpRegen®	$ 6,081	$ 5,488	49%	35%
OPC1	3,491	6,214	28%	39%
ANP1	2,200	2,012	18%	13%
PNC1	156	487	1%	3%
RND1	394	754	3%	5%
Other programs and non-program expenses	150	750	1%	5%
Total research and development expenses	$ 12,472	$ 15,705	100%	100%

Research and development expenses. For the twelve months ended December 31, 2024, the $3.2 million year-over-year decrease in total research and development expenses is mainly attributable to: (i) a $2.7 million decrease for our OPC1 program as compared to the prior year primarily due to delays in obtaining clearance from the FDA to

proceed with the DOSED study; (ii) a $0.5 million decrease for our preclinical programs; (iii) a $0.6 million decrease for our other research and development programs; and (iv) partially offset by a $0.6 million increase for our OpRegen program.

General and administrative expenses. For the twelve months ended December 31, 2024, the $0.9 million year-over-year increase in general and administrative expenses was primarily attributable to (i) a $0.6 million increase in stock-based compensation; (ii) a $0.4 million increase in personnel costs; and (iii) partially offset by a $0.1 million overall decrease in costs incurred for services provided by third parties.

Other Income and Expenses, Net

The following table shows the amount of other income (expenses), net, during the year ended December 31, 2024 and 2023 (in thousands):

Other income (expenses)	Year Ended December 31, 2024	2023	Dollar Increase (Decrease)	Percent Increase (Decrease)
Interest income, net	$ 1,715	$ 1,629	$ 86	5%
Loss on marketable equity securities, net	(8)	(176)	168	95%
Change in fair value of warrant liability	2,128	—	2,128	100%
Foreign currency transaction loss, net	(269)	(544)	275	51%
Other income (expense), net	(670)	542	(1,212)	(224)%
Total other income (expenses)	$ 2,896	$ 1,451	$ 1,445	100%

Interest income, net. Interest income was greater for the year ended December 31, 2024 as compared to the prior year primarily due to a nominal increase in interest rates and average cash investment balances during 2024 .

Marketable equity securities, net. We expect our net gain or loss on marketable equitable securities to fluctuate each reporting period based on the changes in the market price of the common stock held by us which could impact our net income or loss reported in our consolidated statements of operations for a particular reporting period. These shares are carried at fair market value on our consolidated balance sheet. See Note 4 (Marketable Securities) to our consolidated financial statements included in this report for additional information regarding our marketable equity securities. For the twelve months ended December 31, 2024 and 2023, Lineage recognized a net loss on marketable equity securities of $8,000 and $176,000, respectively, primarily related to changes in the fair market value of the securities during the respective periods.

Change in fair value of warrant liability. The liability-classified warrants issued in connection with the November 2024 registered direct offering are valued at each reporting period end date while the warrants are outstanding using a Black-Scholes option pricing model that maximizes the use of observable inputs and minimizes the use of unobservable inputs to the extent possible. A significant increase or decrease in these inputs could result in significantly higher or lower fair value measurements. The changes in fair value of the liability-classified warrants are recorded in the consolidated statements of operations and we expect this fair value to fluctuate each reporting period. For the year ended December 31, 2024, the Company recorded a $2.1 million change in the fair value of the warrants. There was no comparable change recorded in 2023.

Foreign currency transaction loss, net. Foreign currency transaction loss, net, for each of the years ended December 31, 2024 and 2023 consisted of net foreign currency transaction gains and losses primarily recognized by our subsidiaries CCN and ES Cell International Pte. Ltd. (“ESI”). The functional currency of CCN and ESI is the Israeli New Shekel (“ILS”) and the Singapore Dollar (“SGD”), respectively. For the years ended December 31, 2024 and 2023, the net foreign currency transaction losses were $0.3 million and $0.5 million, respectively. The majority of the net foreign currency transaction losses were generated by CCN’s intercompany notes payable and notes receivable with Lineage, which is U.S. dollar-denominated. The year-over-year net decrease in foreign currency transaction losses was the result of the combined impact of: (i) changes in intercompany balances in 2024 as compared to 2023, and (ii) volatility of the ILS and SGD as compared to the U.S. dollar during 2024 and 2023.

Other income (expenses), net. For the year ended December 31, 2024, the Company recorded $0.7 million related to the allocated transaction costs for warrants issued in connection with the November 2024 registered direct offering. No comparable expense was recorded in the prior year. For the year ended December 31, 2023, the Company recorded an employee retention credit of $0.5 million, and no comparable credit was recorded in 2024. The employee retention credit is a payroll tax refund per employee, under the Coronavirus Aid, Relief, and Economic Security Act which was designed by the U.S. Treasury Department to assist businesses that retained employees during the COVID pandemic. The Company qualified for this credit due to a decline in the quarterly revenue during 2020 and 2021 as compared to the same quarterly period in 2019.

Income Taxes

Under ASC 740, *Income Taxes*, a valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. We established a full valuation allowance as of December 31, 2018 due to the uncertainty of realizing future tax benefits from the net operating loss carryforwards and other deferred tax assets, including foreign net operating losses generated by our subsidiaries.

Lineage recorded a $1.8 million deferred tax benefit due to the ability to offset certain deferred tax assets against the deferred tax liability associated with in-process research and development ("IPR&D"), and the related release of the valuation allowance in the first quarter of 2023. It was determined that a portion of the deferred tax liability related to the indefinite lived assets may be realized prior to the expiration of certain pre 2018 net operating losses. Lineage did not record a deferred tax benefit for the year ended December 31, 2024.

Liquidity and Capital Resources

Overview

As of December 31, 2024, our accumulated deficit was $403.5 million. For the year ended December 31, 2024, we incurred a loss from operations of $21.5 million and had negative cash flow from operations of $23.1 million. Since inception, we have incurred significant operating losses and we expect to continue to incur significant operating losses for the foreseeable future.

As of December 31, 2024, we had $47.8 million in cash, cash equivalents and marketable securities. During the year ended December 31, 2024 we raised approximately $35.6 million in net proceeds through registered direct offerings that closed in February and in November 2024. In January 2025, we received an additional $5.5 million in net proceeds at the second closing of the November 2024 registered direct offering. We may receive up to an additional $36 million in gross proceeds upon the full cash exercise of OpRegen clinical milestone-linked warrants which each have an exercise price of $0.91 per share, that were issued in the registered direct offering we announced in November 2024. However, no assurances can be given that any portion of such warrants will be exercised, or if exercised, that they will be exercised on a cash basis.

We have historically funded our operations primarily through proceeds from the sale of our common shares and securities exercisable for or convertible into our common shares, the sale of common stock of our former subsidiaries, research grants, revenues from collaborations, and royalties from product sales that are unrelated to our current cell therapy product candidates.

During the year ended December 31, 2024, we issued and sold 55,830 common shares under our at-the-market offering program for gross proceeds of $70,000. As of December 31, 2024, $39.97 million remained available for sale under our at-the-market offering program. See Note 10 (Shareholders' Equity) to our consolidated financial statements included in this report for additional information regarding our at-the-market offering program.

Cash Flows

(in thousands)	Year Ended December 31, 2024	2023
Cash provided by (used in):		
Operating activities	$ (23,092)	$ (28,566)
Investing activities	(2,308)	46,449
Financing activities	35,857	6,423
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(95)	(250)
Net increase in cash, cash equivalents, and restricted cash	$ 10,362	$ 24,056

Cash Used In Operating Activities

Net cash used in operating activities in 2024 was $23.1 million and consisted of a net loss of $18.6 million plus the net changes in operating assets and liabilities of $8.8 million offset by $4.3 million in non-cash adjustments. The net changes in operating assets and liabilities was primarily due to a $7.7 million reduction in deferred revenues and $1.7 million reduction in accounts payable and accrued liabilities. The non-cash adjustments of $4.3 million were primarily due to stock-based compensation and depreciation, partially offset by the change in the fair value of the warrant liability.

Net cash used in operating activities was $28.6 million for the year ended December 31, 2023, which primarily reflects the loss from operations of $24.7 million plus the changes in operating assets and liabilities of $10.8 million. These items were offset by non-cash expenses of $4.6 million for stock-based compensation and $0.8 million for depreciation and amortization. The foreign currency remeasurement and deferred tax benefit had no effect on cash flows.

Cash (Used In) Provided by Investing Activities

Cash used in investing activities for the year ended December 31, 2024 was $2.3 million and primarily consisted of cash used to purchase U.S. Treasury securities, net of proceeds from maturities of U.S. Treasury securities.

Cash provided by investing activities for the year ended December 31, 2023 was $46.4 million and consisted of $63.3 million in proceeds from the maturity of U.S. Treasury securities during the period and $0.2 million in proceeds from the sale of marketable equity securities, partially offset by $16.4 million used to purchase U.S. Treasury securities and $0.7 million used to purchase equipment.

Cash Provided by Financing Activities

Cash provided by financing activities for the year ended December 31, 2024 was $35.9 million and primarily consisted of net proceeds from the sale of our common shares in registered direct offerings and under our at-the-market offering program.

Cash provided by financing activities for the year ended December 31, 2023 was $6.4 million and primarily consisted of net proceeds from the sale of our common shares under our at-the-market offering program.

Financial Obligations

Our financial obligations primarily consist of obligations to our licensors under license agreements, obligations related to grants received from government entities, including the IIA, obligations under vendor contracts for research services and other purchase commitments with suppliers.

Our obligations to licensors under license agreements and to government entities under the terms of grants we have received require us to make future payments relating to sublicense fees, milestone payments, redemption fees, royalties and patent maintenance costs. Sublicense fees are payable to licensors or government entities when we

sublicense underlying intellectual property to third parties; the fees are based on a percentage of the license-related revenue we receive from sublicensees. Milestone payments are due to licensors or government entities upon future achievement of certain commercial, development and regulatory milestones, including those related to the Roche Agreement. Redemption fees due to the IIA under the Innovation Law are due upon receipt of any milestone payments and royalties received under the Roche Agreement, see Note 13 (Commitment and Contingencies) to the consolidated financial statements included in this report for additional information. Royalties are payable to licensors or government entities based on a percentage of net sales of licensed products, including those related to the Roche Agreement. Patent maintenance costs are payable to licensors as reimbursement for the cost of maintaining licensed patents. Due to the contingent nature of the payments, the amounts and timing of payments to licensors under our in-license agreements and to government entities under the terms of grants we have received are uncertain and may fluctuate significantly from period to period. As of December 31, 2024, we have not included these commitments on our consolidated balance sheet because the achievement and timing of these events are not fixed and determinable.

As discussed in "Part I—Item 1. Business—Grants from Government Entities," above, we have received grants under the Innovation Law and are required to pay royalties to the IIA from the revenues generated from the sale of product candidates and related services developed, in whole or in part pursuant to, or as a result of, a research and development program funded by the IIA. Under the Innovation Law, we are also required to pay redemption fees to the IIA. To date, through a series of separate grants beginning in 2007, CCN has received a total of $15.4 million from the IIA to support the OpRegen program. We are obligated to pay approximately 24.1% of any future payments we may receive under the Roche Agreement to the IIA, up to an aggregate cap on all payments to IIA, such cap growing over time via interest accrual until paid in full. As of December 31, 2024, the aggregate cap amount was approximately $95.4 million. Redemption fees due to the IIA under the Innovation Law are due upon receipt of any milestone payments and royalties received under the Roche Agreement. As of December 31, 2024, we have not included any future financial obligations due to the IIA under the Innovation Law in our consolidated balance sheet because the achievement and timing of the events that would require future payments to the IIA under the Innovation Law is not fixed and determinable. See Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information.

As of December 31, 2024, under the terms of the leases for the facilities from which CCN and Lineage operate, a total of $2.6 million of rent payments will become due, of which $1.2 million will become due in 2025.

In the normal course of business, we enter into services agreements with contract research organizations, contract manufacturing organizations and other third parties. Generally, these agreements provide for termination upon notice, with specified amounts due upon termination based on the timing of termination and the terms of the agreement. The amounts and timing of payments under these agreements are uncertain and contingent upon the initiation and completion of the services to be provided.

Future Funding Requirements and Potential Sources

We expect to continue to incur losses for at least the next several years. We expect that our operating expenses will continue to increase for the foreseeable future as we continue the development of, and seek regulatory approval for, our product candidates. As a result, we will need significant additional capital to fund our operations. Our determination as to when we will seek additional capital and the amount of additional capital that we will need will be based on our evaluation of the progress we make in our research and development programs, changes to the scope and focus of those programs, changes in grant funding for certain of those programs, and projection of future costs, revenues, and rates of expenditure. If we are unable to raise additional capital when and as needed, we may be required to delay, postpone, or cancel our clinical trials or limit the number of clinical trial sites.

We may seek to obtain the additional capital we may need through one or more equity offerings, debt financings, government or other grant funding, or other third-party funding transactions, including potential strategic alliances and licensing or collaboration agreements, or structured financings such as royalty monetization transactions. We cannot provide any assurance that adequate additional capital will be available on favorable terms, if at all. The issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common shares to decline, and the issuance of additional equity securities could result in the dilution of the interests of our current shareholders. If we obtain additional capital through strategic alliances and licensing or collaboration agreements or structured financing, we may be required to relinquish rights to our intellectual property,

our product candidates or rights to future revenue streams or otherwise agree to terms unfavorable to us. The unavailability or inadequacy of additional capital to meet future capital needs could force us to modify, curtail, delay, or suspend some or all aspects of our current planned operations. Our ability to raise additional capital may be adversely impacted due to external factors beyond our control, such as unfavorable global economic conditions, disruptions to and volatility in the credit and financial markets in the United States and worldwide, public health emergencies, geopolitical conflicts, political and economic instability, inflation and relatively high interest rates, and other macroeconomic factors.

We believe that our $47.8 million in cash, cash equivalents and marketable securities at December 31, 2024, will be sufficient to fund our planned operations through at least twelve months from the issuance date of our consolidated financial statements included elsewhere in this report. We believe we will meet our longer-term expected future cash requirements and obligations with our current cash and cash equivalents, milestone and other payments we expect to receive under our collaboration agreements, and proceeds we receive from sales of our common shares under our at-the-market offering program.

Off-Balance Sheet Arrangements

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Under rules and regulations of the SEC, as a smaller reporting company, we are not required to provide the information required by this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of
Lineage Cell Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Lineage Cell Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2024, the related consolidated statements of operations, comprehensive loss, shareholders' equity and cash flows for the year then ended, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2024, and the consolidated results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the (consolidated) financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the (consolidated) financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the (consolidated) financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue recognition based on a cost input measure of progress

As described in Note 3 to the consolidated financial statements, the Company recorded deferred revenue of $20.6 million as of December 31, 2024 and revenue of $8.1 million for the year ended December 31, 2024 from a collaboration agreement. The Company concluded the grant of licenses for the Company's technology or programs, research and development services, and services or obligations in connection with participation in research or steering committees represent a combined performance obligation for which the Company recognizes collaboration revenues

as the services are performed over time. The Company used a cost-based input method to measure progress toward completion of the performance obligation and to calculate the corresponding revenue to recognize each period.

We identified revenue recognition based on a cost input measure of progress as a critical audit matter because of the significant judgment required by management to estimate total costs to complete and measure the progress toward completion of the performance obligation. This, in turn, led to a high degree of auditor judgment and increased audit effort in performing procedures to evaluate key assumptions, including the use of a subject matter expert on technical accounting matters.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. Our audit procedures included the following, among others:

- Inspecting, on a test basis, supporting documentation for costs incurred which are used to measure progress toward completion and to calculate revenue recognition.
- With the assistance of a subject matter expert on technical accounting matters, reviewing the collaboration agreement and management's analysis to evaluate the reasonableness of management's accounting conclusion to recognize revenue each period based on a cost-based input method to measure progress toward completion.
- Inquiring with research and development personnel to evaluate factors related to the nature of the work to be performed and their impact on the total contract costs to be incurred, including progress to date and the estimate of remaining contract costs.
- Performing a retrospective review to assess the Company's historical estimates of remaining costs to complete the research and development services.
- Recalculating the corresponding revenue recognized each period based on the cost-based input method to measure progress toward completion of the performance obligation.

/s/ Moss Adams LLP

San Diego, California
March 10, 2025

We have served as the Company's auditor since 2024.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders of
Lineage Cell Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Lineage Cell Therapeutics, Inc. and Subsidiaries (collectively, the "Company") as of December 31, 2023, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity, and cash flows for the year ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023, and the results of its operations and its cash flows for the year ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ WithumSmith+Brown, PC

We served as the Company's auditor from 2014 to 2024.

San Francisco, California
March 7, 2024

Except for Note 15, as to which the date is
March 10, 2025

PCAOB ID Number 100

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

	December 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 45,789	$ 35,442
Marketable securities	2,016	50
Accounts receivable, net	638	745
Prepaid expenses and other current assets	2,554	2,204
Total current assets	50,997	38,441
NONCURRENT ASSETS		
Property and equipment, net	2,251	2,245
Operating lease right-of-use assets	2,144	2,522
Deposits and other long-term assets	614	577
Goodwill	10,672	10,672
Intangible assets, net	46,540	46,562
TOTAL ASSETS	$ 113,218	$ 101,019
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 5,437	$ 6,270
Operating lease liabilities, current portion	1,097	830
Finance lease liabilities, current portion	55	52
Deferred revenues, current portion	7,388	10,808
Total current liabilities	13,977	17,960
LONG-TERM LIABILITIES		
Deferred tax liability	273	273
Deferred revenues, net of current portion	14,433	18,693
Operating lease liabilities, net of current portion	1,295	1,979
Finance lease liabilities, net of current portion	67	91
Warrant liabilities	6,161	—
TOTAL LIABILITIES	36,206	38,996
Commitments and contingencies (Note 13)		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of December 31, 2024 and 2023	—	—
Common shares, no par value, 450,000 shares authorized as of December 31, 2024 and 2023; 220,416 and 174,987 shares issued and outstanding as of December 31, 2024 and 2023, respectively	484,722	451,343
Accumulated other comprehensive loss	(2,876)	(3,068)
Accumulated deficit	(403,465)	(384,856)
Lineage's shareholders' equity	78,381	63,419
Noncontrolling deficit	(1,369)	(1,396)
Total shareholders' equity	77,012	62,023
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 113,218	$ 101,019

See accompanying notes to the consolidated financial statements.

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS, EXCEPT PER SHARE DATA)

	Year Ended December 31,	
	2024	2023
REVENUES:		
Collaboration revenues	$ 8,149	$ 7,588
Royalties, license and other revenues	1,350	1,357
Total revenues	9,499	8,945
OPERATING EXPENSES:		
Cost of sales	334	671
Research and development	12,472	15,705
General and administrative	18,171	17,302
Total operating expenses	30,977	33,678
Loss from operations	(21,478)	(24,733)
OTHER INCOME (EXPENSES):		
Interest income, net	1,715	1,629
Loss on marketable equity securities, net	(8)	(176)
Change in fair value of warrant liability	2,128	—
Foreign currency transaction loss, net	(269)	(544)
Other income (expense), net	(670)	542
Total other income (expenses)	2,896	1,451
LOSS BEFORE INCOME TAXES	(18,582)	(23,282)
Provision for income tax benefit	—	1,803
NET LOSS	(18,582)	(21,479)
Net (income) loss attributable to noncontrolling interest	(27)	(7)
NET LOSS ATTRIBUTABLE TO LINEAGE	$ (18,609)	$ (21,486)
Net loss per common share attributable to Lineage basic and diluted	$ (0.09)	$ (0.12)
Weighted-average common shares used to compute basic and diluted net loss per common share	200,193	172,663

See accompanying notes to the consolidated financial statements.

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(IN THOUSANDS)

	Year Ended December 31,	
	2024	2023
NET LOSS	$ (18,582)	$ (21,479)
Other comprehensive loss, net of tax:		
Foreign currency translation adjustment	189	353
Unrealized gain on marketable debt securities	3	150
COMPREHENSIVE LOSS	(18,390)	(20,976)
Less: Comprehensive (income) loss attributable to noncontrolling interest	(27)	(7)
COMPREHENSIVE LOSS ATTRIBUTABLE TO LINEAGE COMMON SHAREHOLDERS	$ (18,417)	$ (20,983)

See accompanying notes to the consolidated financial statements.

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(IN THOUSANDS)

	Common Shares		Accumulated	Noncontrolling	Accumulated Other Comprehensive Income /	Total Shareholders'
	Shares	Amount	Deficit	Deficit	(Loss)	Equity
BALANCE - December 31, 2022	**170,093**	**$ 440,280**	**$ (363,370)**	**$ (1,403)**	**$ (3,571)**	**$ 71,936**
Shares issued through ATM financing	4,775	6,625	—	—	—	6,625
Financing related fees	—	(221)	—	—	—	(221)
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	53	(37)	—	—	—	(37)
Shares issued upon exercise of stock options	66	56	—	—	—	56
Stock-based compensation	—	4,640	—	—	—	4,640
Unrealized gain on marketable debt securities	—	—	—	—	150	150
Foreign currency translation adjustment	—	—	—	—	353	353
Net loss	—	—	(21,486)	7	—	(21,479)
BALANCE - December 31, 2023	**174,987**	**451,343**	**(384,856)**	**(1,396)**	**(3,068)**	**62,023**
Shares issued through registered direct financings	45,041	29,711	—	—	—	29,711
Shares issued through ATM financing	56	70	—	—	—	70
Financing related fees	—	(1,685)	—	—	—	(1,685)
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	45	(23)	—	—	—	(23)
Shares issued upon exercise of stock options	287	229	—	—	—	229
Stock-based compensation	—	5,077	—	—	—	5,077
Unrealized gain on marketable debt securities	—	—	—	—	3	3
Foreign currency translation adjustment	—	—	—	—	189	189
Net loss	—	—	(18,609)	27	—	(18,582)
BALANCE - December 31, 2024	**220,416**	**$ 484,722**	**$ (403,465)**	**$ (1,369)**	**$ (2,876)**	**$ 77,012**

See accompanying notes to the consolidated financial statements.

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)

	Year Ended December 31,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	$ (18,609)	$ (21,486)
Net loss attributable to noncontrolling interest	27	7
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities:		
Issuance costs for common stock warrant liabilities	688	—
Loss on marketable equity securities, net	8	176
Accretion of income on marketable debt securities	(229)	(679)
Depreciation and amortization expense	587	562
Change in right-of-use assets and liabilities	(42)	91
Amortization of intangible assets	22	130
Stock-based compensation	5,077	4,640
Change in fair value of warrant liability	(2,128)	—
Deferred income tax benefit	—	(1,803)
Foreign currency remeasurement and other loss	273	600
Changes in operating assets and liabilities:		
Accounts receivable	106	(446)
Prepaid expenses and other current assets	489	(418)
Accounts payable and accrued liabilities	(1,681)	(2,295)
Deferred revenue	(7,680)	(7,645)
Net cash used in operating activities	(23,092)	(28,566)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of marketable equity securities	18	196
Purchases of marketable debt securities	(8,761)	(16,403)
Maturities of marketable debt securities	7,000	63,330
Purchase of equipment	(565)	(674)
Net cash (used in) provided by investing activities	(2,308)	46,449
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	229	88
Common shares received and retired for employee taxes paid	(23)	(37)
Proceeds from sale of common shares under ATM, net of offering costs	68	6,426
Proceeds from sale of common shares under registered direct financing, net of offering costs	13,889	—
Proceeds from sale of common shares with warrants under registered direct financing, net of offering costs	21,919	—
Payment of financed insurance premium	(171)	—
Repayment of finance lease liabilities	(54)	(54)
Net cash provided by financing activities	35,857	6,423
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(95)	(250)
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	10,362	24,056
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	35,992	11,936
At end of the period	$ 46,354	$ 35,992
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	$ 9	$ 10
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:		
Financing costs in accounts payable and accrued liabilities	$ 179	$ —
Fair value of warrant liability recognized upon issuance in registered direct financing	$ 8,289	$ —
Financed insurance premium	$ 855	$ —
Reconciliation of cash, cash equivalents and restricted cash, end of period:		
Cash and cash equivalents	$ 45,789	$ 35,442
Restricted cash included in deposits and other long-term assets (see Note 13 (Commitments and Contingencies))	565	550
Total cash, cash equivalents, and restricted cash	$ 46,354	$ 35,992

See accompanying notes to the consolidated financial statements.

