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 , 2023

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 ☐
	Smaller reporting company ☒
Non-accelerated filer ☒	
	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 30, 2023, the last business day of the registrant's most recently completed second fiscal quarter, was $

185.6
million.

The number of common shares outstanding as of March 1, 2024 was

188,533,536
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DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2024 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;
- 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 Israel-Hamas war, 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 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 or our collaborators may not 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 are dependent on our third-party collaboration with Roche to develop and commercialize RG6501 (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, 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.

• 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. Accordingly, political and economic conditions in Israel and war, terrorist attacks or other armed conflicts involving Israel, such as the Israel-Hamas war, 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. 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 materially and adversely affected in the future by the effects of a public health crisis.

• 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.

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

• 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.

• 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.

• 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.

• 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.

ITEM 1. BUSINESS

Overview

We are a clinical-stage biotechnology company developing novel allogeneic, or "off-the-shelf," cell therapies to address unmet medical needs. Our programs are based on our proprietary cell-based technology platform and associated development 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 created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages. Cells derived from such lineages 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 augment the patient's functional activity.

Our business strategy is to efficiently leverage our technology platform and our development, formulation, delivery, 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. 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.

Our most advanced unpartnered product candidate is OPC1, an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury (“SCI”). OPC1 has been tested in two clinical trials to date: a five patient Phase 1 clinical trial in acute thoracic SCI, where all subjects were followed for at least 10 years, and a 25 patient Phase 1/2a multicenter clinical trial in subacute cervical SCI, where all subjects were evaluated for at least two years. Results from both 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”). In February 2024, we announced the clearance by the FDA of our Investigational New Drug (“IND”) amendment for OPC1. Pursuant to the IND amendment, we have initiated activities to open our first clinical site in the 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 to administer OPC1 to the spinal parenchyma in subacute and chronic SCI patients. We expect the initial clinical site opening to occur in the second quarter of 2024.

Our neuroscience focused pipeline of allogeneic, or “off-the-shelf”, cell therapy programs currently includes:

- RG6501 (OpRegen), an allogeneic RPE cell replacement therapy currently in a Phase 2a multicenter, open-label, single arm clinical trial, being conducted by Genentech, for the treatment of GA secondary to AMD, also known as atrophic or dry AMD.
- OPC1, an allogeneic oligodendrocyte progenitor cell therapy which will be evaluated in the DOSED clinical study, to test the safety and utility of a novel spinal cord delivery device in both subacute and chronic spinal cord injuries and continues to be evaluated in long-term follow-up from a Phase 1/2a multicenter clinical trial for subacute cervical spinal cord injuries.
- ANP1, an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of debilitating 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 novel hypoimmune induced pluripotent stem cell ("iPSC") line being developed in collaboration with Eterna Therapeutics Inc. ("Eterna"), which will be evaluated for differentiation into cell transplant product candidates for central nervous system ("CNS") diseases and other neurology indications.

Other Programs

We have additional undisclosed product candidates being considered for development, and we may consider others, which cover a range of therapeutic areas and unmet medical needs. 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.

Our efforts to broaden the application of our cell therapy platform and support long-term growth include a strategic collaboration we entered into with Eterna. This reflects a portion of our corporate strategy to capitalize on our process development capabilities by combining them with cell engineering and/or editing technologies, to create novel cell therapies with potentially superior product profiles compared to currently marketed therapies, if any.

In addition to seeking to create value for shareholders by developing product candidates and advancing those candidates through clinical development, we also may seek to create value from our non-core intellectual property or related technologies and capabilities, through licensing collaborations and/or other strategic transactions, such as our business development approach to our VAC dendritic cell therapy platform.

2023 Select Business Highlights

We achieved numerous strategic and operational accomplishments during 2023, including advancing our clinical programs and product development in several key programs.

- Continued execution under our collaboration with Roche and Genentech for the development of RG6501 (OpRegen) across multiple functional areas.

- Submitted an IND amendment for OPC1 for the treatment of chronic and subacute spinal cord injury, which was subsequently cleared by the FDA.

- Data from our Phase 1/2a clinical study of OpRegen presented at the Association for Research in Vision and Ophthalmology (ARVO) as well as the 23rd EURETINA Congress and Eyecelerator meetings, demonstrating evidence of rapid improvement of outer retinal structure in OpRegen treated patients with GA secondary to AMD.

- U.S. patent exclusively licensed to us covering proprietary manufacturing and differentiation process for RPE cells issued.

- Organized and hosted the 1st Annual Spinal Cord Injury Investor Symposium in partnership with the Christopher & Dana Reeve Foundation with additional support from CIRM.

- Added to the broad-market Russell 3000® Index.

- Entered into option and license agreement with Eterna to develop iPSC lines for potential neurology indications and initiated development activities.

Business Strategy

Our goal is to address unmet medical needs by developing and advancing allogeneic, or "off-the-shelf," treatments comprised of functional cells delivered 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 cell types, and use those differentiated cells as treatments to restore

diseased or diminished functions, such as impaired vision, loss of movement, sensation, and hearing, or to increase immune response to tumors or infectious agents.

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

One 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 RG6501 (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.

In addition, with the clearance of our IND amendment for OPC1 by the FDA in February 2024, we expect to commence the DOSED clinical study in the second quarter of 2024, 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 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 Eterna for the development of RND1, a novel hypoimmune iPSC line, which will be evaluated for differentiation into cell transplant product candidates for CNS diseases and other neurology indications. 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 gene editing technology.

VAC2 is a clinical stage dendritic cell product candidate, which was the subject of a Phase 1 clinical trial in advanced non-small cell lung cancer conducted by our partner, Cancer Research UK. Encouraging primary and secondary endpoint results were reported in 2023. Because many different antigens could be employed as part of this allogeneic dendritic cell system, we believe that strategic alliances offer the best alternatives to advance the VAC platform moving forward.

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 our facility located in Jerusalem, Israel, but such work may be supplemented or complemented by our additional facility located in Carlsbad, California.

Cell Therapy Technology Platform

We believe we are a leader in pluripotent, cell-based asset development based on proprietary directed differentiation protocols of cellular lineages and our cell manufacturing capabilities. 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. We are currently in clinical development for various pluripotent cell-derived product candidates such as RPE cells, oligodendrocyte progenitor cells, and dendritic cells, and preclinical development for auditory neurons and photoreceptor cells. In addition, we are considering the differentiation of 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 are usually well-tolerated. Lineage's cell therapy approach 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. Whereas small molecule product development typically requires selection and validation of a drug target, followed by screening millions of molecules (e.g., a "library" of compounds) to identify hits, followed by chemical modification guided by structure-activity relationship or "SAR" to develop a hit into a more potent lead, the process of developing a new cell therapy from pluripotent lines can be comparatively faster because the target cell type is already known to be "validated", insofar as it is well-established in the literature as being the cell type which is dysfunctional or deficient in the patient. One of the most challenging steps in developing a new cell therapy is the establishment of a controllable and reproducible differentiation protocol which can create the quality and purity of cells needed to support clinical testing and commercial supply. This development process avoids mass screening campaigns and is typically accomplished via the combination of literature reviews and in-house experience with pluripotent cell differentiation. This approach also can facilitate pipeline expansion at a lower cost than traditional methods (**Figure 1**).

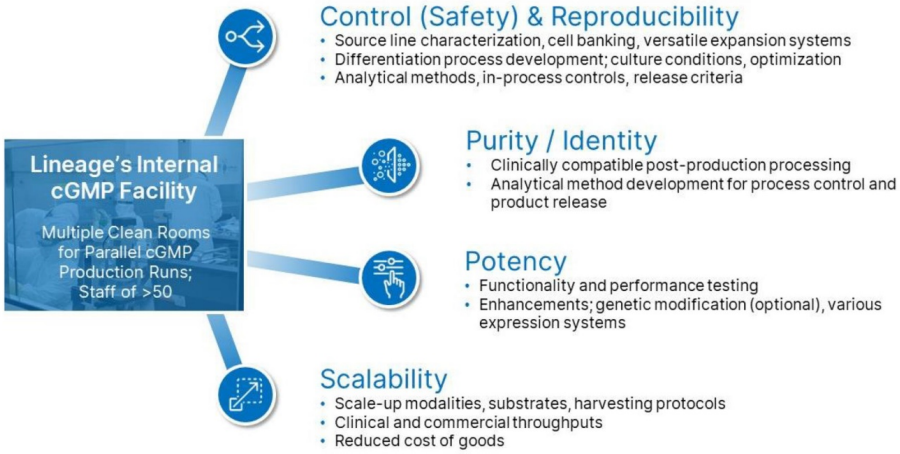
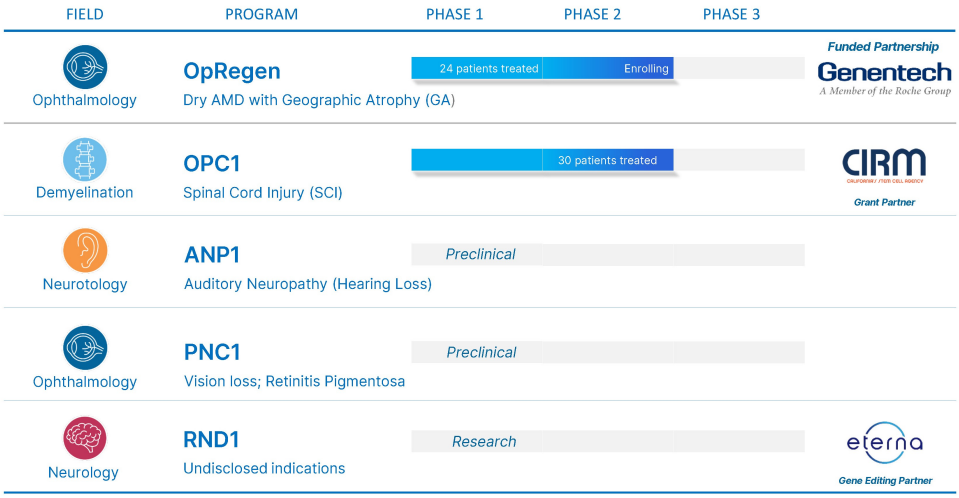


Figure 1. Lineage's Internal cGMP Facility Capabilities

In addition to our corporate headquarters located in Carlsbad, California, in late 2022, we opened a new research and development (R&D) facility also located in Carlsbad. This facility expands our R&D capabilities in the U.S. and may support the development of current and future allogeneic cell transplant programs. We also have a modern and innovative manufacturing facility in the Bio Park on the campus of the Hadassah University Hospital in Jerusalem, 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



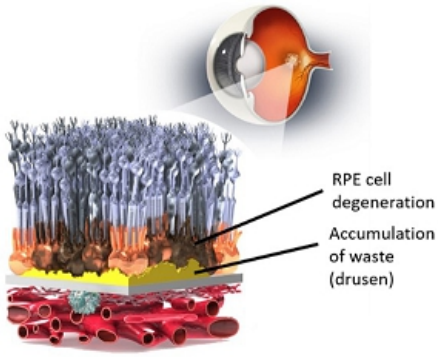
Clinical Stage Cell Transplant Programs

RG6501 (OpRegen®)

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 14 (Commitments and Contingencies) to our consolidated financial statements included in this report for discussion on the Roche Agreement.

OpRegen has been granted Fast Track Designation 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. Additionally, dry AMD may also lead to wet AMD, a condition for which there are several FDA-approved treatments administered locally 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.



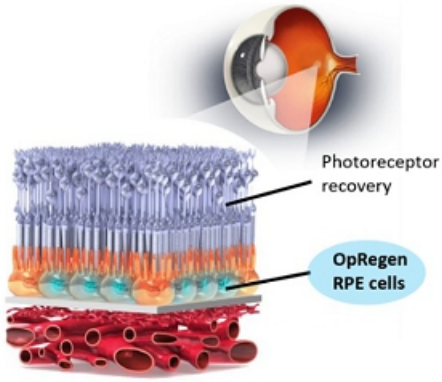


Figure 3. Dry AMD involves the loss of retina cells, creating an area of GA, which causes impaired vision and blindness	Figure 4. OpRegen is an injection of RPE cells delivered to the retina, with the potential to replace lost retinal cells and/or preserve or restore vision

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 OpRegen therapeutic approach is designed to replace damaged or lost RPE cells with the goal of slowing disease progression 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 one year 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.

Results from imaging analyses of structural changes and visual data from this study were presented at the 2023 ARVO Annual Meeting. Preliminary evidence of outer retinal structure and visual function improvements with OpRegen was observed in patients with GA and impaired vision (Cohort 4 [n=12]) where patients had an average 7.6 letter gain in visual acuity at 12 months post OpRegen transplant in the OpRegen-treated eye. Notably, three patients in Cohort 4 (25%) had a 15 letter or greater gain in visual acuity in the OpRegen-treated eye at 12 months post OpRegen transplant. Long term vision preservation with outer retinal structure improvement observed in the OpRegen-treated eye persisted for up to 4 years following a single administration of OpRegen.

Importantly, extensive OpRegen surgical bleb coverage of areas of GA was found to be critical for optimizing patient outcomes including: demonstrated improvement in outer retinal layers, demonstrated resolution of complete RPE and outer retinal atrophy (cRORA) near borders of baseline GA and slower rates of RPE and external limiting membrane (ELM) loss. Five patients in Cohort 4 who had a surgically delivered bleb containing OpRegen that extensively covered their atrophic areas and the foveal center, experienced an average 12.8 letter gain in their OpRegen-treated eye. Signs of improvement in areas of cRORA included: greater hyperreflectivity at the level of RPE/ Bruch's membrane; less choroidal hypertransmission; reduction of retinal subsidence, and greater continuity of outer retinal layers. These findings support the view that dry AMD may not be an irreversible, degenerative condition and that some portion of diseased retinal tissue may be recoverable in atrophic end-stage disease patients.

Despite dry AMD generally being considered an irreversible and degenerative disease leading to vision loss, positive durable long-term visual benefits from OpRegen-treated eyes in the Phase 1/2 clinical study continue to suggest that OpRegen RPE cells may provide support to patients' remaining retinal cells, including those near or within atrophic areas. Recent results at 24 months of follow-up in 10 of 12 patients treated as part of Cohort 4, where patients had better baseline vision and smaller areas of GA at baseline than earlier cohorts who were legally blind, and for which follow up data are available, have recently been analyzed. Notably, Cohort 4 patients treated with OpRegen who exhibited average visual acuity gains of +7.6 letters at 12-months post OpRegen transplant, remained above baseline at 24 months (+5.5 letters) post OpRegen transplant. BCVA gains at 12 and 24 months averaged slightly higher among the 5 patients with extensive surgical bleb coverage of their GA lesion than those with no or limited bleb coverage, and these greater BCVA gains were associated with evidence of anatomical improvement in outer retinal structure. These improvements to retinal structure can be detected within the first three months following a cell transplant and these structural and visual improvements are still observable two years following a single administration of OpRegen. Evidence of durable engraftment for OpRegen RPE cells has now extended to 4 years in one of the earliest treated patients, supporting the potential for OpRegen to be a one-time treatment. Overall, in the study (N=24), OpRegen continues to show an acceptable safety profile, which remains unchanged following inclusion of the long-term follow-up safety data.

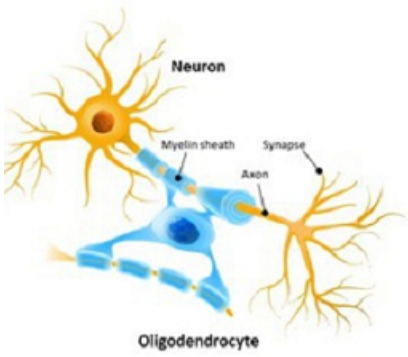
RG6501 (OpRegen) is currently being developed under an exclusive worldwide collaboration between us and Roche and Genentech. See "—Collaborations—Roche Collaboration Agreement," below.

In November 2022, Genentech launched a Phase 2a, multicenter, open-label, single arm clinical study of RG6501 (OpRegen), with patient enrollment initiated in March 2023. The study is intended to optimize subretinal surgical delivery and evaluate the safety and activity of OpRegen in up to 60 patients with GA secondary to AMD. The primary objectives of the study are to evaluate (i) the proportion of patients with subretinal surgical delivery of OpRegen to target regions under the retina, and (ii) to evaluate 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. A key secondary objective is to evaluate 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

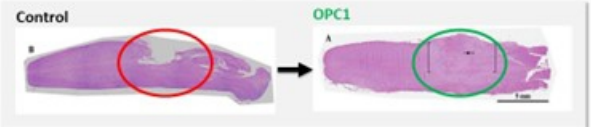
OPC1 is an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute SCI. SCI occurs when the spinal cord is subjected to a severe crush or contusion injury, such as that caused by a car or motorcycle accident, and typically results in severe functional impairment, including limb paralysis, aberrant pain signaling, and/or loss of bladder and 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 rapidly 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 have applied for additional funding from CIRM for continued clinical development of OPC1 for the treatment of SCI. See "—Grants from Government Entities," 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

Thoracic phase 1 clinical trial (N=5)

- All subjects followed for at least 10 years
- No unexpected serious adverse events attributable to the OPC1 transplant:
  - No evidence of neurological decline
  - No enlarging masses
  - No further spinal cord damage
  - No syrinx formation
  - *Journal of Neurosurgery Spine, Vol 37, Issue 3, 2022*

Cervical phase 1/2a clinical trial (N=25)

- All subjects evaluated for at least 2 years
- No unexpected serious adverse events related to the OPC1 transplant
- No enrolled patients had worsening of neurological function
- Durable motor improvements:
  - 4 of 6 subjects gained at least 2 motor levels of improvement on at least one side at 12 months (cohort 2)
  - 5 of 6 subjects gained at least 2 motor levels of improvement on at least one side at 24 months (cohort 2)
  - 1 subject achieved 3 motor levels of improvement on one side; maintained at 3 years (cohort 2)
  - *Journal of Neurosurgery Spine, Vol 37, Issue 6, 2022*

The FDA designated OPC1 as a Regenerative Medicine Advanced Therapy ("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 our cell therapy manufacturing facility in Jerusalem, Israel. Improvements to the manufacturing process were performed to create enhancements to the 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. We are currently in the planning stages for the 2ndAnnual Spinal Cord Injury Investor Symposium.

In December 2023, we submitted an IND amendment for OPC1 to enable the initiation of the DOSED clinical study to evaluate the safety and utility of the Neurgain device in both subacute and chronic spinal cord injury patients. In February 2024, we announced the FDA clearance of the IND amendment. The DOSED clinical study will be an open label, multicenter, device safety study in approximately 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 spinal cord delivery device, the Neurgain device, to administer OPC1 to the spinal parenchyma. The primary endpoint is safety, as measured by the frequency and severity of AEs through 30 days following OPC1 injection that are related to the injection procedure. Secondary endpoints are safety and tolerability, as measured by the frequency and severity of AEs, including AEs of special interest, through 90 days following OPC1 injection, that are related to OPC1 and/or the concomitant short-term immunosuppression. We expect initial clinical site opening for the DOSED clinical study to occur in the second quarter of 2024, following customary trial preparations.

We are actively working both on expanding our existing and establishing new collaborations with SCI patient engagement and advocacy organizations, with the overarching goals of enhancing awareness of SCI and elevating the

oprietary technology platform, we have developed a unique differentiation process for generating auditory neuron progenitor (“ANP”) cells. In February 2023, 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.

Research Development Programs

RND1

RND1 is a novel hypoimmune iPSC cell line being developed in collaboration with Eterna, which we intend to evaluate for differentiation into cell transplant product candidates for CNS diseases and other neurology indications.

In February 2023, we entered into an option and license agreement with Eterna to develop engineered hypoimmune iPSC lines that we will evaluate for differentiation into cell transplant product candidates for CNS diseases and other neurology indications. 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 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 create 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 Eterna and our selection of specific gene edits for the initial cell line to be developed by Eterna. 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.

Business Development Opportunities

VAC Platform

VAC is our immuno-oncology platform using dendritic cells loaded with antigens for the treatment of cancer. As the most potent type of antigen-presenting cell in the body, dendritic cells instruct the human body's immune system to attack and eliminate harmful pathogens and unwanted cells, including cancer cells.

