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, 2025

OR

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

Commission file number 001-12830

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

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

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

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

Securities registered pursuant to Section 12(b) of the Act

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common shares	**LCTX**	**NYSE American LLC**

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 13(a) of the Exchange Act. ☐

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

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

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

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

The aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the registrant's common shares on the NYSE American on June 30, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was $161.5 million.

The number of common shares outstanding as of March 5, 2026 was 249,087,529.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2026 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 AlloSCOPE™ platform and 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 timing and likelihood of regulatory filings and approvals;
- expected regulatory pathways;
- the potential of our cell therapy platform;
- our ability to obtain additional capital to fund our operations;
- the potential that holders of outstanding warrants to purchase our common shares will exercise such warrants on a cash basis;
- our expectations and plans regarding existing and potential future collaborations with third parties such as pharmaceutical and biotechnology companies, government agencies, academic laboratories, and research institutes for the discovery, development, and/or commercialization of novel cell therapy products;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- the potential scope and value of our intellectual property rights; and
- the effects on our operations and workforce and on clinical trials (including those involving OpRegen®) of the ongoing Israeli regional conflict, the escalation of hostilities in the Middle East resulting from the strikes by Israel and the United States on Iran that commenced on February 28, 2026, and broader geopolitical conflicts, political and economic instability, public health emergencies and macroeconomic conditions.

Forward-looking statements reflect our views and expectations as of the date of this report about future events and our future performance and condition, and involve known and unknown risks, uncertainties and other factors that may cause our actual activities, performance, results or condition to be materially different from those expressed or implied by the forward-looking statements. You should refer to Part I, Item 1A. "Risk Factors" of this report for a discussion of important factors that may cause our actual activities, performance, results and condition to differ materially from those expressed or implied by our forward-looking statements. As a result of a variety of factors, including those discussed in Part I, Item 1A. of this report, our forward-looking statements may prove to be inaccurate, and the inaccuracy may be material. Accordingly, you should not place undue reliance on any forward-

looking statement. We anticipate that subsequent events and developments may cause our current views and expectations to change. However, while we may elect to update the forward-looking statements in this report at some point in the future, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date after the date of this report.