LINEAGE CELL THERAPEUTICS, INC. AND SUBSIDIARIES
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1. Organization, Basis of Presentation and Liquidity

We are a clinical-stage biotechnology company developing novel allogeneic, or "off-the-shelf," cell therapies for serious neurological and ophthalmic conditions. Our programs are based on our proprietary, cell-based technology platform and associated development, formulation, delivery and manufacturing capabilities. From this platform, we design, develop, manufacture, and test specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. The cells we manufacture are produced by applying directed differentiation processes to established, well-characterized, and self-renewing pluripotent cell lines. These processes are based on specific developmental lineages and generated cells with desired characteristics. Functional cells developed from such lineages and which are relevant to the underlying condition are transplanted into patients in an effort to (a) *replace* or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and (b) *restore* or enhance the patient's functional activity.

Our business strategy is to efficiently leverage our technology platform and our development and manufacturing capabilities to advance our programs internally or in conjunction with strategic partners to further enhance their value and probability of success.

A significant area of focus is a collaboration we entered into with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively or individually, “Roche” or “Genentech”), under which our lead cell therapy program known as OpRegen®, is being developed for the treatment of ocular disorders, including geographic atrophy (“GA”) secondary to age-related macular degeneration (“AMD”). OpRegen (also known as RG6501) is a suspension of human allogeneic retinal pigmented epithelial (“RPE”) cells and is currently being evaluated in a Phase 2a multicenter clinical trial in patients with GA secondary to AMD which is referred to as the “GAlette Study”. OpRegen subretinal delivery has the potential to counteract RPE cell loss in areas of GA lesions by supporting retinal cell health and improving retinal structure and function. Under the terms of the Collaboration and License Agreement we entered into with Roche in December 2021 (the “Roche Agreement”), we received a $50.0 million upfront payment in January 2022 and are eligible to receive up to an additional $620.0 million in developmental, regulatory, and commercialization milestone payments. We also are eligible to receive tiered double-digit percentage royalties on net sales of OpRegen in the U.S. and other major markets. In May 2024, we entered into an additional agreement with Genentech (“Services Agreement”) pursuant to which we agreed to provide Genentech with supplemental clinical, technical, training, manufacturing, and procurement services that support the ongoing advancement of the OpRegen program in exchange for certain payments. In September 2024, Roche and Genentech announced receipt of Regenerative Medicine Advanced Therapy (“RMAT”) designation from the U.S. Food and Drug Administration (“FDA”) for OpRegen for the treatment of GA secondary to dry AMD.

Our most advanced internally owned product candidate is OPC1, an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury (“SCI”). Improved functional activity can lead to greater mobility and enhanced quality of life for patients and significant cost-savings for caregivers and payors. OPC1 also has an extensive long-term safety profile based on two clinical trials conducted to date: a five-patient Phase 1 safety trial in acute thoracic SCI, where all active subjects have been followed for at least 13 years, and a 25-patient Phase 1/2a multicenter dose-escalation trial in subacute cervical SCI, where all active subjects were evaluated for at least 7 years. Results from these studies have been published in the Journal of Neurosurgery Spine. OPC1 clinical development has been supported in part by a $14.3 million grant from the California Institute for Regenerative Medicine (“CIRM”). We plan to apply for additional funding from CIRM to support continued clinical development of OPC1 for the treatment of SCI when CIRM begins accepting new applications, which they have indicated they will do in Spring 2025. See “Grants from Government Entities – Grants from the California Institute for Regenerative Medicine,” below. In December 2023, we filed an Investigational New Drug (“IND”) amendment for OPC1 as it relates to our proposed DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) clinical study, to evaluate the safety and utility of a novel spinal cord delivery device designed to administer OPC1 to the spinal parenchyma in subacute and chronic SCI patients. In March 2024, we received written correspondence from the FDA, advising us that due to their significant workload and conflicting PDUFA priorities at the agency, its review of our IND amendment and the DOSED study protocol was still ongoing, which remained so throughout 2024. On January 31, 2025, the FDA informed us that we could proceed with the DOSED study and shortly thereafter we announced that we were initiating the study. The study will enroll both subacute (between 21 to 42 days

following injury) and chronic (between 1 to 5 years following injury) SCI patients. The DOSED study will be the first study of OPC1 to include patients with a chronic injury, a condition which comprises the majority of SCI patients. We expect DOSED will enable future subsequent studies aimed to demonstrate OPC1's ability to impact functional outcomes. UC San Diego Health, was named as the first participating site for the DOSED study. The DOSED study is expected to commence enrollment in the second quarter of 2025. See "Clinical Stage Cell Transplant Programs – OPC1," below for additional information

Our complete pipeline of allogeneic, or "off-the-shelf", neurology and ophthalmic cell therapy programs currently available to us for development includes:

- *OpRegen (RG6501)*, an allogeneic RPE cell replacement therapy currently in a Phase 2a multicenter, open-label, single arm clinical trial, the GAlette Study, being conducted by Genentech, for the treatment of GA secondary to AMD.
- *OPC1*, an allogeneic oligodendrocyte progenitor cell therapy currently in a Phase 1b, multicenter, open -label safety trial, the DOSED study, which is designed to test the safety and utility of a novel spinal cord delivery device in subacute and chronic SCI patients. OPC1 continues to be evaluated in long-term follow-up from two completed Phase 1 and Phase 1/2a multicenter clinical trials in thoracic and subacute cervical SCI patients.
- ReSonance™ (ANP1), an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of sensorineural hearing loss.
- *PNC1*, an allogeneic photoreceptor cell transplant currently in preclinical development for the treatment of vision loss due to photoreceptor dysfunction or damage.
- *RND1,* a cell transplant program for an undisclosed indication, currently being developed through a gene editing collaboration with Factor Biosciences Limited.
- *A proprietary hypoimmune cell line,* which may have utility in additional central nervous system indications.

Other Programs and Technologies

Although we have to date focused on neurological and ophthalmic cell types, the pluripotent cells which our platform is based on are capable of becoming any of the cell types of the human body. We currently maintain a list of additional undisclosed product candidates which may be considered for development, or partnership in the future, and which altogether cover a range of therapeutic areas and conditions. Generally, these product candidates are based on the same platform technology and employ a similar guided cell differentiation and transplant approach as the product candidates detailed above, but in some cases may also include genetic modifications designed to enhance efficacy and/or safety profiles. We may elect not to develop or partner any of these product candidates.

In addition to seeking to create value for shareholders by developing product candidates through clinical development, we also may seek to create value from our intellectual property or related technologies and capabilities, through licensing collaborations and/or other strategic transactions.

Basis of Presentation

Certain prior period amounts in the consolidated financial statements and accompanying notes have been reclassified to conform to the current period presentation. The reclassification of these items had no impact on net loss, net loss per share, financial position or cash flows in the current or prior periods. Specifically, our reclassifications are (i) operating lease right-of-use assets are now presented separately from property and equipment, net, on the consolidated balance sheets, (ii) cost of sales are now included in operating expenses on the consolidated statements of operations, and (iii) foreign currency transaction gains (losses) are now presented separately from other income (expenses) on the consolidated statements of operations.

Use of Estimates

The preparation of consolidated financial statements in conformity with generally accepted accounting principles in the United States of America ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period with consideration given to materiality. Estimates and assumptions which are subject to significant judgment include those related to revenue recognition under collaborative agreements, impairment of intangible assets, deferred income taxes and tax reserves, and judgments used to determine whether warrants, at the time of their issuance, should be classified as liabilities or equity. Actual results could differ materially from those estimates.

Segments and Principles of Consolidation

Our chief operating decision maker ("CODM"), the Chief Executive Officer, manages the Company's business activities as a single operating and reportable segment at the consolidated level. See Note 15 (Segment Information) for additional information. Lineage's consolidated financial statements include the accounts of its subsidiaries. The following table reflects Lineage's ownership, directly or through one or more subsidiaries, of the outstanding shares of its operating subsidiaries as of December 31, 2024.

Subsidiary	Field of Business	Lineage Ownership	Country
Cell Cure Neurosciences Ltd.	Manufacturing of Lineage's product candidates	94%[(1)]	Israel
ES Cell International Pte. Ltd.	Research and clinical grade cell lines	100%	Singapore

(1) Includes shares owned by Lineage and ES Cell International Pte. Ltd. ("ESI").

All material intercompany accounts and transactions have been eliminated in consolidation. As of December 31, 2024, Lineage consolidates its direct and indirect wholly owned or majority-owned subsidiaries because Lineage has the ability to control their operating and financial decisions and policies through its ownership, and the noncontrolling interest is reflected as a separate element of shareholders' equity on Lineage's consolidated balance sheets.

Liquidity

On December 31, 2024, we had $47.8 million of cash, cash equivalents and marketable securities. On December 31, 2024, the Company had restricted cash of $0.1 million required to be set aside for its corporate credit card facility. Additionally, Cell Cure Neuroscience, Ltd. ("CCN") has restricted cash related to its lease. See Note 13 (Commitments and Contingencies). Based on our current operating plan, we believe that our cash, cash equivalents and marketable securities, will be sufficient to enable us to carry out our planned operations through at least twelve months from the issuance date of our consolidated financial statements.

Capital Resources

Since inception, we have incurred significant operating losses and have funded our operations primarily through the issuance of equity securities, the sale of common stock of our former subsidiaries, receipt of proceeds from research grants, revenues from collaborations, royalties from product sales, and sales of research products and services.

As of December 31, 2024, $39.97 million remained available for sale under our at-the-market offering program ("ATM"). See Note 10 (Shareholders' Equity) for additional information.

As of December 31, 2024, we had $2.0 million of marketable securities. We may use our marketable securities for liquidity as necessary and as market conditions allow. The market value of our marketable securities may not represent the amount that could be realized in a sale of such securities due to various market and regulatory factors, including trading volume, prevailing market conditions and prices at the time of any sale and subsequent sales of securities by the entities. In addition, the value of our marketable securities may be significantly and adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and

financial markets in the United States and worldwide resulting from pandemics, geopolitical conflicts, political and economic instability, rising inflation and interest rates, and other macroeconomic factors.

Additional Capital Requirements

Our financial obligations primarily consist of obligations to licensors under license agreements, obligations related to grants received from government entities, including the Israel Innovation Authority ("IIA"), obligations under contracts with vendors who provide research services and purchase commitments with suppliers.

Our obligations to licensors under license agreements and our obligations related to grants received from government entities require us to make future payments, such as sublicense fees, milestone payments, redemption fees, royalty fees and patent maintenance fees. Sublicense fees are payable to licensors or government entities when we sublicense the applicable intellectual property to third parties; the fees are based on a percentage of the license-related revenue we receive from sublicensees. Milestone payments, including those related to the Roche Agreement, are due to licensors or government entities upon achievement of commercial, development and regulatory milestones. Redemption fees due to the IIA under the Innovation Law are due upon receipt of milestone payments and royalties received under the Roche Agreement. See Note 13 (Commitment and Contingencies) for additional information. Royalties, including those related to royalties we may receive under the Roche Agreement, are payable to licensors or government entities based on a percentage of net sales of licensed products. Patent maintenance fees are payable to licensors as reimbursement for the cost of maintaining license patents. Due to the contingent nature of the payments, the amounts and timing of payments to licensors under our in-license agreements are uncertain and may fluctuate significantly from period to period. As of December 31, 2024, we have not included these commitments on our consolidated balance sheet because the achievement of events that would trigger our payment obligations and the timing thereof are not fixed and determinable.

In the normal course of business, we enter into services agreements with contract research organizations, contract manufacturing organizations and other third parties. Generally, these agreements provide for termination upon notice, with specified amounts due upon termination based on the timing of termination and the terms of the agreement. The amounts and timing of payments under these agreements are uncertain and contingent upon the initiation and completion of the services to be provided.

2. Significant Accounting Policies

Cash and cash equivalents – Lineage considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2024 and 2023, Lineage had $21.6 million and $21.0 million in money market funds, respectively, considered to be cash equivalents. Additionally, as of December 31, 2024 and 2023, Lineage had $17.4 and $8.9 million in marketable debt securities, classified as cash equivalents due to their original maturity of three months or less at the time of purchase.

Restricted cash – At December 31, 2024 and 2023, the Company had restricted cash of $0.1 million required to be set aside for its corporate credit card facility. Additionally, CCN has restricted cash related to its office lease. See Note 13 (Commitments and contingencies).

Marketable debt securities - Lineage accounts for its holdings of U.S. Treasury securities in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 320-10-50, *Debt Securities*. Marketable debt securities purchased with an original maturity of three months or less have been classified as cash equivalents and those purchased with an original maturity of more than three months have been classified as "available-for-sale" and are carried at estimated fair value on the consolidated balance sheet. Unrealized gains and losses are excluded from earnings and are included in other comprehensive income or loss and reported as a separate component of stockholders' equity or deficit until realized. Realized gains or losses on available-for-sale debt securities are included in other income (expense). The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion, together with interest on securities, are included in interest income on the Company's consolidated statement of operations. The cost of securities sold is based on the specific-identification method. In accordance with the Company's investment policy, management invests in debt securities with high credit quality, including U.S. government securities.

Any unrealized losses attributable to current expected credit loss ("CECL") would be recorded through an allowance for credit losses, limited to the amount by which the fair value is below amortized cost, with the offsetting amount recorded in other income or expense in the consolidated statement of operations. To date, no such credit losses have occurred or have been recorded. Unrealized losses not attributable to an expected credit loss and unrealized gains on investments are recorded in other comprehensive income (loss) on the consolidated statements comprehensive loss. Realized gains and losses, if any, on investments classified as available-for-sale securities are included in other income or expense. The amortized cost of investments classified as available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion are included in interest. See Note 4 (Marketable Securities) for additional information.

Marketable equity securities - Lineage accounts for the shares it holds in HBL Hadasit Bio-Holdings Ltd ("HBL") and OncoCyte Corporation ("OCX") as marketable equity securities in accordance with ASC 320-10-25, *Investments – Debt and Equity Securities*, as amended by Accounting Standards Update ("ASU") 2016-01, *Financial Instruments–Overall: Recognition and Measurement of Financial Assets and Financial Liabilities,* further discussed below.

The HBL shares have a readily determinable fair value quoted on the Tel Aviv Stock Exchange ("TASE") under the trading symbol "HDST" where share prices are denominated in New Israeli Shekels (NIS). Lineage has not owned any shares of OCX since June 30, 2024. Shares of OCX have readily determinable fair values quoted on the NYSE American under trading symbol "OCX".

Accounts receivable, net – Net accounts receivables amounted to $0.6 million and $0.7 million as of December 31, 2024 and 2023, respectively. Net trade receivables include an allowance for credit losses of approximately zero and $0.1 million as of December 31, 2024 and 2023, for those amounts deemed uncollectible by Lineage. Lineage establishes an allowance for credit losses based on the evaluation of the collectability of its receivables using a variety of factors, including the length of time receivables are past due, significant events that may impair the customer's ability to pay, such as a bankruptcy filing or deterioration in the customers operating results or financial position, and historical experience. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted. Accounts receivable, net is primarily comprised of royalty-based revenue and other service revenue. Lineage has deemed the risk of customer default within its royalty-based revenues to be low, as the receivable amounts: i) are based on estimates and/or reports directly communicated by its royalty-related sublicensees, and ii) have not historically been impacted by macro-economic uncertainties (i.e., interest rates, inflation, GDP growth) as it relates to collectability. As such, a credit loss allowance per the provisions of CECL is not determined to be necessary. Lineage has deemed the risk of customer default within the other service revenues to be low primarily due to customer creditworthiness.

Concentrations of credit risk, significant sources of supply, and significant customers – Financial instruments that potentially subject Lineage to significant concentrations of credit risk consist primarily of cash, cash equivalents and marketable debt securities. Lineage limits the amount of credit exposure of cash balances by maintaining its accounts in high credit quality financial institutions. Cash equivalent deposits with financial institutions may occasionally exceed the limits of insurance on bank deposits; however, Lineage has not experienced any losses on such accounts. Lineage mitigates its credit exposure on marketable debt securities by investing in short term U.S. Treasuries securities.

Lineage relies on single-source, third-party suppliers for a few key components of our product candidates. If these single-source, third-party suppliers are unable to continue providing a key component, the initiation or progress of any clinical studies of its product candidates may be impeded.

For the years ended December 31, 2024 and 2023, $8.1 million and $7.6 million, respectively, of the Company's total revenue came from our collaboration under the Roche Agreement.

Property and equipment, net – Property and equipment, including finance lease right-of-use assets, are stated at cost, net of accumulated depreciation and amortization. The cost of property and equipment is depreciated or amortized using the straight-line method over the estimated useful life of the asset, ranging from 3 to 10 years. Finance lease right-of-use assets are amortized over the lease term. Leasehold improvements are amortized over the shorter of the useful life or the lease term. See Note 5 (Property and Equipment, Net) for additional information.

Goodwill and IPR&D – Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the values assigned to the assets acquired and liabilities assumed. Goodwill is tested for impairment in accordance with ASU 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*. In-process research and development ("IPR&D") assets are indefinite-lived intangible assets until the completion or abandonment of the associated research and development ("R&D") efforts. Once the R&D efforts are completed or abandoned, the IPR&D will either be amortized over the asset's estimated life as a finite-lived intangible asset or be impaired, respectively, in accordance with ASC 350, *Intangibles – Goodwill and Other*. In accordance with ASC 350, goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment at least annually and between annual tests if we become aware of an event or a change in circumstances that would indicate the asset may be impaired.

Intangible assets – Intangible assets, consisting primarily of acquired patents, patent applications, and licenses to use certain patents are stated at acquired cost, less accumulated amortization. Amortization expense is computed using the straight-line method over the estimated useful lives of the assets, generally over 5 to 10 years.

Impairment of long-lived assets – Long-lived assets, including property and equipment and intangible assets, are reviewed annually for impairment and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. If an impairment indicator is present, Lineage evaluates recoverability by a comparison of the carrying amount of the assets to future undiscounted net cash flows expected to be generated by the assets. If the assets are impaired, the impairment recognized is measured by the amount by which the carrying amount exceeds the estimated fair value of the assets. The Company did not recognize any impairment losses for the years ended December 31, 2024 and 2023.

Leases - We account for leases in accordance with ASC 842, *Leases*. We determine if an arrangement is a lease at inception. Leases are classified as either financing or operating, with classification affecting the pattern of expense recognition in the consolidated statements of operations. Under the available practical expedients for the adoption of ASC 842, we account for the lease and non-lease components as a single lease component. We recognize right-of-use ("ROU") assets and lease liabilities for leases with terms greater than twelve months in the consolidated balance sheet. ROU assets represent our right to use an underlying asset during the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating and finance lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. We use the implicit rate when readily determinable. The operating and finance lease ROU assets also includes any lease payments made and excludes lease incentives. Our lease terms used to determine operating and finance lease ROU assets and liabilities may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term. Lease expense for finance lease payments is recognized as amortization of ROU assets and related interest. Operating leases ROU assets are included in noncurrent assets and finance leases ROU assets are included in property and equipment; finance and lease liabilities are included in the current and long-term liabilities in the consolidated balance sheets.

Accounting for warrants - The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in FASB ASC Topic 480, Distinguishing Liabilities from Equity ("ASC 480") and ASC Topic 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's common shares, whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance. Liability and equity-classified warrants are valued using a Black-Scholes option pricing model at issuance, and for liability-classified warrants, at each reporting period end date while the warrants are outstanding. Changes in fair value of liability-classified warrants are recorded in the consolidated statements of operations, and reflected as an adjustment to reconcile net loss to net cash used in operating activities in the consolidated statements of cash flows. See Note 10 (Shareholders' Equity) for additional information.

Transactions with noncontrolling interests of subsidiaries - Lineage accounts for a change in ownership interests in its subsidiaries that does not result in a change of control of the subsidiary by Lineage under the provisions of ASC 810-10-45-23, *Consolidation – Other Presentation Matters,* which prescribes the accounting for changes in ownership interest that do not result in a change in control of the subsidiary, as defined by GAAP, before and after the transaction. Under this guidance, changes in a controlling shareholder's ownership interest that do not result in a change of control, as defined by GAAP, in the subsidiary are accounted for as equity transactions. Thus, if the controlling shareholder retains control, no gain or loss is recognized in the statements of operations of the controlling shareholder. Similarly, the controlling shareholder will not record any additional acquisition adjustments to reflect its subsequent purchases of additional shares in the subsidiary if there is no change of control. Only a proportional and immediate transfer of carrying value between the controlling and the noncontrolling shareholders occurs based on the respective ownership percentages.

Foreign currency translation adjustments and other comprehensive income or loss - In countries in which Lineage operates where the functional currency is other than the U.S. dollar, assets and liabilities are translated using published exchange rates in effect at the consolidated balance sheet date. Revenues and expenses and cash flows are translated using an approximate weighted average exchange rate for the period. Resulting foreign currency translation adjustments are recorded as other comprehensive income or loss, net of tax, in the consolidated statements of comprehensive income or loss and included as a component of accumulated other comprehensive income or loss on the consolidated balance sheets. Foreign currency translation adjustments are primarily attributable to CCN and ESI, Lineage's consolidated foreign subsidiaries. For the years ended December 31, 2024 and 2023, the total comprehensive loss includes gains from foreign currency translation adjustments, of $0.2 million and $0.4 million, respectively, net of an insignificant amount of tax. As of December 31, 2024 and 2023, we had cumulative translation adjustments of $2.5 million and $2.7 million, respectively, net of an insignificant amount of tax.

Foreign currency transaction gains and losses - For transactions denominated in other than the functional currency of Lineage or its subsidiaries, Lineage recognizes transaction gains and losses in the consolidated statements of operations and classifies the gain or loss based on the nature of the item that generated it. Lineage's foreign currency transaction gains and losses are primarily generated by CCN's and ESI's intercompany debt owed to Lineage which is U.S. dollar-denominated, while the functional currency is the Israeli New Shekel ("ILS") and the Singapore Dollar ("SGD"), respectively. At each balance sheet date, Lineage remeasures the intercompany debt using the current exchange rate at that date pursuant to ASC 830, *Foreign Currency Matters.*

Revenue recognition from royalties, license and other revenues - For agreements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, Lineage recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Lineage estimates and recognizes royalty revenues based on all available information, including estimates provided by the customer or licensee from which Lineage obtains such estimates directly for each reporting period. Actual revenues ultimately received may differ from those estimates recorded and are adjusted in the period when information on actuals is available to Lineage.

Revenue Recognition from collaborative agreements - At contract inception, we review collaborative agreements to determine if the accounting treatment falls under ASC *Topic 606, Revenue from Contracts with Customers* ("ASC 606"), or ASC *Topic 808, Collaborative Arrangements* ("ASC 808"). For agreements that may be within the scope of ASC 808, we may analogize to ASC 606 for some aspects of the agreements. If elements of the collaboration reflect a vendor-customer relationship, then those elements are within the scope ASC 606. The classification of transactions under our arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants.