VAC2 is an allogeneic, or non-patient specific, cancer vaccine candidate designed to stimulate patient immune responses to an antigen, human telomerase reverse transcriptase ("hTERT"), which is commonly expressed in cancerous cells but is not usually found in normal adult cells. VAC2 is produced by our pluripotent cell technology using a directed differentiation method and is comprised of a population of mature dendritic cells to which the hTERT antigen was introduced via an mRNA construct which is loaded into the dendritic cell via electroporation. The VAC1 autologous program, which preceded VAC2 but relied on the same antigen, served as proof of concept behind our approach to utilize dendritic cell vaccines targeting telomerase to treat cancer.

We believe that as an allogeneic therapy, VAC has the potential to stimulate a more robust immune response through an adjuvant effect resulting from the partial immune mismatch between the VAC cells and patients receiving the therapy. We believe that VAC can be used as a platform technology that can be modified to carry a diverse number or type of antigen, including patient-specific tumor neo-antigens.

In September 2014, Asterias Biotherapeutics, Inc. ("Asterias") initiated clinical development of VAC2 by entering into a Clinical Trial and Option Agreement (the "CRUK Agreement") with Cancer Research UK ("CRUK") and Cancer Research Technology Limited ("CRT"), a wholly owned subsidiary of CRUK, under which CRUK agreed to fund Phase 1 clinical development of VAC2 in non-small cell lung cancer ("NSCLC"). CRUK was responsible, at its own cost, for manufacturing clinical grade VAC2 and for carrying out the Phase 1 clinical trial of VAC2. In April 2022, we announced that CRUK had completed patient enrollment in the ongoing Phase 1 clinical trial of VAC2 for the treatment of NSCLC. In July 2023, we announced encouraging primary and secondary endpoint results from this study: five of eight patients treated had a best response of immune-related stable disease, and three demonstrated immune-related progressive disease; no patients had treatment emergent serious adverse events and all patients completed per protocol vaccination; and three of eight treated patients reached the 2-year survival endpoint. Further

analyses from immunogenicity of VAC2 in the tumor, skin punch biopsies, and peripheral responses are currently being conducted by CRUK.

In April 2021, Lineage entered into a worldwide license and development collaboration agreement with Immunomic Therapeutics, Inc. ("ITI"). See "—Collaborations—ITI Collaboration Agreement," below. ITI is currently evaluating its next step under the agreement.

Because many different antigens could be employed as part of this allogeneic dendritic cell system, we believe that strategic collaborations offer the best alternatives to advance the VAC platform moving forward and we continue to be engaged in exploratory discussions for the development of various VAC assets. We intend to continue monitoring the neoantigen vaccine landscape to help inform our corporate strategy and determine the best development path for VAC2 or any other VAC platform programs.

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.

One key principle of our approach to collaborations is to share rewards and risks of conducting large-scale clinical trials and commercializing a product, but also to provide the broadest patient population with the earliest access to our therapies.

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.

Lineage is obligated to pay 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, 2023, the aggregate cap amount was $93.2 million. In addition, pursuant to the Second Amended and Restated License Agreement, dated June 15, 2017, between our foreign subsidiary located in Jerusalem, Israel, Cell Cure Neurosciences Ltd. ("Cell Cure"), and

Hadasit Medical Research and Development Ltd. ("Hadasit"), as amended, and a letter agreement entered into between Cell Cure and Hadasit on December 17, 2021, Cell Cure is obligated to pay 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 14 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information related to our obligations to the IIA and Hadasit.

ITI Collaboration Agreement

On April 16, 2021, Lineage entered a worldwide license and development collaboration with ITI (the "ITI Agreement"). Lineage is the sole and exclusive owner of the rights to the VAC platform and has licensed to ITI patents and materials for the development and commercialization of a novel cancer immunotherapy agent derived from this platform utilizing an antigen provided by ITI.

Under terms of the ITI Agreement, Lineage is entitled to initial fees totaling up to $2.0 million, $1.0 million of which we received in 2021, and up to an additional $67.0 million in development and commercial milestones across multiple indications. Lineage will also be eligible to receive royalties of up to 10% on net sales of future products. ITI has received a research and development grade of the VAC-CMV product candidate and is evaluating its next steps.

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 Cell Cure'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 Cell Cure, we undertook in writing, vis-à-vis the IIA, to comply with, and to ensure the compliance by Cell Cure 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, Cell Cure received a total of $15.4 million from the IIA to support the OpRegen program. See Note 14 (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, following FDA clearance of our IND amendment for OPC1, we applied for clinical program (CLIN2) funding from CIRM to support the DOSED clinical study. Subsequently, in February 2024, CIRM's governing board determined to postpone acceptance of CLIN1 and CLIN2 applications submitted after January 31, 2024, in response to an unprecedented influx of applications and resulting review and budgetary issues. CIRM disclosed that the amount of funds requested by all then-currently submitted clinical stage applications exceeded the amount of funds available in its 2023/2024 fiscal year budget and based on the historical success rate of 50 to 60 percent, then-currently submitted applications have the potential to deplete its remaining fiscal year budget. According to CIRM, the postponement of its acceptance of applications and CIRM's progress towards addressing its review and budgetary issues will be re-evaluated at the June 2024 meeting of its governing board, which currently is scheduled for June 27, 2024.

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 methods, 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. We also rely on contractual obligations with employees and third parties to protect our proprietary rights. For example, in addition to protecting our proprietary rights with patents, we rely on other intellectual property such as unpatented trade secrets, improvements, know-how and innovation, and we take steps necessary to protect these rights, including through confidentiality agreements with our corporate partners, employees, consultants and vendors. 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. 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. 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.

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 have rights to issued U.S. and international patents and pending patent applications relating to OpRegen. The issued patents have expiration dates ranging from 2028 to 2038. The pending applications, if issued, will have estimated patent expiration dates ranging from 2028 to 2042. These U.S. and international issued patents and pending applications also include those in-licensed from Hadasit, a wholly owned subsidiary of Hadassah Medical Organization. We also solely own pending U.S. and international patent applications relating to a cryopreserved thaw-and-inject formulation. These pending U.S. patent applications, and pending international patent applications, if issued, will have estimated patent expiration dates in 2038. 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 have numerous U.S. and international issued patents and pending patent applications that are relevant to neural cells, such as oligodendrocyte progenitor cells, including patent families acquired from Geron Corporation ("Geron") 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. We have seven patent families owned by us 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 three 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 seven patent families owned by us range from 2036 to 2043. The commercial success of OPC1 depends, in part, upon our ability to exclude competition for this product with the existing patent portfolio, regulatory exclusivity, undisclosed know-how and/or trade secrets, or a combination of these barriers to entry.

Auditory Neurons

We have two pending patent applications for our ANP1 program, a pending U.S. provisional patent application and a pending PCT patent application. It is anticipated that the pending provisional patent application will be converted to a PCT patent application in 2024. 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 2025 and, if issued, would have estimated patent expiration dates in 2043.

Photoreceptors

We have rights to three 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. One of these patent families is owned by Hadasit and licensed to us and includes U.S. and international pending patent applications with estimated patent expiration dates in 2038 (the "Hadasit-Owned Patent Families"). We also have a pending PCT patent application jointly owned by us and Hadasit resulting from the collaborative efforts of Hadasit and Cell Cure pursuant to the photoreceptor development program under the Second Amended and Restated License Agreement between Hadasit and Cell Cure. It is anticipated that this jointly owned PCT patent application will be

converted to a U.S. utility patent application and one or more international patent applications in 2024 and, if issued, would have estimated patent expiration dates in 2043. The photoreceptor development program will be removed from the scope of that license agreement effective April 19, 2024, such that the pending PCT patent application will be jointly owned by us and Hadasit, and our rights to the Hadasit-Owned Patent Families shall cease.

VAC Platform

We have numerous U.S. and international issued patents and pending patent applications that are relevant to dendritic cells, directed to the differentiation of pluripotent stem cells, including hES cells, into hematopoietic progenitor cells and immature and mature dendritic cells. These patent rights include a patent family with claims directed to immunogenic compositions comprising antigen-presenting dendritic cells and methods of eliciting an anti-telomerase immune response in a subject by administering to the subject such compositions with estimated patent expiration dates, if issued in 2041. We also solely own a pending PCT patent application relating to VAC processes. It is anticipated that this pending PCT patent application will be converted to a U.S. patent application and one or more international patent applications in 2025 and if issued, would have estimated patent expiration dates in 2043.

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 and 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. 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, 2023, we had 75 employees, of which 23 were employed by Lineage and 52 were employed by Cell Cure and work in Israel. Of the 75 employees, 68 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 and product manufacturing for our cell therapy product candidates, are conducted at our facility in Jerusalem, Israel. 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 components 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 components 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, Cell Cure entered into a Second Amended and Restated License Agreement (the “Hadasit License Agreement”) with Hadasit, pursuant to which Hadasit granted Cell Cure 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, Cell Cure 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, Cell Cure pays Hadasit an annual minimal non-refundable royalty.

Cell Cure 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, whichever is the first to occur, and upon the first commercial sale in the United States or European Union, 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 Cell Cure. 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 Cell Cure 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. Lineage notified Hadasit on January 20, 2024, of its intent to remove the Photoreceptor Field from the scope of the Hadasit License Agreement, effective April 19, 2024.

The Hadasit License Agreement terminates upon the expiration of Cell Cure’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, Cell Cure 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 Cell Cure and Hadasit, and indemnification obligations of Cell Cure.

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

In March 2020, Lineage and its wholly owned subsidiary Asterias entered into a Second Amendment to Clinical Trial and Option Agreement (the “CTOA Amendment”) with CRUK and CRT, which amends the Clinical Trial and Option Agreement entered into between Asterias, CRUK and CRT dated September 8, 2014, as amended September 8, 2014. Pursuant to the 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.

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.

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 and a Non-Exclusive License Agreement entered into between Asterias and WARF in October 2013 (collectively, the “WARF Agreements”).

Under the WARF Agreements, we have a worldwide non-exclusive license under certain WARF patents and WARF-owned primate (including human) stem cell lines covered by such patents 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 cells. 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 WARF Agreements will terminate with respect to licensed patents upon the expiration of the last licensed patent to expire and with respect to licensed cell lines until terminated by a party. We may terminate the WARF Agreements at any time with prior written notice, and WARF may terminate the WARF Agreements upon a 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.

Royalty Agreement with Geron

In connection with Asterias's acquisition of Geron's stem cell assets in October 2013, we entered into a royalty agreement with Geron (the "Royalty Agreement") pursuant to which we agreed to pay Geron a 4% royalty on net sales by us or any of our affiliates or sales agents of any products that we develop and commercialize that are covered by the patents Geron contributed to us. In the case of sales of such products by a person other than us or one of our affiliates or sales agents, we will be required to pay Geron 50% of all royalties and cash payments received by us or by our affiliate in respect of a product sale. The Royalty Agreement will terminate at the expiration or termination date of the last issued patent contributed by Geron under the Royalty Agreement. We estimate that the latest patent expiration date will occur in 2029.

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. 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 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 HCT/P establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate 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, the FDA has not 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; 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. When regulated independently, 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 data privacy, security, and protection laws to which we may be subject include, without limitation, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018 ("CCPA"), as amended by the California Privacy Rights Act of 2020 ("CPRA"), the Virginia Consumer Data Protection Act ("VCDPA"), Colorado Privacy Act ("CPA"), Connecticut Data Privacy Act ("CDPA"), Utah Consumer Privacy Act ("UPA"), Israel's Protection of Privacy Law 5741-1981, the European Union's General Data Protection Regulation 2016/679 ("EU GDPR"), the EU GDPR as it forms part of United Kingdom ("UK") law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"), and the ePrivacy Directive. In addition, several states within the United States have enacted comprehensive data privacy laws, similar to the active laws in California, Virginia, Colorado, Connecticut and Utah. These states include Delaware, Indiana, Iowa, Montana, New Jersey, Oregon, Tennessee and Texas.

The CCPA and EU GDPR are examples of increasingly stringent and evolving regulatory frameworks related to personal data processing, which increase compliance obligations and exposure for noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business's collection, use, and disclosure of personal data and a requirement to respond to certain requests from California residents to exercise certain rights related to their personal data. The CCPA also provides for civil penalties for violation of the provisions of the act and a private right of action for certain data breaches. The VCDPA, CPA, CDPA and UPA have similar requirements and provisions, though none of them allow for a private right of action. U.S. federal and state consumer protection laws also require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data.

The EU GDPR applies to any company established in the European Economic Area ("EEA") and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include

limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances. Moreover, under the 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, individuals may initiate litigation related to processing of their personal data. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU. Guidance developed at both the EU level and at the national level in individual EU Member States concerning implementation and compliance practices is often updated or otherwise revised. There is, moreover, 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.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the EEA, such as the United States, that the European Commission does not consider to provide an adequate level of data privacy and security. Following the Schrems II decision of the Court of Justice of the EU in 2020, there is considerable uncertainty as to the permissibility of international data transfers under the GDPR. The European Commission released a set of "Standard Contractual Clauses" ("SCCs"), that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. In addition, President Biden issued an Executive Order on October 7, 2022 to address the data privacy concerns raised in the Schrems II decision through introducing, among other measures, further safeguards and oversight of personal data collection by U.S. signals intelligence activities and providing individuals with a redress mechanism in the U.S. for their data protection concerns. Further, on July 10, 2023, the European Commission adopted its adequacy decision for the EU-US Data Privacy Framework (successor to the invalidated EU-U.S. Privacy Shield). However, it remains likely that such a new Adequacy Decision will be contested by privacy advocates and 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 FTC and 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 European Union, 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 Federal Trade Commission 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 U.S. Department of Health and Human Services ("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. Moreover, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also 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 and 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. 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.

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, 2023 and 2022:

	Year ended December 31,	
Sources of Revenues	**2023**	**2022**
Collaboration revenues	84.8%	90.9%
Royalties, license and other revenues	15.2%	9.1%

Our collaboration revenues for the years ended December 31, 2023 and 2022 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, 2023 and 2022 represent cash flows generated under patent families that Asterias acquired from Geron. See Note 3 (Revenue) and Note 14 (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, 2023 or 2022 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 Bristol-Myers Squibb Company, Eli Lilly and Company, Novo Nordisk A/S, Novartis AG, Johnson & Johnson, Merck & Co Inc., Gilead Sciences Inc., Bayer AG, BioNTech SE, Moderna Inc., Sana Biotechnology Inc., Century Therapeutics Inc., MAIA Biotechnologies, 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 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, 2023 and 2022 were $24.7 million and $22.5 million, respectively, and we had an accumulated deficit of $384.9 million as of December 31, 2023. 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 either transplanted into patients to replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury or administered by injection as a means of helping the body mount a more robust and effective immune response to cancer or infectious diseases. 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 development of our product candidates. We and our collaborators face significant challenges and uncertainties associated with the manufacture, preclinical and clinical development, regulatory approval pathway, and third-party payor coverage and reimbursement of our product candidates required for successful commercialization, including:

- 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 developing products 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 $15.7 million and $14.0 million during the fiscal years ended December 31, 2023 and 2022, respectively, and we expect to continue to incur substantial research and development expenses. If we successfully develop a new technology or product, 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.

At December 31, 2023, we had $35.5 million of cash, cash equivalents and marketable securities. We believe that our cash, cash equivalents and marketable securities as of December 31, 2023, together with the $13.8 million raised in net proceeds from the registered direct offering of our common shares we completed in February 2024, will be sufficient to fund our planned operations for at least the next 12 months after the issuance of 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 Israel-Hamas war 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 such as the COVID-19 pandemic, geopolitical conflicts including the Israel-Hamas war and the war in Ukraine, 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.

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. 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 14 (Commitments and Contingencies) to our consolidated financial statements included in this report, pursuant to the terms of grants received by Cell Cure 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 the 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 the 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 securities exchange 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. 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 shareholder proxies 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 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 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, 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.

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;
- Roche may believe that data generated in clinical trials for OpRegen may be negative, inconclusive, or do not otherwise demonstrate adequate 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 other product candidates 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.

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 14 (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, terrorist attacks or other armed conflicts involving Israel, such as the Israel-Hamas war that began in October 2023, 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, such as the COVID-19 pandemic, 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, Cell Cure, at its facility in Jerusalem, Israel, and more than two-thirds of our employees are Cell Cure employees who are based in the same facility. Accordingly, political and economic conditions in Israel and terrorist attacks, 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 Israel-Hamas war that began in October 2023, our operations at our Cell Cure facility in Jerusalem were temporarily impacted. Further, a number of our employees in Israel are members of the military reserves and subject to immediate call-up in response to the ongoing war. 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 our employees in Israel, including Cell Cure's chief executive officer, have been activated for military duty and additional employees may also be activated, which could disrupt our operations. In addition, the general impact on employees operating in a region at war could adversely impact our operations. Although we have business continuity plans in place to address medium- or long-term disruptions that could result from the war, any long-term closure of our Cell Cure 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 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, 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, 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 Cell Cure facility. For example, a natural disaster, explosion, 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 manmade disaster affecting our Cell Cure 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. The ongoing war, other ongoing and revived hostilities or other Israeli 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 Israel-Hamas war began in October 2023. 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.

Cell Cure is an Israeli company. Several countries, principally in the Middle East, still restrict doing business with Israel and Israeli companies. Since the Israel-Hamas war began, 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 the ongoing war, other 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 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 Cell Cure 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."

Cell Cure 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. Such grants are applied for on a yearly basis and may not be available or only partially granted in the future, which would increase our costs.

Cell Cure 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, 2023, the aggregate cap amount was approximately $93.2 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 Cell Cure 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. Further grants may not be approved or reduced in the future, which would increase our costs. IIA approval is not required for the marketing or distribution of products resulting from the IIA-funded research or development in the ordinary course of business.

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 as of the date of this report from CIRM, a state agency established to fund stem cell research and development of new stem cell-based treatments. In February 2024, following FDA clearance of our IND amendment for OPC1, we applied for clinical program (CLIN2) funding from CIRM to support the DOSED clinical study. Subsequently, in February 2024, CIRM's governing board determined to postpone acceptance of new CLIN1 and CLIN2 applications submitted after January 31, 2024 until after the governing board's June 2024 meeting, at which time the governing board will re-evaluate the temporary action and CIRM's progress towards addressing the review and budgetary constraints that led to the postponement. The governing board's meeting currently is scheduled for June 27, 2024. As a result of the postponement, we will have to resubmit our application and we do not expect CIRM will even begin to review our application until later this year. And, CIRM's governing board may determine to extend the postponement, including because CIRM's governing board may determine that CIRM's 2023/2024 fiscal year budget for CLIN1 and CLIN2 programs will be depleted by funding granted to applications submitted on or before January 31, 2024. We cannot provide any assurance that CIRM will accept our CLIN2 application for review or that CIRM will award us any additional funding for the OPC1 program. In addition, if our application is accepted and approved in the future, any funding we receive from CIRM may not be applied toward expenses incurred for the DOSED clinical study prior to CIRM's approval of our application. If we are unable to timely obtain another CIRM grant or if the grant funding is insufficient, the timeline for the conduct of the DOSED clinical study may be adversely affected or we may be unable to complete the study. We may need to raise funds through other mechanisms 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 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.

Cell Cure 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 Cell Cure 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, 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, 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 Israel-Hamas war 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 negatively affected clinical trials of our product candidates. In particular, patient enrollment was delayed in our OpRegen Phase 1/2a clinical trial and the VAC2 Phase 1 clinical trial conducted by Cancer Research UK. Clinical trial sites paused enrollment to focus on, and direct resources to, the COVID-19 pandemic, to adhere to national or local guidelines restricting non-essential operations and gatherings, or in the interest of patient safety. Additionally, some enrolled patients in those trials 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, including our Chief Executive Officer. All of our officers and other 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 Mr. Culley or other members of our senior management could have a material adverse effect on us. Further, the replacement of any of such individuals 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 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 could be interpreted, changed, modified or applied adversely to us. For example, the Biden administration and Congress have proposed various U.S. federal tax law changes, which if enacted could have a material impact on our business, cash flow, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to the federal tax laws. 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. tax expense.