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

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

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

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

RISK FACTOR SUMMARY

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

- We are dependent on our third-party collaboration with F. Hoffmann-La Roche Ltd and Genentech, Inc to develop and commercialize RG6501 (OpRegen). If our collaborators are not successful in developing and commercializing OpRegen and/or they terminate the collaboration, we will lose a significant source of potential revenue, development and potential regulatory approval of OpRegen may be significantly delayed, and we may not be successful in establishing an alternative strategic collaboration or pursuing independent development and commercialization of OpRegen.
- Any failure or delay in the successful transfer of manufacturing process know-how by us to Roche or the inability of Roche to manufacture comparable cells could halt or delay the continued development of OpRegen.
- We have incurred operating losses since inception, and we do not know if or when we will attain profitability. 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 as determined by the U.S. Food & Drug Administration ("FDA").
- Our investigational allogeneic cell therapies represent a novel approach to the treatment of serious medical conditions, which gives rise to significant challenges. Clinical development of our product candidates is a lengthy and expensive process with a high level of uncertainty as to timing and ultimate outcome. We may not be successful in identifying new product candidates and neither we nor our collaborators may succeed in developing or obtaining regulatory approval to market and sell any of our product candidates.
- Our decisions regarding whether to advance our programs internally or through strategic relationships may not maximize the value of our pipeline for our shareholders, and misjudgments in these decisions could materially adversely affect our business.
- We will need to raise substantial additional capital and capital raising transactions may cause dilution to our existing shareholders, restrict our operations, or require us to relinquish rights to or dilute our economic interest in our product candidates or technology. If we are unable to obtain adequate capital, we may delay, reduce, limit the pace of, suspend or discontinue our product and technology development programs, which could significantly harm our business and prospects and cause the market price of our common shares to decline.
- We may expend our limited resources to identify or pursue particular product candidates and fail to identify other new product candidates or to capitalize on other product candidates that may be more profitable or for which there is a greater likelihood of success.
- If we fail to meet our obligations under our in-license agreements, we may lose our rights to key technologies on which our business depends.
- All of our manufacturing operations currently are conducted by our subsidiary Cell Cure Neurosciences Ltd. ("CCN") at our facility in Jerusalem, Israel, and the escalation of conflict and hostilities in the Middle East or any other event or condition, such as political and economic conditions in Israel or the broader region, war, cyberattacks, terrorist attacks or other armed conflicts involving Israel and the broader region 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 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 FDA and other regulatory authorities, which could increase the complexity, cost and timeline for their development and regulatory approval.
- The administration of our cell therapy product candidates requires surgical transplantation, which exposes us to additional regulatory, clinical, operational and commercial risks that could materially adversely affect our business, results of operations and prospects.
- Disruptions at the FDA and other government agencies, including due to a lack of funding, changes in leadership or significant personnel turnover, could delay or disrupt clinical and preclinical development and potential marketing approval of our product candidates and hinder our ability to raise additional capital.
- The 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, review and/or verification procedures that could result in final clinical data that is materially different and unfavorable.
- The manufacture of our cell therapy product candidates is complex, highly regulated and subject to a multitude of risks. We have limited experience manufacturing our product candidates on a clinical scale and no experience manufacturing on a commercial scale. Any failure to manufacture our product candidates in sufficient quantities in accordance with applicable quality standards and regulatory requirements and at acceptable costs may result in significant clinical development delays, or impair the ability to obtain approval for or commercialize our product candidates.
- Because developing cell therapy products is based on novel technologies that are unproven and may not result in approvable or marketable products, the lack of success, or perceived lack of success, of other companies developing or seeking to develop cell therapy products may adversely impact investor sentiment regarding our business and the market opportunities for our product candidates.
- Use of our product candidates could be associated with side effects, adverse events, or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon a product candidate, limit the commercial profile of an approved label, or result in other significant negative consequences that could severely harm our business, financial condition, results of operations, and prospects. In addition, adverse safety events involving other cell therapies, including therapies receiving conditional or time-limited approvals, could increase regulatory scrutiny and negatively affect investor sentiment and the perception of the cell therapy field.
- 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, and if a product candidate is approved, commercialization.
- The commercial success of any product candidate will depend upon the degree of market acceptance by physicians, patients and third-party payors, and if the market opportunities for our product candidates prove to be significantly smaller than we estimate, our business prospects may suffer.
- 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 production as well as for clinical trials of our product candidates.
- The market price of our common shares has been and may continue to be volatile.
- Our largest shareholder, who is affiliated with a member of our board of directors, owns a significant percentage of our common shares and will be able to exert substantial influence over the election of directors and matters subject to shareholder approval, including potential change of control transactions.
- There is no assurance that we will be able to maintain compliance with the NYSE American's continued listing standards, and failure to do so could result in the suspension of trading or delisting of our common shares, which could substantially impair our shareholders' ability to sell their shares and our ability to raise additional capital.

ITEM 1. BUSINESS

Overview

We are a clinical-stage biotechnology company developing cell replacement therapies to treat serious medical conditions. Certain diseases and medical events can arise from the loss of critical cellular activity and lead to devastating or difficult-to-treat conditions or impairments. Our work is grounded in the emerging evidence that replacing or supporting those cells that have become dysfunctional or "lost" (destroyed or dead) can restore or replenish normal function and improve treatment and recovery paradigms. We call this approach "Replace and Restore". We believe cellular therapies aimed at entirely replacing dysfunctional or destroyed cells may have more durable, broader, or suitable applicability than traditional pharmaceutical products, which often seek to affect just a single molecular target or group of biological pathways. Transplantation of replacement cells represents an emerging branch of medicine, and we believe we are uniquely positioned to capitalize on its opportunities by demonstrating the value of administering mature, differentiated cells to patients. We are developing a portfolio of assets based on this mechanism and our most clinically-advanced program to date is OpRegen (RG6501), an allogeneic retinal pigmented epithelial (RPE) cell replacement therapy currently in Phase 2a development under a worldwide collaboration with F. Hoffman-La Roche Ltd. and Genentech, Inc., a member of the Roche Group (collectively or individually, "Roche" or "Genentech"), for the treatment of geographic atrophy (GA) secondary to dry-AMD.