The Company determines revenue recognition for agreements within the scope of Topic 606 in accordance with ASU 2014-09*, Revenues from Contracts with Customers (Topic 606)*, and in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration it is entitled to receive in exchange for such product or service. In doing so, Lineage follows a five-step approach: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when (or as) the customer obtains control of the product or service. Lineage considers the terms of a contract and all relevant facts and circumstances

when applying the revenue recognition standard. Lineage applies the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances.

The terms of our collaborative agreements typically include one or more of the following: (i) upfront fees; (ii) milestone payments related to achievement of development or commercial milestones; (iii) royalties on net sales of licensed products; and (iv) reimbursement of cost-sharing of research and development ("R&D") expenses. Each of these payments eventually result in collaboration revenues. When a portion of non-refundable upfront fees or other payments received are allocated to continuing performance obligations under the terms of a collaborative agreement, they are recorded as deferred revenue and recognized as collaboration revenue when (or as) the underlying performance obligation is satisfied.

To identify the performance obligations within the collaboration agreements, we first identify all the promises in the contract (i.e., explicit and implicit), which may include a customer option to acquire additional goods or services for free or at a discount. We exclude any immaterial promises from the assessment of identifying performance obligations. When an option is identified as providing a customer with a material right, the option is identified as a performance obligation. A portion of the transaction price is then allocated to the option and recognized when (or as) the future goods or services related to the option are provided, or when the option expires.

As part of the accounting treatment for these agreements, we must develop estimates and assumptions that require judgment to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. The following items are estimated in the calculation of the stand-alone selling price: forecasted revenues and development costs, development timelines, discount rates and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if they can be satisfied at a point in time or over time, and we measure the services delivered to our collaboration partners each reporting period, which is based on the progress of the related program. If necessary, we adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis which would affect revenue and net income (loss) in the period of adjustment. In addition, variable considerations (e.g., milestone payments) must be evaluated to determine if it is constrained and, therefore, excluded from the transaction price.

- *Upfront fees* - If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize collaboration revenues from the transaction price allocated to the license when the license is transferred to the licensee, and the licensee is able to use and benefit from the license. When the license is determined to be non-distinct, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time, and, if over time, the appropriate method of measuring progress for purposes of recognizing collaboration revenue from the allocated transaction price. For example, when we receive upfront fees for the performance of research and development services, or when research and development services are not considered to be distinct from a license, we recognize collaboration revenue for those units of account over time using a measure of progress. We evaluate the measure of progress at each reporting period and, if necessary, adjust the measure of performance and related revenue as a change in estimate.
- *Milestone payments* - At the inception of each collaboration agreement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the collaboration partner's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of milestones that are within our or the collaboration partner's control, such as operational developmental milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and net income (loss) in the period of adjustment. Revisions to our estimate of the transaction price may also result in negative collaboration revenues and net income (loss) in the period of adjustment.
- *Royalties* - For collaboration agreements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to

which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

- *Reimbursement, cost-sharing payments* - Under certain collaborative agreements, we will receive reimbursement for a portion of our R&D expenses. Such reimbursements are reviewed for gross versus net reporting considerations and reflected either as a reduction of R&D expense or as reimbursement revenue in our consolidated statements of operations.

Research and development expenses - Research and development expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct expenses and indirect research-related overhead expenses including compensation and related benefits, stock-based compensation, consulting fees, research and laboratory fees, rent of research facilities, amortization of intangible assets, and license fees paid to third parties to acquire patents or licenses to use patents and other technology. Research and development costs with no future benefit or alternative use will be expensed as incurred. Research and development expenses incurred and reimbursed by grants from third parties approximate the grant income recognized in the consolidated statements of operations. Royalties and sublicensing fees are recorded as research and development expenses, unless these costs are associated with royalties from product sales, which we classify as cost of sales in our consolidated statements of operations. We expect our total research and development expenses to fluctuate each reporting period based on several factors including (i) the stage of development for each cell therapy program, (ii) the availability of resources to work on each program, and (iii) the timing of contractual obligations.

General and administrative expenses - General and administrative expenses consist of employee and director compensation and related benefits, including stock-based compensation, for executive and corporate personnel, professional and consulting fees, and allocated overhead such as facilities rent and equipment rent and maintenance, insurance costs allocated to general and administrative expenses, costs of patent applications, prosecution and maintenance, stock exchange-related costs, depreciation expense, marketing costs, legal and accounting costs, and other miscellaneous expenses.

Stock-based compensation - Lineage follows accounting standards governing share-based payments in accordance with ASC 718, *Compensation – Stock Compensation*, which require the measurement and recognition of compensation expense for all share-based payment awards made to directors and employees based on estimated fair values.

The Company recognizes share-based compensation for equity awards granted to employees, non-employee director and consultants as an expense on the consolidated statements of operations. Share-based compensation is recognized over the requisite service period of the individual awards using the straight-line attribution method, which generally equals the vesting period. Employees stock options primarily have a ten-year life and generally vest 25% on the first anniversary of the grant and in 1/36th equal installments on each monthly anniversary thereafter, such that options are fully vested on the four-year anniversary of the date of grant. The exercisability and vesting periods of options granted to directors and consultants vary. Restricted stock units subject to time-based vesting generally vest in four equal annual installments beginning on the first anniversary of the grant date. Restricted stock units subject to performance-based vesting will vest in connection with the achievement of certain development milestones (see Note 11 (Stock-Based Awards) for additional details).

For employee, non-employee director and consultant stock options, we utilize the Black-Scholes option pricing model for valuing share-based payment awards. Lineage's determination of fair value of share-based payment awards on the date of grant using that option-pricing model is affected by the price of Lineage's common shares as well as by assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to: (i) the expected stock price volatility over the term of the awards, based upon our historical volatility; (ii) the expected term of options granted, which is derived using the simplified method, which is an average of the contractual term of the option and its vesting period, as we do not have sufficient historical exercise data upon which to estimate the expected term; and (iii) the risk-free rate, which is based on the U.S. Treasury yield in effect at the time of grant for U.S. Treasury notes with maturities similar to the expected term of the awards. Stock option forfeitures are accounted for as they occur.

For restricted stock units (“RSUs”) subject to service and/or performance vesting conditions, the grant-date fair value is established based on the closing price of Lineage’s common shares on such date. Stock-based compensation expense for RSUs subject to only service conditions is recognized on a straight-line basis over the service period. Stock-based compensation expense for RSUs with both service and performance conditions is recognized on a graded basis only if it is probable that the performance condition will be achieved. Lineage accounts for forfeitures of RSUs as they occur in determining stock-based compensation expense.

Although the fair value of employee stock options and RSUs are determined in accordance with FASB guidance, changes in the assumptions can materially affect the estimated value and therefore the amount of compensation expense recognized in the consolidated financial statements.

Income taxes - Lineage accounts for income taxes in accordance with ASC Topic 740, *Income Taxes* ("ASC 740"), which prescribe the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. ASC 740 guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. Lineage files a U.S. federal income tax return as well as California combined and foreign income tax returns. Lineage’s judgments regarding future taxable income may change over time due to changes in market conditions, changes in tax laws, tax planning strategies or other factors. If Lineage assumptions, and consequently the estimates, change in the future with respect to Lineage’s own deferred tax assets and liabilities, the valuation allowance may be increased or decreased, which may have a material impact on Lineage’s consolidated financial statements. Lineage recognizes accrued interest and penalties related to unrecognized tax benefits, if any, as income tax expense; however, no amounts were accrued for the payment of interest and penalties as of December 31, 2024 and 2023. We provided a reserve against our federal and California research and development credits generated. The carryforward amounts for these credits have been reported net of these reserves. Accordingly, no accrued interest and penalties related to unrecognized tax benefits have been recorded as of December 31, 2024 and 2023.

On December 22, 2017, the United States enacted major federal tax reform legislation, Public Law No. 115-97, commonly referred to as the 2017 Tax Cuts and Jobs Act (“2017 Tax Act”), which enacted a broad range of changes to the Internal Revenue Code. Beginning in 2018, the 2017 Tax Act subjects a U.S. stockholder to tax on Global Intangible Low Tax Income (“GILTI”) earned by certain foreign subsidiaries. In general, GILTI is the excess of a U.S. shareholder’s total net foreign income over a deemed return on tangible assets. The provision further allows a deduction of 50% of GILTI, however this deduction is limited to the Company’s pre-GILTI U.S. income. See Note 12 (Income Taxes) for additional information.

Current interpretations under ASC 740 state that an entity can make an accounting policy election to either recognize deferred taxes for temporary basis differences expected to reverse as GILTI in future years or to provide for the tax expense related to GILTI in the year the tax is incurred as a period expense. We have elected to account for GILTI as a current period expense when incurred.

Basic and diluted net income (loss) per share attributable to common shareholders - Basic earnings per share is calculated by dividing net income or loss attributable to Lineage common shareholders by the weighted average number of common shares outstanding, net of stock options and RSUs, subject to repurchase by Lineage, if any, during the period. Diluted earnings per share is calculated by dividing the net income or loss attributable to Lineage common shareholders by the weighted average number of common shares outstanding, adjusted for the effects of potentially dilutive common shares issuable under outstanding stock options, restricted stock awards and warrants, using the treasury-stock method, convertible preferred stock, if any, using the if-converted method, and treasury stock held by subsidiaries, if any.

For the years ended December 31, 2024 and 2023, respectively, Lineage reported a net loss attributable to common shareholders, and therefore, all potentially dilutive common shares were considered antidilutive for those periods.

The following common share equivalents were excluded from the computation of diluted net loss per common share for the periods presented because including them would have been antidilutive (in thousands):

	Year Ended December 31,	
	2024	2023
Stock options	26,726	21,663
Restricted stock units	501	668
Warrants	33,158	—

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures ("ASU 2023-07"). ASU 2023-07 expands disclosures about a public entity's reportable segments and requires more enhanced information about a reportable segment's expenses, interim segment profit or loss, and how a public entity's chief operating decision maker uses reported segment profit or loss information in assessing segment performance and allocating resources. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024 and its adoption did not have a significant impact on our consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03"). The purpose of ASU 2024-03 is to improve the disclosures about a public business entity's expenses and address requests from investors for more detailed information about the types of expenses (including purchases of inventory, employee compensation, depreciation, amortization, and depletion) in commonly presented expense captions (such as cost of sales, SG&A, and research and development) ASU 2024-03 is effective for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. We are currently assessing the impact that this new guidance will have on our consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) - Improvements to Income Tax Disclosures. The new standard requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. The standard is effective for us beginning in fiscal year 2025, with early adoption permitted, and is expected to be applied prospectively, but retrospective application is permitted. We are currently evaluating the impact of ASU 2023-09 on the consolidated financial statements and related disclosures.

3. Revenue

Our disaggregated revenues were as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Revenues under collaborative agreements		
Upfront license fees [1]	$ 8,149	$ 7,588
Total revenues under collaborative agreements	8,149	7,588
Royalties, license and other revenues [2]	1,350	1,357
Total revenue	$ 9,499	$ 8,945

(1) All of the upfront license fee revenue recognized each period was included within deferred revenue as contract liabilities at the beginning of the period. This revenue originated from the $50.0 million upfront payment under the Roche Agreement.

(2) Of the royalties, license and other revenues recognized each period, $30,000 and $87,000 was included within deferred revenues as contract liabilities as of January 1, 2024 and 2023, respectively.

We are recognizing the $50.0 million upfront payment under the Roche Agreement utilizing an input method of costs incurred over total estimated costs to be incurred. At each reporting period, we update our total estimated collaboration costs, and any resulting adjustments are recorded on a cumulative basis which would affect revenue and deferred revenue in the period of adjustment. We believe the input methodology represents the most appropriate measure of progress towards satisfaction of the identified performance obligations.

For contracts with customers including collaboration partners which are within the scope of ASU 2014-09 – Revenue from Contracts with Customers (Topic 606), the aggregate amount of the transaction price allocated to remaining performance obligations as of December 31, 2024 was $25.6 million, of which $21.8 million is reported as deferred revenues. The $25.6 million is expected to be substantially converted to revenue by December 2026.

Accounts receivable, net, and deferred revenues (contract liabilities) from contracts with customers, including collaboration partners, consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Accounts receivable, net - beginning of the year [1]	$ 676	$ 297
Accounts receivable, net - end of the period [1]	$ 638	$ 676
Contract liabilities [1]		
Deferred revenues - beginning of the year	$ 29,501	$ 37,146
Deferred revenues - end of the period [2]	$ 21,821	$ 29,501

(1) Excludes grants receivable which are outside the scope of ASU 2014-09.

(2) Deferred revenue related to the Roche Agreement was $20.6 million as of December 31, 2024.

The following table presents amounts under our collaboration agreements included in the transaction price (i.e., cumulative amounts triggered or probable) as of December 31, 2024 (in thousands):

	Upfront[1]	Development[2]	Reimbursements[3]	Total
Collaboration partner and agreement date:				
ITI (April 2021)[4]	$ 500	$ 500	$ 2,220	$ 3,220
Roche (December 2021)[5]	50,000	—	—	50,000
Total amounts under our collaboration agreements included in the transaction price	**$ 50,500**	**$ 500**	**$ 2,220**	**$ 53,220**

(1) Upfront license fees.

(2) Event-based development and regulatory milestones amounts.

(3) Reimbursements and costs-sharing payments.

(4) Regarding the accounting treatment for the Immunomic Therapeutics, Inc.("ITI") collaborative agreement, the license and related development deliverables were determined to be highly interdependent and interrelated and have been combined as one performance obligation. Delivery is determined to be over time and revenue will be recognized utilizing an input method of costs incurred over total estimated costs in the work plan. The regulatory milestones are variable considerations that are fully constrained until the uncertainty of each milestone has been resolved. Sales-based milestones and royalties are variable considerations that will not be included in the transaction price until the related commercialization and sales have occurred. The cost reimbursements are considered variable consideration and are included in the transaction price. Revenues related to the cost reimbursements are presented gross on the consolidated statement of operations instead of a reduction to the costs being reimbursed. We currently estimate the unsatisfied performance obligations within the contract to be completed during the year ending December 31, 2025.

(5) Regarding the accounting treatment for the Roche Agreement collaboration, the license, technology transfer and related clinical deliverables were determined to be highly interdependent and interrelated and have been combined as one performance obligation. Delivery is determined to be over time and revenue will be recognized utilizing an input method of costs incurred over total estimated costs to complete the performance obligation. A material customer option for additional goods and services was included in the transaction price, and $12.0 million of the transaction price was allocated to the second performance obligation. The option will be recognized when the customer exercises the option or when this option expires. Regulatory and development milestones are variable considerations that are fully constrained until the uncertainty of each milestone has been resolved. Sales-based milestones and royalties are variable considerations that will not be included in the transaction price until the related commercialization milestones and sales targets have occurred. We currently estimate the unsatisfied performance obligations within the contract to be substantially completed by December 31, 2026.

4. Marketable Securities

The following table summarizes the fair value of marketable securities held by the Company and their location in the Company's consolidated balance sheet (in thousands):

	December 31, 2024	December 31, 2023
Marketable debt securities		
Included within cash and cash equivalents	$ 17,432	$ 8,856
Included within marketable securities	$ 1,992	$ —
Marketable equity securities		
Included within marketable securities	$ 24	$ 50

Marketable Debt Securities

The following tables summarize the available-for-sale debt securities classified within cash and cash equivalents and within marketable securities in the Company's consolidated balance sheet as of December 31, 2024 and 2023 (in thousands):

	December 31, 2024			
Financial Assets:	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasury securities	$ 19,420	$ 4	$ —	$ 19,424
Total	$ 19,420	$ 4	$ —	$ 19,424

	December 31, 2023			
Financial Assets:	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasury securities	$ 8,855	$ 1	$ —	$ 8,856
Total	$ 8,855	$ 1	$ —	$ 8,856

The Company has not recognized an allowance for credit losses on any securities in an unrealized loss position as of December 31, 2024 and 2023. The Company believes that any individual unrealized losses represent temporary declines resulting from changes in interest rates, and we intend to hold these marketable debt securities to their maturity.

As of December 31, 2024, the amortized cost and estimated fair value of the Company's available-for-sale debt securities by contractual maturity are shown below (in thousands):

Available-for-sale debt securities maturing:	Amortized Cost	Estimated Fair Value
In one year or less	$ 19,420	$ 19,424
Total available-for-sale debt securities	$ 19,420	$ 19,424

Marketable Equity Securities

Marketable equity securities are reported at fair value with unrealized gains and losses related to mark-to-market adjustments included in income. Lineage's marketable equity securities have consisted of shares of common stock of OCX and of HBL. All share prices are determined based on the closing price of OCX and HBL common stock on the last trading day of the applicable quarter. Lineage has not owned any shares of OCX since June 30, 2024.

The following table represents the realized and unrealized loss on marketable equity securities for the periods presented (in thousands):

	Year Ended December 31,	
	2024	2023
Loss on marketable equity securities, net	$ (8)	$ (176)
Less: Loss recognized in earnings on marketable equity securities sold	4	23
Unrealized loss recognized on marketable equity securities held at end of period, net	$ (4)	$ (153)

5. Property and Equipment, Net

At December 31, 2024 and 2023, property and equipment, net was comprised of the following (in thousands):

	December 31, 2024	December 31, 2023
Equipment, furniture and fixtures	$ 4,131	$ 3,614
Leasehold improvements	2,300	2,313
Right-of-use assets - finance lease	204	198
Accumulated depreciation and amortization	(4,384)	(3,880)
Property and equipment, net	$ 2,251	$ 2,245

Depreciation and amortization expense was $587,000 and $562,000 for the years ended December 31, 2024 and 2023, respectively. These amounts include amortization expense for right-of-use finance lease assets of $55,000 and $50,000 for the years ended December 31, 2024 and 2023, respectively.

6. Goodwill and Intangible Assets, Net

At December 31, 2024 and 2023, goodwill and intangible assets, net consisted of the following (in thousands):

	December 31, 2024	December 31, 2023
Goodwill [1]	$ 10,672	$ 10,672
Intangible assets:		
Acquired IPR&D – OPC1 (from the Asterias Merger) [2]	$ 31,700	$ 31,700
Acquired IPR&D – VAC (from the Asterias Merger) [2]	14,840	14,840
	46,540	46,540
Intangible assets subject to amortization:		
Acquired patents	18,953	18,953
Acquired royalty contracts [3]	650	650
Accumulated amortization [4]	(19,603)	(19,581)
	—	22
Intangible assets, net	$ 46,540	$ 46,562

(1) Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in the Asterias Merger, see Note 13 (Commitment and Contingencies) for further discussion on the Asterias Merger. To date, we have not recognized any goodwill impairment.

(2) Asterias had two IPR&D intangible assets that were valued at $46.5 million as part of the purchase price allocation that was performed in connection with the Asterias Merger. The fair value of these assets at the acquisition date consisted of $31.7 million pertaining to the OPC1 program and $14.8 million pertaining to the VAC platform.

(3) Asterias had royalty cash flows under patent families it acquired from Geron Corporation. Such patent families are expected to continue to generate revenue, are not used in the OPC1 or the VAC platform, and are considered to be separate intangible assets under ASC Topic 805, *Business Combinations*.

(4) The acquired patents and acquired royalty contracts were fully amortized as of the end of the first quarter of 2024.

Lineage recognized $22,000 and $130,000 in amortization expense of intangible assets during each of the years ended December 31, 2024 and 2023, respectively.

7. Accounts Payable and Accrued Liabilities

At December 31, 2024 and 2023, accounts payable and accrued liabilities consist of the following (in thousands):

	December 31, 2024	December 31, 2023
Accounts payable	$ 1,174	$ 2,050
Accrued compensation	3,066	3,123
Accrued liabilities	1,197	1,097
Total	$ 5,437	$ 6,270

8. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. To increase the comparability of fair value measures, the following hierarchy prioritizes the inputs to valuation methodologies used to measure fair value in accordance with (ASC 820-10-50), *Fair Value Measurements and Disclosures*:

- Level 1 – Inputs to the valuation methodology are quoted prices for identical assets or liabilities in active markets.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Inputs to the valuation methodology that are unobservable. Unobservable inputs are those in which little or no market data exists, reflect those that a market participant would use, and are therefore determined using estimates and assumptions developed by the Company.

We have not transferred any instruments between the three levels of the fair value hierarchy.

The carrying value of cash, restricted cash, accounts receivable, accounts payable, and accrued liabilities approximate their respective fair values due to their relative short maturities. We measure our cash equivalents, marketable securities and our liability classified warrants at fair value on a recurring basis. The fair values of such assets and liabilities were as follows as of December 31, 2024 and 2023 (in thousands):

		Fair Value Measurements Using		
	Balance at December 31, 2024	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market fund [1]	$ 21,570	$ 21,570	$ —	$ —
Marketable debt securities [1]	17,432	17,432	—	—
Marketable debt securities	1,992	1,992	—	—
Marketable equity securities [2]	24	24	—	—
Total assets measured at fair value	$ 41,018	$ 41,018	$ —	$ —
Liabilities:				
Warrant liabilities [3]	$ 6,161	$ —	$ —	$ 6,161
Total liabilities measured at fair value	$ 6,161	$ —	$ —	$ 6,161

	Balance at December 31, 2023	Fair Value Measurements Using		
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Money market fund [1]	$ 21,029	$ 21,029	$ —	$ —
Marketable debt securities [1]	8,856	8,856	—	—
Marketable equity securities [2]	50	50	—	—
Total assets measured at fair value	$ 29,935	$ 29,935	$ —	$ —

(1) Included in cash and cash equivalents in the accompanying consolidated balance sheet. Marketable debt securities purchased with an original maturity of three months or less have been classified as cash equivalents.

(2) Lineage's marketable equity securities include the shares of stock of OCX and HBL. Both securities have readily determinable fair values quoted on the NASDAQ or TASE (Level 1). These securities are measured at fair value and reported as current assets on the accompanying consolidated balance sheets based on the closing trading price of the security as of the date being presented. Lineage has not owned any shares of OCX since June 30, 2024.

(3) In determining fair value of the liability classified warrants, Lineage utilizes a Black-Scholes option pricing model that maximizes the use of observable inputs and minimizes the use of unobservable inputs to the extent possible. A significant increase or decrease in these Level 3 inputs could result in a significantly higher or lower fair value measurement.

The following table sets forth a summary of changes to Level 3 fair value measurements for the year ended December 31, 2024 (in thousands):

	Common Share Warrant Liabilities
Balance - December 31, 2023	$ —
Issued	8,289
Change in fair value of warrant liability recognized in the consolidated statement of operations	(2,128)
Balance - December 31, 2024	$ 6,161

Level 3 inputs - Significant assumptions used in valuing the warrant liabilities for the year ended December 31, 2024, were as follows:

	December 31, 2024
Expected stock price volatility	69.70% - 71.18%
Risk-free interest rate	4.27% - 4.30%
Expected dividend yield	—
Expected term (in years)	3.39 – 3.50

The expected stock price volatility assumption is determined using historical volatility of the Company's common stock. The risk-free interest rate assumption is based on the U.S. Treasury yield curve whose term is consistent with the expected term of the stock options. The expected dividend yield is 0% as the Company has not paid and does not anticipate paying dividends on its common stock. The expected term represents the period from the warrant issuance to the earlier of (a) May 21, 2028, and (b) the 90th day following the date of the public disclosure of the intent to advance OpRegen (also known as RG6501) into a multi-center phase 2 or 3 clinical trial which includes a control or comparator arm, or if the date of such public disclosure occurs prior to May 21, 2025, the 90th day following May 21, 2025, with each such 90-day period subject to extension if certain conditions, including equity conditions, some of which are outside of our control, are not satisfied.