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, 2023, 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 2042. Our federal research and development tax credit carryforwards expire in varying amounts between 2023 and 2043, the California research and development tax credit carryforwards have no expiration date. See Note 13 (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, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, 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.

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 currently have subsidiaries in Israel and Singapore. If we succeed in growing our business, we expect to 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. 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 Cell Cure, 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 Cell Cure. As a result, we are exposed to some currency fluctuation risks. Fluctuation in the exchange rate of the foreign currency has an influence on and may adversely affect our comprehensive loss and cash flows.

An extended curtailment or halt of operations at the FDA, SEC and other government agencies, including due to a U.S. federal government shutdown, could delay or disrupt clinical and preclinical development and potential marketing approval of our product candidates and 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 staff at federal agencies from performing key functions that may adversely affect our business. For example, 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, a government shutdown could prevent 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. While we currently have an effective shelf registration statement on Form S-3, a shelf registration statement on Form S-3 typically can only be used for three years, subject to a limited extension, and that three-year period for our current shelf S-3 registration statement ends on March 19, 2024. 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 the FDA, SEC or other regulatory agencies from hiring and retaining personnel and conducting their regular activities, 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

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.

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.

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.

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. 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. Additionally, Congress is considering additional health reform measures.

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 U.S. Department of Health & Human Services ("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 addition, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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;

• 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; and

• 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.

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 spinal cord injuries, but there is no guarantee we will be able to maintain orphan drug designation or obtain the benefits associated with orphan drug designation, including marketing exclusivity.

We have orphan drug designation from the FDA for OPC1 for the treatment of acute spinal cord injuries. 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.

Orphan drug designation may not effectively protect OPC1 from competition because different drugs or biologics can be approved for the same indication and only the first biologic with an orphan drug designation to receive FDA approval for the treatment of acute spinal cord injuries will receive marketing exclusivity. OPC1 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

our request for orphan drug designation was materially defective or if we are unable to assure sufficient quantities of the commercial product to meet the needs of patients with acute spinal cord injuries.

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 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;

• 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 by us or any third party on which we may depend 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 the pluripotent cells to obtain the desired cell product candidate. Manufacturing our product candidates 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 or vaccines 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 Cell Cure 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, 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 that we or a third-party manufacturer uses, or the technologies incorporated into these processes, will result in viable

or scalable yields of our cell therapy product candidates that will be safe and effective. 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.

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 Cell Cure 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, 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.

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 have received RMAT designation from the FDA for OPC1 for the treatment of subacute spinal cord injuries. There is no assurance that we will be able to 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.

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 14 (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 technology, human pluripotent stem cells, and hES cell lines, hydrogel technology and other technology from other companies.

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;

• 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;

• 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.

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, our competitors could use our technology and create products that compete with our products, without paying license fees or royalties to us. The preparation, filing, and prosecution of patent applications 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 from infringing uses.

We also rely on trade secrets, including know-how, technology and other unpatented proprietary information, to establish and maintain a competitive position for our product candidates and any products. We seek to protect these trade secrets, in part, by entering into nondisclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into invention and patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing or unwilling to protect trade secrets. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secrets.

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 and defend patent and other intellectual property rights that are important to the commercialization of our products and product candidates. The degree of patent 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 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 and patented technologies, 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 European Union 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 Cell Cure'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 such as the COVID-19 pandemic, 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 manmade disasters, prolonged public health emergencies, such as the COVID-19 pandemic, and wars and other armed conflicts, such as the ongoing wars between Russia and Ukraine and between Israel and Hamas;

• market conditions in the biotechnology sector and general political and economic conditions, including the legal, political and economic uncertainty related to the upcoming 2024 U.S. Presidential election; 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 24.3% of our outstanding common shares as of December 31, 2023 and approximately 26.2% of our outstanding common shares as of March 1, 2024 as a result of the purchase by certain of our directors or their affiliates in our registered direct offering completed in February 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 future issuance of additional securities may be dilutive to our shareholders and may create downward pressure on the trading price of our common shares.

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, 2023, we had 21,663,463 common shares reserved for issuance upon the exercise of outstanding options and 667,869 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 11 (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 1, 2024, $40 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.

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 for a substantial period of time at a low price per share, which we believe would be an average of less than $0.20 over 30 days, and we fail to effect a reverse stock split within a reasonable time after being notified by the exchange, the exchange will consider delisting 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. If a security sells at a price below $0.06, the exchange may immediately suspend the security from further trading on 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. If our common shares are removed from the index because they do not meet the criteria for continued

inclusion, 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.

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 Israel-Hamas war 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 Cell Cure 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.

The Israel-Hamas war, the war in 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, terrorist attacks or other armed conflicts involving Israel, such as the Israel-Hamas war that began in October 2023, 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.

There is an increasing focus from certain investors, employees, collaborators, and other stakeholders concerning ESG matters. While we have internal efforts directed at ESG matters and preparations for any increased required future disclosures, we may be perceived to be not acting responsibly in connection with these matters, which could negatively impact us. Moreover, the SEC has recently proposed, and may continue to propose, certain mandated ESG reporting requirements, such as the SEC's proposed rules designed to enhance and standardize climate-related disclosures, which, if adopted, would significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders deem to negatively impact our reputation, which could adversely affect the price of our common shares. At the same time, anti-ESG sentiment has gained some momentum across the United States, with several states having enacted or proposed "anti-ESG" policies or legislation, which may conflict with other laws or regulations. The criteria by which companies' ESG practices are assessed are evolving, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. Alternatively, if we elect not to or are unable to satisfy new criteria or do not meet the criteria of a specific third-party

provider of ESG ratings, some investors may conclude that our policies with respect to ESG are inadequate and choose not to invest in us.

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.

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 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 14 (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. The lease for office space we previously leased in Alameda, California expired on January 31, 2023.

Cell Cure Facilities

Under various leases, Cell Cure 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 14 (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 1, 2024, there were approximately 358 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, 2023, there were no unregistered sales of equity securities by us during the year ended December 31, 2023.

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, 2023, 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, 2023 as compared to the year ended December 31, 2022. 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 to address unmet medical needs. Our programs are based on our proprietary cell-based technology platform and associated development 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 created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages. Cells derived from such lineages 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 augment the patient's functional activity.

Our business strategy is to efficiently leverage our technology platform and our development, formulation, delivery, 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. 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.

Our most advanced unpartnered product candidate is OPC1, an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury ("SCI"). OPC1 has been tested in two clinical trials to date: a five patient Phase 1 clinical trial in acute thoracic SCI, where all subjects were followed for at least 10 years, and a 25 patient Phase 1/2a multicenter clinical trial in subacute cervical SCI, where all subjects were evaluated for at least two years. Results from both 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"). In February 2024, we announced the clearance by the FDA of our Investigational New Drug ("IND") amendment for OPC1. Pursuant to the IND amendment, we have initiated activities to open our first clinical site in the 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 to administer OPC1 to

the spinal parenchyma in subacute and chronic SCI patients. We expect the initial clinical site opening to occur in the second quarter of 2024.

Our neuroscience focused pipeline of allogeneic, or “off-the-shelf”, cell therapy programs currently includes:

• RG6501 (OpRegen), an allogeneic RPE cell replacement therapy currently in a Phase 2a multicenter, open-label, single arm clinical trial, being conducted by Genentech, for the treatment of GA secondary to AMD, also known as atrophic or dry AMD.

• OPC1, an allogeneic oligodendrocyte progenitor cell therapy which will be evaluated in the DOSED clinical study to test the safety and utility of a novel spinal cord delivery device in both subacute and chronic spinal cord injuries and continues to be evaluated in long-term follow-up from a Phase 1/2a multicenter clinical trial for subacute cervical spinal cord injuries.

• ANP1, an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of debilitating 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 novel hypoimmune induced pluripotent stem cell (“iPSC”) line being developed in collaboration with Eterna Therapeutics Inc. (“Eterna”), which will be evaluated for differentiation into cell transplant product candidates for central nervous system ("CNS") diseases and other neurology indications.

Other Programs

We have additional undisclosed product candidates being considered for development, and we may consider others, which cover a range of therapeutic areas and unmet medical needs. 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.

Our efforts to broaden the application of our cell therapy platform and support long-term growth include a strategic collaboration we entered into with Eterna. This reflects a portion of our corporate strategy to capitalize on our process development capabilities by combining them with cell engineering and/or editing technologies, to create novel cell therapies with potentially superior product profiles compared to currently marketed therapies, if any.

In addition to seeking to create value for shareholders by developing product candidates and advancing those candidates through clinical development, we also may seek to create value from our non-core intellectual property or related technologies and capabilities, through licensing collaborations and/or other strategic transactions, such as our business development approach to our VAC dendritic cell therapy platform.

Israel-Hamas War

All of our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, are conducted by our subsidiary, Cell Cure, at its facility in Jerusalem, Israel, and more than two-thirds of our employees are Cell Cure employees who are based in the same facility. As of the date of this report, our operations have not been materially or adversely impacted as a result of the Israel-Hamas war that began in October 2023.

As a result of safety concerns and in response to government-imposed restrictions on movement and travel and other precautions taken to address the ongoing war, our operations at our facilities in Israel were temporarily impacted. Further, a number of our employees in Israel are members of the military reserves and subject to immediate call-up in response to the war in Israel. A number of our employees in Israel have been activated for military duty and additional employees may also be activated. In addition, the general impact on employees operating in a region at war could adversely impact our operations. Although we have business continuity plans in place to address medium- or long-term disruptions that could result from the war, 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, terrorist attacks or other armed conflicts involving Israel, such as the Israel-Hamas war that began in October 2023, 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, research and development costs, impairment of long-lived intangible assets, deferred income taxes and tax reserves, and assumptions used to value stock-based awards or other equity instruments. 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, 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. For further information, see Note 3 (Revenue) in the accompanying notes to the consolidated financial statements included in this report.

Research and development costs

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 expenses which have an alternative future use will be capitalized as intangible assets, and 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 on our consolidated statements of operations. We estimate preclinical, clinical, and other research related expenses based on services performed, pursuant to arrangements with contract research organizations, that conduct studies and research on our behalf. We estimate these expenses based on regular reviews with internal management personnel and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. Based upon the combined inputs of internal and external resources, if the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the expense accordingly. 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.

Impairment of long-lived intangible assets

Our long-lived 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 7 (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, 2023 and 2022. 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, 2023 and 2022. For further information, see Note 13 (Income Taxes) in the accompanying notes to the consolidated financial statements included in this report.

Stock-based compensation

We follow accounting standards governing share-based payments, which require the measurement and recognition of compensation expense for all share-based compensation awards made to directors and employees, including employee stock options, based on estimated fair values. We utilize the Black-Scholes option pricing model. Our determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as 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; (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 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 unit ("RSUs") awards 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. For RSUs subject to a market condition, the grant-date fair value is estimated using a Monte Carlo valuation model. The model is based on random projections of stock price paths and must be repeated numerous times to achieve a probabilistic assessment. Lineage recognizes stock-based compensation expense for RSUs subject to market-based vesting conditions regardless of whether it becomes probable that the vesting conditions will be achieved, and stock-based compensation expense for such RSUs is not reversed if vesting does not actually occur.

Although the fair value of employee stock options is 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. For further information, see Note 12 (Stock-Based Awards) to our consolidated financial statements included in this report.

Results of Operations

Comparison of Years Ended December 31, 2023 and 2022

Revenues

The following table shows our revenues for the years ended December 31, 2023 and 2022 (amounts in thousands except percentages).

	Year Ended December 31,		Dollar Increase (Decrease)	Percent Increase (Decrease)
	2023	2022		
Collaboration revenues	$ 7,588	$ 13,367	$ (5,779)	(43)%
Royalties, license and other revenues	1,357	1,336	21	2%
Total revenues	8,945	14,703	(5,758)	(39)%
Cost of sales	(671)	(728)	57	(8)%
Gross profit	$ 8,274	$ 13,975	$ (5,701)	(41)%

Total revenues for the year ended December 31, 2023 were $8.9 million compared to $14.7 million for the year ended December 31, 2022. The $5.8 million decrease in collaboration revenues was primarily due to lower collaboration revenues under the Roche Agreement, related to an overall increase in the total estimated costs to be incurred under this collaboration agreement. Collaboration revenues may fluctuate from period to period based on changes in estimated costs to support performance obligations. The $7.6 million is part of the $50.0 million upfront payment which was included in deferred revenues at December 31, 2022 (see Note 3 (Revenue) to our consolidated financial statements included in this report for additional information).

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

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 expenses which have an alternative future use will be capitalized as intangible assets, and 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 our 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. 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, 2023 and 2022 (amounts in thousands, except percentages).

	Year Ended December 31,		Dollar Increase (Decrease)	Percent Increase (Decrease)
	2023	2022		
Research and development	$ 15,705	$ 13,987	$ 1,718	12%
General and administrative	17,302	22,508	(5,206)	(23)%
Total operating expenses	$ 33,007	$ 36,495	$ (3,488)	(10)%

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	
	2023	2022	2023	2022
OpRegen®	$ 5,488	$ 5,043	35%	36%
OPC1	6,214	5,039	39%	36%
ANP1	2,012	741	13%	5%
PNC1	487	458	3%	3%
RND1	754	10	5%	1%
All other programs	750	2,696	5%	19%
Total research and development expenses	$ 15,705	$ 13,987	100%	100%

Research and development expenses. For the twelve months ended December 31, 2023, the $1.7 million year-over-year increase in total research and development expenses is mainly attributable to a $0.4 million increase in our OpRegen program, a $1.2 million increase in our OPC1 program, and a $2.0 million increase in preclinical programs. These increases were partially offset by a $1.9 million decrease in our other research and development programs, primarily related to reduced manufacturing activities.

General and administrative expenses. For the twelve months ended December 31, 2023, the $5.2 million year-over-year decrease in general and administrative expenses was primarily attributable to (i) a $4.2 million decrease in legal and litigation expense, primarily due to the settlement of the Asterias litigation, and (ii) an overall reduction in costs incurred for services provided by third parties, consulting costs and rent-related expenses.

Other Income and Expenses, Net

The following table shows the amount of other income (expenses), net, during the year ended December 31, 2023 and 2022 (in thousands):

Other income (expenses), net	Year Ended December 31, 2023	2022	Dollar Increase (Decrease)	Percent Increase (Decrease)
Interest income, net	$ 1,629	$ 829	$ 800	97%
Loss on marketable equity securities, net	(176)	(2,194)	2,018	(92)%
Gain on revaluation of warrant liability	2	225	(223)	(99)%
Other expenses, net	(4)	(2,152)	2,148	(100)%
Total	$ 1,451	$ (3,292)	$ 4,743	(144)%

Interest income, net. During the third quarter of 2022, we began to invest our excess cash in short-term U.S. Treasury securities resulting in an increase in interest income. The increasing interest rates from 2022 to 2023 also contributed to the year over year increase. See Note 4 (Marketable Debt Securities) to our consolidated financial statements included in this report for additional information regarding our marketable debt securities.

Marketable equity securities, net. We expect our net gain or loss on marketable equitable securities to fluctuate based on mark-to-market adjustments resulting from changes in the market price of the common stock of OncoCyte Corporation (“OncoCyte”) and Hadasit Bio-Holdings Ltd (“HBL”). These shares are carried at fair market value on our consolidated balance sheet. See Note 5 (Marketable Equity 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, 2023 and 2022, Lineage recognized a net loss on marketable equity securities of $0.2 million and $2.2 million, respectively, primarily related to changes in the fair market value of the securities during the respective periods.

Other expenses, net. For the years ended December 31, 2023 and 2022, other expenses, net primarily includes foreign currency transaction losses of $0.5 million and $2.0 million, respectively. The majority of these foreign

currency transaction gains and losses are generated by Cell Cure's intercompany notes payable and notes receivable with Lineage, which is U.S. dollar-denominated, while Cell Cure's functional currency is the Israeli New Shekel ("ILS"). The year-over-year decrease in foreign currency transaction losses was the result of the combined impact of (i) changes in intercompany balances in 2023 as compared to 2022, and (ii) volatility of the ILS as compared to the U.S. dollar during 2023 and 2022. For the year ended December 31, 2023, the foreign currency transaction losses of $0.5 million was offset by the employee retention credit (discussed below) which was not applicable in the prior year.

Under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), the Company is eligible for an employee retention credit subject to certain criteria. The employee retention credit is a payroll tax refund per employee, which was designed by the U.S. Treasury Department to assist businesses that retained employees during the COVID pandemic. For the year ended December 31, 2023, we recorded an employee retention credit of $0.5 million, 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.

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 in-process research and development ("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. Lineage did not record a deferred tax benefit for the year ended December 31, 2022.

For the year ended December 31, 2022, Lineage recorded a withholding tax of $0.5 million on interest expense deemed paid to Lineage from Cell Cure on the purchase of intellectual property pursuant to the U.S. Israeli tax treaty. There was no comparable tax expense recorded for the year ended December 31, 2023. See Note 13 (Income Taxes) for additional information.

Liquidity and Capital Resources

Overview

As of December 31, 2023, our accumulated deficit was $384.9 million. For the year ended December 31, 2023, we incurred a loss from operations of $24.7 million and had negative cash flow from operations of $28.6 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, 2023, we had $35.5 million in cash, cash equivalents and marketable securities. In February 2024, we raised approximately $13.8 million in net proceeds through a registered direct offering of our common shares.

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. We do not expect sales of shares of our former subsidiaries that we own to be a significant source of additional funds. See Note 5 (Marketable Equity Securities) to our consolidated financial statements included in this report for additional information regarding those marketable equity securities. During the year ended December 31, 2023, we issued and sold 4,774,603 common shares under our at-the-market offering program for gross proceeds of $6.6 million.

As of December 31, 2023, $57.2 million remained available for sale under our at-the-market offering program. As of March 1, 2024, $40 million was available for sale under our ATM offering program. See Note 11 (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, 2023	2022
Cash provided by (used in):		
Operating activities	$ (28,566)	$ 1,059
Investing activities	46,449	(46,159)
Financing activities	6,423	1,632
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(250)	(873)
Net increase (decrease) in cash and restricted cash	$ 24,056	$ (44,341)

Cash (used in) provided by operating activities

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 the 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.

Net cash provided by operating activities was $1.1 million for the year ended December 31, 2022, which primarily reflects the net changes in assets and liabilities of $18.7 million, plus the $5.0 million in non-cash expenses for stock-based compensation and depreciation and amortization, less the loss from operations of $22.5 million. The change in assets and liabilities was impacted by the receipt of the $50.0 million upfront payment under the Roche Agreement, and subsequent related payments to the IIA and Hadasit (see Note 14 (Commitments and Contingencies) to the consolidated financial statements included in this report for further explanation), partially offset by the accrual of the litigation settlement also as described in Note 14 (Commitments and Contingencies) to the consolidated financial statements included in this report. The loss on marketable equity securities and foreign currency remeasurement had no effect on the cash flows.

Cash provided by (used in) investing activities

Cash provided by investing activities for the year ended December 31, 2023 was $46.4 million and consisted of $63.3 million in U.S. Treasury securities which matured 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 used in investing activities for the year ended December 31, 2022 was $46.2 million and consisted of $53.4 million related to the purchase of U.S. Treasury securities and $0.4 million for the purchase of equipment, offset with $7.7 million in U.S. Treasuries which matured during the year.

Cash provided by financing activities

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.

Cash provided by financing activities for the year ended December 31, 2022 was $1.6 million and consisted of $1.0 million of proceeds from the exercise of warrants to purchase shares of Cell Cure and $0.6 million of proceeds from the exercise of employee stock options.

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 to provide 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've 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 14 (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've received are uncertain and may fluctuate significantly from period to period. As of December 31, 2023, 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, Cell Cure 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 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, 2023 the aggregate cap amount was approximately $93.2 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, 2023, 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 14 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information.

Under the terms of the leases for the facilities from which Cell Cure and Lineage operate, a total of $3.2 million of rent payments will become due, of which $1.0 million will become due in 2024.

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 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 such as the COVID-19 pandemic, geopolitical conflicts, political and economic instability, inflation and relatively high interest rates, and other macroeconomic factors.