The cells we have or may seek to manufacture are intended to replace the same type of cells that the patient has lost, or which have become dysfunctional due to various conditions, such as in dry age-related macular degeneration (dry-AMD), spinal cord injury (SCI), hearing loss and Type 1 Diabetes (T1D). We view the term cell transplant as more applicable to our approach than "stem cell therapy", because we never administer stem cells to patients. Instead, we utilize stem cells solely as a source material, from which to create and deliver partly or fully differentiated (i.e. mature) and functionally active "replacement" cells that are intended to be substantially identical to the cells which have been impacted by disease or trauma. These replacement cells are then transplanted, historically in a one-time procedure, to treat conditions caused by the loss or dysfunction of a specific cell type. Additionally, each of our product candidates is allogeneic and is derived from a single, carefully selected and cultured cell line for the life of the product, which eliminates donor variability and may mitigate certain regulatory and clinical risks.

Our programs are based on our proprietary, in-house, cell-based manufacturing platform, which we call AlloSCOPE™ (Allogeneic, Scalable, Consistent, Off-the-shelf, Pluripotent Cell Engineering), and supported by our associated development, formulation, manufacturing, and delivery capabilities. The AlloSCOPE platform is a proprietary differentiation and production modality from which, i) a single, well-characterized pluripotent cell line can create a stable current Good Manufacturing Practice (cGMP) master cell bank (MCB), ii) a vial from our MCB can create a cGMP working cell bank (WCB), and iii) a vial from our WCB can create several hundred to many thousands of vials of a final, allogeneic cell-based product, ready for patient dosing. This process confers consistent, cost-effective, and scalable cell-based production. Importantly, the AlloSCOPE platform can be applied across multiple programs, which we believe could offer advantages in the pursuit of commercially successful, allogeneic and "off the shelf" cell therapies. In some instances, we also apply a proprietary "thaw-and-inject" formulation into our product profiles, which allows for rapid dosing and "immediate use" of our cells. This formulation technology can greatly reduce the lengthy dose preparation steps often associated with certain cell therapy programs.

Our business strategy aims to efficiently leverage our AlloSCOPE platform and our development and manufacturing expertise to create a pipeline of related but discrete cell-based assets, some of which we may advance internally toward commercialization and some of which we may seek to partner during early or late development, if we believe doing so will enhance their probability of success and value to Lineage and our shareholders . All of our product candidates are based on our core AlloSCOPE platform, and utilize our extensive expertise in the directed differentiation and scalable production of pluripotent cells into discrete cell types of the human body.

The AlloSCOPE Manufacturing Platform

AlloSCOPE, which stands for Allogeneic, Scalable, Consistent, Off-the-shelf, Pluripotent Cell Engineering, is the name we've given to our proprietary allogeneic cell manufacturing platform. AlloSCOPE describes a proprietary differentiation and production modality from which we have demonstrated the ability to manufacture allogeneic,

cell-based product derived from a single initial cell line, conferring consistent, cost-effective, and scalable cell-based production. We believe this enables our capability to produce millions of doses of a consistent and cost-effective cell-based product. From our AlloSCOPE platform, we develop, manufacture, and test specialized human cells with anatomical and physiological functions similar or substantially identical to cells found naturally in the human body. The cells we manufacture are produced by applying directed differentiation processes to established, well-characterized, and self-renewing pluripotent cell lines. These processes are based on specific developmental lineages and generate cells with desired characteristics. Functional cells developed from such lineages, and which are relevant to the underlying condition, are transplanted into patients in an effort to (a) replace or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and (b) restore or enhance the patient's functional activity in that target tissue.