9. Related Party Transactions

In connection with the putative shareholder class action lawsuits filed in February 2019 and October 2019 challenging the Asterias Merger (see Note 13 (Commitments and Contingencies)), Lineage agreed to pay the expenses for the legal defense of Neal Bradsher, a member of the Lineage board of directors, Broadwood Partners, L.P. ("Broadwood Partners"), a shareholder of Lineage and an affiliate of Mr. Bradsher, and Broadwood Capital, Inc., which serves as the general partner of Broadwood Partners, all of whom were named defendants in the lawsuits, prior to being dismissed. From inception of the matter through July 2023, Lineage incurred approximately $626,000 in legal expenses on behalf of the foregoing parties, and since then Lineage has not incurred any additional such expenses.

On February 6, 2024, Lineage entered into a stock purchase agreement with certain investors relating to the purchase and sale in a registered direct offering of an aggregate of 13,461,540 of Lineage's common shares. The offering price was $1.04 per common share. The offering closed on February 8, 2024. Broadwood Partners purchased 6,730,770 common shares in the offering and Don Bailey, a member of Lineage's board of directors, purchased 96,155 shares in the offering.

On November 19, 2024, Lineage entered into securities purchase agreements with certain unaffiliated healthcare focused institutional investors and with Broadwood Partners relating to the purchase and sale in a registered direct offering of an aggregate of up to 39,473,688 of our common shares and accompanying warrants to purchase an aggregate of up to 39,473,688 of our common shares at a combined purchase price of $0.76 per common share and accompanying warrant. In January 2025, following receipt of stockholder approval of the issuance of our common shares and accompanying warrant pursuant to the terms of the securities purchase agreement between us and Broadwood Partners, Broadwood Partners purchased 7,894,737 common shares and an accompanying warrant to purchase an aggregate of up to 7,894,737 common shares. Such warrant will be exercisable for one common share at an exercise price of $0.91 per common share commencing on May 21, 2025 and will expire on the earlier of (a) May 21, 2028, and (b) the 90th day following the date of the public disclosure of the intent to advance OpRegen (also known as RG6501) into a multi-center phase 2 or 3 clinical trial which includes a control or comparator arm, or if the date of such public disclosure occurs prior to May 21, 2025, the 90th day following May 21, 2025, with each such 90-day period subject to extension if certain conditions, including equity conditions, some of which are outside of our control, are not satisfied.

10. Shareholders' Equity

Preferred Shares

Lineage is authorized to issue 2,000,000 preferred shares, no par value. The preferred shares may be issued in one or more series as the Lineage board of directors may determine by resolution. The Lineage board of directors is authorized to fix the number of shares of any series of preferred shares and to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed on the preferred shares as a class, or upon any wholly unissued series of any preferred shares. The Lineage board of directors may, by resolution, increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series of preferred shares subsequent to the issue of shares of that series. As of December 31, 2024 and 2023, there were no preferred shares issued or outstanding.

Common Shares

At December 31, 2024, Lineage was authorized to issue 450,000,000 common shares, no par value. As of December 31, 2024 and 2023, there were 220,416,326 and 174,986,671 common shares issued and outstanding, respectively.

At-The-Market Offering Program

In May 2020, Lineage entered into a Controlled Equity Offering℠ Sales Agreement (the "Prior Sales Agreement") with Cantor Fitzgerald & Co., as sales agent, pursuant to which Lineage could sell its common shares from time to time through an ATM program.

In December 2021, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of up to $64.1 million of common shares through the ATM program under the Prior Sales Agreement, which was

updated, amended and supplemented by a prospectus supplement filed with the SEC on May 18, 2023 (the prospectus supplement filed in December 2021, as updated, amended and supplemented by the prospectus supplement filed in May 2023, the "Prior Prospectus Supplement").

In March 2024, Lineage terminated the Prior Sales Agreement and entered into a sales agreement (the "ATM Sales Agreement") with B. Riley Securities, Inc., as sales agent ("Sales Agent"), under which Lineage may offer and sell its common shares from time to time through an ATM program.

In March 2024, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of $40.00 million of common shares through the ATM program under the ATM Sales Agreement which was updated, amended and supplemented by a prospectus supplement filed with the SEC on May 14, 2024 in connection with the offer and sale of $39.97 million of common shares through the ATM program under the ATM Sales Agreement (the prospectus supplement filed in March 2024, as updated, amended and supplemented by the prospectus supplement filed in May 2024, the "2024 Prospectus Supplement").

Prior to its termination in March 2024, Lineage had sold 4,912,803 common shares under the Prior Prospectus Supplement at a weighted average price per share of $1.41 for gross proceeds of $6.9 million. During the three months ended March 31, 2024, Lineage sold 30,000 common shares under the Prior Prospectus Supplement at a weighted average price per share of $1.23 for gross proceeds of $37,000. During the three months ended June 30, 2024, Lineage sold 25,830 common shares under the 2024 Prospectus Supplement at a weighted average price per share of $1.30 for gross proceeds of $33,000. Lineage did not sell any common shares under the 2024 Prospectus Supplement during the six months ended December 31, 2024. As of December 31, 2024, $39.97 million remained available for sale under the 2024 Prospectus Supplement.

The shares offered under the 2024 Prospectus Supplement are registered pursuant to Lineage's effective shelf registration statement on Form S-3 (File No. 333-277758), which was filed with the SEC on March 7, 2024 and declared effective on May 14, 2024.

Lineage agreed to pay Sales Agent a commission of up to 3.0% of the aggregate gross proceeds from the sale of shares under the ATM Sales Agreement, reimburse its legal fees and disbursements, and provide Sales Agent with customary indemnification and contribution rights. The Sales Agreement may be terminated by Sales Agent or Lineage at any time upon notice to the other party, or by Sales Agent at any time in certain circumstances, including the occurrence of a material and adverse change in Lineage's business or financial condition that makes it impractical or inadvisable to market the shares or to enforce contracts for the sale of the shares.

February 2024 Registered Direct Offering

On February 6, 2024, Lineage entered into a stock purchase agreement with certain investors relating to the purchase and sale in a registered direct offering of an aggregate of 13,461,540 of Lineage's common shares. The offering price was $1.04 per common share. The offering closed on February 8, 2024 with gross proceeds of $14.0 million. Finance related fees for this offering totaled approximately $0.1 million. See Note 9 (Related Party Transactions) for shares issued in this offering to a related party.

November 2024 Registered Direct Offering

On November 19, 2024, we entered into securities purchase agreements with unaffiliated healthcare focused institutional investors and with Broadwood Partners relating to the purchase and sale in a registered direct offering of an aggregate of up to 39,473,688 of our common shares and accompanying warrants to purchase an aggregate of up to 39,473,688 of our common shares at a combined purchase price of $0.76 per common share and accompanying warrant.

On November 21, 2024, we closed the first tranche of the offering and in connection therewith we issued to the unaffiliated healthcare focused institutional investors an aggregate of 31,578,951 common shares and accompanying warrants to purchase an aggregate of up to 31,578,951 of our common shares at a combined purchase price of $0.76 per common share and accompanying warrant. Each warrant is exercisable for one common share at an exercise price

of $0.91 per common share and will be exercisable beginning May 21, 2025 and will expire on the earlier of (a) May 21, 2028, and (b) the 90th day following the date of the public disclosure of the intent to advance OpRegen® (also known as RG6501) into a multi-center phase 2 or 3 clinical trial which includes a control or comparator arm, or if the date of such public disclosure occurs prior to May 21, 2025, the 90th day following May 21, 2025, with each such 90-day period subject to extension if certain conditions, including equity conditions, some of which are outside of our control, are not satisfied. The warrants also provide for cashless exercise in certain circumstances, including if the shares issuable upon exercise thereof are not covered by an effective registration statement. The aggregate gross proceeds from this closing was $24 million, with $2.3 million for related issuance costs. The warrants issued at this closing had a fair value of approximately $7.9 million at issuance and are classified as warrant liabilities in the Company's consolidated financial statements. See Note 8 (Fair Value Measurements) for additional information.

The offering of the securities to Broadwood Partners was subject to obtaining shareholder approval to satisfy applicable NYSE American rules, which was obtained at our special meeting of shareholders on January 27, 2025. Following such meeting, we closed the second tranche of the offering and in connection therewith we issued to Broadwood Partners 7,894,737 common shares and an accompanying warrant to purchase an aggregate of up to 7,894,737 common shares, at a combined purchase price of $0.76 per common share and accompanying warrant. The terms of such warrant are substantially the same as those described above. The aggregate gross proceeds from this closing was $6 million, with approximately $0.5 million for related issuance costs. See Note 8 (Fair Value Measurements) for additional information.

We entered into an engagement letter with H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which Wainwright agreed to serve as our exclusive placement agent, on a reasonable best efforts basis, in connection with the offering described above. Pursuant to the engagement letter, we paid Wainwright a cash fee equal to 7% of the aggregate gross proceeds and a management fee equal to 1.0% of the aggregate gross proceeds we received at each closing. In addition, at each closing, we issued to Wainwright (or its designees) warrants to purchase our common shares with terms that are substantially similar to those described above except that the warrants issued to Wainwright (or its designees) have an exercise price of $0.95 per share. In the aggregate we issued to Wainwright (or its designees) warrants to purchase 1,973,684 of our common shares. The warrants issued to Wainwright (or its designees) in connection with the first closing had a fair value of approximately $0.4 million at issuance and are classified as warrant liabilities in the Company's consolidated financial statements. See Note 8 (Fair Value Measurements) for additional information.

The purchase and sale of our common shares and accompanying warrants described above was made pursuant to the registration statement on Form S-3 (File No. 333-277758), which was declared effective by the Securities and Exchange Commission on May 14, 2024.

11. Stock-Based Awards

Equity Incentive Plan Awards

In September 2021, our shareholders approved the Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan, and in September 2023, our shareholders approved an amendment to increase the number of common shares that may be issued thereunder by 19,500,000 (as amended to date, the "2021 Plan"). The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, RSUs, and other stock awards. All of our employees (including those of our affiliates), non-employee directors and consultants are eligible to participate in the 2021 Plan.

Subject to adjustment for certain changes in our capitalization, the aggregate number of our common shares that may be issued under the 2021 Plan will not exceed the sum of (i) 34,500,000 shares and (ii) the number of shares subject to awards granted under the Lineage Cell Therapeutics Inc. 2012 Equity Incentive Plan (the "2012 Plan") that were outstanding when the 2021 Plan became effective and are not issued because such awards expire or otherwise terminate. As a result of the approval of the 2021 Plan by our shareholders, no additional awards will be granted under the 2012 Plan. As of December 31, 2024, there were 21,877,761 shares available for grant under the 2021 Plan.

A summary of activity under the 2021 Plan is as follows (in thousands, except per share amounts):

	Number of Options Outstanding (in thousands)	Weighted Average Exercise Price (per share)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2023	10,824	$ 1.42	8.63	$ 4
Options granted	6,584	$ 1.11		
Options exercised	(20)	$ 1.40		
Options expired/forfeited/cancelled	(730)	$ 1.34		
Balance at December 31, 2024	16,658	$ 1.30	8.23	$ —
Options exercisable at December 31, 2024	5,969	$ 1.42	7.5	$ —
Options exercisable and expected to vest at December 31, 2024	16,658	$ 1.30	8.23	$ —

	Number of RSUs Outstanding	Weighted Average Grant Date Fair Value per Share
Balance at December 31, 2023	668	$ 1.11
RSUs forfeited	(100)	$ 0.21
RSUs vested	(67)	$ 1.50
Balance at December 31, 2024	501	$ 1.24

A summary of activity of the 2012 Plan, and the 2018 inducement option (which was issued to a Lineage executive outside of all equity plans), is as follows (in thousands, except per share amounts):

	Number of Options Outstanding (in thousands)	Weighted Average Exercise Price (per share)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2023	10,839	$ 1.83	5.30	$ 1,047
Options exercised	(267)	$ 0.75		
Options expired/forfeited/cancelled	(504)	$ 2.15		
Balance at December 31, 2024	10,068	$ 1.84	4.58	$ —
Options exercisable at December 31, 2024	9,784	$ 1.82	4.53	$ —
Options exercisable and expected to vest at December 31, 2024	10,068	$ 1.84	4.58	$ —

Stock-based Compensation Expense

The fair value of each option award is estimated on the date of grant using a Black-Scholes option pricing model applying the weighted-average assumptions noted in the following table:

	Year Ended December 31,	
	2024	2023
Expected life (in years)	6.11	6.20
Risk-free interest rates	4.2%	4.2%
Volatility	76.2%	74.7%
Dividend yield	—	—

Operating expenses include stock-based compensation expense as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Research and development	$ 646	$ 794
General and administrative	4,431	3,846
Total stock-based compensation expense	$ 5,077	$ 4,640

As of December 31, 2024, total unrecognized compensation costs related to unvested stock options and unvested RSUs under all equity plans, were $8.2 million, which is expected to be recognized as expense over a weighted average period of approximately 2.4 years for stock options and 1.1 years for RSUs. For the years ended December 31, 2024 and 2023, the weighted average grant-date fair value per share for options granted during the year under the 2021 Plan was $0.77 and $1.00, respectively. No RSUs were granted in the year ended December 31, 2024 or 2023. The total intrinsic value of options exercised during the years ended December 31, 2024 and 2023 was $135,000 and $38,000, respectively. The fair value of the options vested during the years ended December 31, 2024 and 2023 was $4,853,000 and $3,947,000, respectively.

12. Income Taxes

For the year ended December 31, 2024, Lineage did not record a tax provision or deferred tax benefit.

For the year ended December 31, 2023, Lineage recorded a $1.8 million deferred tax benefit, due to the ability to offset certain deferred tax assets against the deferred tax liability associated with IPR&D, and the related release of the valuation allowance. It was determined that a portion of the deferred tax liability related to the indefinite lived assets may be realized prior to the expiration of certain pre 2018 net operating losses.

The domestic and foreign breakout of loss before net income tax benefit was as follows:

	Year Ended December 31,	
	2024	2023
Domestic	$ (18,864)	$ (23,402)
Foreign	282	120
Loss before net income tax benefit	$ (18,582)	$ (23,282)

Income taxes differed from the amounts computed by applying the indicated current U.S. federal income tax rate to pretax losses from operations as a result of the following:

	Year Ended December 31,	
	2024	2023
Computed tax benefit at federal statutory rate	21%	21%
Research and development and other credits	2%	(1)%
Permanent differences	1%	(1)%
Change in valuation allowance	(34)%	(12)%
State tax benefit	10%	2%
GILTI inclusion	—%	(1)%
Income tax benefit (expense)	—%	8%

The primary components of the deferred tax assets and liabilities at December 31, 2024 and 2023 were as follows (in thousands):

Deferred tax assets/(liabilities):	December 31, 2024	December 31, 2023
Net operating loss carryforwards	$ 68,180	$ 63,461
Research and development and other credits	9,433	8,890
Patents and licenses	1,612	1,606
Stock-based compensation	3,841	3,117
Operating lease liability	233	240
Capitalized research expense	8,441	6,217
Other	1,688	1,707
Total deferred tax assets	93,428	85,238
Valuation allowance	(86,314)	(80,513)
Deferred tax assets, net of valuation allowance	7,114	4,725
Operating lease ROU assets	(219)	(221)
Intangibles	(7,168)	(4,771)
Marketable securities at fair value	—	(6)
Total deferred tax liabilities	(7,387)	(4,998)
Net deferred tax liabilities	$ (273)	$ (273)

Lineage has established an accrual for uncertain tax positions related to its U.S. research and development credits. As of December 31, 2024 and 2023, there was no accrued interest related to uncertain tax positions. A reconciliation of beginning and ending balances for unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Balance at the beginning of the period	$ 2,963	$ —
Additions for tax positions related to the current year	190	354
Additions for tax positions related to prior years	—	2,609
Balance at the end of the period	$ 3,153	$ 2,963

Under ASC 740, a valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. Lineage established a full valuation allowance as of December 31, 2018 due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets, including foreign net operating losses generated by its subsidiaries.

As of December 31, 2024 and 2023, Lineage had gross federal net operating loss carryforwards, of approximately $177 million and $163.1 million, respectively. The pre-2018 federal net operating loss carryforwards expire in varying amounts between 2030 and 2037. The post-2017 federal net operating loss carryforwards can be carried forward indefinitely and can only offset 80 percent of taxable income. As of December 31, 2024 and 2023, Lineage's foreign subsidiaries had net operating loss carryforwards of approximately $63.4 and $64.8 million, respectively, which carryforward indefinitely.

As of December 31, 2024 and 2023, Lineage has net operating losses of $213.6 million and $188.8 million, respectively for state tax purposes. The California net operating losses expire in varying amounts between 2030 and 2044.

The state of California suspended the use of NOL deductions for tax years 2024 through 2026 if the California taxable income is greater than or equal to $1 million. Accordingly, the Company may not be able to offset taxable income with their NOL carryforwards for these years. The state of California also limited the use of their research and development credits to $5 million for tax years 2024 through 2026.

As of December 31, 2024 and 2023, Lineage had research tax credit carryforwards for federal tax purposes of $4.7 million and $4.3 million, respectively. These tax credits reflect the amounts for Lineage and its' domestic subsidiaries. For federal purposes, the credits generated each year have a carryforward period of 20 years. The federal tax credits expire in varying amounts between 2023 and 2044.

As of December 31, 2024 and 2023, Lineage had research tax credit carryforwards for California tax purposes of $4.7 million and $4.6 million, respectively. These tax credits reflect the amounts for Lineage and its' domestic subsidiaries. The state tax credits have no expiration period.

On December 17, 2021, Lineage and its subsidiary, CCN, entered into a Collaboration and License Agreement with Roche, wherein Lineage granted to Roche exclusive worldwide rights to develop and commercialize RPE cell therapies. Under the agreement Roche paid Lineage a $50.0 million upfront payment, which was received in January of 2022. See Note 13 (Commitments and Contingencies) for additional information.

For the tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act of 2017 ("TCJA") eliminates the option to currently deduct research and development expenses and requires taxpayers to capitalize and amortize them over five years for research activities performed in the United States and 15 years for research activities performed outside the United States pursuant to IRC Section 174. Although Congress is considering legislation that would repeal and defer this capitalization and amortization requirement for research activities performed in the United States, it is not certain that this provision will be repealed or otherwise modified. If the requirement is not repealed or replaced, it will continue to defer our tax deduction for research and development expense in future years.

During December 2021, in an intercompany transaction, Lineage acquired the economic rights to CCN's interest in certain intellectual property. This transaction generated a gain to CCN of $31.7 million which was fully offset by net operating loss carryforwards in Israel. For book and California income tax purposes, this transaction eliminates in consolidation. For federal income tax purposes, the activities of our foreign subsidiaries are not included in the consolidated tax return. However, under the regulations related to global intangible low-taxed income ("GILTI"), the profits of our foreign subsidiaries may be included, see further discussion below.

The 2017 Tax Act subjects a U.S. stockholder to GILTI earned by certain foreign subsidiaries. In general, GILTI is the excess of a U.S. stockholder's total net foreign income over a deemed return on tangible assets. The provision further allows a deduction of 50% of GILTI, however this deduction is limited to the company's pre-GILTI U.S. income. For the years ended December 31, 2024 and 2023, Lineage's combined foreign entities generated a profit arising from intercompany transactions. As a result, there was an inclusion of $1.2 million and $1.1 million for GILTI purposes for 2024 and 2023, respectively. The resulting net income for federal income tax purposes was fully offset by their federal net operating loss carryforwards.

Other Income Tax Matters

Internal Revenue Code Section 382 places a limitation ("Section 382 Limitation") on the amount of taxable income that can be offset by NOL carryforwards after a change in control (generally greater than 50% change in ownership within a three-year period) of a loss corporation. California has similar rules. Generally, after a change in control, a loss corporation cannot deduct NOL carryforwards in excess of the Section 382 Limitation. Due to these "change in ownership" provisions, utilization of the NOL and tax credit carryforwards may be subject to an annual limitation regarding their utilization against taxable income in future periods.

Lineage files a U.S. federal income tax return as well as a California combined and foreign income tax returns. In general, Lineage is no longer subject to tax examination by major taxing authorities for years before 2020. Although the statute is closed for purposes of assessing additional income and tax in these years, the taxing authorities may still make adjustments to the NOL and credit carryforwards used in open years. Therefore, the statute should be considered open as it relates to the NOL and credit carryforwards used in open years.

Lineage may be subject to potential examination by U.S. federal, U.S. states or foreign jurisdiction authorities in the areas of income taxes. These potential examinations may include questioning the timing and amount of deductions, the nexus of income among various tax jurisdictions and compliance with U.S. federal, U.S. state and

foreign tax laws. Based on Lineage's assessment, no liabilities for uncertain tax positions should be recorded as of December 31, 2024 and 2023.

Lineage's practice is to recognize interest and penalties related to income tax matters in tax expense. As of December 31, 2024 and 2023, Lineage has no accrued interest and penalties.

13. Commitments and Contingencies

Real Property Leases

Carlsbad Lease

In May 2019, Lineage entered into a lease for approximately 8,841 square feet of rentable space in an office park in Carlsbad, California. The lease was amended in December 2022 and the term was extended for a period of thirty-seven months (the "Extended Term") commencing on March 1, 2023 (the "Extended Term Commencement Date"). Monthly base rent for the first twelve months of the Extended Term was $25,200, and is subject to 3% annual increases. Rent was abated for months two through four of the Extended Term. As security for the performance of its obligations under the lease, Lineage provided the landlord a security deposit of $17,850, which is included in deposits and other long-term assets on the consolidated balance sheet as of December 31, 2024.

In addition to base rent, Lineage pays a pro-rata portion of increases in certain expenses, including real property taxes, utilities (to the extent not separately metered to the leased space) and the landlord's operating expenses, over the amounts of those expenses incurred by the landlord. These pro-rata charges are expensed as incurred and excluded from the calculation of the right-of-use assets and lease liabilities.

Carlsbad Sublease

In September 2022, Lineage entered into a sublease for approximately 4,500 square feet of rentable industrial space in Carlsbad, California for a term that commenced on October 1, 2022 and was originally set to expire on March 31, 2024. In February 2024, Lineage extended the term of the sublease for 24 months through March 31, 2026 on similar terms. During the extension period, the base rent is $23,000 per month for the first twelve months and will increase to $23,500 for the remaining twelve months. As security for the performance of its obligations under the sublease, Lineage provided the landlord with a security deposit of $22,500, which is included in deposits and other long-term assets on the consolidated balance sheet as of December 31, 2024.

CCN Leases

As of December 31, 2024, CCN leases approximately 2,096 square meters (approximately 22,600 square feet) of combined office and laboratory space in Jerusalem, Israel under a master lease, as amended, that expires December 31, 2027. Cumulative base rent and construction allowance payments are approximately 165,000 Israeli New Shekels ('ILS") per month (approximately $45,000 as of December 31, 2024), excluding any future rent escalations, and includes options to extend the lease term for five years. The U.S. dollar value of the ILS denominated base rent and construction allowance payments fluctuates based upon currency exchange rates. In addition to base rent, CCN pays a pro-rata share of real property taxes and certain costs related to the operation and maintenance of the building in which the leased premises are located, including parking usage fees. These pro-rata charges are expensed as incurred and excluded from the calculation of the ROU assets and lease liabilities.

CCN has security deposits denominated in ILS with the landlord for this master lease held as restricted cash during the term of the lease. The U.S. dollar value of the ILS denominated security deposits fluctuates based upon currency exchange rates and was $465,000 as of December 31, 2024, which is included in deposits and other long-term assets on the consolidated balance sheet.