We believe that our $35.5 million in cash, cash equivalents and marketable securities at December 31, 2023, together with the approximately $13.8 million in net proceeds from the registered direct offering of our common shares we completed in February 2024, will be sufficient to fund our planned operations through for least twelve months from the issuance date of our consolidated financial statements included elsewhere in this report.

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

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Lineage Cell Therapeutics, Inc. and Subsidiaries (collectively, the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity, and cash flows for each of the two years in the period 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 2022, and the results of its operations and its cash flows for each of the two years in the period 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 audits. 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 audits 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 audits 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 audits 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 audits 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 audits provide 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 a critical audit matter 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.

Accounting for Revenue Recognition

Description of the Matter

The Company recorded deferred revenue of $28.7 million as of December 31, 2023 and revenue of $7.6 million for the year ended December 31, 2023 from a collaboration agreement. As described in Note 3, the Company has concluded that 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.

Auditing the Company's accounting for revenues from this collaboration agreement was especially complex and required significant judgments, primarily in evaluating the period in which the performance obligation was satisfied and evaluating estimates of total expected inputs under the input method for revenue recognized over time.

How We Addressed the Matter in Our Audit

To test the measurement of efforts toward satisfying the performance obligation, our audit procedures included, among others, gaining an understanding of the internal control process over revenue from collaboration agreements, reviewing management's analysis for accuracy and completeness by agreeing data to the underlying agreement, evaluating the assumptions used for forecasting, performing analytical procedures on budget to actual and forecasted costs, evaluating the application of the input method for the recognition of revenue, and on a sample basis, testing the estimated costs and actual costs incurred to underlying source documents.

/s/ WithumSmith+Brown, PC

We have served as the Company's auditor since 2014.

San Francisco, California
March 7, 2024

PCAOB ID Number 100

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

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 35,442	$ 11,355
Marketable securities	50	46,520
Accounts receivable, net (Note 3)	745	297
Prepaid expenses and other current assets	2,204	1,828
Total current assets	38,441	60,000
NONCURRENT ASSETS		
Property and equipment, net (Notes 6 and 14)	4,767	5,673
Deposits and other long-term assets	577	627
Goodwill	10,672	10,672
Intangible assets, net	46,562	46,692
TOTAL ASSETS	$ 101,019	$ 123,664
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 6,270	$ 8,608
Operating lease liabilities, current portion (Note 14)	830	916
Finance lease liabilities, current portion (Note 14)	52	36
Deferred revenues, current portion (Note 3)	10,808	9,421
Total current liabilities	17,960	18,981
LONG-TERM LIABILITIES		
Deferred tax liability (Note 13)	273	2,076

Deferred revenues, net of current portion (Note 3)	18,693	27,725
Operating lease liabilities, net of current portion (Note 14)	1,979	2,860
Finance lease liabilities, net of current portion (Note 14)	91	84
Other long-term liabilities	—	2
TOTAL LIABILITIES	38,996	51,728
Commitments and contingencies (Note 14)		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of December 31, 2023 and 2022	—	—
Common shares, no par value, 450,000 and 250,000 shares authorized as of December 31, 2023 and 2022, respectively; 174,987 and 170,093 shares issued and outstanding as of December 31, 2023 and 2022, respectively	451,343	440,280
Accumulated other comprehensive loss	(3,068)	(3,571)
Accumulated deficit	(384,856)	(363,370)
Lineage's shareholders' equity	63,419	73,339
Noncontrolling deficit	(1,396)	(1,403)
Total shareholders' equity	62,023	71,936

TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 101,019	$ 123,664

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,	
	2023	2022
REVENUES:		
Collaboration revenues	$ 7,588	$ 13,367
Royalties, license and other revenues	1,357	1,336
Total revenues	8,945	14,703
Cost of sales	(671)	(728)
Gross profit	8,274	13,975
OPERATING EXPENSES:		
Research and development	15,705	13,987
General and administrative	17,302	22,508
Total operating expenses	33,007	36,495
Loss from operations	(24,733)	(22,520)
OTHER INCOME (EXPENSES):		
Interest income, net	1,629	829
Loss on marketable equity securities, net	(176)	(2,194)
Gain on revaluation of warrant liability	2	225
Other expenses, net	(4)	(2,152)
Total other income (expenses), net	1,451	(3,292)
LOSS BEFORE INCOME TAXES	(23,282)	(25,812)
Provision for income tax benefit (expense)	1,803	(541)

NET LOSS	(21,479)	(26,353)
Net (income) loss attributable to noncontrolling interest	(7)	80
NET LOSS ATTRIBUTABLE TO LINEAGE	(21,486)	(26,273)
	$	$
NET LOSS PER COMMON SHARE ATTRIBUTABLE TO LINEAGE		
Basic and Diluted	(0.12)	(0.15)
	$	$
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		
Basic and Diluted	172,663	169,792

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,	
	2023	2022
NET LOSS	$ (21,479)	$ (26,353)
Other comprehensive loss, net of tax:		
Foreign currency translation adjustment	353	1,790
Unrealized gain (loss) on marketable debt securities	150	(150)
COMPREHENSIVE LOSS	(20,976)	(24,713)
Less: Comprehensive (income) loss attributable to noncontrolling interest	(7)	80
COMPREHENSIVE LOSS ATTRIBUTABLE TO LINEAGE COMMON SHAREHOLDERS	$ (20,983)	$ (24,633)

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 Deficit	Noncontrolling Deficit	Accumulated Other Comprehensive Income / (Loss)	Total Shareholders' Equity
	Shares	Amount				
BALANCE - December 31, 2021	**169,477**	**$ 434,529**	**$ (337,097)**	**$ (1,323)**	**$ (5,211)**	**$ 90,898**
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	20	(17)	—	—	—	(17)
Stock-based compensation	—	4,287	—	—	—	4,287
Shares issued upon exercise of stock options	596	490	—	—	—	490
Subsidiary warrant exercise, net	—	991	—	—	—	991
Unrealized loss on marketable debt securities	—	—	—	—	(150)	(150)
Foreign currency translation gain	—	—	—	—	1,790	1,790
NET LOSS	—	—	(26,273)	(80)	—	(26,353)
BALANCE - December 31, 2022	**170,093**	**440,280**	**(363,370)**	**(1,403)**	**(3,571)**	**71,936**
Shares issued through ATM	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 gain	—	—	—	—	353	353
NET LOSS	—	—	(21,486)	7	—	(21,479)

			(	(	(	
	174,987	451,343	384,856	1,396	3,068	62,023
BALANCE - December 31, 2023	$	$	)	$)	$)	$

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,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	$ (21,486)	$ (26,273)
Net income (loss) allocable to noncontrolling interest	7	(80)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash (used in) provided by operating activities:		
Loss on marketable equity securities, net	176	2,194
Accretion of income on marketable debt securities	(679)	(501)
Depreciation expense, including amortization of leasehold improvements	562	582
Change in right-of-use assets and liabilities	91	(35)
Amortization of intangible assets	130	145
Stock-based compensation	4,640	4,287
Gain on revaluation of warrant liability	(2)	(225)
Deferred income tax benefit	(1,803)	—
Foreign currency remeasurement and other loss	602	2,272
Gain on sale of assets	—	(11)
Changes in operating assets and liabilities:		
Accounts receivable, net (Note 3)	(446)	50,314
Prepaid expenses and other current assets	(418)	446
Accounts payable and accrued liabilities (Note 7)	(2,295)	(18,702)
Deferred revenue (Note 3)	(7,645)	(13,354)
Net cash (used in) provided by operating activities	(28,566)	1,059

CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of marketable equity securities	196	—
Purchases of marketable debt securities	(16,403)	(53,412)
Maturities of marketable debt securities	63,330	7,666
Purchase of equipment	(674)	(413)
Net cash provided by (used in) investing activities	46,449	(46,159)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	88	648
Common shares received and retired for employee taxes paid	(37)	(17)
Proceeds from exercise of subsidiary warrants, net	—	991
Proceeds from sale of common shares	6,625	148
Payments for offering costs	(199)	(106)
Repayment of finance lease liabilities	(54)	(32)
Net cash provided by financing activities	6,423	1,632
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(250)	(873)
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	24,056	(44,341)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	11,936	56,277
At end of the period	$ 35,992	$ 11,936
SUPPLEMENTAL DISCLOSURES		
Cash paid for interest	$ 10	$ 13
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:		
Property and equipment expenditures in accounts payable	$ 8	$ 28
Amortization of financing costs	$ 22	$ -

Receivable from exercise of stock options	$ -	$ 32

Reconciliation of cash, cash equivalents and restricted cash, end of period:

Cash and cash equivalents	$ 35,442	$ 11,355
Restricted cash included in deposits and other long-term assets (see Note 14 (Commitments and Contingencies))	550	581
Total cash, cash equivalents, and restricted cash	$ 35,992	$ 11,936

See accompanying 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 to address unmet medical needs. Our programs are based on our proprietary cell-based technology platform and associated development 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 created by applying directed differentiation protocols to established, well-characterized, and self-renewing pluripotent cell lines. These protocols generate cells with characteristics associated with specific and desired developmental lineages. Cells derived from such lineages 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 augment the patient's functional activity.

Our business strategy is to efficiently leverage our technology platform and our development, formulation, delivery, 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. 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.

Our most advanced unpartnered product candidate is OPC1, an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury (“SCI”). OPC1 has been tested in two clinical trials to date; a five patient Phase 1 clinical trial in acute thoracic SCI, where all subjects were followed for at least 10 years, and a 25 patient Phase 1/2a multicenter clinical trial in subacute cervical SCI, where all subjects were evaluated for at least two years. Results from both 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”). In February 2024, we announced the clearance by the FDA of our Investigational New Drug ("IND") amendment for OPC1. Pursuant to the IND amendment, we have initiated activities to open our first clinical site in the 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 to administer OPC1 to the spinal parenchyma in subacute and chronic SCI patients. We expect the initial clinical site opening to occur in the second quarter of 2024.

Our neuroscience focused pipeline of allogeneic, or “off-the-shelf”, cell therapy programs currently includes:

- RG6501 (OpRegen), an allogeneic RPE cell replacement therapy currently in a Phase 2a multicenter, open-label, single arm clinical trial, being conducted by Genentech, for the treatment of GA secondary to AMD, also known as atrophic or dry AMD.
- OPC1, an allogeneic oligodendrocyte progenitor cell therapy which will be evaluated in the DOSED clinical study to test the safety and utility of a novel spinal cord delivery device in both subacute and chronic spinal cord injuries and continues to be evaluated in long-term follow-up from a Phase 1/2a multicenter clinical trial for subacute cervical spinal cord injuries.

• ANP1, an allogeneic auditory neuron progenitor cell transplant currently in preclinical development for the treatment of debilitating 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 novel hypoimmune induced pluripotent stem cell (“iPSC”) line being developed in collaboration with Eterna Therapeutics Inc. (“Eterna”), which will be evaluated for differentiation into cell transplant product candidates for central nervous system ("CNS") diseases and other neurology indications.

Other Programs

We have additional undisclosed product candidates being considered for development, and we may consider others, which cover a range of therapeutic areas and unmet medical needs. 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.

Our efforts to broaden the application of our cell therapy platform and support long-term growth include a strategic collaboration we entered into with Eterna. This reflects a portion of our corporate strategy to capitalize on our process development capabilities by combining them with cell engineering and/or editing technologies, to create novel cell therapies with potentially superior product profiles compared to currently marketed therapies, if any.

In addition to seeking to create value for shareholders by developing product candidates and advancing those candidates through clinical development, we also may seek to create value from our non-core intellectual property or related technologies and capabilities, through licensing collaborations and/or other strategic transactions, such as our business development approach to our VAC dendritic cell therapy platform.

Use of estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. 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. Significant estimates and assumptions which are subject to significant judgment include those related to revenue recognition under collaborative agreements, research and development costs, impairment of long-lived intangible assets, deferred income taxes and tax reserves, and assumptions used to value stock-based awards or other equity instruments. Actual results could differ materially from those estimates.

Principles of consolidation

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, 2023.

Subsidiary	Field of Business	Lineage Ownership	Country
Cell Cure Neurosciences Ltd .	Manufacturing of Lineage’s product candidates	94 %[1][2]	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.

(2) In July 2022, Hadasit Bio-Holdings Ltd. exercised warrants to purchase

21,999
ordinary shares of Cell Cure Neurosciences Ltd. ("Cell Cure"). Lineage’s own er ship percentage of Cell Cure decreased to approximately

94
% as a result of the warrant exercise. As of December 31, 2023 , our ownership percent age of Cell Cure was approximately

94
%.

All material intercompany accounts and transactions have been eliminated in consolidation. As of December 31, 2023, Lineage consolidated 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, 2023, we had $

35.5

million of cash, cash equivalents and marketable securities. Based on our current operating plan, we believe that our cash, cash equivalents and marketable securities, combined with the $

13.8

million net raised in February 2024 through a registered direct offering (See Note 19 - Subsequent Events), 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, OncoCyte Corporation and AgeX Therapeutics, Inc., receipt of proceeds from research grants, revenues from collaborations, royalties from product sales and sales of research products and services.

As of December 31, 2023, $

57.2

million remained available for sale under our at the market offering program ("ATM"). See Note 11 (Shareholders' Equity) for additional information.

As of December 31, 2023, we had $

0.1

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 the recent pandemics, including the COVID-19 pandemic, 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, royalties and patent maintenance costs. 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 14 (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 costs 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, 2023, 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

Revenue recognition - Lineage recognizes revenue in accordance with Financial Accounting Standards Board ("FASB") 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.

Marketable Debt Securities - Lineage accounts for its holdings of U.S. Treasury securities in accordance with 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. All marketable debt securities purchased with an original maturity of more than three months have been classified as "available-for-sale" and are carried at estimated fair value. 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), net. 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.

Lineage's investments are accounted for as available-for-sale securities and are carried at fair value on the consolidated balance sheets. 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 and comprehensive loss. 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 of operations and 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 Debt Securities) for additional information.

Marketable equity securities - Lineage accounts for the shares it holds in OncoCyte and HBL 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.

OncoCyte shares have readily determinable fair values quoted on the NYSE American under trading symbol "OCX". 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).

Royalties from product sales and license fees - 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.

Collaborative agreements - In December 2021, Lineage entered into the Roche Agreement for the development and commercialization of OpRegen. Under the terms of the Roche Agreement, Roche agreed to pay 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 is also eligible to receive tiered double-digit percentage royalties on net sales of OpRegen. See Note 14 (Commitments and Contingencies) for additional information regarding this agreement.

In April 2021, Lineage entered a worldwide license and collaboration agreement with Immunomic Therapeutics, Inc.("ITI") for the development and commercialization of an allogeneic version of an immunomic oncology target utilizing the VAC platform. Under the terms of this agreement, Lineage is entitled to upfront licensing fees totaling up to $

2.0
million, $

1.0
million of which was received in 2021, and up to $

67.0
million in development and commercial milestones across multiple indications. Lineage also will be eligible to receive royalties up to

10
% on net sales of future products. See Note 14 (Commitments and Contingencies) for additional information regarding this agreement.

As of December 31, 2023, deferred revenue on the consolidated balance sheet, related to the collaboration agreements with each of Roche and ITI, was $

28.7
million and $

0.8
million, respectively. For the twelve months ended December 31, 2023, we recognized $

7.6
million of revenue on the consolidated statement of operations, related to the Roche Agreement. See Note 3 (Revenue) for additional information.

We review collaborative agreements to determine if the accounting treatment falls under Accounting Standards Codification, *Topic 606, Revenue from Contracts with Customers* (“ASC 606”), or Accounting Standards Codification *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 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.

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 restricted stock units ("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, 2023 and 2022, 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,	
	2023	2022
Stock options	21,663	18,173
Restricted stock units	668	939

Accounts receivable, net – Net accounts receivables amounted to $

0.7
million and $

0.3
million as of December 31, 2023 and 2022, respectively. Net trade receivables include an allowance for doubtful accounts of approximately $

0.1

million as of December 31, 2023 and 2022, for those amounts deemed uncollectible by Lineage. Lineage establishes an allowance for doubtful accounts based on the evaluation of the collectability of its receivables on 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. The net balance in accounts receivable is primarily comprised of royalty-based revenue, and therefore Lineage has applied the CECL considerations to this specific balance. 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.

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 and finance leases are included as assets in property and equipment; finance and lease liabilities are included in the current and long-term liabilities in the consolidated balance sheets.

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.

Going concern assessment – Lineage assesses going concern uncertainty for its consolidated financial statements to determine if Lineage has sufficient cash and cash equivalents on hand and working capital to operate for a period of at least one year from the date the consolidated financial statements are issued or are available to be issued, which is referred to as the "look-forward period" as defined by FASB's ASU No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to Lineage, Lineage will consider various scenarios,

forecasts, projections, and estimates, and Lineage will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and its ability to delay or curtail those expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, Lineage makes certain assumptions concerning its ability to curtail or delay research and development programs and expenditures within the look-forward period in accordance with ASU No. 2014-15.

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, 2023 and 2022, Lineage had $

21.0
million and $

4.1
million in money market funds, respectively, considered to be cash equivalents. Additionally, as of December 31 2023, Lineage had $

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, 2023 and 2022, the Company had restricted cash of $

0.1

million required to be set aside for its corporate credit card facility. Additionally, Cell Cure has restricted cash related to its office lease. See Note 14 (Commitments and contingencies).

Concentrations of credit risk and significant sources of supply – 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.

Property and equipment, net – Property and equipment is 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. Leasehold improvements are amortized over the shorter of the useful life or the lease term. See Note 6 (Property and Equipment, Net) for additional information.

Long-lived intangible assets – Long-lived 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 long-lived 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

no

t recognize any impairment losses for the years ended December 31, 2023 and 2022.

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.

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 expenses which have an alternative future use will be capitalized as intangible assets, and 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 on 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.

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 Cell Cure and ESI, Lineage's consolidated foreign subsidiaries. For the years ended December 31, 2023 and 2022, the total comprehensive loss includes gains from foreign currency translation adjustments, of $

0.4
million and $

1.8
million, respectively, net of an insignificant amount of tax. As of December 31, 2023 and 2022, we had cumulative translation adjustments of $

2.7
million and $

3.1
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. The majority of Lineage's foreign currency transaction gains and losses are generated by Cell Cure's intercompany debt owed to Lineage, which is U.S. dollar-denominated, while Cell Cure's functional currency is the Israeli New Shekel ("ILS"). 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.* These foreign currency remeasurement gains and losses are included in other expenses, net. For the years ended December 31, 2023 and 2022, other expenses, net includes foreign currency transaction losses of $

0.5
million and $

2.0
million, respectively.

Income taxes - Lineage accounts for income taxes in accordance with ASC 740, *Income Taxes*, 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, 2023 and 2022. 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, 2023 and 2022.

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 13 (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.

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, officers and directors 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 and officers' 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 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 12 (Stock-Based Awards) for additional details).

For employee and director 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 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. For RSUs subject to a market condition, the grant-date fair value is estimated using a Monte Carlo valuation model. The model is based on random projections of stock price paths and must be repeated numerous times to achieve a probabilistic assessment. Lineage recognizes stock-based compensation expense for RSUs subject to market-based vesting conditions regardless of whether it becomes probable that the vesting conditions will be achieved, and stock-based compensation expense for such RSUs is not reversed if vesting does not actually occur.

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.

Recently Adopted Accounting Pronouncements -

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 is intended to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 is effective for Lineage beginning January 1, 2023 and its adoption did no t have a significant effect on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies that are adopted by the Company as of the specified effective date. The Company has evaluated recently issued accounting pronouncements and does not believe any will have a material impact on the Company's consolidated financial statements or related financial statement disclosures.