Supplemental Information – Leases

Supplemental cash flow information related to leases is as follows (in thousands):

	Year Ended December 31,	
	2024	2023
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 1,218	$ 1,129
Operating cash flows from finance leases	$ 9	$ 10
Financing cash flows from finance leases	$ 54	$ 54
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 597	$ —
Finance leases	$ 36	$ 79

Supplemental balance sheet information related to leases was as follows (in thousands, except lease term and discount rate):

	December 31, 2024	December 31, 2023
Operating leases		
Right-of-use assets	$ 2,143	$ 2,522
Right-of-use lease liabilities, current	$ 1,097	$ 830
Right-of-use lease liabilities, noncurrent	1,295	1,979
Total operating lease liabilities	$ 2,392	$ 2,809
Finance leases		
Right-of-use assets	$ 204	$ 198
Accumulated amortization	(89)	(67)
Right-of-use assets, net	$ 115	$ 131
Right-of-use lease liabilities, current	$ 55	$ 52
Right-of-use lease liabilities, noncurrent	67	91
Total finance lease liabilities	$ 122	$ 143
Weighted average remaining lease term		
Operating leases	2.5 years	3.5 years
Finance leases	2.4 years	3.0 years
Weighted average discount rate		
Operating leases	6.4%	6.5%
Finance leases	7.1%	6.9%

Future minimum lease commitments are as follows as of December 31, 2024 (in thousands):

	Operating Leases	Finance Leases
Year Ending December 31,		
2025	$ 1,178	$ 64
2026	738	39
2027	685	29
Total lease payments	2,601	132
Less imputed interest	(209)	(10)
Total	$ 2,392	$ 122

Operating lease expense was $1.1 million for the twelve months ended December 31, 2024 and 2023, respectively.

Collaborations

Roche Agreement

In December 2021, Lineage entered into the Roche Agreement, wherein Lineage granted to Roche exclusive worldwide rights to develop and commercialize RPE cell therapies, including Lineage's proprietary cell therapy known as OpRegen, for the treatment of ocular disorders, including GA secondary to AMD.

Under the terms of the Roche Agreement, Roche paid Lineage a $50.0 million upfront payment and Lineage is eligible to receive up to an additional $620.0 million in developmental, regulatory and commercialization milestone payments. Lineage also is eligible for tiered double-digit percentage royalties on net sales of OpRegen in the U.S. and other major markets. All regulatory and commercial milestone payments and royalty payments are subject to the existence of certain intellectual property rights that cover OpRegen at the time such payments would otherwise become due, and the royalty payments on net sales of OpRegen are subject to financial offsets based on the existence of competing products. Roche assumed responsibility for further clinical development and commercialization of OpRegen. Lineage is responsible for completing activities related to the ongoing clinical study, for which enrollment is complete, and performing certain manufacturing and process development activities.

Unless earlier terminated by either party, the Roche Agreement will expire on a product-by-product and country-by-country basis upon the expiration of all of Roche's payment obligations under the agreement. Roche may terminate the agreement in its entirety, or on a product-by-product or country-by-country basis, at any time with advance written notice. Either party may terminate the agreement in its entirety with written notice for the other party's material breach if such party fails to cure the breach or upon certain insolvency events involving the other party.

In January 2022, Lineage received the $50.0 million upfront payment from Roche. Subsequently, Lineage, via CCN, paid $12.1 million to the IIA, and $8.9 million to Hadasit Medical Research Services and Development Ltd. ("Hadasit"). Such payments were made in accordance with obligations under the Innovation Law (as discussed below) and under the terms of CCN's agreements with Hadasit (as discussed below). The payment obligation to Hadasit was reduced by $1.9 million in accordance with the provisions of such agreements discussed below that reduce the sublicensing fee payable to Hadasit for costs related to Lineage's performance obligations under the Roche Agreement. To the extent such costs are not incurred within five years after the execution of the Roche Agreement, CCN will be required to pay Hadasit 21.5% of the amount of costs not incurred.

Agreements with Hadasit and IIA

The OpRegen program was supported in part with licenses to technology obtained from Hadasit, the technology transfer company of Hadassah Medical Center, and through a series of research grants from the IIA, an independent agency created to address the needs of global innovation ecosystems. A subset of the intellectual property underlying OpRegen was originally generated at Hadassah Medical Center and licensed to CCN for further development.

Under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744, and the regulations, guidelines, rules, procedures and benefit tracks thereunder (collectively, the "Innovation Law"), annual research and development programs that meet specified criteria and were approved by a committee of the IIA were eligible for grants. The grants awarded were typically up to 50% of the project's expenditures, as determined by the IIA committee and subject to the benefit track under which the grant was awarded.

The terms of the grants under the Innovation Law generally require that the products developed as part of the programs under which the grants were given be manufactured in Israel. The know-how developed thereunder may not be transferred outside of Israel unless prior written approval is received from the IIA. Transfer of IIA-funded know-how outside of Israel is subject to approval and payment of a redemption fee to the IIA calculated according to formulas provided under the Innovation Law. In November 2021, the IIA research committee approved an application made by CCN with respect to the grant of an exclusive license and transfer of the technological know-how for OpRegen to Roche. Under the provisions for the redemption fee, Lineage paid the IIA approximately 24.1% of the upfront payment it received under the Roche Agreement, or $12.1 million, and is obligated to pay the IIA approximately 24.1% of any milestone and royalty payments which may be received under the Roche Agreement, up to an aggregate cap on all payments, such cap growing over time via interest accrual until paid in full. As of December 31, 2024, the aggregate cap amount was approximately $95.4 million.

Pursuant to the Second Amended and Restated License Agreement, dated June 15, 2017, between CCN and Hadasit, and a certain letter agreement entered into on December 17, 2021, CCN paid a sublicensing fee to Hadasit of $8.9 million or 21.5% of the $50.0 million upfront payment under the Roche Agreement (subject to certain reductions), and CCN is obligated to pay Hadasit (i) a maximum of 21.5% of all milestone payments Lineage receives under the Roche Agreement (subject to certain reductions, including for costs related to Lineage's performance obligations under the Roche Agreement), and (ii) up to 50% of all royalty payments (subject to a maximum payment of 5% of net sales of products), Lineage receives under the Roche Agreement. The letter agreement generally terminates upon the termination of the Roche Agreement.

Second Amendment to Clinical Trial and Option Agreement and License Agreement with Cancer Research UK

In May 2020, Lineage and Asterias entered into a Second Amendment to the Clinical Trial and Option Agreement (the "Second CTOA Amendment") with CRUK and Cancer Research Technology ("CRT"). The Second CTOA Amendment amended the initial agreement and the first amendment to the Clinical Trial and Option Agreement, each of which is dated September 8, 2014, between Asterias, CRUK and CRT. Pursuant to the Second CTOA Amendment, Lineage assumed all obligations of Asterias and exercised early its option to acquire data generated in the Phase 1 clinical trial of VAC2 in non-small cell lung cancer being conducted by CRUK.

Lineage and CRT effectuated the option by simultaneously entering into a license agreement (the "CRT License Agreement") pursuant to which Lineage paid a signature fee of £1,250,000 (approximately $1.6 million based upon exchange rates in effect when the fee was paid). For the primary licensed product for the first indication, the CRT License Agreement provides for milestone fees of up to £8,000,000 based upon initiation of a Phase 3 clinical trial and the filing for regulatory approval and up to £22,500,000 in sales-based milestones payments. Additional milestone fees and sales-based milestone payments would be payable for other products or indications, and mid-single-digit royalty payments are payable on sales of commercial products.

Either party may terminate the CRT License Agreement for the uncured material breach of the other party. CRT may terminate the CRT License Agreement in the case of Lineage's insolvency or if Lineage ceases all development and commercialization of all products under the CRT License Agreement.

Other Contingent Obligations

We have obligations under license agreements and grants received from government entities to make future payments to third parties, which become due and payable on the achievement of certain development, regulatory and commercial milestones or on the sublicense of our rights to another party. These commitments include sublicense fees, milestone payments, redemption fees and royalties. Sublicense fees are payable to licensors or government entities when we sublicense underlying intellectual property to third parties; the fees are based on a percentage of the license-related revenue we receive from sublicensees. Milestone payments are due to licensors or government entities upon the future achievement of certain development and regulatory milestones. Redemption fees due to the IIA under the Innovation Law are due upon receipt of any milestone or royalty payment received in respect of IIA-funded programs. Royalties are payable to licensors or government entities based on a percentage of net sales of licensed

products. As of December 31, 2024, we have not included these commitments on our consolidated balance sheet because the achievement and timing of these events are not fixed and determinable.

Litigation – General

From time to time, we are subject to legal proceedings and claims in the ordinary course of business. While management presently believes that the ultimate outcome of these proceedings, individually and in the aggregate, will not materially harm our financial position, cash flows, or overall trends in results of operations, legal proceedings are subject to inherent uncertainties, and unfavorable rulings or outcomes could occur that have individually or in aggregate, a material adverse effect on our business, financial condition or operating results. We are not currently subject to any pending material litigation, other than ordinary routine litigation incidental to our business.

Asterias Merger

In November 2018, Lineage, Asterias Biotherapeutics, Inc. ("Asterias"), and Patrick Merger Sub, Inc., a wholly owned subsidiary of Lineage, entered into an Agreement and Plan of Merger pursuant to which Lineage agreed to acquire all of the outstanding common stock of Asterias in a stock-for-stock transaction (the "Asterias Merger"). The Asterias Merger closed in March 2019. In October 2019, a putative class action lawsuit was filed against the company and certain other named defendants challenging the Asterias Merger.

In February 2023, the court approved a Stipulation and Agreement of Compromise and Settlement pursuant to which, Lineage and certain insurers of the defendants paid $10.65 million (the "Settlement Amount") into a fund created for the benefit of the purported class and in consideration for the full and final release, settlement and discharge of all claims. Approximately $7.12 million of the Settlement Amount was funded by certain insurers and approximately $3.53 million was paid by Lineage during the first quarter of 2023.

Lineage and all defendants have denied, and continue to deny, the claims alleged in the lawsuit and the settlement does not reflect or constitute any admission, concession, presumption, proof, evidence or finding of any liability, fault, wrongdoing or injury or damages, or of any wrongful conduct, acts or omissions on the part any defendant.

Premvia Litigation Settlement

In July 2019, the Company, along with other named defendants, was sued in the Superior Court of the State of California in a matter captioned Gonzalez v. Aronowitz, M.D., et al. The plaintiff asserted medical negligence and product liability causes of action relating to the 2017 and 2018 use in a clinical trial of a product candidate, Premvia, that the Company is no longer developing and has no plans to pursue, and that is not related to the cell therapy candidates the Company currently is developing. In February 2023, the Company and the other defendants each entered into settlement agreements with the plaintiff pursuant to which the defendants without admitting any liability, which the defendants expressly denied, each agreed to pay specified amounts to the plaintiff in exchange for a full settlement and release and discharge of claims. The Company's insurance covered the full amount paid by the Company excluding the $25,000 insurance deductible.

HBL Books and Records Request

On April 17, 2023, CCN received a motion for disclosure of documents pursuant to Section 198A of the Israeli Companies Law 5759-1999. The motion was filed in the district court in Tel Aviv-Yafo (the "Court") by HBL Hadasit Bio-Holdings Ltd. ("HBL"), currently an approximately 5% shareholder of CCN. According to the motion, the requested production of documents is intended to allow HBL to examine the possibility of pursuing a derivative action related to, among other things, the validity of an intercompany Collaboration and License Agreement (the "Intercompany Agreement") entered into between Lineage and CCN pursuant to which CCN conveyed certain rights and other assets to Lineage, and Lineage agreed to undertake certain liabilities and obligations of CCN relating to the OpRegen® program. In its motion, HBL alleges, among other things, that Lineage, in its capacity as CCN's controlling shareholder, and members of CCN's board of directors caused damage to CCN because the Intercompany Agreement was an interested party transaction that was not fairly priced and exploits CCN's resources for the benefit of Lineage. The motion seeks an order to compel CCN to disclose and deliver to HBL the documents described in the motion, such additional, cumulative, or alternative relief as the court deems appropriate, and reimbursement of HBL's expenses, including attorneys' fees. The Court held a hearing on the motion on March 14, 2024 at which the Court proposed, and the parties agreed, to retain a third-party valuation firm to assess the fairness of the valuation that was performed in support of the Intercompany Agreement. It is impossible at this time to assess whether the outcome of

this proceeding will have a material adverse effect on Lineage's consolidated results of operations, cash flows or financial position. Therefore, in accordance with ASC 450, *Contingencies*, Lineage has not recorded any accrual for a contingent liability associated with this legal proceeding based on its belief that a liability, while possible, is not probable nor estimable, and any range of potential contingent liability amounts cannot be reasonably estimated at this time. Lineage records legal expenses as incurred.

Employment Contracts

Lineage has employment agreements with all of its executive officers. Under the provisions of the agreements, Lineage may be required to incur severance obligations for matters relating to changes in control, as defined in the agreements, and involuntary terminations.

Indemnification

In the normal course of business, Lineage may agree to indemnify and reimburse other parties, typically Lineage's clinical research organizations, investigators, clinical sites, and suppliers, for losses and expenses suffered or incurred by the indemnified parties arising from claims of third parties in connection with the use or testing of Lineage's products and services. Indemnification could also cover third party infringement claims with respect to patent rights, copyrights, or other intellectual property pertaining to Lineage products and services. The term of these indemnification agreements generally continue in effect after the termination or expiration of the particular research, development, services, or license agreement to which they relate. In addition, Lineage has entered into indemnification agreements with officers and members of its board of directors that will require Lineage, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as officers or directors. The potential future payments Lineage could be required to make under the indemnification agreements described in this paragraph will generally not be subject to any specified maximum amount. Generally, Lineage has not been subject to any material claims or demands for indemnification. Lineage maintains liability insurance policies that limit its financial exposure under the indemnification agreements described in this paragraph. Accordingly, Lineage has not recorded any liabilities for these agreements as of December 31, 2024 or 2023.

Royalty Obligations and License Fees

We have licensing agreements with research institutions, universities and other parties providing us with certain rights to use intellectual property in conducting research and development activities in exchange for the payment of royalties on future product sales, if any. In addition, in order to maintain these licenses and other rights, we must comply with various conditions including the payment of patent related costs and annual minimum maintenance fees.

As part of the Asterias Merger, Lineage acquired royalty revenues for cash flows generated under patent families that Asterias acquired from Geron Corporation. Lineage continues to make royalty payments to Geron from royalties generated from these patents. Royalty revenues and royalty payments are included within royalties, license and other revenues and cost of sales, respectively, in our consolidated statements of operations.

14. Employee Benefit Plan

We have a defined contribution 401(k) plan for all employees. Under the terms of the plan, employees may make voluntary contributions as a percentage or defined amount of compensation. We provide a safe harbor contribution of up to 5.0% of the employee's compensation, not to exceed eligible limits, and subject to employee participation. For each of the years ended December 31, 2024 and 2023, we incurred approximately $0.2 million in expenses related to the safe harbor contribution.

15. Segment Information

Our chief operating decision maker ("CODM"), the Chief Executive Officer, manages the Company's business activities as a single operating and reportable segment at the consolidated level. The information in our consolidated financial statements is the only regularly provided financial information our CODM receives and there are no other significant expense categories regularly reviewed. Accordingly, our CODM uses consolidated net loss to measure segment profit or loss, allocate resources and assess performance. Further, the CODM reviews and utilizes revenue and functional expenses (cost of sales, research and development, and general and administrative) at the consolidated level to manage the Company's operations. Other segment items included in consolidated net loss are interest income,

loss on marketable equity securities, change in fair value of warrant liability, foreign currency transaction loss, and other income (expense), and the provision for income tax benefit, which are reflected in the consolidated statements of comprehensive income.

16. Enterprise-Wide Disclosures

Geographic Area Information

For the years ended December 31, 2024 and 2023 none of our revenue was generated outside of the United States.

The composition of Lineage's long-lived tangible assets, consisting of plant and equipment, net, and operating lease right-of-use assets between those in the United States and in foreign countries, as of December 31, 2024 and 2023, is set forth below (in thousands):

	Property and equipment, net Year Ended December 31,		Operating lease right-of-use assets Year Ended December 31,	
	2024	2023	2024	2023
United States	$ 105	$ 156	$ 685	$ 671
Foreign [1]	2,146	2,089	1,459	1,851
Total	$ 2,251	$ 2,245	$ 2,144	$ 2,522

(1) Assets in foreign countries principally include laboratory equipment and leasehold improvements in Israel.

17. Subsequent Events

On November 19, 2024, we entered into securities purchase agreements with unaffiliated healthcare focused institutional investors and with Broadwood Partners relating to the purchase and sale in a registered direct offering of an aggregate of up to 39,473,688 of our common shares and accompanying warrants to purchase an aggregate of up to 39,473,688 of our common shares at a combined purchase price of $0.76 per common share and accompanying warrant. Each warrant has an exercise price of $0.91 per share.

The offering of the securities to Broadwood Partners was subject to obtaining shareholder approval to satisfy applicable NYSE American rules, which was obtained at our special meeting of shareholders on January 27, 2025. Following such meeting, we closed the second tranche of the offering and in connection therewith we issued to Broadwood Partners 7,894,737 common shares and an accompanying warrant to purchase an aggregate of up to 7,894,737 common shares, at a combined purchase price of $0.76 per common share and accompanying warrant. The terms of such warrant are the same as those described above. The aggregate gross proceeds from this closing was $6 million, with approximately $0.5 million for related issuance costs.

Pursuant to the Wainwright engagement letter, we paid Wainwright a cash fee equal to 7% of the aggregate gross proceeds and a management fee equal to 1.0% of the aggregate gross proceeds we received at this closing. In addition, at this second closing, we issued to Wainwright (or its designees) warrants to purchase our common shares with terms that are substantially similar to those described above except that the warrants issuable to Wainwright have an exercise price of $0.95 per share. In the aggregate we issued to Wainwright (or its designees) warrants to purchase 394,736 of our common shares in connection with this closing. See Note 10 (Shareholders' Equity) for additional information regarding the registered direct offering.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Exchange Act. Our management, including our principal executive officer and our principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. Following this review and evaluation, management collectively determined that our disclosure controls and procedures were effective as of December 31, 2024 to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act: (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms; and (ii) is accumulated and communicated to management, including principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f), is a process designed by, or under the supervision of, our principal executive officer, and our principal financial officer, and effected by our Board of Directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. The scope of management's assessment of the effectiveness of internal control over financial reporting includes our consolidated subsidiaries.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024, based on criteria established in the 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management believes that, as of that date, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. As a non-accelerated filer, we are not required to have, nor have we, engaged our independent registered public accounting firm to perform an audit of internal control over financial reporting pursuant to SEC rules that permit us to provide only management's report in this Annual Report on Form 10-K.

ITEM 9B. OTHER INFORMATION

(a) None.

(b) During the period from October 1, 2024 to December 31, 2024, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated any Rule 10b5-1 trading arrangement (as defined in Item 408(a)(1)(i) of Regulation S-K) or any non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item will be included in our definitive proxy statement to be filed with the SEC within 120 days after December 31, 2024, in connection with the solicitation of proxies for our 2025 annual meeting of shareholders (the "2025 Proxy Statement"), and is incorporated herein by reference.

We have a written Code of Ethics that applies to our principal executive officer, our principal financial officer and accounting officer, our other executive officers, and our directors. The purpose of the Code of Ethics is to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with or submit to the Securities and Exchange Commission and in our other public communications; (iii) compliance with applicable governmental rules and regulations; (iv) prompt internal reporting of violations of the Code of Ethics to an appropriate person or persons identified in the Code; and (v) accountability for adherence to the Code. A copy of our Code of Ethics has been posted on our internet website and can be found at *www.lineagecell.com*. If we amend or waive a provision of our Code of Ethics that applies to our chief executive officer or chief financial officer, we will post the amended Code of Ethics or information about the waiver on our internet website.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item will be included in the 2025 Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT, AND RELATED STOCKHOLDER MATTERS

The information required by this Item will be included in the 2025 Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this Item will be included in the 2025 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item will be included in the 2025 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBIT AND, FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements.

The following financial statements of Lineage are filed in this report:

(a)(2) Financial Statement Schedules

All financial statement schedules have been omitted, since the required information is not applicable or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements and accompanying notes included in this report.

(a)(3) Exhibits.

Exhibits not filed or furnished herewith are incorporated by reference to exhibits previously filed with the SEC, as reflected in the table below. We will furnish a copy of any exhibit to stockholders, without charge upon written request to Lineage Cell Therapeutics, Inc., Attention: Corporate Secretary, 2173 Salk Avenue, Suite 200 Carlsbad, CA 92008, or by calling (442) 287-8990.

		Incorporation by Reference			
Exhibit Number	**Description**	**Exhibit Number**	**Filing**	**Filing Date**	**File No.**
PLANS OF ACQUISITION					
2.01^	Agreement and Plan of Merger dated November 7, 2018, among Registrant, Patrick Merger Sub, Inc. and Asterias Biotherapeutics, Inc. ("Asterias")	2.1	8-K	November 8, 2018	001-12830
ARTICLES OF INCORPORATION AND BYLAWS					
3.01	Restated Articles of Incorporation, as amended	3.1	10-Q	May 10, 2018	001-12830
3.02	Certificate of Ownership	3.1	8-K	August 12, 2019	001-12830
3.03	Amended and Restated Bylaws	3.1(a)	8-K	June 13, 2024	001-12830
INSTRUMENTS DEFINING RIGHTS OF SECURITY HOLDERS					
4.01	Specimen of Common Share Certificate		S-1	December 18, 1991	033-44549
4.02*	Description of Capital Stock of the Registrant				
4.03(a)	Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement dated November 19, 2024, between Lineage Cell Therapeutics, Inc. and the purchaser parties thereto	4.1	8-K	November 20, 2024	001-12830
4.03(b)	Form of Placement Agent Warrant	4.3	8-K	November 20, 2024	001-12830
4.03(c)*	Warrant issued to Broadwood Partners, L.P. on January 27, 2025				
MANAGEMENT CONTRACTS AND COMPENSATORY PLANS					
10.01+	Form of Indemnification Agreement entered into between the Registrant and its Directors and Officers	10.1	10-Q	August 11, 2022	001-12830

10.02+	Amended and Restated Employment Agreement dated September 26, 2022 between Registrant and Brian Michael Culley	10.2	10-Q	November 10, 2022	001-12830
10.02(a)+	Amendment No. 1 to Employment Agreement entered into as of March 6, 2024 between Registrant and Brian M. Culley	10.1	10-Q	May 9, 2024	001-12830
10.03+	Amended and Restated Employment Agreement dated September 26, 2022 between Registrant and George A. Samuel III	10.3	10-Q	November 10, 2022	001-12830
10.03(a)+	Amendment No. 1 to Employment Agreement entered into as of March 6, 2024 between Registrant and George A. Samuel III	10.3	10-Q	May 9, 2024	001-12830
10.04+	Employment Agreement dated November 14, 2022 between Registrant and Jill A. Howe	10.7	10-K	March 9, 2023	001-12830
10.04(a)	Amendment No. 1 to Employment Agreement entered into as of March 6, 2024 between Registrant and Jill A. Howe	10.2	10-Q	May 9, 2024	001-12830
10.05+	Inducement Stock Option Agreement between Registrant and Brian Culley	10.18	10-K	March 14, 2019	001-12830
10.06+	Lineage Cell Therapeutics 2012 Equity Incentive Plan, as amended July 2015 ("2012 Plan")	4.1	S-8	July 15, 2015	333-205661
10.06(b)+	Amendment to 2012 Plan effective June 2017	4.2	S-8	July 7, 2017	333-219204
10.06(c)+	Amendment to 2012 Plan effective July 2019	99.3	S-8	August 8, 2019	333-233132
10.06(d)+	Amendment to 2012 Plan effective August 2019	10.1	10-Q	November 12, 2019	001-12830
10.06(e)+	2012 Plan Form of Employee Incentive Stock Option Agreement	10.7	10-Q	November 12, 2013	001-12830
10.06(f)+	2012 Plan Form of Non-employee Director Stock Option Agreement	10.8	10-Q	November 12, 2013	001-12830
10.06(g)+	2012 Plan Stock Option Grant Agreement	10.2	10-Q	November 12, 2019	000-12830
10.06(h)+	2012 Plan Form of Restricted Stock Unit	10.6	10-K	March 12, 2020	001-12830
10.07+	Lineage Cell Therapeutics 2021 Equity Incentive Plan, effective as of September 2021 ("2021 Plan")	10.1	8-K	September 15, 2021	001-12830
10.07(a)+	Amendment to 2021 Plan effective September 6, 2023	10.01	8-K	September 7, 2023	001-12830
10.07(b)+	2021 Plan Form of Stock Option Grant Notice and Agreement for Employees and Consultants	99.2	S-8	September 28, 2021	333-259853
10.07(c)+	2021 Plan Form of Stock Option Grant Notice and Agreement for Non-Employee Directors	99.3	S-8	September 28, 2021	333-259853
10.07(d)+	2021 Plan Form of Restricted Stock Unit Award Grant Notice and Agreement	99.4	S-8	September 28, 2021	333-259853
10.08+	Executive Performance Incentive Bonus Plan, adopted September 2022	10.5	10-Q	November 10, 2022	001-12830
COMMERCIAL AGREEMENTS					
10.09	Commercial License and Option Agreement between Registrant and Wisconsin Alumni Research Foundation ("WARF Agreement")	10.1	8-K	January 9, 2008	001-12830
10.09(a)	First Amendment to WARF Agreement dated March 11, 2009	10.38	10-K	March 23, 2009	001-12830
10.10**	Second Amended and Restated License Agreement dated June 15, 2017, between Cell Cure Neurosciences, Ltd. and Hadasit Medical Research Services and Development Ltd. ("Hadasit License")	10.1	10-Q	August 8, 2024	001-12830
10.10(a)	Amendment to Hadasit License dated January 8, 2018	10.38	10-K	March 15, 2018	001-12830
10.10(b)††	Second Amendment to Hadasit License dated December 1, 2019	10.4(b)	10-K	March 10, 2022	001-12830

10.10(c)††	Side Letter Agreement dated December 17, 2021 between Hadasit Medical Research Services and Development Ltd., Cell Cure Neurosciences Ltd., Genentech, Inc. and F. Hoffmann-La Roche Ltd	10.4(c)	10-K	March 10, 2022	001-12830
10.10(d)††	Second Side Letter Agreement dated December 17, 2021 between Hadasit Medical Research Services and Development Ltd. and Cell Cure Neurosciences Ltd.	10.4(d)	10-K	March 10, 2022	001-12830
10.11†	Debt and Note Purchase Agreement dated June 16, 2017, as amended June 29, 2017, between Registrant and HBL-Hadasit Bio-Holdings Ltd.	10.3	10-Q	August 9, 2017	001-12830
10.12†	Share Purchase and Transfer Agreement dated June 16, 2017, by and among Registrant and HBL-Hadasit Bio-Holdings Ltd. and Cell Cure Neurosciences Ltd.	10.4	10-Q	August 9, 2017	001-12830
10.13†	Non-exclusive License Agreement dated October 7, 2013 between WARF and Asterias	10.5	Asterias 10-Q	November 12, 2013	000-55046
10.14	Form of Securities Purchase Agreement dated November 19, 2024, between Lineage Cell Therapeutics, Inc. and the purchaser parties thereto	10.1	8-K	November 20, 2024	001-12830
10.15	Form of Securities Purchase Agreement dated November 19, 2024, between Lineage Cell Therapeutics, Inc. and Broadwood Partners, L.P.	10.2	8-K	November 20, 2024	001-12830
10.16††	Collaboration and License Agreement dated December 17, 2021, between F. Hoffmann-La Roche Ltd, Genentech, Inc., Cell Cure Neurosciences Ltd., and Registrant	10.13	10-K	March 10, 2022	001-12830
19.01*	Insider Trading Policy effective June 11, 2024				
OTHER EXHIBITS					
21.01*	List of Subsidiaries of the Registrant				
23.01*	Consent of Moss Adams LLP				
23.02*	Consent of WithumSmith+Brown, PC				
31.01*	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002				
31.02*	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002				
32.01#	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
97	Lineage Cell Therapeutics, Inc. Clawback Policy	97	10-K	March 7, 2024	001-12830
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

^ The schedules and exhibits to the merger agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.
* Filed herewith.
# Furnished herewith.
+ Indicates management contract or compensatory plan or arrangement.
† Portions of this exhibit have been omitted pursuant to a request for confidential treatment.
†† Certain information in this exhibit has been omitted pursuant to Item 601 of Regulation S-K.
** This exhibit previously was filed as Exhibit 10.2 to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2017 with certain information omitted pursuant to an order issued by the SEC on September 12,

2017 granting confidential treatment under the Securities Exchange Act of 1934 for such omitted information through August 9, 2024. In accordance with CF Disclosure Guidance: Topic No. 7, the Company is electing to transition to compliance with the requirements set out in Regulation S-K Item 601(b)(10), and, accordingly is refiling this exhibit with portions of it redacted in compliance with Regulation S-K Item 601(b)(10) as indicated therein.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 10, 2025

LINEAGE CELL THERAPEUTICS, INC.

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Brian M. Culley BRIAN M. CULLEY	Chief Executive Officer and Director (Principal Executive Officer)	March 10, 2025
/s/ Jill Ann Howe JILL ANN HOWE	Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2025
/s/ Deborah Andrews DEBORAH ANDREWS	Director	March 10, 2025
/s/ Dipti Amin DIPTI AMIN	Director	March 10, 2025
/s/ Don M. Bailey DON M. BAILEY	Director	March 10, 2025
/s/ Neal C. Bradsher NEAL C. BRADSHER	Director	March 10, 2025
/s/ Anula Jayasuriya ANULA JAYASURIYA	Director	March 10, 2025
/s/ Michael H. Mulroy MICHAEL H. MULROY	Director	March 10, 2025
/s/ Angus C. Russell ANGUS C. RUSSELL	Director	March 10, 2025

DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

Lineage Cell Therapeutics, Inc. (the "***Company***") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934: common shares (the "common shares").

The following is a description of the rights of the common shares and related provisions of: (i) the Company's Restated Articles of Incorporation, as amended through September 6, 2023 (as amended by the Certificate of Ownership, the "***Articles***"); (ii) the Company's Second Amended and Restated Bylaws adopted June 11, 2024 (the "***Bylaws***"); and (iii) applicable California law. This description is qualified in its entirety by, and should be read in conjunction with, the Articles, the Bylaws and applicable California law. The Articles and Bylaws are filed as exhibits to the the Company's Annual Report on Form 10-K (the "Annual Report") to which this document is also filed as an exhibit. The Annual Report is filed with the U.S. Securities and Exchange Commission and is publicly available.

Authorized Capital Stock

Pursuant to the Articles, the Company is authorized to issue an aggregate of 452,000,000 shares of capital stock consisting of 450,000,000 common shares and 2,000,000 preferred shares. All of the outstanding common shares are fully paid and non-assessable.

Common Shares

Voting Rights

Each holder of common shares is entitled to one vote for each common share held on every matter properly submitted to the shareholders for their vote; provided that such holders may have cumulative voting rights in the election of directors if the candidates' names have been placed in nomination prior to commencement of the voting and a shareholder has given notice prior to commencement of the voting of the shareholder's intention to cumulate votes.

Dividend Rights

Subject to any preferential rights or preferences of preferred shares outstanding, if any, holders of the common shares are entitled to any dividend declared by the Company's Board of Directors (the "***Board***") out of funds legally available for that purpose.

Liquidation Rights

Subject to any preferential rights or preferences of holders of preferred shares outstanding, if any, holders of the common shares are entitled to receive on a pro rata basis all of the Company's remaining assets available for distribution to the holders of the common shares in the event of the liquidation, dissolution, or winding up of the Company's operations.

No Preemptive or Similar Rights

Holders of the common shares do not have any preemptive rights to become subscribers or purchasers of additional shares of any class of the Company's capital stock. There are no redemption or sinking fund provisions applicable to the common shares.

Rights of Preferred Shares May be Senior to Common Shares

The Company may issue preferred shares in one or more series, at any time, with such rights, preferences, privileges and restrictions as the Board may determine, all without further action of the Company's shareholders. Any series of

preferred shares authorized by the Board in the future may be senior to and have greater rights and preferences than the common shares and may have restrictions on the Company's repurchase or redemption of shares.

Anti-takeover Provisions of the Articles, Bylaws and California Law

Provisions of the Articles and Bylaws may delay or discourage transactions involving an actual or potential change in control of the Company or change in its management, including transactions in which shareholders might otherwise receive a premium for their shares, or transactions that its shareholders might otherwise deem to be in their best interests. Among other things, the Articles and Bylaws:

- provide that, except for a vacancy caused by the removal of a director by the shareholders or by court order, a vacancy on the Board may be filled by approval of a majority of the remaining directors, though less than a quorum, or by a sole remaining director;

- provide that special meetings of shareholders may be called by (i) the chairperson of the Board, (ii) the Company's chief executive officer or president, (iii) the Board or (iv) one or more shareholders entitled to cast not less than 10% of the votes on the record date established pursuant to the Bylaws for that meeting;

- provide that shareholders seeking to present proposals before a meeting of shareholders or to nominate candidates for election as directors at a meeting of shareholders must meet certain eligibility criteria, provide notice in writing in a timely manner that meets specific requirements as to the form and content of such notice, and comply with applicable requirements of state law and of the Securities Exchange Act of 1934 and the rules and regulations thereunder;

- authorize the Board to issue preferred shares in series and to fix rights and preferences of the series (including, among other things, whether, and to what extent, the shares of any series will have voting rights and the extent of the preferences of the shares of any series with respect to dividends and other matters); and

- provide that, at a meeting of shareholders at which directors are to be elected, no shareholder shall be entitled to cumulate votes unless the candidates' names have been placed in nomination prior to commencement of the voting and a shareholder has given notice prior to commencement of the voting of the shareholder's intention to cumulate vote.

In addition, as a California corporation, the Company is subject to the provisions of Section 1203 of the California General Corporation Law, which requires it to provide a fairness opinion to its shareholders in connection with their consideration of any proposed "interested party" reorganization transaction.

Listing

The common shares are listed on the NYSE American and on the Tel Aviv Stock Exchange under the symbol "LCTX."

Transfer Agent and Registrar

The transfer agent and registrar for the common shares is Equiniti Trust Company, LLC.

Exhibit 4.03(c)

COMMON SHARE PURCHASE WARRANT

LINEAGE CELL THERAPEUTICS, INC.

Warrant Shares: 7,894,737 Issue Date: January 27, 2025

THIS COMMON SHARE PURCHASE WARRANT (the "Warrant") certifies that, for value received, Broadwood Partners L.P. or its assigns (the "Holder") is entitled, upon the terms and conditions hereinafter set forth, at any time on or after May 21, 2025 (the "Initial Exercise Date") and on or prior to 5:00 p.m. (New York City time) on the earlier of (i) the three (3) year anniversary of the Initial Exercise Date, and (ii) the 90th day following the date of the public disclosure of the occurrence of the Milestone Event, subject to the satisfaction of the Equity Conditions (as defined below) or if the date of the public disclosure of the occurrence of the Milestone Event occurs prior to the Initial Exercise Date, the 90th day following the Initial Exercise Date, subject to the satisfaction of the Equity Conditions (the "Termination Date"), but not thereafter, to subscribe for and purchase from Lineage Cell Therapeutics, Inc., a California corporation (the "Company"), up to 7,894,737 Common Shares (as subject to adjustment hereunder, the "Warrant Shares"). The purchase price of one Common Share under this Warrant shall be equal to the Exercise Price, as defined in Section 2(b).

For purposes of this Warrant, "Equity Conditions" means, with respect to a given date of determination: (i) on such applicable date of determination one or more registration statements (each, the "Acceleration Registration Statement") shall be effective and the prospectus contained therein shall be available on such applicable date of determination (with, for the avoidance of doubt, any Warrant Shares previously issued pursuant to such prospectus deemed unavailable) for the issuance of all the Warrant Shares issuable upon exercise of this Warrant in connection with the event requiring such determination (such applicable aggregate number of Common Shares, each, a "Required Minimum Securities Amount"); (ii) on each day during the period of (x) the ninety (90) calendar following the public disclosure of the occurrence of the Milestone Event, subject to the conditions herein or (y) if the date of the public disclosure of the occurrence of the Milestone Event occurs prior to the Initial Exercise Date, the 90th day following the Initial Exercise Date, subject to the conditions herein (collectively, the "Equity Conditions Measuring Period"), the Common Shares are listed or designated for quotation (as applicable) on a Trading Market and shall not have been suspended from trading on a Trading Market (other than suspensions of not more than two (2) days and occurring prior to the applicable date of determination due to business announcements by the Company) nor shall delisting or suspension by a Trading Market have been threatened (with a reasonable prospect of delisting occurring after giving effect to all applicable notice, appeal, compliance and hearing periods) or reasonably likely to occur or pending as evidenced by (A) a writing by such Trading Market or (B) the Company falling below the minimum listing maintenance requirements of such Trading Market on which the Common Shares are then listed or designated for quotation (as applicable); (iii) during the Equity Conditions Measuring Period, the Company shall have delivered all Warrant Shares issuable upon exercise of this Warrant on a timely basis in accordance herewith and all other share capital required to be delivered by the Company on a timely basis as set forth in the other Transaction Documents; (iv) any Warrant Shares to be issued in connection with the event

requiring determination may be issued in full without violating the rules or regulations of the Trading Market on which the Common Shares are then listed or designated for quotation (as applicable); (v) on each day during the Equity Conditions Measuring Period, no public announcement of a pending, proposed or intended Fundamental Transaction shall have occurred which has not been abandoned, terminated or consummated; (vi) the Company shall have no knowledge of any fact that would reasonably be expected to cause the applicable Acceleration Registration Statement to not be effective or the prospectus contained therein to not be available for the issuance of all the Warrant Shares issuable upon exercise of this Warrant in connection with the event requiring such determination and no Public Information Failure (as defined below) exists or is continuing; (vii) the Holder shall not be in possession of any material, non-public information provided to any of them by the Company, any of its Subsidiaries or any of their respective affiliates, employees, officers, representatives, agents or the like; (viii) on each day during the Equity Conditions Measuring Period, the Company otherwise shall have been in compliance with each, and shall not have breached any representation or warranty in any material respect (other than representations or warranties subject to material adverse effect or materiality, which may not be breached in any respect) or any covenant or other term or condition of any Transaction Document, including, without limitation, the Company shall not have failed to timely make any payment pursuant to any Transaction Document; (ix) on the applicable date of determination all Warrant Shares to be issued in connection with the event requiring this determination may be issued in full without resulting in a breach of any provision of the Common Warrants; (x) the Warrant Shares to be issued in connection with the event requiring this determination are duly authorized and listed and eligible for trading without restriction on a Trading Market.

"Public Information Failure" means at any time either (x) the Company fails for any reason to satisfy the requirements of Rule 144(c)(1), including, without limitation, the failure to satisfy the current public information requirement under Rule 144(c) or (y) the Company has ever been an issuer described in Rule 144(i)(1)(i) or becomes such an issuer in the future, and the Company shall fail to satisfy any condition set forth in Rule 144(i)(2).

Section 1. Definitions. Capitalized terms used and not otherwise defined herein shall have the meanings set forth in that certain Securities Purchase Agreement (the "Purchase Agreement"), dated November 19, 2024, among the Company and the purchasers signatory thereto.

Section 2. Exercise.

a) Exercise of Warrant. Exercise of the purchase rights represented by this Warrant may be made, in whole or in part, at any time or times on or after the Initial Exercise Date and on or before the Termination Date by delivery to the Company of a duly executed PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise"). Within the earlier of (i) one (1) Trading Day and (ii) the number of Trading Days comprising the Standard Settlement Period (as defined in Section 2(d)(i) herein) following the date of exercise as aforesaid, the Holder shall deliver the aggregate Exercise Price for the Warrant Shares specified in the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank unless the cashless exercise procedure specified in Section 2(c) below is specified in

the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Warrant Shares available hereunder and the Warrant has been exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation as soon as reasonably practicable following the date on which the final Notice of Exercise is delivered to the Company, and in any event within three (3) Trading Days of such date. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Warrant Shares purchasable hereunder in an amount equal to the applicable number of Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Trading Day of receipt of such notice. **The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Warrant Shares hereunder, the number of Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof.**

b) Exercise Price. The exercise price per Common Share under this Warrant shall be **$0.91**, subject to adjustment hereunder (the "Exercise Price").

c) Cashless Exercise. If at the time of exercise hereof there is no effective registration statement registering, or the prospectus contained therein is not available for the issuance of the Warrant Shares to the Holder, then this Warrant may also be exercised, in whole or in part, at such time by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Warrant Shares equal to the quotient obtained by dividing [(A-B)*(X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) both executed and delivered pursuant to Section 2(a) hereof on a day that is not a Trading Day or (2) both executed and delivered pursuant to Section 2(a) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) the Bid Price of the Common Share on the principal Trading Market as reported by Bloomberg L.P. ("Bloomberg") as of the time of the Holder's execution of the applicable Notice of Exercise if such Notice of Exercise is executed during "regular trading hours" on a Trading Day and is delivered within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(a) hereof, or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is both executed and delivered pursuant to Section 2(a) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price of this Warrant, as adjusted hereunder; and

(X) = the number of Warrant Shares that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant if such exercise were by means of a cash exercise rather than a cashless exercise.

"Bid Price" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Share is then listed or quoted on a Trading Market, the bid price of the Common Share for the time in question (or the nearest preceding date) on the Trading Market on which the Common Share is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the OTCQB Venture Market (the "OTCQB") or the OTCQX Best Market (the "OTCQX") is not a Trading Market, the volume weighted average price of the Common Share for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Share is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Share are then reported on The Pink Open Market operated by the OTC Markets, Inc. (the "Pink Market") (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per Common Share so reported, or (d) in all other cases, the fair market value of a share of Common Share as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Share is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Share for such date (or the nearest preceding date) on the Trading Market on which the Common Share is then listed or quoted as reported by Bloomberg (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if the OTCQB or the OTCQX is not a Trading Market, the volume weighted average price of the Common Share for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Share is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Share are then reported on the Pink Market, the most recent bid price per Common Share so reported, or (d) in all other cases, the fair market value of a Common Share as determined by an independent appraiser selected in good faith by the Holders of a majority in interest of the Securities then outstanding and reasonably acceptable to the Company, the fees and expenses of which shall be paid by the Company.

If Warrant Shares are issued in such a cashless exercise, the parties acknowledge and agree that in accordance with Section 3(a)(9) of the Securities Act, the Warrant Shares shall take on the registered characteristics of the Warrants being exercised. The Company agrees not to take any position contrary to the foregoing.

d) Mechanics of Exercise.

i. Delivery of Warrant Shares Upon Exercise. The Company shall cause the Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Warrant Shares to or resale of the Warrant Shares by the Holder or (B) this Warrant is being exercised via cashless exercise, and otherwise by physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earlier of (i) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company (if applicable), and (ii) the number of Trading Days comprising the Standard Settlement Period, in each case (i) or (ii), after the delivery to the Company of the Notice of Exercise and subject to the payment of aggregate Exercise Price to the Company (if applicable) (such date, the "Warrant Share Delivery Date"). Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Warrant Shares with respect to which this Warrant has been exercised, irrespective of the date of delivery of the Warrant Shares, provided that payment of the aggregate Exercise Price (other than in the case of a cashless exercise) is received by the Warrant Share Delivery Date. If the Company fails for any reason to deliver to the Holder the Warrant Shares subject to a Notice of Exercise by the Warrant Share Delivery Date, the Company shall pay to the Holder, in cash, as liquidated damages and not as a penalty, for each $1,000 of Warrant Shares subject to such exercise (based on the VWAP of the Common Share on the date of the applicable Notice of Exercise), $10 per Trading Day (increasing to $20 per Trading Day on the third (3rd) Trading Day after the Warrant Share Delivery Date) for each Trading Day after such Warrant Share Delivery Date until such Warrant Shares are delivered or Holder rescinds such exercise. The Company agrees to maintain a transfer agent that is a participant in the FAST program so long as this Warrant remains outstanding and exercisable. As used herein, "Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Share as in effect on the date of delivery of the Notice of Exercise.

ii. Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Warrant Shares called for by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

iii. Rescission Rights. If the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares pursuant to Section 2(d)(i) by the Warrant Share Delivery Date (subject to receipt of the aggregate exercise price for the applicable exercise (other than in the case of a cashless exercise)), then the Holder will have the right to rescind such exercise.

iv. Compensation for Buy-In on Failure to Timely Deliver Warrant Shares Upon Exercise. In addition to any other rights available to the Holder, if the Company fails to cause the Transfer Agent to transmit to the Holder the Warrant Shares in accordance with the provisions of Section 2(d)(i) above pursuant to an exercise on or before the Warrant Share Delivery Date (subject to receipt of the aggregate exercise price for the applicable exercise (other than in the case of a cashless exercise)), and if after such date the Holder is required by its broker to purchase (in an open market transaction or otherwise) or the Holder's brokerage firm otherwise purchases, Common Shares to deliver in satisfaction of a sale by the Holder of the Warrant Shares which the Holder anticipated receiving upon such exercise (a "Buy-In"), then the Company shall (A) pay in cash to the Holder the amount, if any, by which (x) the Holder's total purchase price (including brokerage commissions, if any) for the Common Shares so purchased exceeds (y) the amount obtained by multiplying (1) the number of Warrant Shares that the Company was required to deliver to the Holder in connection with the exercise at issue times (2) the price at which the sell order giving rise to such purchase obligation was executed, and (B) at the option of the Holder, either reinstate the portion of the Warrant and equivalent number of Warrant Shares for which such exercise was not honored (in which case such exercise shall be deemed rescinded) or deliver to the Holder the number of Common Shares that would have been issued had the Company timely complied with its exercise and delivery obligations hereunder. For example, if the Holder purchases Common Shares having a total purchase price of $11,000 to cover a Buy-In with respect to an attempted exercise of Common Shares with an aggregate sale price giving rise to such purchase obligation of $10,000, under clause (A) of the immediately preceding sentence the Company shall be required to pay the Holder $1,000. The Holder shall provide the Company written notice indicating the amounts payable to the Holder in respect of the Buy-In and, upon request of the Company, evidence of the amount of such loss. Nothing herein shall limit a Holder's right to pursue any other remedies available to it hereunder, at law or in equity including, without limitation, a decree of specific performance and/or injunctive relief with respect to the Company's failure to timely deliver Common Shares upon exercise of the Warrant as required pursuant to the terms hereof.

v. No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise

be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price or round up to the next whole share.

vi. Charges, Taxes and Expenses. Issuance of Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto. The Company shall pay all Transfer Agent fees required for same-day processing of any Notice of Exercise and all fees to the Depository Trust Company (or another established clearing corporation performing similar functions) required for same-day electronic delivery of the Warrant Shares.

vii. Closing of Books. The Company will not close its shareholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

e) Reserved.