3. Revenue

Our disaggregated revenues were as follows (in thousands):

	Year Ended December 31,	
	2023	**2022**
Revenues under collaborative agreements		
Upfront license fees [1]	$ 7,588	$ 13,367
Total revenues under collaborative agreements	7,588	13,367
Royalties, license and other revenues [2]	1,357	1,336
Total revenue	$ 8,945	$ 14,703

(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, $

87,000
and $

0
was included within deferred revenues as contract liabilities as of January 1, 2023 and 2022, 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 net income (loss) 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, 2023 was $

31.1
million, of which $

29.5
million has been collected and is reported as deferred revenues. The $

31.1
million is expected to be 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, 2023	December 31, 2022
Accounts receivable, net - beginning of the period [1]	$ 297	$ 50,640
Accounts receivable, net - end of the period [1]	$ 676	$ 297
Contract liabilities [1][2]		
Deferred revenues - beginning of the period	$ 37,146	$ 50,500
Deferred revenues - end of the period	$ 29,501	$ 37,146

(1) Excludes amounts outside the scope of ASU 2014-09 - Revenue from Contracts with Customers (Topic 606).

(2) As of December 31, 2023 and 2022, $

10.8
million and $

9.4
million, respectively, was recorded within current deferred revenues with the remainder included within long-term deferred revenue on the consolidated balance sheet.

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, 2023 (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 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, 2024.

(5) Regarding the accounting treatment for the collaborative agreement, 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 completed by December 31, 2026.

4. Marketable Debt Securities

As of December 31, 2023, Lineage had $

8.9

million in marketable debt securities classified in the consolidated balance sheet within cash equivalents, as they had an original maturity of three months or less when purchased. As of December 31, 2022, Lineage had $

46.0

million in marketable debt securities which had an original maturity of more than three months when purchased, and therefore are not classified as cash equivalents on the consolidated balance sheet.

The following table is a summary of available-for-sale debt securities classified within cash and cash equivalents or marketable securities in the Company's consolidated balance sheet as of December 31, 2023 and 2022 (in thousands):

	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

	December 31, 2022			
Financial Assets:	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasury securities	$ 46,247	$ 2	$ (152)	$ 46,097
Total	$ 46,247	$ 2	$ (152)	$ 46,097

The Company has not recognized an allowance for credit losses on any securities in an unrealized loss position as of December 31, 2023 and 2022. We believe that the individual unrealized losses represent temporary declines resulting from changes in interest rates, and we intend to hold these marketable securities to their maturity. The Company currently does not intend to sell these securities prior to maturity and does not consider these investments to be other-than-temporarily impaired at December 31, 2023.

As of December 31, 2023, 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	$ 8,855	$ 8,856
Total available-for-sale debt securities	$ 8,855	$ 8,856

5. 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 consist of the shares of stock of OncoCyte Corporation and Hadasit Bio-Holdings Ltd ("HBL"). All share prices are determined based on the closing price of OncoCyte and HBL common stock on the last day of the applicable quarter, or the last trading day of the applicable quarter, if the last day of a quarter fell on a day that was not a trading day.

As of December 31, 2023, Lineage owned approximately

7,500

shares of OncoCyte common stock, which had a fair value of $

19,000

based on the closing price of OncoCyte common stock of $

2.50
per share on that date. As of December 31, 2022, Lineage owned approximately

56,000
shares of OncoCyte common stock, which had a fair value of $

0.4
million based on the closing price of OncoCyte common stock of $

6.42
per share on that date. The fair market value of the HBL shares was $

31,000
and $

62,000
as of December 31, 2023 and 2022.

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

	Year Ended December 31,	
	2023	2022
Loss on marketable equity securities, net	$ (176)	$ (2,194)
Less: Loss recognized in earnings on marketable equity securities sold	23	-
Unrealized loss recognized on marketable equity securities held at end of period, net	$ (153)	$ (2,194)

6. Property and Equipment, Net

At December 31, 2023 and 2022, property and equipment, net was comprised of the following (in thousands):

	December 31, 2023	December 31, 2022
Equipment, furniture and fixtures	$ 3,614	$ 3,264
Leasehold improvements	2,313	2,150
Right-of-use assets - Operating Lease	5,880	5,988
Right-of-use assets - Finance Lease	198	121
Accumulated depreciation and amortization	(7,238)	(5,850)
Property and equipment, net	$ 4,767	$ 5,673

Depreciation and amortization expense amounted to $

562,000
and $

582,000
for the years ended December 31, 2023 and 2022, respectively. Additionally, amortization expense for right-of-use finance lease assets amounted to $

50,000
and $

14,000
for the years ended December 31, 2023 and 2022, respectively.

7. Goodwill and Intangible Assets, Net

At December 31, 2023 and 2022, goodwill and intangible assets, net consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
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
Intangible assets subject to amortization:		
Acquired patents	18,953	18,953
Acquired royalty contracts [3]	650	650
Total intangible assets	66,143	66,143
Accumulated amortization [4]	(19,581)	(19,451)
Intangible assets, net	$ 46,562	$ 46,692

(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 14 (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 long-lived intangible assets under ASC Topic 805, *Business Combinations* .

(4) As of December 31, 2023 the acquired patents were fully amortized and the acquired royalty contracts had a remaining unamortized balance of $

22,000,
which will be amortized during 2024.

Lineage recognized approximately $

0.1

in amortization expense of intangible assets during each of the years ended December 31, 2023 and 2022.

8. Accounts Payable and Accrued Liabilities

At December 31, 2023 and 2022, accounts payable and accrued liabilities consist of the following (in thousands):

	December 31, 2023	December 31, 2022
Accounts payable	$ 2,050	$ 2,393
Accrued compensation	3,123	2,382
Accrued liabilities	1,097	3,833
Total	$ 6,270	$ 8,608

9. 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 (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 are unobservable; that reflect management's own assumptions about the assumptions market participants would make and significant to the fair value.

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, 2023 and 2022 (in thousands):

		Fair Value Measurements Using		
	Balance at December 31, 2023	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	50	50	—	—
Total assets measured at fair value	$ 29,935	$ 29,935	$ —	$ —

	Balance at December 31, 2022	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]	$ 4,102	$ 4,102	$ —	$ —
Marketable debt securities	46,097	46,097	—	—
Marketable equity securities	423	423	—	—
Total assets measured at fair value	$ 50,622	$ 50,622	$ —	$ —
Liabilities:				
Warrants to purchase Cell Cure ordinary shares [2]	$ 2	$ —	$ —	$ 2
Total liabilities measured at fair value	$ 2	$ —	$ —	$ 2

(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. There were no marketable debt securities classified as cash equivalents at December 31, 2022.

(2) In determining fair value of the liability classified warrants, Lineage utilizes a Black-Scholes pricing model that maximizes the use of observable inputs and minimizes the use of unobservable inputs to the extent possible, and also considers counterparty credit risk in its assessment of fair value. The significant unobservable inputs used in the fair value measurement of the Company's Level 3 Cell Cure warrant liabilities are volatility and share value. A significant increase or decrease in these Level 3 inputs could result in a significantly higher or lower fair value measurements.

Lineage's marketable equity securities includes the shares of stock of OncoCyte and HBL. Both securities have readily determinable fair values quoted on the NYSE American 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.

10. 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 14 (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., a shareholder of Lineage, and Broadwood Capital, Inc., which serves as the general partner of Broadwood Partners, L.P., all of whom were named defendants in the lawsuits, prior to being dismissed. As of December 31, 2023, and 2022, Lineage had incurred a cumulative total of approximately $

626,000
and $

620,000
, respectively, in legal expenses on behalf of the foregoing parties.

11. 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, 2023 and 2022, there were

no

preferred shares issued or outstanding.

Common Shares

At December 31, 2022, Lineage was authorized to issue

250,000,000
common shares,

no
par value. In September 2023, Lineage's shareholders approved an increase in the number of authorized common shares, no par value, from

250,000,000
to

450,000,000
. As of December 31, 2023 and December 31, 2022, there were

174,986,671

and

170,093,114

common shares issued and outstanding, respectively.

At The Market Offering Program

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

In March 2021, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of $

25.0
million of common shares through the ATM program under the Sales Agreement (“March 2021 Prospectus Supplement”).

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 (which included $

14.1
million of its common shares which then remained unsold under the March 2021 Prospectus Supplement) through the ATM program under the Sales Agreement. Following the filing of the prospectus supplement in December 2021, no further sales were made or will be made under the March 2021 Prospectus Supplement. The prospectus supplement filed in December 2021 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 “ATM Prospectus Supplement”).

As of December 31, 2023, Lineage had sold

4,882,803
common shares under the ATM Prospectus Supplement at a weighted average price per share of $

1.41
for gross proceeds of $

6.9
million. As of December 31, 2023, $

57.2
million remained available for sale under the ATM Prospectus Supplement. During the year ended December 31, 2023,

4,774,603
shares were sold under the ATM Prospectus Supplement for gross proceeds of $

6.6
million and net proceeds of $

6.4
million. There were

no
such sales during 2022.

The shares offered under the ATM Prospectus Supplement are registered pursuant to Lineage’s effective shelf registration statement on Form S-3 (File No. 333-254167), which was filed with the SEC on March 5, 2021 and declared effective on March 19, 2021.

Lineage agreed to pay Cantor Fitzgerald a commission of

3.0
% of the aggregate gross proceeds from the sale of shares under the Sales Agreement, reimburse its legal fees and disbursements, and provide Cantor Fitzgerald with customary indemnification and contribution rights. The Sales Agreement may be terminated by Cantor Fitzgerald or Lineage at any time upon notice to the other party, or by Cantor Fitzgerald 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.

12. 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, nonstatutory 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, 2023, there were

27,078,144
shares available for grant under the 2021 Plan.

On February 11, 2022, Lineage granted

694,424
RSUs to certain employees, including the Company's executive officers, to further align management with the achievement of certain development milestones under the Roche Agreement. For each RSU, half of the common shares subject to the RSU will vest in four equal annual installments beginning on the first anniversary of the grant date. The other half of the common shares will vest in connection with the achievement of certain development milestones set forth in the Roche Agreement. Additionally, on March 10, 2022, Lineage granted

300,000
RSUs to its Chief Executive Officer.

100,000
of these RSUs were forfeited on March 9, 2023, and

100,000
will vest on or prior to each of the second and third anniversaries of such date, in each case upon the achievement of certain per share performance targets, calculated based on the trailing 20-day volume weighted average price of the Company's common shares as of the date of determination. If such per share performance targets are not achieved by the applicable vesting date, then such RSUs will be forfeited.

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, 2022	6,001	$ 1.40	8.58	$ —
Options granted	5,758	$ 1.45		
Options expired/forfeited/cancelled	(935)	$ 1.43		
Balance at December 31, 2023	10,824	$ 1.42	8.63	$ 4
Options exercisable at December 31, 2023	2,593	$ 1.41	7.75	$ —
Options exercisable and expected to vest at December 31, 2023	10,824	$ 1.42	8.63	$ 4

	Number of RSUs Outstanding	Weighted Average Grant Date Fair Value per Share
Balance at December 31, 2022	939	$ 1.09
RSUs forfeited	(191)	$ 0.85
RSUs vested	(80)	$ 1.50

Balance at December 31, 2023	668	$	1.11

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, 2022	12,172	$ 1.83	5.69	$ 1,364
Options exercised	(66)	$ 0.84		
Options expired/forfeited/cancelled	(1,267)	$ 1.83		
Balance at December 31, 2023	10,839	$ 1.83	5.30	$ 1,047
Options exercisable at December 31, 2023	9,591	$ 1.78	5.05	$ 984
Options exercisable and expected to vest at December 31, 2023	10,839	$ 1.83	5.30	$ 1,047

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, 2023	2022
Expected life (in years)	6.20	6.21
Risk-free interest rates	4.2 %	2.4 %
Volatility	74.7 %	73.7 %
Dividend yield	—	—

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

	Year ended December 31, 2023	2022
Research and development	$ 794	$ 747
General and administrative	3,846	3,540
Total stock-based compensation expense	$ 4,640	$ 4,287

As of December 31, 2023, total unrecognized compensation costs related to unvested stock options and unvested RSUs under all equity plans (including the 2018 inducement option), were $

8.6

million, which is expected to be recognized as expense over a weighted average period of approximately 2.5 years. For the years ended December 31, 2023 and 2022, the weighted average grant-date fair value per share of options granted during the year under the 2021 Plan was $

1.00

and $

0.93

, respectively. For the year ended December 31, 2022, the weighted average grant-date fair value per share of RSUs granted during the year under the 2021 Plan was $

1.12

.

No

RSUs were granted in the year ended December 31, 2023. The total intrinsic value of options exercised during the years ended December 31, 2023 and 2022 was $

38,000

and $

367,000

, respectively. The fair value of the options vested during the years ended December 31, 2023 and 2022 was $

3,947,000

and $

4,122,000

, respectively.

13. Income Taxes

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. For the year ended December 31, 2022, Lineage did not record a tax provision or deferred tax benefit.

For the year ended December 31, 2022, Lineage recorded a withholding tax of $

0.5
million on interest expense deemed paid to Lineage from Cell Cure on the purchase of intellectual property pursuant to the U.S. Israeli tax treaty. There was no comparable tax expense for the year ended December 31, 2023.

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

	Year Ended December 31,	
	2023	2022
Domestic	$ (23,402)	$ (22,961)
Foreign	120	(2,851)
Loss before net income tax benefit	$ (23,282)	$ (25,812)

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,	
	2023	2022
Computed tax benefit at federal statutory rate	21%	21%
Research and development and other credits	(1)%	3%
Withholding tax	—%	(2)%
Permanent differences	(1)%	(2)%
Change in valuation allowance	(12)%	(28)%
State tax benefit	2%	7%
GILTI inclusion	(1)%	(1)%
Income tax benefit (expense)	8%	(2)%

The primary components of the deferred tax assets and liabilities at December 31, 2023 and 2022 were as follows (in thousands):

Deferred tax assets/(liabilities):	December 31, 2023	December 31, 2022
Net operating loss carryforwards	$ 63,461	$ 58,816
Research and development and other credits	8,890	10,463
Patents and licenses	1,606	1,500
Stock-based compensation	3,117	2,308
Operating lease liability	240	—
Capitalized research expense	6,217	3,066
Other	1,707	2,555

Total deferred tax assets	85,238	78,708
Valuation allowance	(80,513)	(78,209)
Deferred tax assets, net of valuation allowance	4,725	499
Operating lease ROU assets	(221)	(4)
Intangibles	(4,771)	(2,464)
Marketable securities at fair value	(6)	(107)
Total deferred tax liabilities	(4,998)	(2,575)
Net deferred tax liabilities	$ (273)	$ (2,076)

Lineage has established an accrual for uncertain tax positions related to its U.S. research and development credits. As of December 31, 2023 and 2022, there was no accrued interest related to uncertain tax positions. Lineage does not believe it is reasonably possible that its unrecognized tax benefits will significantly change in the next twelve months. A reconciliation of beginning and ending balances for unrecognized tax benefits is as follows (in thousands):

	Year Ended December 31, 2023	2022
Balance at the beginning of the period	$ —	$ —
Additions for tax positions related to the current year	354	—
Additions for tax positions related to prior years	2,609	—
Reductions for tax positions related to prior years	—	—
Reductions related to settlements	—	—
Reductions related to a lapse of statute	—	—
Balance at the end of the period	$ 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, 2023 and 2022, Lineage had gross federal net operating loss carryforwards, of approximately $

163.1
million and $

150.6
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, 2023 and 2022, Lineage's foreign subsidiaries had net operating loss carryforwards of approximately $

64.8
and $

66.6
million, respectively, which carryforward indefinitely.

As of December 31, 2023 and 2022, Lineage has net operating losses of $

188.8
million and $

160.2
million, respectively for state tax purposes. The California net operating losses expire in varying amounts between 2030 and 2043 .

As of December 31, 2023 and 2022, Lineage had research tax credit carryforwards for federal tax purposes of $

4.3
million and $

4.5
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 2043 .

As of December 31, 2023 and 2022, Lineage had research tax credit carryforwards for California tax purposes of $

4.6
million and $

6.0
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, Cell Cure, 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 14 (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 Cell Cure's interest in certain intellectual property. This transaction generated a gain to Cell Cure 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, 2023 and 2022, Lineage's combined foreign entities generated a profit arising from intercompany transactions. As a result, there was an inclusion of $

1.1
million and $

1.7
million for GILTI purposes for 2023 and 2022, 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 2019. 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, 2023 and 2022. Lineage’s management does not expect that the total amount of unrecognized tax benefits will materially change over the next twelve months.

Lineage’s practice is to recognize interest and penalties related to income tax matters in tax expense. As of December 31, 2023 and 2022, Lineage has no accrued interest and penalties.

14. 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”). The lease expires on March 31, 2026 , and rent was abated for months two through four of the Extended Term. The monthly base rent was $

24,666

through the Extended Term Commencement Date, after which it increased to $

25,197

. 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, 2023.

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 ROU 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 expires on March 31, 2024 . 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 prepaid expense and other current assets on the consolidated balance sheet as of December 31, 2023. Base rent is $

22,500

per month until the lease expires. In February 2024, Lineage and the landlord executed an agreement to extend the duration of the term of the sublease for an additional 24 months on similar terms.

Cell Cure Leases

Cell Cure leases

728.5

square meters (approximately

7,842

square feet) of office and laboratory space in Jerusalem, Israel under a lease that expires December 31, 2027 , with an option to extend the lease for five years . Base monthly rent is NIS

39,776

(approximately $

12,200

per month). In addition to base rent, Cell Cure 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. These pro-rata charges are expensed as incurred and excluded from the calculation of the ROU assets and lease liabilities.

In January 2018, Cell Cure entered into a lease for an additional

934
square meters (approximately

10,054
square feet) of office space in the same facility that expires on December 31, 2027 , with an option to extend the lease for five years . Base rent and construction allowance payments are NIS

93,827
per month (approximately $

26,000
per month). Cell Cure has a security deposit denominated in NIS with the landlord held as restricted cash during the term of its facility lease. The value of this security deposit in U.S. dollars fluctuates based upon currency exchange rates and was $

450,000
as of December 31, 2023, which is included in deposits and other long-term assets on the consolidated balance sheet.

In November 2021, Cell Cure entered into a lease for an additional

133
square meters (approximately

1,432
square feet) of office space in the same facility that commenced on December 1, 2021, and expires on December 31, 2027 , with an option to extend the lease for five years . The base monthly rent was NIS

11,880
(approximately US $

3,757
) through October 31, 2022 and increased to NIS

12,494
(approximately US $

3,951
) on November 1, 2022.

In August 2022, Cell Cure entered into a lease for

300
square meters (approximately

3,229
square feet) of office and laboratory space in Jerusalem, Israel that expires December 31, 2027 , with an option to extend the lease for five years . Base monthly rent is

16,350
NIS (approximately $

4,800
per month). When executing this lease, Cell Cure modified the expiration dates and options terms for the leases identified above to align with this lease. The adjustment to the right-of-use asset and lease liability to reflect the lease modification for the 2-year extension was $

0.7
million, while the additional right-of-use asset and lease liability recorded for the new lease was $

0.2
million.

Supplemental Information – Leases

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

	Year Ended December 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 1,129	$ 1,047

Operating cash flows from finance leases	$ 10	$ 3
Financing cash flows from finance leases	$ 54	$ 32
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ —	$ 2,286
Finance leases	$ 79	$ 90

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

	December 31, 2023	December 31, 2022
Operating leases		
Right-of-use assets	$ 5,880	$ 5,988
Accumulated amortization	(3,358)	(2,471)
Right-of-use assets, net	$ 2,522	$ 3,517
Right-of-use lease liabilities, current	$ 830	$ 916
Right-of-use lease liabilities, noncurrent	1,979	2,860
Total operating lease liabilities	$ 2,809	$ 3,776
Finance leases		
Right-of-use assets	$ 198	$ 121
Accumulated amortization	(67)	(16)
Right-of-use assets, net	$ 131	$ 105
Right-of-use lease liabilities, current	$ 52	$ 29
Right-of-use lease liabilities, noncurrent	91	84
Other current liabilities	—	7
Total finance lease liabilities	$ 143	$ 120
Weighted average remaining lease term		
Operating leases	3.5 years	4.3 years
Finance leases	3.0 years	4.1 years
Weighted average discount rate		
Operating leases	6.5 %	6.3 %

Finance leases	6.9 %	6.9 %

Future minimum lease commitments are as follows as of December 31, 2023 (in thousands):

	Operating Leases	Finance Leases
Year Ending December 31,		
2024	$ 953	$ 62
2025	882	51
2026	644	26
2027	683	20
Total lease payments	3,162	159
Less imputed interest	(353)	(16)
Total	$ 2,809	$ 143

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 Cell Cure, 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 Cell Cure's agreements with Hadasit (as discussed below). The payment 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, Cell Cure will be required to pay Hadasit

21.5

% of the amount of costs not incurred.