Section 3. Certain Adjustments.

a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on its Common Shares or any other equity or equity equivalent securities payable in Common Shares (which, for avoidance of doubt, shall not include any Common Shares issued by the Company upon exercise of this Warrant), (ii) subdivides outstanding Common Shares into a larger number of shares, (iii) combines (including by way of reverse stock split) outstanding Common Shares into a smaller number of shares, or (iv) issues by reclassification of Common Shares any shares of capital stock of the Company, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of Common Shares (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of Common Shares outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged. Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of shareholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

b) Subsequent Rights Offerings. In addition to any adjustments pursuant to Section 3(a) above, if at any time the Company grants, issues or sells any Common Share Equivalents or rights to purchase stock, warrants, securities or other property pro rata to the record holders of any class of Common Shares (the "Purchase Rights"), then the Holder will be entitled to acquire, upon the terms applicable to such Purchase Rights, the aggregate Purchase Rights which the Holder could have acquired if the Holder had held the number of Common Shares acquirable upon complete exercise of this Warrant immediately before the date on which a record is taken for the grant, issuance or sale of such Purchase Rights, or, if no such record is taken, the date as of which the record holders of Common Shares are to be determined for the grant, issue or sale of such Purchase Rights.

c) Pro Rata Distributions. During such time as this Warrant is outstanding, if the Company shall declare or make any dividend or other distribution of its assets (or rights to acquire its assets) to holders of Common Shares, by way of return of capital or otherwise (including, without limitation, any distribution of cash, stock or other securities, property or options by way of a dividend, spin off, reclassification, corporate rearrangement, scheme of arrangement or other similar transaction) (a "Distribution"), at any time after the issuance of this Warrant, then, in each such case, the Holder shall be entitled to participate in such Distribution to the same extent that the Holder would have participated therein if the Holder had held the number of Common Shares acquirable upon complete exercise of this Warrant immediately before the date of which a record is taken for such Distribution, or, if no such record is taken, the date as of which the record holders of Common Shares are to be determined for the participation in such Distribution.

d) Fundamental Transaction. If, at any time while this Warrant is outstanding, (i) the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person, (ii) the Company (or any Subsidiary), directly or indirectly, effects any sale, lease, license, assignment, transfer, conveyance or other disposition of all or substantially all of the assets of the Company in one or a series of related transactions, (iii) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Shares are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of greater than 50% of the outstanding Common Shares or greater than 50% of the voting power of the common equity of the Company, (iv) the Company, directly or indirectly, in one or more related transactions effects any reclassification, reorganization or recapitalization of the Common Shares or any compulsory share exchange pursuant to which the Common Shares is effectively converted into or exchanged for other securities, cash or property, or (v) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off, merger or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires greater than 50% of the outstanding Common Shares or greater than 50% of the voting power of the common equity of the Company, except, in each case of the preceding clauses (i) through and including (v), actions taken solely in connection with an internal reorganization (each a "Fundamental Transaction"), then, upon any subsequent exercise of this Warrant, the Holder shall have the right to receive, for each Warrant Share that would have been issuable

upon such exercise immediately prior to the occurrence of such Fundamental Transaction, at the option of the Holder, the number of Common Shares of the successor or acquiring corporation or of the Company, if it is the surviving corporation, and any additional consideration (the "Alternate Consideration") receivable as a result of such Fundamental Transaction by a holder of the number of Common Shares for which this Warrant is exercisable immediately prior to such Fundamental Transaction. For purposes of any such exercise, the determination of the Exercise Price shall be appropriately adjusted to apply to such Alternate Consideration based on the amount of Alternate Consideration issuable in respect of one Common Share in such Fundamental Transaction, and the Company shall apportion the Exercise Price among the Alternate Consideration in a reasonable manner reflecting the relative value of any different components of the Alternate Consideration. If holders of Common Shares are given any choice as to the securities, cash or property to be received in a Fundamental Transaction, then the Holder shall be given the same choice as to the Alternate Consideration it receives upon any exercise of this Warrant following such Fundamental Transaction. Notwithstanding anything to the contrary, in the event of a Fundamental Transaction, the Company or any Successor Entity (as defined below) shall, at the Holder's option, exercisable at any time concurrently with, or within 30 days after, the consummation of the Fundamental Transaction (or, if later, the date of the public announcement of the applicable Fundamental Transaction), purchase this Warrant from the Holder by paying to the Holder an amount of cash equal to the Black Scholes Value (as defined below) of the remaining unexercised portion of this Warrant on the date of the consummation of such Fundamental Transaction; provided, however, that, if the Fundamental Transaction is not within the Company's control, including not approved by the Company's Board of Directors, the Holder shall only be entitled to receive from the Company or any Successor Entity the same type or form of consideration (and in the same proportion), at the Black Scholes Value of the unexercised portion of this Warrant, that is being offered and paid to the holders of Common Shares of the Company in connection with the Fundamental Transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of Common Shares are given the choice to receive from among alternative forms of consideration in connection with the Fundamental Transaction; provided, further, that if holders of Common Shares of the Company are not offered or paid any consideration in such Fundamental Transaction, such holders of Common Shares will be deemed to have received common stock of the Successor Entity (which Successor Entity may be the Company following such Fundamental Transaction) in such Fundamental Transaction. "Black Scholes Value" means the value of this Warrant based on the Black-Scholes Option Pricing Model obtained from the "OV" function on Bloomberg determined as of the day of consummation of the applicable Fundamental Transaction for pricing purposes and reflecting (A) a risk-free interest rate corresponding to the U.S. Treasury rate for a period equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date, (B) an expected volatility equal to the lesser of 100% and the 100 day volatility obtained from the HVT function on Bloomberg (determined utilizing a 365 day annualization factor) as of the Trading Day immediately following the public announcement of the applicable contemplated Fundamental Transaction, (C) the underlying price per share used in such calculation shall be the highest VWAP during the period beginning on the Trading Day immediately preceding the public

announcement of the applicable Fundamental Transaction (or, if earlier, the consummation of the Fundamental Transaction) and ending on the Trading Day of the Holder's request pursuant to this Section 3(d), (D) a remaining option time equal to the time between the date of the public announcement of the applicable contemplated Fundamental Transaction and the Termination Date and (E) a zero cost of borrow. The payment of the Black Scholes Value will be made by wire transfer of immediately available funds (or such other consideration) within the later of (i) five Business Days of the Holder's election and (ii) the date of consummation of the Fundamental Transaction. The Company shall cause any successor entity in a Fundamental Transaction in which the Company is not the survivor (the "Successor Entity") to assume in writing all of the obligations of the Company under this Warrant and the other Transaction Documents in accordance with the provisions of this Section 3(d) pursuant to written agreements in form and substance reasonably satisfactory to the Holder and approved by the Holder (without unreasonable delay) prior to such Fundamental Transaction and shall, at the option of the Holder, deliver to the Holder in exchange for this Warrant a security of the Successor Entity evidenced by a written instrument substantially similar in form and substance to this Warrant which is exercisable for a corresponding number of shares of capital stock of such Successor Entity (or its parent entity) equivalent to the Common Shares acquirable and receivable upon exercise of this Warrant prior to such Fundamental Transaction, and with an exercise price which applies the exercise price hereunder to such shares of capital stock (but taking into account the relative value of the Common Shares pursuant to such Fundamental Transaction and the value of such shares of capital stock, such number of shares of capital stock and such exercise price being for the purpose of protecting the economic value of this Warrant immediately prior to the consummation of such Fundamental Transaction), and which is reasonably satisfactory in form and substance to the Holder. Upon the occurrence of any such Fundamental Transaction, the Successor Entity shall be added to the term "Company" under this Warrant (so that from and after the occurrence or consummation of such Fundamental Transaction, each and every provision of this Warrant and the other Transaction Documents referring to the "Company" shall refer instead to each of the Company and the Successor Entity or Successor Entities, jointly and severally), and the Successor Entity or Successor Entities, jointly and severally with the Company, may exercise every right and power of the Company prior thereto and the Successor Entity or Successor Entities shall assume all of the obligations of the Company prior thereto under this Warrant and the other Transaction Documents with the same effect as if the Company and such Successor Entity or Successor Entities, jointly and severally, had been named as the Company herein. For the avoidance of doubt, the Holder shall be entitled to the benefits of the provisions of this Section 3(d) regardless of (i) whether the Company has sufficient authorized Common Shares for the issuance of Warrant Shares and/or (ii) whether a Fundamental Transaction occurs prior to the Initial Exercise Date.

e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of Common Shares deemed to be issued and outstanding as of a given date shall be the sum of the number of Common Shares (excluding treasury shares, if any) issued and outstanding.

f) Notice to Holder.

i. Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by a permitted notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

ii. Notice to Allow Exercise by Holder. If (A) the Company shall declare a dividend (or any other distribution in whatever form) on the Common Shares, (B) the Company shall declare a special nonrecurring cash dividend on or a redemption of the Common Shares, (C) the Company shall authorize the granting to all holders of the Common Shares rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the approval of the shareholders of the Company shall be required in connection with any reclassification of the Common Shares, any consolidation or merger to which the Company (or any of its Subsidiaries) is a party, any sale or transfer of all or substantially all of its assets, or any compulsory share exchange whereby the Common Share is converted into other securities, cash or property, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by email to the Holder at its last email address as it shall appear upon the Warrant Register of the Company, at least 20 calendar days prior to the applicable record or effective date hereinafter specified, a notice stating (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Shares of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined or (y) the date on which such reclassification, consolidation, merger, sale, transfer or share exchange is expected to become effective or close, and the date as of which it is expected that holders of the Common Shares of record shall be entitled to exchange their shares of the Common Shares for securities, cash or other property deliverable upon such reclassification, consolidation, merger, sale, transfer or share exchange; provided that the failure to deliver such notice or any defect therein or in the delivery thereof shall not affect the validity of the corporate action required to be specified in such notice. Upon occurrence of the Milestone Event, the Company shall notify the Holder as soon as practicable thereafter. To the extent that any notice provided in this Warrant constitutes, or contains, material, non-public information regarding the Company or any of the Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 8-K. The Holder shall remain entitled to exercise this Warrant during the period commencing on the date of such notice to the effective date of the event triggering such notice except as may otherwise be expressly set forth herein.

Section 4. Transfer of Warrant.

a) Transferability. This Warrant and all rights hereunder (including, without limitation, any registration rights) are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company or its designated agent, together with a written assignment of this Warrant substantially in the form attached hereto duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, and in the denomination or denominations specified in such instrument of assignment, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date on which the Holder delivers an assignment form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of Warrant Shares without having a new Warrant issued.

b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be dated the Issue Date of this Warrant and shall be identical with this Warrant except as to the number of Warrant Shares issuable pursuant thereto.

c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual notice to the contrary.

Section 5. Miscellaneous.

a) No Rights as Shareholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a shareholder of the Company prior to the exercise hereof as set forth in Section 2(d)(i), except as expressly set forth in Section 3. Without limiting any rights of a Holder to receive Warrant Shares on a "cashless exercise" pursuant to Section 2(c) or to receive cash payments pursuant to Section 2(d)(i) and Section 2(d)(iv) herein, in no event shall the Company be required to net cash settle an exercise of this Warrant.

b) Loss, Theft, Destruction or Mutilation of Warrant. The Company covenants that upon receipt by the Company of evidence reasonably satisfactory to it of the loss, theft, destruction or mutilation of this Warrant or any stock certificate relating to the Warrant Shares, and in case of loss, theft or destruction, of indemnity or security reasonably satisfactory to it (which, in the case of the Warrant, shall not include the posting of any bond), and upon surrender and cancellation of such Warrant or stock certificate, if mutilated, the Company will make and deliver a new Warrant or stock certificate of like tenor and dated as of such cancellation, in lieu of such Warrant or stock certificate.

c) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Trading Day, then, such action may be taken or such right may be exercised on the next succeeding Trading Day.

d) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Shares a sufficient number of shares to provide for the issuance of the Warrant Shares upon the exercise of any purchase rights under this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market upon which the Common Shares may be listed. The Company covenants that all Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Warrant Shares upon the exercise of this Warrant and

(iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be, necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

e) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be determined in accordance with the provisions of the Purchase Agreement.

f) Restrictions. The Holder acknowledges that the Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, will have restrictions upon resale imposed by state and federal securities laws.

g) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder's rights, powers or remedies, notwithstanding the fact that the right to exercise this Warrant terminates on the Termination Date. Without limiting any other provision of this Warrant or the Purchase Agreement, if the Company willfully and knowingly fails to comply with any provision of this Warrant, which results in any material damages to the Holder, the Company shall pay to the Holder such amounts as shall be sufficient to cover any costs and expenses including, but not limited to, reasonable attorneys' fees, including those of appellate proceedings, incurred by the Holder in collecting any amounts due pursuant hereto or in otherwise enforcing any of its rights, powers or remedies hereunder.

h) Notices. Any notice, request or other document required or permitted to be given or delivered to the Holder by the Company shall be delivered in accordance with the notice provisions of the Purchase Agreement.

i) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Shares or as a shareholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

j) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions

of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

k) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors and permitted assigns of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Warrant Shares.

l) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company, on the one hand, and the Holder of this Warrant, on the other hand.

m) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

n) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

****

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

LINEAGE CELL THERAPEUTICS, INC.

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

NOTICE OF EXERCISE

TO: **LINEAGE CELL THERAPEUTICS, INC.**

(1)The undersigned hereby elects to purchase _____ Warrant Shares of the Company pursuant to the terms of the attached Warrant (only if exercised in full), and tenders herewith payment of the exercise price in full, together with all applicable transfer taxes, if any.

(2)Payment shall take the form of (check applicable box):

[ ] in lawful money of the United States; or

[ ] if permitted the cancellation of such number of Warrant Shares as is necessary, in accordance with the formula set forth in subsection 2(c), to exercise this Warrant with respect to the maximum number of Warrant Shares purchasable pursuant to the cashless exercise procedure set forth in subsection 2(c).

(3)Please issue said Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____

The Warrant Shares shall be delivered to the following DWAC Account Number:

_____

_____

_____

[SIGNATURE OF HOLDER]

Name of Investing Entity: _____
Signature of Authorized Signatory of Investing Entity: _____
Name of Authorized Signatory: _____
Title of Authorized Signatory: _____
Date: _____

EXHIBIT B

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information. Do not use this form to exercise the Warrant to purchase shares.)

FOR VALUE RECEIVED, the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name:

(Please Print)

Address:

(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____ __, _____

Holder's Signature:

Holder's Address:

Exhibit 19.01

Insider Trading Policy
(As of June 11, 2024)

INTRODUCTION

The Board of Directors (the "***Board***") of Lineage Cell Therapeutics, Inc. (the "***Company***") has adopted this Insider Trading Policy (this "***Policy***") to promote compliance by Insiders (as defined below) with laws that prohibit certain persons aware of material nonpublic information about a company from (i) trading in securities of that company, or (ii) providing material nonpublic information to other persons who may trade on the basis of such information.

Federal and state securities laws generally prohibit the purchase or sale of a company's securities by persons aware of material nonpublic information about that company. These laws also prohibit persons aware of such material nonpublic information from disclosing such information to others who may trade on the basis of such information. Companies and their controlling persons are also subject to liability if they fail to take reasonable steps to prevent insider trading by their personnel.

It is important that you understand the breadth of activities that constitute illegal insider trading and their potentially severe consequences. The U.S. Securities and Exchange Commission (the "***SEC***") and the Financial Industry Regulatory Authority investigate and are very effective at detecting insider trading. The SEC pursues insider trading violations vigorously. Cases have been successfully prosecuted against trading by insiders through foreign accounts, trading by family members and friends, and trading involving only a small number of securities.

Ultimately, you are responsible for determining whether you are in possession of material nonpublic information and ensuring that you, and your family members, household members and controlled entities whose transactions are subject to this Policy, as discussed below, comply with this Policy and do not engage in illegal insider trading. Any action on the part of the Company, the Compliance Officer (as defined below) or any other officer, employee or director under this Policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under securities laws.

ADMINISTRATION OF THIS POLICY

The Company's General Counsel (or equivalent) will serve as the "***Compliance Officer***" for this Policy and shall be responsible for the administration of this Policy. If the Company does not have a General Counsel, or if the General Counsel is absent or is otherwise unavailable, or a matter under this Policy involves the General Counsel, then the Company's Chief Financial Officer or principal financial officer shall serve as the Compliance Officer. If the Company's Chief Financial Officer or principal financial officer is serving as the Compliance Officer but is absent or is otherwise unavailable or a matter under this Policy involves the Company's Chief Financial Officer or principal financial officer, then another employee of the Company designated by the Nominating and Corporate Governance Committee of the Board shall serve as the Compliance Officer for this Policy.

APPLICABILITY OF POLICY

Who is covered by this Policy?

This Policy applies to (i) directors, officers, and other employees of the Company and its subsidiaries, and (ii) any other persons, such as consultants, contractors and temporary staff,

who have access to material nonpublic information and are designated by the Company as subject to this Policy (the persons described in clauses (i) and (ii) are collectively called "***Insiders***"). Consultants, contractors and temporary staff are not employees of the Company, and nothing in this Policy should be construed to the contrary.

This Policy also applies to Family Members and Controlled Entities (as such terms are defined below) of Insiders. Insiders are responsible for ensuring that any transaction subject to this Policy engaged in by a Family Member or Controlled Entity complies with this Policy.

For purposes of this Policy, with respect to any particular Insider, (i) a "***Family Member***" means (a) any family member (*e.g.*, spouse, parent, sibling or child) of such Insider who lives in the same household as such Insider and (b) any family member of such Insider who does not live in the same household as such Insider but whose transactions in Company Securities (as defined below) or the securities of Business Partners (as defined below) are directed by such Insider or are subject to such Insider's influence or control (*e.g.*, a family member who consults with the Insider before they trade in Company Securities); and (ii) a "***Controlled Entity***" means any entity that such Insider controls or whose transactions in securities are subject to such Insider's influence or control.

What transactions are covered by this Policy?

Transactions in Company Securities.

Except for Exempt Transactions (as defined below), this Policy applies to all transactions in Company Securities, as well as to derivative securities relating to the Company Securities, whether or not issued by the Company (*e.g.*, exchange-traded put and call options).

For purposes of this Policy, "***Company Securities***" means any securities issued by the Company, including, but not limited to, common shares, preferred shares, securities convertible into or exercisable or exchangeable for securities issued by the Company (*e.g.*, put and call options, convertible debentures, warrants), stock options and other equity-based awards, and debt securities (*e.g.*, debentures, bonds and notes).

Transactions in Other Companies' Securities.

This Policy also generally applies to transactions in securities of publicly traded companies (1) with which the Company does business, such as the Company's collaborators, partners, customers, vendors or suppliers and/or (2) that are involved in a potential transaction or business relationship with the Company (collectively, "***Business Partners***"), in each case, when the Insider becomes aware of material nonpublic information about the Business Partner in the course of employment with, or the performance of services on behalf of, the Company. All Insiders should treat material nonpublic information about Business Partners with the same care required regarding information related directly to the Company. Keep in mind that information that is not material to the Company may nevertheless be material to a Business Partner.

Transactions After Termination of Insider Status.

If you are aware of material nonpublic information at the time your status as an Insider terminates, notwithstanding the termination of Insider status, this Policy will continue to apply to your transactions until such information becomes public or no longer material.

What transactions are <u>not</u> covered by this Policy?

Notwithstanding anything to the contrary in this Policy, this Policy's trading restrictions do not apply to (collectively, "***Exempt Transactions***"):

- the purchase of Company Securities from the Company;

- the sale of Company Securities to the Company;
- the purchase and sale of broadly diversified indexes, mutual funds, similar professionally managed "commingled pools" or exchange-traded funds that invest in Company Securities in addition to securities of other companies, or derivative securities whose prices are based on those indexes or funds;
- the exercise of a stock option awarded by the Company under one of its equity incentive plans; provided that no shares of the Company are sold in the market to fund the exercise price of such stock option or to satisfy any tax withholding obligation (the "cashless exercise" of a Company stock option through a broker involves the sale of shares of the Company in the market, and therefore would not qualify under this exception); provided, further, that, for the avoidance of doubt, this Policy does apply to subsequent transactions in the shares of the Company's stock issued upon exercise of a stock option;
- the surrender of shares of the Company to satisfy any tax withholding obligation in a manner permitted by the applicable equity award agreement; provided that no shares of the Company are sold in the market in connection therewith;
- transactions executed under a Rule 10b5-1 trading program that (i) is entered into at a time when not in possession of material nonpublic information concerning the Company, (ii) complies with Rule 10b5-1 ("***Rule 10b5-1***") promulgated under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), or any successor rule, (iii) meets the Company's Rule 10b5-1 trading program requirements (attached as Exhibit A), and (iv) has been approved in advance, in writing, by the Compliance Officer; or
- purchases of Company Securities in the Company's 401(k) plan, if any, resulting from an Insider's periodic contribution of money to the plan pursuant to the Insider's payroll deduction election; provided, however, that this Policy's trading restrictions do apply to elections an Insider may make under the 401(k) plan to: (i) increase or decrease the percentage of the Insider's periodic contributions that will be allocated to the Company stock fund; (ii) make an intra-plan transfer of an existing account balance into or out of the Company stock fund; (iii) borrow money against the Insider's 401(k) plan account if the loan will result in a liquidation of some or all of the Insider's Company stock fund balance; and (iv) pre-pay a 401(k) plan loan if the pre-payment will result in allocation of loan proceeds to the Company stock fund.

STATEMENT OF POLICY

What is the Company's general policy on insider trading and disclosure of nonpublic information?

The Company opposes the unauthorized disclosure of any nonpublic information by an Insider acquired in the course of employment with, or the performance of services on behalf of, the Company and the misuse of material nonpublic information acquired in the course of employment with, or the performance of services on behalf of, the Company in securities trading.

What policies and procedures am I required to adhere to before trading in securities?

Trading on Material Nonpublic Information is Prohibited.

Insiders may not engage in any transaction involving a purchase or sale of Company Securities, including any offer to purchase or offer to sell, directly or through Family Members or other persons or entities, if they are aware of material nonpublic information relating to the Company

(for the avoidance of doubt, the foregoing does not apply to Exempt Transactions). Similarly, Insiders may not trade in the securities of Business Partners if they become aware of material nonpublic information about such Business Partner in the course of employment with, or the performance of services on behalf of, the Company. Such prohibitions against trading remain in effect until such material information is considered public, or at such time as such nonpublic information is no longer material. For purposes of this Policy, as a general rule, information will be considered public at the open of the market on the Trading Day after the first full Trading Day following the widespread public release of the applicable information. For example, if the Company announces nonpublic material information *before* 9:30 a.m. Eastern Time on Tuesday, such information will be considered public at 9:30 a.m. Eastern Time on Wednesday, assuming Tuesday is a full Trading Day. However, if the Company announces material nonpublic information *during* the market on Tuesday *or after* the market closes on Tuesday, such information will be considered public at 9:30 a.m. Eastern Time on Thursday, assuming Wednesday is a full Trading Day. A "***Trading Day***" is a day on which the United States national stock exchange on which the Company's common stock is primarily listed is open for trading. For the avoidance of doubt, a "full Trading Day" includes a Trading Day on which such stock exchange is scheduled to be open for trading for abbreviated hours.

Trading Windows; Preclearance; Special Blackout Periods.

Financial Insiders (as defined below) must not trade in Company Securities other than during a trading window (a "***Trading Window***"). The Compliance Officer will determine when a Trading Window begins and when it ends. However, Trading Windows will generally begin at the open of the market on the Trading Day after the first full Trading Day following the widespread public release of the Company's financial results for the prior fiscal quarter or year and ends on the last Trading Day of the fiscal quarter. For example, if the Company broadly disseminates a press release announcing its quarterly or annual financial results *before* 9:30 a.m. Eastern Time on Tuesday, the Trading Window would begin at 9:30 a.m. Eastern Time on Wednesday, assuming Tuesday is a full Trading Day. However, if the Company broadly disseminates such press release *during* the market on Tuesday *or after* the market closes on Tuesday, the Trading Window would begin at 9:30 a.m. Eastern Time on Thursday, assuming Wednesday is a full Trading Day.

For purposes of this Policy, "***Financial Insiders"*** means all (i) members of the Board, (ii) officers of the Company, (iii) persons who directly report to the Company's Chief Executive Officer, (iv) persons in a manager position or above in the Finance Department, and (v) all other persons that may be designated by the Compliance Officer from time to time.

Even during a Trading Window, Financial Insiders, as well as the Family Members and Controlled Entities of Financial Insiders, must obtain written preclearance from the Compliance Officer of any proposed transactions to which this Policy's restrictions apply prior to commencing any transaction, including in derivative securities not issued by the Company but that relate to Company Securities. The Compliance Officer is under no obligation to approve a transaction submitted for preclearance and may determine not to permit the transaction. When making a request for preclearance, the requestor should carefully consider whether they may be aware of any material nonpublic information relating to the Company and must fully describe the applicable facts and circumstances to the Compliance Officer.

The Company may from time to time prohibit Financial Insiders and other Insiders from trading during a Trading Window because of material nonpublic information known to the Company and not yet disclosed to the public. These event and circumstances-specific prohibitions are called "**special blackout periods**." The Company will notify you in writing, including via email, if a special blackout period applies to you. If a special blackout period applies to you, you must not trade until you are informed by the Compliance Officer that the special blackout period has ended. The existence of a special blackout period may not be announced to all Insiders and you should

not communicate the existence of a special blackout period to any other person, except to the extent necessary to ensure your Family Members and Controlled Entities likewise do not trade during the special blackout period. Exceptions to the Policy's restrictions will not be granted during special blackout periods. Even if the Company has not designated you as a person to whom a special blackout period applies, you should not trade if you are aware of material nonpublic information because you are responsible at all times for not engaging in illegal insider trading.

Trading in the Company's securities during a Trading Window or in accordance with a preclearance under this Policy is not considered a "safe harbor," and you should use good judgment at all times to ensure you are not trading on the basis of material nonpublic information in violation of securities laws or this Policy.

No Exception for Hardship.

An Insider may, from time to time, have to forego a proposed transaction even if he or she planned to make the transaction before learning of the material nonpublic information and even though the Insider believes he or she may suffer an economic loss or forego anticipated profit by waiting. The existence of a personal financial emergency does not excuse you from compliance with applicable securities laws or this Policy.

May I disclose material nonpublic information about the Company or any of its Business Partners to others?

Maintaining the Confidentiality of Nonpublic Information.

Unauthorized disclosure of any confidential information of the Company or its Business Partners is prohibited.

Maintaining the confidentiality of Company information is essential for competitive, security and other business reasons, as well as to comply with applicable securities laws. You should treat all information you learn about the Company or its business plans in connection with your employment with, or the performance of services on behalf of, the Company as confidential and proprietary to the Company. Inadvertent disclosure of confidential information may expose the Company and you to significant risk of investigation and litigation.

The timing and nature of the Company's disclosure of material information to outsiders is subject to legal rules, the breach of which could result in substantial liability to you, the Company and its management. Accordingly, it is important that responses to inquiries about the Company by the press, analysts or others in the financial community be made on the Company's behalf only through authorized individuals.

This Policy should not be interpreted to modify any agreement between the Company and an Insider relating to use or protection of confidential information, or the Insider's obligations relating to confidential information under the Company's Code of Business Conduct and Ethics or under any other Company policy.

If you receive inquiries about the Company from analysts, reporters, or others, decline to comment and direct them to the Chief Executive Officer, Chief Financial Officer, or such other persons as the Chief Executive Officer or Chief Financial Officer may designate.

Prohibition on "Tipping."

Insiders may be liable under securities laws for communicating (or "tipping") material nonpublic information about the Company or its Business Partners to another person who trades, directly or indirectly, on the information tipped to them. "Tipping" is illegal and prohibited under this Policy. No Insider shall disclose material nonpublic information relating to the Company or a Business Partner to any other person (including, but not limited to, Family Members, friends, business

associates and investors), unless any such disclosure is made in accordance with the Company's policies regarding the protection or authorized disclosure of nonpublic information. Further, Insiders may not make recommendations or express opinions on the basis of material nonpublic information as to trading in Company Securities or the securities of Business Partners. Even if you are not in possession of material nonpublic information, do not recommend to any other person that they buy or sell securities of the Company. Remember that "tipping" material nonpublic information is always prohibited, and that your recommendation could be imputed to the Company and may be misleading if you do not have all relevant information.

Do not discuss material nonpublic information where it may be overheard, such as in restaurants, elevators, restrooms, and other public places. Remember that phone conversations are often overheard and that persons other than intended recipients may retrieve voicemails, e-mails, text messages and other electronic communications.

May I trade in Company derivative securities or short sell Company Securities?

The Company considers it improper and inappropriate for Insiders to engage in short-term or speculative transactions in Company Securities or in other transactions in Company Securities that may lead to inadvertent violations of the insider trading laws. Accordingly, trading in Company Securities is subject to the following restrictions:

Short Sales. You may not engage in "short sales" of Company Securities (*i.e.*, sales of securities that are not then owned), including a "sale against the box" (*i.e.*, a sale with delayed delivery).

Publicly Traded Options. You may not engage in transactions in publicly traded options (*e.g.*, puts, calls and other derivative securities) on an exchange or in any other organized market on Company Securities.

Standing Orders. Standing orders should be used only for a very brief period of time and only during a Trading Window (if applicable). A standing order placed with a broker to sell or purchase securities at a specified price leaves you with no control over the timing of the transaction. A standing order transaction executed by the broker when you are aware of material nonpublic information may result in unlawful insider trading and violation of this Policy. Should you have an open standing order, you must cancel the order prior to the end of the Trading Window or as soon as you become aware of material nonpublic information, including as soon as you become aware of the existence of a special blackout period.

Hedging Transactions. You may not engage in any kind of hedging transaction that could reduce or limit your holdings, ownership or interest in or to any Company Securities, including without limitation outstanding stock options, deferred share units, restricted share units, or other compensation awards the value of which are derived from, referenced to or based on the value or market price of securities of the Company. Prohibited transactions include the purchase of financial instruments, including prepaid variable forward contracts, instruments for the short sale or purchase or sale of call or put options, equity swaps, collars, or units of exchangeable funds, that are designed to or that may reasonably be expected to have the effect of hedging or offsetting a decrease in the market value of any securities of the Company. For the avoidance of doubt, this restriction does not apply to the purchase and sale of broadly diversified indexes, mutual funds, similar professionally managed "commingled pools" or exchange-traded funds that invest in Company Securities in addition to securities of other companies, or derivative securities whose prices are based on those indexes or funds.

Margin Accounts and Pledges. Securities held in a margin account or pledged as collateral for a loan may be sold without your consent by the broker if you fail to meet a margin call or by the lender in foreclosure if you default on the loan. Because a margin or foreclosure sale may occur at a time when you are aware of material nonpublic information or otherwise are not permitted to

trade in Company Securities, you are prohibited from holding Company Securities in a margin account or pledging Company Securities as collateral for a loan.

May I pre-establish a time for the purchase or sale of Company Securities at a time that I am not aware of material nonpublic information?

Yes, directors, officers and other employees of the Company may establish written trading programs pursuant to Rule 10b5-1. Any such trading program is subject to the restrictions and limitations in Exhibit A, which may be updated from time to time to conform with changes to Rule 10b5-1 or the practices thereunder. Once a Rule 10b5-1 trading program is implemented in accordance with Exhibit A, trades pursuant to, and in accordance with, such program are not subject to the limitations and restrictions set forth in this Policy. Every Rule 10b5-1 trading program (or the form of program established by an investment bank or other third party) must be reviewed and approved by the Compliance Officer prior to establishment to confirm compliance with this Policy and applicable securities laws.

POTENTIAL CRIMINAL AND CIVIL LIABILITY AND/OR DISCIPLINARY ACTION

What legal liability may I be subject to if I engage in securities transactions on the basis of material nonpublic information?

Insiders that engage in securities transactions at a time when they are aware of material nonpublic information may be subject to penalties that include:

- imprisonment for up to 20 years;
- criminal fines of up to $5 million; and
- civil fines of up to three times the profit gained or the loss avoided.

What legal liability may I be subject to if I disclose material nonpublic information to others who engage in securities transactions?

Insiders may be liable for improper transactions by any person (commonly called a “tippee”) to whom they have disclosed material nonpublic information in breach of a duty to the Company or to whom they have made recommendations or expressed opinions on the basis of such information as to trading in securities. The SEC has imposed large penalties even when the disclosing person did not profit from the trading. The SEC, the stock exchanges and the Financial Industry Regulatory Authority use sophisticated electronic surveillance techniques to uncover insider trading.

Could the Company incur liability for my actions if I engage in securities transactions at a time that I have material nonpublic information?

If the Company fails to take appropriate steps to prevent illegal insider trading, the Company may have “controlling person” liability for a trading violation, with civil penalties, as well as a criminal penalty of up to $25 million. The civil penalties can extend personal liability to the Company’s directors, officers and other supervisory personnel if they fail to take appropriate steps to prevent insider trading.

What disciplinary actions may the Company take for violations of this Policy?

The Company expects strict compliance with this Policy and the procedures under this Policy by all Insiders. Failure to so comply may result in serious legal consequences for you, as well as the Company. A failure to follow the letter and spirit of this Policy and its procedures would be considered a matter of extreme seriousness. All Insiders must execute a certificate in the form attached as Exhibit B, pursuant to which they certify that, among other things, such persons are currently, and will continue to be, in compliance with this Policy.

Insiders who violate this Policy may be subject to disciplinary action by the Company. Such disciplinary action may include ineligibility for future participation in the Company's equity incentive plans, other Company imposed sanctions, suspension or termination of employment.

DEFINITION OF MATERIAL NONPUBLIC INFORMATION

Material nonpublic information has two important elements: materiality and public availability.

What information is material?

It is not possible to define all categories of material information. However, information should be regarded as material if there is a reasonable likelihood that it would be considered important to an investor in making an investment decision (*i.e.*, a decision to buy, hold or sell a security), or if it would significantly alter the total mix of information available to investors. While it may be difficult under this standard to determine whether particular information is material, there are various categories of information that are particularly sensitive and, as a general rule, should always be considered material. Examples of such information include:

- financial results;
- projections of future earnings or losses;
- news of a pending or proposed merger or acquisition;
- news of the disposition of a subsidiary or significant assets;
- impending bankruptcy or financial liquidity problems;
- gain or loss of a substantial customer or supplier;
- establishment or termination of a significant licensor, licensee or other collaborator or partner;
- changes in a dividend policy;
- new project developments or announcements of a significant nature;
- results of, or significant developments related to, an important clinical trial;
- significant decisions or communications relating to a product or product candidate by the U.S. Food and Drug Administration or a similar regulatory authority outside the U.S.
- stock splits;
- new equity or debt offerings;
- significant litigation exposure due to actual or threatened litigation or developments in existing litigation;
- significant changes in senior management;
- information as to the success, failure or even the unchanging status of particular aspects of the Company's business; and
- significant cybersecurity incidents, such as a data breach or any other significant disruption in the Company's operations or the loss, potential loss, breach or unauthorized access of its property or assets.

Both positive and negative information may be material. Because trading that receives scrutiny will be evaluated after the fact with the benefit of hindsight, questions concerning the materiality of particular information should be resolved in favor of materiality, and trading should be avoided.

What constitutes nonpublic information?

Nonpublic information is information that has not been previously disclosed to the general public and is otherwise not available to the general public. One common misconception is that material information loses its "nonpublic" status as soon as a press release is issued disclosing the information. In fact, information is considered available to the public only when it has been released broadly to the marketplace (*e.g.*, by a press release or an SEC filing) and the investing public has had time to absorb the information fully. For a discussion of when, as a general rule, information is considered public for purposes of this Policy, see "STATEMENT OF POLICY—What policies and procedures am I required to adhere to before trading in securities?—Trading on Material Nonpublic Information is Prohibited," above.

ADDITIONAL INFORMATION: DIRECTORS AND OFFICERS

Members of the Board and certain officers of the Company must also comply with the reporting obligations and limitations on short-swing transactions set forth in Section 16 of the Exchange Act. The practical effect of these provisions is that such persons who purchase and sell Company Securities within a six-month period must disgorge all profits to the Company whether or not they had knowledge of any material nonpublic information. Under these provisions, and so long as certain other criteria are met, neither the receipt of a stock option under a Company equity incentive plan, nor exercising that option, is deemed a purchase under Section 16; however, the sale of any such shares is a sale under Section 16.

POLICY INTERPRETATION AND AMENDMENTS

The Compliance Officer is authorized to interpret this Policy as necessary. The Compliance Officer may authorize deviations in the procedures in this Policy, provided those deviations are consistent with the general purpose of this Policy and applicable securities laws. Any such deviations must be confirmed in writing.

Any amendment to this Policy must be approved by the Board or the Nominating and Corporate Governance Committee of the Board.

This Policy replaces and supersedes all prior insider trading policies of the Company. In the event of any conflict or inconsistency between this Policy and any other materials previously distributed by the Company with respect to the subject matter of this Policy, this Policy shall govern.

The Company reviews and updates its policies, including this Policy, from time to time, and the Company reserves the right to amend, alter or terminate this Policy at any time and for any reason, subject to applicable law. A current copy of the Company's policy regarding insider trading is available upon request from the Compliance Officer. It is your responsibility to comply with the terms of the Company's policies as they may be in effect from time to time.

QUESTIONS ABOUT THIS POLICY

Please direct your questions as to any matters discussed in this Policy to the Compliance Officer.

EXHIBIT A

Rule 10b5-1 trading programs established pursuant to this Policy (each a "***Program***") are limited to:

(a) A written trading plan (commonly called a non-discretionary Rule 10b5-1 plan) that permits automatic trading of Company Securities through a third party broker (an "***Automatic Trading Program***") established by a director, officer or other employee of the Company (a "***Program Eligible Person***" or "***you***" in this Exhibit A) at a time when the Program Eligible Person is not aware of material nonpublic information (and, in the case of directors, officers and Financial Insiders, during a Trading Window). The Automatic Trading Program must specify the number (or dollar value) of Company Securities to be purchased or sold, the price (which may be a fixed price, market price or minimum/maximum price) at which the Company Securities are to be traded, and the date(s) on which the trades are to be made. Alternatively, the Automatic Trading Program may include a written formula or algorithm, or computer program, for determining the amount of securities to be purchased or sold and the price at which and the date on which the securities were to be purchased or sold (*e.g.*, the number of shares could be specified as a percentage of the holdings of the Program Eligible Person); or

(b) A Program where transactions in Company Securities are initiated by the trustee of a so-called "blind" trust, provided the Program is established by a Program Eligible Person at a time when the Program Eligible Person is not aware of material nonpublic information. A "blind" trust is a trust established by a Program Eligible Person. An independent trustee without any involvement or even knowledge of the Program Eligible Person must make the investment and disposition decisions. The trustee should be a recognized financial institution possessing trust powers. Under this type of Program, the Program Eligible Person cannot exert any influence over, or even communicate with, the trustee regarding specific investments. If the trustee becomes aware of material nonpublic information regarding the Company, whether from the Program Eligible Person or otherwise, the trustee may not engage in a purchase or sale of Company Securities.

Additional Program Restrictions. All Programs are subject to the requirements of Rule 10b5-1 and to the following:

- The Program must provide that no trades may occur thereunder until expiration of the applicable cooling-off period specified in Rule 10b5-1(c)(ii)(B), and no trades occur under the Program until after that time.
    - The applicable cooling-off period varies based on the status of the Program Eligible Person.
    - For directors and officers, the cooling-off period ends on the later of (x) 90 days after adoption or modification of the Program; and (y) two business days following disclosure of the Company's financial results in a Form 10-Q or Form 10-K for the fiscal quarter in which the Program was adopted.
    - For all other Program Eligible Persons, the cooling-off period ends 30 days after the adoption or modification of the Program.
- The Program must include an expiration date that is at least six months but not more than 18 months from the effective date of the Program. Shorter-term Programs may be viewed as an attempt to make advantageous short-term trades, and longer-term Programs are likely to have to be amended or terminated, which defeats the ultimate purpose of Programs.

- Once the Program is established, the Program must not permit the Program Eligible Person to exercise any influence or control over the amount of Company Securities to be traded, the price(s) at which they are to be traded or the date(s) on which the trades are to be made.
- The Program Eligible Person cannot engage in any separate transaction (*e.g.*, a hedging transaction) that directly or indirectly alters or offsets a trade under the Program.
- The Program must allow for the cancellation of a transaction and/or suspension of a Program upon notice and request by the Company to the extent the Program or any proposed trade thereunder (i) fails to comply with applicable law (*e.g.*, exceeding the number of shares which the Program Eligible Person may sell under Rule 144 in a rolling three month period), or (ii) would create material adverse consequences for the Company (*e.g.*, due to the imposition of lock-up agreements on the Program Eligible Person).
- Any Program entered into by a Program Eligible Person must be the only outstanding Program for such Program Eligible Person, subject to the exceptions set out in Rule 10b5-1(c)(ii)(D).
- Subject to and in accordance with the terms of Rule 10b5-1, a Program Eligible Person may not have more than one “single trade” Program during any 12-month period.
- The Program must be entered into (a) in good faith and not as part of a plan or scheme to evade the prohibitions of the securities laws (including, without limitation, Rule 10b5-1) and (b) at a time when the Program Eligible Person is not aware of material nonpublic information about the Company; and if the Program Eligible Person is a director or officer of the Company, the Program for such director or officer must include representations by the director or officer certifying as to the matters described in clauses (a) and (b).

Amendment, Suspension or Termination of Programs. Any modification or change to the amount, price, or timing of the purchase or sale of the securities underlying a Program is considered a termination of such Program and the adoption of a new Program. Amendments, suspensions, and terminations of Programs will be viewed in hindsight and could call into question whether the Program was entered into in good faith. As a result, amendments, suspensions, and terminations of Programs (unless in accordance with the terms of the Program when established) require preapproval of the Compliance Officer, who will inquire into the change in circumstances that has occurred since the inception of the Program giving rise to the requested amendment, suspension, or termination. Scheduled sales or purchases of securities pursuant to a Program will not be halted during the pendency of the amendment, suspension, or termination request. The Company has the right at any time to require additional and/or different requirements in connection with the amendment, suspension, or termination of a Program in order to protect you and the Company from potential liability. Further, a Program may be terminated or suspended by the Company at any time and for any reason.

In addition, you may voluntarily amend, suspend or terminate a Program, subject to these conditions:

- A Program Eligible Person may only amend, suspend or terminate their Program during a Trading Window and following preclearance by the Compliance Officer.

- A Program Eligible Person may not amend, suspend or terminate their Program if at the time of the amendment, suspension or termination, the Program Eligible Person possesses material nonpublic information concerning the Company. A Program Eligible Person must sign a certificate in favor of the Company affirmatively stating that they do not possess material nonpublic information concerning the Company at the time of the amendment, suspension or termination.
- The amendment, suspension or termination must include any applicable cooling-off period pursuant to Rule 10b5-1.
- No suspension of a Program may exceed 60 calendar days.
- At least one year must elapse between the termination of a Program and the entry into a new Program.
- A Program Eligible Person will be limited to one amendment or suspension of their Program during its term.

Company Disclosure. The Company will be required to make certain disclosures in accordance with Rule 10b5-1 regarding any adoption, modification or termination of a Program by any person subject to Section 16 of the Exchange Act. Upon the occurrence of any such adoption, modification or termination, such persons must promptly furnish the Compliance Officer with information regarding the date of adoption, termination or modification of the Program, the Program's duration, the aggregate number of securities to be sold or purchased under the Program and any other information reasonably requested by the Compliance Officer.

You have the ultimate and exclusive responsibility for adhering to the requirements set forth herein. Any action on the part of the Company, the Compliance Officer, or any other person pursuant to this Policy (or otherwise) does not in any way constitute legal advice or insulate you from liability under securities laws. You must notify the Compliance Officer if you become aware of a breach of the requirements, either by you or by another person subject to this Policy. The Company shall have no liability to any Program Eligible Person as a result of the establishment of a Program, any disclosure by the Company with respect thereto, or any cancellation or transactions and/or suspension of a Program as discussed above.

EXHIBIT B

CERTIFICATION OF COMPLIANCE

TO: Compliance Officer

FROM: ____

RE: Lineage Cell Therapeutics, Inc. Insider Trading Policy

I have received, reviewed and understand the above-referenced Insider Trading Policy and undertake, as a condition to my present and continued employment (or, if I am not an employee, affiliation) with Lineage Cell Therapeutics, Inc., or any of its subsidiaries or Controlled Entities to comply fully with the policies and procedures contained therein, as the same may be amended from time to time.

_____ _____

Signature Date

_____

Title

Exhibit 21.1

Lineage Cell Therapeutics, Inc.

The following is a list of subsidiaries of Lineage Cell Therapeutics, Inc. as of December 31, 2024, omitting some subsidiaries which, considered in the aggregate, would not constitute a significant subsidiary.

Subsidiary	State or Jurisdiction of Incorporation or Organization
Cell Cure Neurosciences Ltd	Israel
ES Cell International Pte. Ltd	Singapore

Exhibit 23.01

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-277758, 333-166862, 333-167822, 333-174282, 333-182964, 333-183557, 333-187710, 333-188066, 333-201824, 333-209000, 333-217182, 333-218807, 333-254155, and 333-254167) and Form S-8 (No. 333-101651, 333-122844, 333-163396, 333-192531, 333-205661, 333-219204, 333-233132, 333-254158, 333-259853, and 333-275505) of Lineage Cell Therapeutics, Inc. (the "Company"), of our report dated March 10, 2025, relating to the consolidated financial statements of the Company as of and for the year ended December 31, 2024, appearing in this Annual Report on Form 10-K of the Company for the year ended December 31, 2024.

/s/ Moss Adams LLP

San Diego, California
March 10, 2025

Exhibit 23.02

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Registration Nos. 333-166862, 333-167822, 333-174282, 333-182964, 333-183557, 333-187710, 333-188066, 333-201824, 333-209000, 333-217182, 333-218807, 333-254155, 333-254167 and 333-277758), and Form S-8 (Registration Nos. 333-101651, 333-122844, 333-163396, 333-192531, 333-205661, 333-219204, 333-233132, 333-254158, 333-259853 and 333-275505) of Lineage Cell Therapeutics, Inc. of our report dated March 7, 2024, except for Note 15, as to which the date is March 10, 2025, relating to the consolidated financial statements of Lineage Cell Therapeutics, Inc. as of and for the year ended December 31, 2023, which appears in this Form 10-K.

/s/ WithumSmith+Brown, PC

San Francisco, California
March 10, 2025

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Brian M. Culley, certify that:

1. I have reviewed this annual report on Form 10-K of Lineage Cell Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2025

/s/ Brian M. Culley
Brian M. Culley
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jill Ann Howe, certify that:

1. I have reviewed this annual report on Form 10-K of Lineage Cell Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2025

/s/ Jill Ann Howe
Jill Ann Howe
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Lineage Cell Therapeutics, Inc. (the "Company") for the year ended December 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Brian M. Culley, Chief Executive Officer of the Company, and Jill Ann Howe, Chief Financial Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2025

/s/ Brian M. Culley
Brian M. Culley
Chief Executive Officer
(Principal Executive Officer)

/s/ Jill Ann Howe
Jill Ann Howe
Chief Financial Officer
(Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to Lineage Cell Therapeutics, Inc. and will be retained by Lineage Cell Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.