ITI Collaboration Agreement

In April 2021, Lineage entered into a collaborative agreement with ITI whereby Lineage agreed to perform up to approximately $

2.2

million worth of certain research, development, manufacturing, and oversight activities related to the development of an allogeneic VAC-CMV product candidate. ITI will reimburse Lineage for these costs and full-time employee costs for the manufacturing of the VAC-CMV product candidate. As of December 31, 2023, Lineage has a remaining performance obligation of approximately $

1.6

million for the aforementioned activities. Upon execution of the agreement in April 2021, $

0.5

million was paid by ITI to Lineage. Upon delivery of research-grade VAC-CMV product generated by Lineage, ITI paid an additional $

0.5

million in August 2021. ITI is currently evaluating its next step under the agreement.

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 Cell Cure 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 Cell Cure 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, 2023, the aggregate cap amount was approximately $

93.2
million.

Pursuant to the Second Amended and Restated License Agreement, dated June 15, 2017, between Cell Cure and Hadasit, and a certain letter agreement entered into on December 17, 2021, Cell Cure 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 Cell Cure is obligated to pay Hadasit (i) 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 of any milestone payments, 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 and royalties received under the Roche Agreement. Royalties are payable to licensors or government entities based on a percentage of net sales of licensed products. As of December 31, 2023, 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.

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, Cell Cure 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 Cell Cure. 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 Cell Cure pursuant to which Cell Cure conveyed certain rights and other assets to Lineage, and Lineage agreed to undertake certain liabilities and obligations of Cell Cure relating to the OpRegen® program. In its motion, HBL alleges, among other things, that Lineage, in its capacity as Cell Cure’s controlling shareholder, and members of Cell Cure’s board of directors caused damage to Cell Cure because the Intercompany Agreement was an interested party transaction that was not fairly priced and exploits Cell Cure’s resources for the benefit of Lineage. The motion seeks an order to compel Cell Cure 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. Cell Cure filed an opposition to the motion on July 9, 2023. The Court set a hearing date for the motion of March 14, 2024. 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. The potential future payments Lineage could be required to make under these indemnification agreements 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. Accordingly, Lineage has not recorded any liabilities for these agreements as of December 31, 2023 or 2022.

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.

15. 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, 2023 and 2022, we incurred approximately $

0.2

million in expenses related to the safe harbor contribution.

16. Segment Information

Lineage's executive management team, as a group, represents the entity's chief operating decision makers. Lineage's executive management team views Lineage's operations as

one

segment that includes the research and development of therapeutic products for retinal diseases, neurological diseases and disorders and oncology. As a result, the financial information disclosed materially represents all the financial information related to Lineage's sole operating segment.

17. Enterprise-Wide Disclosures

Geographic Area Information

For the years ended December 31, 2023 and 2022 none of our revenue was generated outside of the United States.

The composition of Lineage's long-lived assets, consisting of plant and equipment, net, between those in the United States and in foreign countries, as of December 31, 2023 and 2022, is set forth below (in thousands):

	Year Ended December 31,	
	2023	2022
United States	$ 827	$ 1,384
Foreign [1]	3,940	4,289
Total	$ 4,767	$ 5,673

(1) Assets in foreign countries principally include laboratory equipment and leasehold improvements in Israel.

Major Sources of Revenues

The following table presents Lineage's consolidated revenues disaggregated by source (in thousands, except percentages).

	Year Ended December 31,		Percent of Total	
	2023	2022	2023	2022
REVENUES:				
Collaboration revenues	$ 7,588	$ 13,367	84.8 %	90.9 %
Royalties, license and other revenues	1,357	1,336	15.2 %	9.1 %
Total revenues	$ 8,945	$ 14,703	100 %	100 %

18. Selected Quarterly Financial Information (UNAUDITED) (in thousands, except per share data)

Lineage has derived this data from the unaudited consolidated interim financial statements that, in Lineage's opinion, have been prepared on substantially the same basis as the audited consolidated financial statements contained herein and include all normal recurring adjustments necessary for a fair presentation of the financial information for the periods presented. These unaudited consolidated quarterly results should be read in conjunction with the consolidated financial statements and notes thereto included herein. The consolidated operating results in any quarter are not necessarily indicative of the consolidated results that may be expected for any future period.

Year Ended December 31, 2023	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues	$ 2,386	$ 3,225	$ 1,246	$ 2,088
Operating expenses	8,909	8,122	7,782	8,194
Loss from operations	(6,642)	(5,024)	(6,705)	(6,362)
Net loss attributable to Lineage	(4,372)	(5,229)	(7,110)	(4,775)
Basic and diluted net loss per share	$ (0.03)	$ (0.03)	$ (0.04)	$ (0.03)
Year Ended December 31, 2022				
Revenues	$ 5,237	$ 4,553	$ 2,998	$ 1,915
Operating expenses	11,457	8,572	8,014	8,452

Loss from operations	(6,396)	(4,234)	(5,251)	(6,639)
Net loss attributable to Lineage	(7,087)	(6,763)	(6,069)	(6,354)
Basic and diluted net loss per share	(0.04)	(0.04)	(0.04)	(0.03)
	$	$	$	$

Quarterly and year-to-date computations of net loss per share amounts are calculated using the respective period weighted average shares outstanding. Therefore, the sum of the per share amounts for the quarters may not agree with the per share amounts for the year.

19. Subsequent Events

On February 8, 2024, Lineage completed a registered direct offering of

13,461,540
of its common shares at a price of $

1.04
per share. An existing significant shareholder, Broadwood Partners, L.P., which is affiliated with Neal Bradsher, a member of Lineage's board of directors, purchased

6,730,770
common shares in the offering, and Don M. Bailey, a member of Lineage's board of directors purchased

96,155
common shares in the offering. Net proceeds to Lineage from the offering were approximately $

13.8
million.

On February 6, 2024, Lineage filed a prospectus supplement to update and amend the ATM Prospectus Supplement to reduce the dollar amount of common shares Lineage may sell in its at-the-market offering program. Accordingly, from and after February 6, 2024, Lineage may offer and sell from time-to-time common shares having an aggregate offering price of up to $

40.0
million in its at-the-market offering program.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

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, 2023. Following this review and evaluation, management collectively determined that our disclosure controls and procedures were effective as of December 31, 2023 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 2023 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, 2023, 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.

ITEM 9B. OTHER INFORMATION

(a) On March 6, we and each of Brian M. Culley, Jill A. Howe, and George A. Samuel III, each of whom is one of our executive officers, entered into an amendment to their respective employment agreements. Under the terms of each of their employment agreements before they were amended, if their employment was terminated by us without cause (as defined in their employment agreements) or if they resigned for good reason (as defined in their employment agreements), among other benefits payable to them, we would pay the applicable executive a specified percentage of their target bonus for the year in which their employment was terminated. Under the terms of the amendment, (1) if the applicable executive's target bonus for the year in which their employment is terminated has not been set at the time their employment is terminated, then the amount of their target bonus for the immediately preceding year will be deemed to be the target bonus for the year in which their employment is terminated; and (2) if the applicable executive has not been paid their bonus for the immediately preceding year at the time their employment is terminated solely because executive's employment is terminated before the date on which such bonus otherwise would be paid, they will also receive a payment equal to 100% of the target bonus of such preceding year.

(b) During the period from October 1, 2023 to December 31, 2023, 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, 2023, in connection with the solicitation of proxies for our 2024 annual meeting of shareholders (the "2024 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 2024 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 2024 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 2024 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 2024 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	3.2	8-K	August 12, 2019	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	4.2	10-K	March 11, 2021	001-12830
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
10.03+	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
10.04+	Amended and Restated Employment Agreement dated September 26, 2022 between Registrant and Gary S. Hogge	10.4	10-Q	November 10, 2022	001-12830

10.04(a)*+	Separation, Release and Consulting Agreement dated November 30, 2023 between Registrant and Gary S. Hogge				
10.04(b)*+	Amendment to Stock Option Agreements dated December 4, 2023 between Registrant and Gary S. Hogge				
10.05+	Employment Agreement dated November 14, 2022 between Registrant and Jill A. Howe	10.7	10-K	March 9, 2023	001-12830
10.06+	Inducement Stock Option Agreement between Registrant and Brian Culley	10.18	10-K	March 14, 2019	001-12830
10.07+	Lineage Cell Therapeutics 2012 Equity Incentive Plan, as amended July 2015 ("2012 Plan")	4.1	S-8	July 15, 2015	333-205661
10.07(a)+	Amendment to 2021 Plan effective September 6, 2023	10.01	8-K	September 7, 2023	001-12830
10.07(b)+	Amendment to 2012 Plan effective June 2017	4.2	S-8	July 7, 2017	333-219204
10.07(c)+	Amendment to 2012 Plan effective July 2019	99.3	S-8	August 8, 2019	333-233132
10.07(d)+	Amendment to 2012 Plan effective August 2019	10.1	10-Q	November 12, 2019	001-12830
10.07(e)+	2012 Plan Form of Employee Incentive Stock Option Agreement	10.7	10-Q	November 12, 2013	001-12830
10.07(f)+	2012 Plan Form of Non-employee Director Stock Option Agreement	10.8	10-Q	November 12, 2013	001-12830
10.07(g)+	2012 Plan Stock Option Grant Agreement	10.2	10-Q	November 12, 2019	000-12830
10.07(h)+	2012 Plan Form of Restricted Stock Unit	10.6	10-K	March 12, 2020	001-12830
10.08+	Lineage Cell Therapeutics 2021 Equity Incentive Plan, effective as of September 2021 ("2021 Plan")	10.1	8-K	September 15, 2021	001-12830
10.08(a)+	Amendment to 2021 Plan effective September 6, 2023	10.01	8-K	September 7, 2023	001-12830
10.08(b)+	2021 Plan Form of Stock Option Grant Notice and Agreement for Employees and Consultants	99.2	S-8	September 28, 2021	333-259853
10.08(c)+	2021 Plan Form of Stock Option Grant Notice and Agreement for Non-Employee Directors	99.3	S-8	September 28, 2021	333-259853
10.08(d)+	2021 Plan Form of Restricted Stock Unit Award Grant Notice and Agreement	99.4	S-8	September 28, 2021	333-259853
10.09+	Executive Performance Incentive Bonus Plan, adopted September 2022	10.5	10-Q	November 10, 2022	001-12830
COMMERCIAL AGREEMENTS					
10.10	Commercial License and Option Agreement between Registrant and Wisconsin Alumni Research Foundation ("WARF Agreement")	10.1	8-K	January 9, 2008	001-12830
10.10(a)	First Amendment to WARF Agreement dated March 11, 2009	10.38	10-K	March 23, 2009	001-12830
10.11†	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")	10.2	10-Q	August 9, 2017	001-12830
10.11(a)	Amendment to Hadasit License dated January 8, 2018	10.38	10-K	March 15, 2018	001-12830
10.11(b)††	Second Amendment to Hadasit License dated December 1, 2019	10.4(b)	10-K	March 10, 2022	001-12830

10.11(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
10.11(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
10.12†	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
10.13†	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
10.14	Royalty Agreement dated October 1, 2013 between Asterias and Geron Corporation	10.6	Asterias S-1/A	August 13, 2013	333-187706
10.15	Exclusive Sublicense Agreement between Geron Corporation and Asterias	10.7	Asterias S-1/A	August 13, 2013	333-187706
10.16†	Non-exclusive License Agreement dated October 7, 2013 between WARF and Asterias	10.5	Asterias 10-Q	November 12, 2013	000-55046
10.17†	Clinical Trial and Option Agreement dated September 8, 2014 between Asterias and Cancer Research UK and Cancer Research Technology Limited ("CRT")	10.1	Asterias 10-Q/A	January 13, 2015	001-36646
10.18(a)††	Second Amendment to Clinical Trial and Option Agreement dated May 6, 2020 between Cancer Research UK, CRT, Asterias Biotherapeutics, Inc. and Registrant	10.1	10-Q	August 6, 2020	001-12830
10.18(b)††	License Agreement dated May 6, 2020 between CRT and Registrant	10.2	10-Q	August 6, 2020	001-12830
10.18(c)	First Amendment to License Agreement dated April 16, 2021, between CRT and Registrant	10.1	10-Q	August 12, 2021	001-12830
10.19††	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
10.20	Stipulation and Agreement of Compromise and Settlement dated October 26, 2022	10.21	10-K/A	April 27, 2023	001-12830
10.21	Stock Purchase Agreement dated February 6, 2024	10.1	8-K	February 6, 2024	001-12830

OTHER EXHIBITS

21.01*	List of Subsidiaries of the Registrant
23.01*	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
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.

101.SCH*	XBRL Taxonomy Extension Schema - 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.

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 7, 2024

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 7, 2024
/s/ Jill Ann Howe JILL ANN HOWE	Chief Financial Officer (Principal Financial and Accounting Officer)	March 7, 2024
/s/ Deborah Andrews DEBORAH ANDREWS	Director	March 7, 2024
/s/ Dipti Amin DIPTI AMIN	Director	March 7, 2024
/s/ Don M. Bailey DON M. BAILEY	Director	March 7, 2024
/s/ Neal C. Bradsher NEAL C. BRADSHER	Director	March 7, 2024
/s/ Alfred D. Kingsley ALFRED D. KINGSLEY	Director	March 7, 2024
/s/ Anula Jayasuriya ANULA JAYASURIYA	Director	March 7, 2024
/s/ Michael H. Mulroy MICHAEL H. MULROY	Director	March 7, 2024
/s/ Angus C. Russell ANGUS C. RUSSELL	Director	March 7, 2024

Exhibit 10.04(a)

November 30, 2023

Gary S. Hogge, DVM, PhD.
c/o Lineage Cell Therapeutics, Inc.
2173 Salk Avenue, Suite 200
Carlsbad, CA 92008

Re: Separation, Release and Consulting Agreement

Dear Gary:

This Separation, Release and Consulting Agreement (this "***Agreement***") summarizes the terms and conditions of the separation, release and consulting agreement that Lineage Cell Therapeutics, Inc. ("***Lineage***") is offering you in connection with your employment termination.

1.Employment Termination and Final Accrued Payments.

(a) Separation Date. As previously communicated to you, your last day of employment with Lineage or any of its subsidiaries or affiliates is November 30, 2023 (the "***Separation Date***"). You understand and agree that effective as of the Separation Date, each of (i) that certain Amended and Restated Employment Agreement between you and Lineage made as of September 26, 2022 (the "***Employment Agreement***") and (ii) that certain Indemnification Agreement between you and Lineage made as of May 9, 2022 (the "***Indemnification Agreement***"), is terminated.

(b)Accrued Salary and Paid Time Off. Lineage will pay you all accrued base salary, and all accrued and unused paid time off earned through the Separation Date, subject to required payroll deductions and withholdings. You are entitled to these payments even if you do not sign this Agreement.

(c) Expense Reimbursements. You agree to submit, within 30 calendar days after the Separation Date, expense reports to Lineage seeking reimbursement for any business expenses incurred through the Separation Date. Lineage will reimburse you for these business expenses, pursuant to its standard policies and practices.

2.Separation Benefits. In consideration of and in return for the promises and covenants undertaken by you and Lineage herein, and the releases and other promises given by you herein, in accordance with the terms of the Employment Agreement, if you sign, date and return this Agreement to Lineage within 21 calendar days from the date you receive it, and you subsequently do not revoke your acceptance of this Agreement, and you comply with your continuing obligations owed to Lineage, including pursuant to the Employee Confidential

Information and Invention Assignments Agreement between you and Lineage dated February 21, 2018 (the "***Confidentiality Agreement***"), the Employment Agreement, the Indemnification Agreement and this Agreement (collectively, the "***Obligations***"), Lineage agrees to (collectively, the "***Separation Benefits***"):

(a) pay you in regularly scheduled payments in accordance with our standard payroll practices an aggregate amount of $412,485.00, which is equal to 9 months of your base salary as in effect immediately prior to the Separation Date plus a prorated target bonus for 2023; and

(b)make a payment each month during the COBRA Premium Period (as defined below) of 100% of the premium of any health insurance benefits you were receiving as of the Separation Date under a Lineage employee health insurance plan subject to the Consolidated Omnibus Budget Reconciliation Act ("***COBRA***"); provided that you timely elect to have such COBRA coverage; provided, further, that, in the event you become covered under another employer's group health plan during the COBRA Premium Period, you must immediately notify Lineage of such event. "***COBRA Premium Period***" means the period starting on the Separation Date and ending on the earliest to occur of: (i) 9 months following the Separation Date or (ii) the date you become eligible for group health insurance coverage through a new employer.

Lineage shall not be obligated to make any of the payments described above until the expiration of any applicable revocation period with respect to this Agreement. All compensation payable to you hereunder is subject to applicable taxes, deductions and withholdings.

3.Consulting Agreement. Although not otherwise obligated to do so, if you sign, date and return this Agreement to Lineage, and you continue to comply with your Obligations, Lineage shall retain you, and you shall provide consulting services as a consultant for Lineage, under the following terms (the "***Consulting Relationship***"):

(a)Consulting Period. The Consulting Relationship will commence on December 4, 2023 and will continue until March 31, 2024, unless terminated earlier pursuant to Section 3(h) below (the "***Consulting Period***"). The Consulting Period can be extended only in writing signed by you and the Chief Executive Officer of Lineage.

(b)Consulting Services. You agree to provide consulting services to Lineage by: (i) assisting Lineage on clinical matters; (ii) transitioning outstanding projects, tasks and relationships to other Lineage personnel or third parties; and (iii) performing such other services as you and Lineage may agree from time to time (collectively, the "***Consulting Services***"). You will not be required to report to Lineage's offices during the Consulting Period. During the Consulting Period, you agree to provide Consulting Services as reasonably requested by Lineage from time to time.

(c)Independent Contractor Relationship. Your relationship with Lineage during the Consulting Period will be that of an independent contractor, and nothing in this Agreement is intended to, or should be construed to, create a partnership, agency, joint venture or employment relationship after the Separation Date. Other than your Separation Benefits, from and after the Separation Date you will not be entitled to any of the benefits that Lineage may make available to its employees, including group health or life insurance, profit-sharing or retirement benefits, and you acknowledge and agree that your relationship with Lineage during

the Consulting Period will not be subject to the Fair Labor Standards Act, the California Labor Code or other laws or regulations governing employment relationships.

(d)Equity Vesting. The termination of your employment with Lineage is effective as of the Separation Date and your engagement as a consultant shall commence at the start of the Consulting Period. As such, it is understood and agreed that your Consulting Services during the Consulting Period, do not constitute "Continuous Service" as defined in, and for purposes of, the Lineage Cell Therapeutics, Inc. 2012 Equity Incentive Plan nor the Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan (collectively, the "***Equity Plan***"), and therefore your outstanding equity awards will cease to vest in accordance with their terms as of the Separation Date. Your rights to exercise or otherwise acquire any vested shares shall be governed and controlled by the Equity Plan and your applicable grant documents (the "***Equity Documents***"). All terms applicable to your equity awards will continue to be subject to the applicable Equity Documents.

(e)Consideration for Consulting Services. Lineage agrees to pay you at a rate of $500 per hour for the Consulting Services, payable monthly within 30 days following receipt by Lineage of an undisputed invoice for Consulting Services performed during the prior month. Unless otherwise agreed upon in writing by Lineage, Lineage's maximum liability for all Consulting Services performed during the term of your Consulting Services shall not exceed $30,000. You agree to provide detailed invoices describing the Consulting Services you performed and the amount of time spent on each activity for Consulting Services.

(f)Limitations on Authority. You will have no responsibilities or authority as a consultant to Lineage other than as provided in this Section 3 of this Agreement. You will have no authority, apparent or otherwise, to bind Lineage to any contractual obligations, whether written, oral or implied, except with the written authorization of Lineage's Chief Executive Officer. You agree not to represent or purport to represent Lineage in any manner whatsoever to any third party (including customers, potential customers, investors, business partners or vendors), unless authorized by Lineage's Chief Executive Officer, in writing, to do so.

(g)Confidential Information and Inventions. You acknowledge and reaffirm that you will continue to be subject to the obligations in the Confidentiality Agreement and Sections 3, 4 and 6 of the Employment Agreement. You agree that, during the Consulting Period and thereafter, you will not use or disclose, other than in furtherance of the Consulting Services, any confidential or proprietary information or materials of Lineage, including any confidential or proprietary information that you obtain or develop in the course of performing the Consulting Services. Any and all work product you create in the course and scope of performing the Consulting Services will be the sole and exclusive property of Lineage. You hereby assign to Lineage all right, title, and interest in all inventions, techniques, processes, materials, and other intellectual property developed in the course and scope of performing the Consulting Services. You further acknowledge and reaffirm you continue to be subject to the obligations of the Confidentiality Agreement. Notwithstanding the foregoing nondisclosure obligations, pursuant to 18 U.S.C. Section 1833(b), you will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made: (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (ii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

(h) New Employment. You acknowledge and agree that during the Consulting Period, you will promptly notify Lineage in writing if you (i) provide any services to any organization that reasonably could be a competitor of Lineage or (ii) become employed on a full-time basis with any organization.

(i) Early Termination of Consulting Period. Either you or Lineage has the right to immediately terminate the Consulting Period at any time and for any reason upon written notice to the other party.

(j) Debarment. You represent that you have never been debarred or convicted, or threatened to be debarred or indicted, for a crime for which a person can be debarred, under §335a (a) or (b) of the Generic Drug Enforcement Act of 1992 or ineligible to receive investigational drugs under 21 CFR, Section 312.70. You agree that you will promptly notify Lineage in the event of any such debarment, ineligibility, conviction, threat, or indictment. The terms of the preceding sentence shall survive the termination or expiration of this Agreement for a period of 3 years. Notwithstanding the provisions of this Section (j), you acknowledge that Lineage shall have the right to terminate this Agreement immediately upon receipt of information regarding the debarment, ineligibility, conviction, threat, or indictment.

(k) Restrictions on Purchases and Sales of Securities. You are aware that Lineage may provide material non-public information to you. You shall comply with U.S. securities laws regarding the purchase or sale of securities by any person who has received material, non-public information.

4. Other Compensation or Benefits. You acknowledge that, except as expressly provided in this Agreement, you have not earned and will not receive from Lineage any additional compensation, bonuses, incentive compensation, severance, or benefits before or after the Separation Date, with the exception of any vested right you may have under the express terms of a written ERISA-qualified benefit plan (*e.g.*, 401(k) account).

5. Return of Lineage Property. You certify that on the Separation Date you returned to Lineage all Lineage documents (and all copies thereof) and other Lineage property and equipment that you had in your possession or control (except as otherwise agreed by the Chief Executive Officer of Lineage in writing), including any materials of any kind that contain or embody any proprietary or confidential information or trade secret information of Lineage (and all reproductions thereof in whole or in part). You agree that you made a diligent search to locate any such documents, property and information and delivered all such documents, property and information on the Separation Date. In addition, if you have used any personally owned computer, server, e-mail system, mobile phone, or portable electronic device (*e.g.*, iPhone, Android device, or iPad) (collectively, "***Personal Systems***") to receive, store, prepare or transmit any Lineage confidential or proprietary data, materials or information, you have provided Lineage with a computer-useable copy of all such information and then permanently delete and expunged all such Lineage confidential or proprietary information from such Personal Systems without retaining any copy or reproduction in any form. Notwithstanding the foregoing, Lineage will provide you with access to Lineage property, as necessary, to the extent needed for you to perform your Consulting Services; *provided that* you must return such Lineage property in the manner set forth in this Section 5 of the Agreement upon request and not later than the last day of the Consulting Period.

6. Nondisparagement. You agree not to disparage Lineage (including its subsidiaries), its officers, directors, employees, shareholders, and agents, in any manner likely to be harmful to its or their business, business reputation, or personal reputation. Nothing in this Agreement will be interpreted or construed to prevent you from giving truthful testimony to any law enforcement officer, court, administrative proceeding or as part of an investigation by any Government Agency (as defined in Section 9(c)). In addition, nothing in this Agreement is intended to prohibit or restrain you in any manner from making disclosures that are protected under federal law or regulation or under other applicable law or regulation.

7.Cooperation and Assistance. You agree to voluntarily cooperate with Lineage, if you have knowledge of facts relevant to any threatened or pending claim, investigation, audit or litigation against or by or involving Lineage, by making yourself reasonably available for interviews with Lineage or its legal counsel, for preparing for and providing deposition testimony, and for preparing for and providing trial testimony. Lineage will reimburse you for reasonable out-of-pocket expenses you incur in connection with any such cooperation (excluding forgone wages, salary, or other compensation).

8.No Admissions. You understand and agree that the promises and payments in consideration of this Agreement shall not be construed to be an admission of any liability or obligation by Lineage to you or to any other person, and that Lineage makes no such admission.

9.Release of Claims.

(a) General Release. In exchange for the Separation Benefits, and other consideration under this Agreement to which you would not otherwise be entitled, including the Consulting Relationship, you hereby generally and completely release Lineage and its directors, officers, employees, shareholders, partners, agents, attorneys, predecessors, successors, parent and subsidiary entities, insurers, affiliates, and assigns (collectively, the "***Released Parties***") of and from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring prior to or on the date that you sign this Agreement (collectively, the "***Released Claims***").

(b)Scope of Release. The Released Claims include: (i) all claims arising out of or in any way related to your employment with Lineage, or the termination of that employment; (ii) except for your eligibility for the Separation Benefits pursuant to the terms of Section 2 above and the Consulting Relationship pursuant to the terms of Section 3 above, all claims related to your compensation or benefits from Lineage, including salary, bonuses, commissions, incentive compensation, vacation pay, expense reimbursements, severance benefits, fringe benefits, stock, stock options, or any other ownership interests in Lineage; (iii) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing related to your employment with Lineage; (iv) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (v) all constitutional, federal, state, and local statutory and common law claims, including claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990 (as amended), the federal Age Discrimination in Employment Act of 1967 (as amended) (the "***ADEA***"), the federal Family and Medical Leave Act, the California Labor Code (as amended), and the California Fair Employment and Housing Act (as amended).

(c)Excluded Claims. Notwithstanding the foregoing, the following are not included in the Released Claims (the "***Excluded Claims***"): (1) any right to indemnification and/or contribution, advancement or payment of related expenses you may have pursuant to Lineage's Bylaws or Restated Articles of Incorporation, as amended, or under any written indemnification or other agreement between Lineage and you, and/or under applicable law; (2) any rights you may have to insurance coverage under any directors and officers liability insurance, other insurance policies of Lineage, COBRA or any similar state law; (3) any claims for worker's compensation, state disability or unemployment insurance benefits, or any other claims that cannot be released as a matter of applicable law; (4) rights to any vested benefits under any stock, compensation or other employee benefit plan of Lineage; (5) any rights you may have as an existing shareholder of Lineage; and (6) any claims arising after the effective date of this Agreement. In addition, nothing in this Agreement prevents you from filing a charge or complaint with the Equal Employment Opportunity Commission or any similar state or local fair employment law agency, the Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal, state or local governmental agency or commission (collectively, the "***Government Agencies***"). This Agreement does not limit your ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agencies. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, to maximum extent permitted by law, you are otherwise waiving any and all rights you may have to individual relief based on any claims that you have released and any rights you have waived by signing this Agreement. You represent and warrant that, other than the Excluded Claims or as set forth on Exhibit A, you are not aware of any claims you have or might have against any of the Released Parties that are not included in the Released Claims.

10.ADEA Waiver. You hereby acknowledge that you are knowingly and voluntarily waiving and releasing any rights you may have under the ADEA, and that the consideration given for the waiver and release you have given in this Agreement is in addition to anything of value to which you were already entitled. You further acknowledge that you have been advised by this writing, as required by the ADEA, that: (a) your waiver and release does not apply to any rights or claims that may arise after the date you sign this Agreement; (b) you should consult with an attorney prior to signing this Agreement; (c) you have 21 calendar days to consider this Agreement (although you may choose voluntarily to sign this Agreement sooner); (d) you have 7 calendar days following the date you sign this Agreement to revoke your acceptance of this Agreement (in a written revocation sent to and received by George A. Samuel III, Lineage's General Counsel and Corporate Secretary); and (e) this Agreement (other than the provisions of Section 3 hereof) will not be effective until the date upon which the revocation period has expired, which will be the eighth calendar day after the date that this Agreement is signed by you provided that you do not revoke it; *provided that*, the provisions of Section 3 of this Agreement shall be effective as of December 4, 2023.

11. Waiver of Unknown Claims. YOU UNDERSTAND THAT THIS AGREEMENT INCLUDES A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS RELATED TO YOUR EMPLOYMENT BY LINEAGE. In giving the releases set forth in this Agreement, which include claims which may be unknown to you at present, you acknowledge that you have read and understand Section 1542 of the California Civil Code which reads as follows: **"A general release does not extend to claims that the creditor or releasing party does not**

know or suspect to exist in his or her favor at the time of executing the release and that, if known by him or her, would have materially affected his or her settlement with the debtor or released party." You hereby expressly waive and relinquish all rights and benefits under that section and any law or legal principle of similar effect in any jurisdiction with respect to your release of claims herein, including the release of unknown and unsuspected claims.

12.Representations. You hereby represent that as of the Separation Date you have been paid all compensation owed and for all hours worked as an employee of Lineage, other than the Separation Benefits; have received all the leave and leave benefits and protections for which you are eligible pursuant to the Family and Medical Leave Act, the California Family Rights Act, the Employment Agreement or otherwise; and have not suffered any on-the-job injury for which you have not already filed a workers' compensation claim.

13.Dispute Resolution. You and Lineage both agree that any and all disputes, claims, or causes of action, in law or equity, including statutory claims, arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment or Consulting Relationship with Lineage, its predecessors or affiliates, or the termination of your employment or Consulting Relationship with Lineage, its predecessors or affiliates, will be resolved pursuant to the Federal Arbitration Act, 9 U.S.C. §1-16, and to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS, Inc. ("***JAMS***") or its successors by a single arbitrator. The arbitration will be held in San Diego, California, or such other location as then-agreed by the parties. ***Both you and Lineage acknowledge that by agreeing to this arbitration procedure, you each waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding***. Any such arbitration proceeding will be governed by JAMS' then applicable rules and procedures for employment disputes, which will be provided to you upon request. In any such proceeding, the arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written arbitration decision including the arbitrator's essential findings and conclusions and a statement of the award. The arbitrator shall have the sole and exclusive authority to determine whether a dispute, claim or cause of action is subject to arbitration under this Agreement and to determine any procedural questions which grow out of such disputes, claims or causes of action and bear on their final disposition. You and Lineage each shall be entitled to all rights and remedies that either would be entitled to pursue in a court of law. Nothing in this Agreement is intended to prevent either Lineage or you from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration pursuant to applicable law. Lineage shall pay all filing fees in excess of those which would be required if the dispute were decided in a court of law, and shall pay the arbitrator's fees and any other fees or costs unique to arbitration. Any awards or orders in such arbitrations may be entered and enforced as judgments in the federal and state courts of any competent jurisdiction.

14.Notices. All notices required or permitted to be given under this Agreement shall be in writing and addressed to the other party at the address or email address (if provided) on the signature page to this Agreement and shall be deemed given: (a) on the day it is delivered personally (with receipt); (b) the day after it is deposited with a nationally recognized courier service for next day delivery; (c) when received if sent by registered or certified mail, return receipt requested; or (d) if delivered by email, when the recipient acknowledges receipt of the email, with an automatic "read receipt" not constituting acknowledgment of an email for the purposes of this Section 14.

15. Miscellaneous. This Agreement, the Confidentiality Agreement and any surviving sections of the Employment Agreement, the Indemnification Agreement and the Equity Documents, constitutes the complete, final and exclusive embodiment of the entire agreement between you and Lineage with regard to its subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of Lineage. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and Lineage, and inure to the benefit of both you and Lineage, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of California without regard to conflict of laws principles. Any ambiguity in this Agreement shall not be construed against either party as the drafter. Any waiver of a breach of this Agreement shall be in writing and shall not be deemed to be a waiver of any successive breach. The words “includes,” “including” and similar terms shall be construed as if followed by the words “without limitation.”

16. Execution. This Agreement may be executed by facsimile, DocuSign® or by email exchange of a portable document format (“pdf”) data file, where such signature shall be valid and binding with the same force and effect as if such facsimile or such pdf file were an original thereof.

[*Balance of Page Intentionally Left Blank*]

If this Agreement is acceptable to you, please sign below on or within 21 calendar days from the date you receive it from Lineage, and then promptly return the fully signed original to Lineage Human Resources. Lineage's offer under this Agreement will automatically expire if Lineage does not receive the fully signed Agreement from you within this timeframe.

We wish you the best in your future endeavors.

Sincerely,

LINEAGE CELL THERAPEUTICS, INC.

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

I HAVE READ, UNDERSTAND AND AGREE FULLY TO THE FOREGOING AGREEMENT:

By: */s/ Gary S. Hogge*
Gary S. Hogge

12/1/2023
Date

Exhibit 10.04(b)

AMENDMENT TO STOCK OPTION AGREEMENTS

This AMENDMENT TO STOCK OPTION AGREEMENTS (this "***Amendment***"), is made and entered into as of December 4, 2023 (the "***Amendment Date***"), by and between Lineage Cell Therapeutics, Inc., a California corporation (the "***Company***"), and Dr. Gary S. Hogge, an individual ("***Dr. Hogge***").

WHEREAS, the Company and Dr. Hogge previously entered into stock option agreements (collectively, the "***Option Agreements***") evidencing stock options granted to Dr. Hogge (collectively, the "***Options***") under either the Lineage Cell Therapeutics, Inc. 2012 Equity Incentive Plan (as amended from time to time, the "***2012 Plan***") or the Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan (as amended from time to time, the "***2021 Plan***" and together with the 2012 Plan, the "***Plans***"), certain of which are described in more detail herein;

WHEREAS, effective November 30, 2023 (the "***Separation Date***"), Dr. Hogge's employment with the Company as Senior Vice President, Clinical and Medical Affairs, as well as any other positions he held as an employee, officer and/or director of the Company or any of its subsidiaries or affiliates, terminated;

WHEREAS, in connection with such termination, Dr. Hogge and the Company entered into a separation, release and consulting agreement dated November 30, 2023 (the "***Separation and Consulting Agreement***"); and

WHEREAS, the Company and Dr. Hogge wish to amend the terms of certain of the Options and Stock Option Agreements in the manner set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the mutual representations, warranties and covenants, and subject to the conditions, set forth herein, and intending to be legally bound hereby, each of the Company and Dr. Hogge acknowledges and agrees as follows:

1.**Defined Terms**. All capitalized terms used herein and not herein defined shall have the meanings ascribed to them, when referring to Options granted under the 2012 Plan, in the 2012 Plan, and when referring to Options granted under the 2021 Plan, in the 2021 Plan.

2. **Stock Options**. The table below accurately describes each Option that is outstanding as of the Amendment Date (each, a "***Subject Option***" and collectively, the "***Subject Options***") and the extent to which the shares subject to the applicable Subject Option are vested or unvested as of the Amendment Date; it being agreed and understood that any Option, or any other equity award, granted to Dr. Hogge prior to the Amendment Date not set forth below is terminated, expired and/or forfeited:

Grant No.	Grant Date	Type (1)	Total Granted Shares (2)	Unexercised Vested Shares	Unvested Shares
021604	03/17/2020	ISO	205,652	168,529	37,000
021605	03/17/2020	NQ	238,348	44,221	0
021681	03/15/2021	ISO	66,817	6,735	60,082
021682	03/15/2021	NQ	352,683	272,931	79,752
021738	03/10/2022	ISO	54,046	0	54,046

021739	03/10/2022	NQ	395,954	187,500	208,454
021839	03/09/2023	ISO	66,523	0	66,523
021840	03/09/2023	NQ	333,477	0	333,477
18062	02/12/2018	ISO	152,362	10,300	0
18063	02/12/2018	NQ	94,837	0	0
22855	02/13/2019	ISO	32,811	32,811	0
22856	02/13/2019	NQ	79,689	0	0

(1) ISO means Incentive Stock Option and NQ means Non-Qualified Stock Option

(2) Refers to the aggregate number of common shares of the Company subject to the applicable Subject Option regardless of vesting status.

3.**Post-Termination of Service Exercise Period**. Notwithstanding the termination of Dr. Hogge's Continuous Service that occurred as of the Separation Date in accordance with the Separation and Consulting Agreement, to the extent the Subject Options were vested as of the Separation Date, the Administrator has approved extensions of the time within which a percentage of the Subject Options may be exercised. Accordingly, Section 2(b)(ii) of each of the Stock Option Agreements is hereby amended to read as follows:

> "(ii) 25% of the number of common shares identified in the "Unexercised Vested Shares" column of the table in Section 2 of the Amendment To Stock Option Agreements made and entered into as of December 4, 2023, by and between the Company and Participant (the "Amendment to Stock Options") of each of the Subject Options (as such term is defined in the Amendment to Stock Options) shall expire on each of March 31, 2024, April 30, 2024, May 31, 2024 and June 30, 2024;"

For the avoidance of doubt, nothing herein shall be deemed to extend the final expiration date set forth in any Stock Option Grant Notice for any of the Subject Options.

4.**Forfeiture of Unvested Shares and Equity Awards**. Notwithstanding anything to the contrary herein, the Company and Dr. Hogge agree that, as of the Separation Date, (i) all common shares identified in the "Unvested Shares" column of the table in Section 2 hereof (the "***Unvested Shares***") are deemed cancelled, that the applicable Subject Option is deemed to have expired, unexercised with respect to the Unvested Shares, and from and after the Separation Date, Dr. Hogge has no right, title or interest in any Unvested Shares; and (ii) other than the Subject Options addressed in Section 2 hereof, all other equity awards granted to Dr. Hogge (including, without limitation, that certain restricted stock unit and performance stock unit granted on February 11, 2022 covering an aggregate of 52,081 common shares and 52,083 common shares, respectively) are terminated, expired and/or forfeited, and Dr. Hogge has no right, title or interest in any such equity awards.

5.**Limitation on Transactions in Common Shares**.

5.1 During the period commencing on the Amendment Date and through and including June 30, 2024 (the "***Lock-Up Period***"), Dr. Hogge hereby agrees not to: (i) sell, offer to sell, contract or agree to

sell, hypothecate, pledge, grant any option to purchase, otherwise dispose of or agree to dispose of, directly or indirectly, more than 20,000 common shares of the Company per calendar day (subject to adjustment in accordance with Section 5.4), (ii) make any short sale with respect to the common shares of the Company, (iii) enter into any swap or hedging or other arrangement (including any short sale or the purchase or sale of, or entry into, any put or call option, or combination thereof, forward or any other derivative transaction or instrument, however described or defined, or other transaction) which is designed or intended to or which reasonably could be expected to lead to or result in a sale or disposition of more than 20,000 common shares of the Company per calendar day (subject to adjustment in accordance with Section 5.4), or that transfers to another, in whole or in part, any of the economic consequences of ownership of any such common shares, even if any such sale or disposition transaction or transactions would be made or executed by or on behalf of someone other than Dr. Hogge, whether any such transaction described in clauses (i), (ii) or (iii) above is to be settled by delivery of such securities, in cash or otherwise; or (iv) otherwise publicly announce any intention to engage in any of the foregoing (any of the foregoing described in clauses (i) through (iv), a "***Prohibited Transfer***").

5.2If any Prohibited Transfer is made or attempted contrary to the provisions of this Amendment, such purported Prohibited Transfer shall be null and void *ab initio*, and the Company shall have the right to refuse to recognize any such purported transferee of the common shares of the Company as one of its equity holders for any purpose. In order to enforce the provisions of this Section 5, the Company may impose stop-transfer instructions with respect to any common shares beneficially owned by Dr. Hogge (and permitted transferees and assigns thereof) until the end of the Lock-Up Period.

5.3During the Lock-Up Period, the Company shall have the right to mark each certificate or book-entry position evidencing common shares beneficially owned by Dr. Hogge with a legend in substantially the following form, in addition to any other applicable legends:

> "THE SECURITIES REPRESENTED HEREBY ARE SUBJECT TO RESTRICTIONS ON TRANSFER SET FORTH IN AN AGREEMENT BY AND BETWEEN THE ISSUER OF SUCH SECURITIES AND THE HOLDER OF THE SHARES. A COPY OF SUCH AGREEMENT WILL BE FURNISHED WITHOUT CHARGE BY THE ISSUER TO THE HOLDER HEREOF UPON WRITTEN REQUEST."

5.4In the event of changes in the outstanding common shares or in the capital structure of the Company by reason of any stock or extraordinary cash dividend, stock split, reverse stock split, an extraordinary corporate transaction such as any recapitalization, reorganization, merger, consolidation, combination, exchange, or other relevant change in capitalization occurring during the Lock-Up Period, the 20,000 common shares referenced in Section 5.1 will be equitably adjusted as to the number of shares.

6.**Acknowledgements**.

6.1Dr. Hogge understands and agrees that to the extent any Subject Option qualified as an Incentive Stock Option, such Subject Option will cease to so qualify in accordance with applicable law;

6.2 Dr. Hogge understands and agrees that the Company will not be responsible for any adverse or unexpected tax consequences imposed by Internal Revenue Code Sections 280G, 409A or 422 or any other law or regulation, and that Dr. Hogge will be solely responsible for any tax liability imposed on Dr. Hogge as a result of this Amendment or the impact on the Options resulting from this Amendment; and

6.3Dr. Hogge understands and agrees that neither the Plans, nor any of the Option Agreements or this Amendment imposes any obligation on the Company to continue any business relationship with the Dr. Hogge, including under the Separation and Consulting Agreement.

7.**No Other Amendments**. Except as specifically modified by this Amendment, the terms of the Option Agreements are and will remain in full force and effect and, except as expressly provided herein, nothing in this Amendment will be construed as a waiver of any of the rights or obligations of the Company or Dr. Hogge under the Option Agreements.

8.**Counterparts**. This Amendment may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument. This Amendment may be executed by facsimile, DocuSign® or by email exchange of a portable document format ("***pdf***") data file, where such signature shall be valid and binding with the same force and effect as if it were an original signature.

9.**Plans Controls**. This Amendment is made under and subject to the provisions of the Plans.

10.**Entire Agreement**. This Amendment, the Option Agreements and the Plans contain the entire understanding and agreement of the Company and Dr. Hogge concerning the subject matter hereof, and collectively supersede any other agreement or understandings, written or oral, between the parties with respect thereto.

11. **Governing Law**. This Amendment and the rights of all persons claiming hereunder will be construed and determined in accordance with the laws of the State of California without giving effect to the conflict of law principles thereof.

12.**Interpretation**. The headings, titles and subtitles set forth in this Amendment are for reference purposes only and shall not affect in any way the meaning or interpretation of this Amendment. Except when the context requires otherwise, any reference in this Amendment to any Section or clause shall be to the Sections and clauses of this Amendment. The words "herein," "hereto," "hereof" and "hereby" and other words of similar import in this Amendment shall be deemed in each case to refer to this Amendment as a whole and not to any particular section or other subdivision of this Amendment. The term "or" means "and/or". The words "include," "includes" and "including" are deemed to be followed by the phrase "without limitation". Reference to any person includes such person's successors and assigns to the extent such successors and assigns are permitted by the terms of any applicable agreement, and reference to a person in a particular capacity excludes such person in any other capacity or individually. Reference to any agreement (including this Amendment), document or instrument means such agreement, document or instrument as amended or modified and in effect from time to time in accordance with the terms thereof and, if applicable, the terms hereof. Reference to any law means such law as amended, modified, codified, replaced or re-enacted, in whole or in part, including rules, regulations, enforcement procedures and any interpretations promulgated thereunder, all as in effect on the date of this Amendment. Any reference to the masculine, feminine or neuter gender shall include such other genders and any reference to the singular or plural shall include the other, in each case unless the context otherwise requires.

13.**No Presumption Against Drafting Party**. Each of the parties acknowledges that it has participated jointly in the negotiation and drafting of this Amendment and has been represented by counsel, or the opportunity to be represented by counsel, in connection with this Amendment and the transactions contemplated hereby. Accordingly, any rule of law or any legal decision that would require interpretation of any claimed ambiguities in this Amendment against the drafting party has no application and is expressly waived.

14.**Specific Performance**. The parties agree that irreparable damage would occur in the event that any of the provisions of this Amendment were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Company shall be entitled to an injunction or

injunctions to prevent breaches of this Amendment by Dr. Hogge and to enforce specifically the terms and provisions hereof.

15. **Further Assurances**. From time to time, at another party's request and without further consideration, each party shall execute and deliver such additional documents and take all such further action as may be reasonably necessary to consummate the transactions contemplated by this Amendment.

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IN WITNESS WHEREOF, the undersigned have executed this Amendment as of the Amendment Date.

DR. GARY S. HOGGE

/s/ Gary S. Hogge

Gary S. Hogge

LINEAGE CELL THERAPEUTICS, INC.

/s/Brian M. Culley

Name: Brian M. Culley

Title: Chief Executive Officer

Exhibit 21.1

Lineage Cell Therapeutics, Inc.

The following is a list of subsidiaries of Lineage Cell Therapeutics, Inc. as of December 31, 2023, 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 23.1

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, and 333-254167), 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, relating to the consolidated financial statements of Lineage Cell Therapeutics, Inc, as of and for the years ended December 31, 2023 and 2022, which appears in this Form 10-K.

/s/ WithumSmith+Brown, PC

San Francisco, California
March 7, 2024

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 7, 2024

/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 7, 2024

/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, 2023 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 7, 2024

/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.

Exhibit 97

LINEAGE CELL THERAPEUTICS, INC.
POLICY ON RECOVERY OF ERRONEOUSLY AWARDED COMPENSATION
November 22, 2023

1.Overview

The Board believes that it is in the best interests of the Company and its shareholders to adopt this Policy to provide for the recovery of certain Incentive-Based Compensation in the event of an Accounting Restatement. This Policy is designed to comply with, and shall be interpreted to be consistent with, Section 10D of the Exchange Act, the regulations and rules promulgated by the SEC thereunder, including, without limitation, Rule 10D-1 promulgated under the Exchange Act ("Rule 10D-1"), and the applicable rules, regulations and listing standards of the Exchange (collectively, and as the same may be in effect from time to time, the "Applicable Rules"). Unless otherwise defined in this Policy, capitalized terms used in this Policy have the meanings given to them in Section 2.

2.Definitions

(a) "Accounting Restatement" means an accounting restatement of the Company's financial statements due to the Company's material noncompliance with any financial reporting requirement under U.S. securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

(b)"Board" means the Board of Directors of the Company, as constituted from time to time.

(c) "Clawback Eligible Incentive-Based Compensation" means, in connection with an Accounting Restatement and with respect to each individual who served as a Senior Executive at any time during the applicable performance period for any Incentive-Based Compensation (whether or not such Senior Executive is serving at the time the Erroneously Awarded Compensation is required to be recouped by the Company), all Incentive-Based Compensation Received by such Senior Executive (i) on or after the Effective Date, (ii) after beginning service as a Senior Executive, (iii) while the Company has a class of securities listed on a national securities exchange, and (iv) during the applicable Look-Back Period.

(d)"Committee" means the Compensation Committee of the Board or such other committee or subcommittee of the Board, if any, duly appointed to administer this Policy and having such powers in each instance as shall be specified by the Board and as specified in Section 3 of this Policy. The Board may also serve as the Committee.

(e)"Company" means Lineage Cell Therapeutics, Inc., a California corporation.

(f)"Effective Date" means October 2, 2023.

(g)"Erroneously Awarded Compensation" means, with respect to each Senior Executive in connection with an Accounting Restatement, the amount of the Clawback Eligible Incentive-Based Compensation that exceeds the amount of the Incentive-Based Compensation that would have been Received had the amount of such Incentive-Based Compensation been calculated based on the restated amounts, as determined by the Committee, calculated by the Committee without regard to any taxes paid. With respect to Incentive-Based Compensation based on (or derived from) TSR or stock price, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in the applicable Accounting Restatement, the Committee shall determine the amount of Erroneously Awarded Compensation based on a reasonable estimate of the effect of the Accounting Restatement on the TSR or stock price upon which the Incentive-Based Compensation was Received.

(h)"Exchange" means the NYSE American.

(i)"Exchange Act" means the Securities Exchange Act of 1934, as amended.

(j)"Financial Reporting Measure" means any measure that is determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measure, including but not limited to, "non-GAAP financial measures" for purposes of Exchange Act Regulation G and Item 10 of Regulation S-K, as well as other measures, metrics and ratios that are not non-GAAP measures, like same store sales. Financial Reporting Measures include but are not limited to the following (and any measures derived from the following): stock price; TSR; revenues; net income; operating income; profitability of one or more reportable segments; financial ratios (e.g., accounts receivable turnover and inventory turnover rates); earnings before interest, taxes, depreciation and amortization; funds from operations and adjusted funds from operations; liquidity measures (e.g., working capital, operating cash flow); return measures (e.g., return on invested capital, return on assets); earnings measures (e.g., earnings per share); sales per square foot or same store sales, where sales is subject to an Accounting Restatement; revenue per user, or average revenue per user, where revenue is subject to an Accounting Restatement; cost per employee, where cost is subject to an Accounting Restatement; any of such financial reporting measures relative to a peer group, where the Company's financial reporting measure is subject to an Accounting Restatement; and tax basis income. A Financial Reporting Measure need not be presented within the Company's financial statements or included in a report or other document filed with the SEC.

(k)"Incentive-Based Compensation" means any compensation granted, earned or vested based wholly or in part upon the attainment of a Financial Reporting Measure, measured on a pre-tax basis. Incentive-Based Compensation includes, without limitation: any non-equity incentive plan awards that are earned based wholly or in part on satisfying a Financial Reporting Measure performance goal; bonuses paid from a "bonus pool," the size of which is determined based wholly or in part on satisfying a Financial Reporting Measure performance goal; other cash awards based on satisfaction of a Financial Reporting Measure performance goal; restricted stock, restricted stock units, performance share units, stock options, and stock appreciation rights that are granted or become vested based wholly or in part on satisfying a Financial Reporting Measure Performance Goal; and proceeds received upon the sale of shares acquired through an incentive plan that were granted or vested based wholly or in part on satisfying a Financial Reporting Measure performance goal.

(l)"Look-Back Period" means, with respect to an Accounting Restatement, the three completed fiscal years of the Company immediately preceding the Restatement Date and any transition period (that results from a change in the Company's fiscal year) within or immediately following those three completed fiscal years (except that a transition period that comprises a period of at least nine months shall count as a completed fiscal year).

(m)"Policy" means this Policy on Recovery of Erroneously Awarded Compensation as the same may be amended, modified, supplemented, and/or restated from time to time.

(n) "Received" means, with respect to Incentive-Based Compensation, actual or deemed receipt, and Incentive-Based Compensation shall be deemed "Received" in the Company's fiscal period during which the applicable Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment or grant of such Incentive-Based Compensation occurs after the end of that period. If an equity award vests only upon satisfaction of a Financial Reporting Measure performance condition, the award shall be deemed Received in the fiscal period when it vests. Ministerial acts or other conditions necessary to effect issuance or payment, such as calculating the amount earned or obtaining Board approval of payment, do not affect the determination of the date Received.

(o)"Restatement Date" means the earlier to occur of (i) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting

Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare an Accounting Restatement, in each case regardless of if or when the restated financial statements are filed.

(p)"SEC" means the U.S. Securities and Exchange Commission.

(q)"Senior Executives" means any person who was the Company's president, principal financial officer, principal accounting officer (or if there is no such accounting officer, the controller), any vice-president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performed a policy-making function, or any other person who performed similar policy-making functions for the Company and any other "key employees" who were designated as "Senior Executives" by the Committee. Executive officers of the Company's parents or subsidiaries may be deemed Senior Executives if they perform policy-making functions for the Company. For purposes of this definition, policy-making function is not intended to include policy-making functions that are not significant. All executive officers of the Company identified by the Board pursuant to Item 401(b) of Regulation S-K shall be deemed Senior Executives.

(r)"TSR" means total shareholder return.

3.Administration of Policy

(a)The Policy shall be administrated by the Committee. All questions of interpretation or application of this Policy shall be determined by the Committee. All Committee decisions shall be final and binding upon all persons and shall be afforded the maximum deference permitted under applicable law. The Committee is authorized to make all determinations necessary, appropriate or advisable for the administration of this Policy and to use any of the Company's resources it deems appropriate to recoup Erroneously Awarded Compensation.

(b)Determinations of financial and/or accounting irregularities for purposes of this Policy shall be made by the Committee independently of, and the Committee shall not be bound by, determinations by management or by any other committee of the Board.

(c)In the administration of this Policy, the Committee is authorized and directed to consult with the full Board or such other committees of the Board as may be necessary or appropriate as to matters within the scope of such other committee's responsibility and authority. Subject to any limitation under applicable law, the Committee may authorize and empower any officer or employee of the Company to take any and all actions necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

4.Accounting Restatements; Recoupment

(a)If the Company is required to prepare an Accounting Restatement, the Company shall determine, in accordance with this Policy and the Applicable Rules, the amount of any Erroneously Awarded Compensation for each Senior Executive in connection with such Accounting Restatement, irrespective of any fault, misconduct or responsibility of any Senior Executive for the Accounting Restatement, and thereafter the Company shall reasonably promptly recover such amount of Erroneously Awarded Compensation. In connection with the foregoing, the Committee, which may act in conjunction with the Company's Audit Committee, shall take all such actions required by this Policy and the Applicable Rules.

(b)If there was Erroneously Awarded Compensation, the Committee shall determine, in its sole discretion, the timing and method(s) for promptly recouping the same, which methods may include, without limitation, one or more of the following: (i) requiring reimbursement of any Erroneously Awarded Compensation; (ii) requiring reimbursement of any equity based compensation awarded; (iii) cancelling outstanding cash or equity-based awards, whether vested or unvested or paid or unpaid; (iv) cancelling or offsetting against any compensation otherwise owed by the Company to the Senior Executive, including any future cash or equity-based awards; (v) requiring the forfeiture of deferred compensation, subject to compliance with Section 409A of the

Internal Revenue Code and the regulations promulgated thereunder; (vi) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards; and (viii) pursuing any other reasonable remedies. Subject to compliance with applicable law, the Committee may effect recoupment under this Policy from any amount otherwise payable to a Senior Executive, including amounts payable to such individual under any otherwise applicable Company plan or program, including base salary, bonuses or commissions and compensation previously deferred by the Senior Executive.

(c)To the extent that the Committee determines to recoup Erroneously Awarded Compensation from a Senior Executive by requiring the repayment of such Erroneously Awarded Compensation to the Company, and such Senior Executive fails to repay all Erroneously Awarded Compensation to the Company when due, the Company may take all actions reasonable and appropriate to recover such Erroneously Awarded Compensation from the applicable Senior Executive. The applicable Senior Executive shall be required to reimburse the Company for any and all expenses reasonably incurred (including legal fees) by the Company in recovering such Erroneously Awarded Compensation in accordance with the immediately preceding sentence.

(d)In the event of an Accounting Restatement, except to the extent permitted by the Applicable Rules, the Committee will generally treat all Senior Executives (including former employees) the same with respect to any actions seeking to recoup Erroneously Awarded Compensation.

5.Impracticability

Notwithstanding anything to the contrary herein, the Company shall not be required to recoup Erroneously Awarded Compensation under this Policy if the Company's committee of independent directors responsible for executive compensation decisions, or in the absence of such a committee, a majority of the independent directors serving on the Board, has determined that recovery would be impracticable in accordance with the Applicable Rules and subject to the procedural and disclosure requirements in the Applicable Rules.

6.Other Recoupment Rights

The Board intends that this Policy shall be applied to the fullest extent of the law. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment that may be available to the Company under applicable law (including, without limitation, Section 304 of the U.S. Sarbanes-Oxley Act of 2002, as amended, or Section 954 of the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, as amended), pursuant to the terms of any other policy of the Company, pursuant to the terms of any employment agreement, equity award agreement, severance or other agreement, and any other legal remedies available to the Company. Nothing herein, and no recoupment or recovery as contemplated by this Policy, shall (i) limit any claims, damages or other legal remedies the Company or any of its affiliates may have against a Senior Executive arising out of or resulting from any actions or omissions by the Senior Executive or (ii) limit the Company's ability to seek recovery, in appropriate circumstances (including circumstances beyond the scope of this Policy) as permitted by applicable law, of any amounts from any employee, whether or not the employee is a Senior Executive.

7.No Indemnification or Company-Paid Insurance

Notwithstanding the terms of any indemnification or insurance policy or any contractual arrangement with any Senior Executive that may be interpreted to the contrary: (a) the Company shall not indemnify any Senior Executive against (i) the loss of any Erroneously Awarded Compensation that is recouped, repaid, returned or recovered pursuant to the terms of this Policy; or (ii) any claims relating to the Company's enforcement of its rights under this Policy; and (b) the Company is prohibited from paying or reimbursing a Senior Executive for the cost of or premiums of any third-party insurance purchased to fund any potential obligations of a Senior Executive under this Policy. Further, the Company shall not enter into any agreement that exempts any Incentive-Based Compensation from the application of this Policy or that waives the Company's right to recoup any Erroneously

Awarded Compensation, and this Policy shall supersede any such agreement (whether entered into before, on or after the Effective Date).

8.Committee Indemnification

No members of the Committee, nor any other members of the Board who assist in the administration of this Policy, nor any officer of employee of the Company authorized and empowered by the Committee who assists in the administration of this Policy shall be personally liable for any action, determination or interpretation made with respect to this Policy, and each of the foregoing shall be fully indemnified by the Company to the fullest extent under applicable law and Company policy with respect to any such action, determination or interpretation. The foregoing sentence shall not limit any other rights to indemnification of the members of the Board or any officer of employee of the Company under applicable law, Company policy or contractual arrangement.

9.Retroactive Application

This Policy applies to any Incentive-Based Compensation that is Received by a Senior Executive on or after the Effective Date, even if such Incentive-Based Compensation was approved, awarded, granted or paid to such Senior Executive prior to the Effective Date. Without limiting the generality of Section 4, and subject to applicable law, the Committee may recoup Erroneously Awarded Compensation under this Policy from any amount of compensation approved, awarded, granted, payable or paid to the Senior Executive prior to, on or after the Effective Date.

10.Notice to Senior Executives

The Company shall provide notice and seek written agreement to this Policy from each Senior Executive in form attached hereto; provided, that the failure to obtain such agreement shall have no impact on the applicability or enforceability of this Policy.

11.Amendment and Termination; Interpretation; Successors

(a)The Board may amend, modify, supplement, restate, rescind, terminate or replace all or any portion of this Policy at any time and from time to time in its sole discretion, including, without limitation, as the Board deems necessary to reflect and comply with applicable law or any of the Applicable Rules. To the extent of any inconsistency between this Policy and any of the Applicable Rules, the Applicable Rules shall control and this Policy shall be deemed amended to incorporate such Applicable Rules unless the Committee shall expressly determine otherwise. Notwithstanding anything to the contrary herein, no amendment, modification, supplement, restatement, rescission, termination or replacement of this Policy shall be effective if such amendment, modification, supplement, restatement, rescission, termination or replacement would (after taking into account any actions taken by the Company contemporaneously with such amendment, modification, supplement, restatement, rescission, termination or replacement) cause the Company to violate any of the Applicable Rules or other applicable law.

(b) This Policy shall be binding and enforceable against all Senior Executives and their beneficiaries, heirs, executors, administrators or other legal representatives, to the fullest extent of the law.