To date we have successfully completed a current cGMP production run from our two-tiered cell banking system for two of our product candidates. In at least one instance, they have been utilized in a U.S. Food and Drug Administration (FDA) cleared clinical trial in 2025. This demonstrates our ability to scale pluripotent cells with the purity, potency, and regulatory quality required for clinical use, a standard which we believe is currently beyond the reach of many companies, and which can become a valuable competitive differentiator for Lineage.

Pipeline

Our pipeline currently includes:

- *OpRegen (designated as RG6501 by Roche and Genentech)*, an allogeneic RPE cell replacement therapy currently in Phase 2a development under a worldwide collaboration with Roche, for the treatment of GA secondary to dry-AMD.
- *OPC1*, an allogeneic oligodendrocyte progenitor cell therapy currently in Phase 1/2a development for the treatment of spinal cord injuries (SCI).
- *ReSonance™* (ANP1), an allogeneic auditory neuron progenitor cell transplant therapy currently in preclinical development under collaboration with William Demant Invest 2 Aps (WDI) for the treatment of auditory neuropathy.
- *ILT1,* an allogeneic cell transplant research initiative focused on addressing the issue of large-scale production of undifferentiated pluripotent cells, which if successful could support the production of islet cells to support a potential treatment of Type 1 Diabetes (T1D).
- *RND1,* a novel hypoimmune induced pluripotent stem cell line being evaluated under a gene editing partnership with Factor Biosciences Limited (Factor) for the development of a cell transplant candidate for the potential treatment of an undisclosed indication.
- *PNC1*, an allogeneic photoreceptor cell therapy research initiative for the potential treatment of vision loss due to photoreceptor dysfunction or damage.
- *LCT-CON*, an undisclosed allogeneic cell transplant research initiative currently receiving internal research & development investment.

Select Business Highlights

We and our partners have achieved numerous clinical, strategic and operational milestones during 2025:

- Reduced-to-practice critical aspects of commercial-scale, cell-based GMP production process (i.e. demonstration of the high-scale production potential from the AlloSCOPE manufacturing platform).
- Successful and ongoing execution of Lineage's contributions to our worldwide collaboration with Roche and Genentech for the development of OpRegen (RG6501) across multiple functional areas.
- Achieved first milestone available under our collaboration and license agreement with Roche and Genentech based on manufacturing and clinical advancements to the OpRegen (RG6501) program.

- Reported durable improvement in best corrected visual acuity (BCVA) in dry AMD patients who received successful targeted administration of OpRegen (RG6501), as reported from a Phase 1/2a clinical study 36-month visual acuity update at Clinical Trials at the Summit 2025.
- Treated the first-ever chronic SCI patient using a novel delivery device in a clinical study of OPC1 in patients with subacute and chronic SCI.
- Entered into collaboration with WDI to advance the preclinical development ReSonance (ANP1) for sensorineural hearing loss.
- Initiated our ILT1 research program to address the manufacturing scale necessary for a cell transplant therapy to potentially treat T1D

Figure 1. Lineage's Allogeneic Cell Transplant Pipeline

Business Strategy

The field of cell therapy has revolutionized oncology, saving lives and creating substantial shareholder value. We believe the natural next frontier of value-creation in cell therapy resides in non-oncology indications, such as neurology, ophthalmology, and metabolic diseases. We also believe Lineage is well-positioned to capitalize on this opportunity, mainly by applying our proprietary cell manufacturing technology to the production and transplantation of differentiated cell types.

Lineage is seeking to be a leader in this new branch of medicine. We prefer the term cell transplant to cell therapy because we don't administer "stem cells" to patients. Instead, we create and deliver mature, differentiated and active "replacement" cells that are substantially functionally identical to the cells which an individual has lost or has become dysfunctional due to disease or trauma. Those cells have been, to date, transplanted in a one-time procedure to treat conditions caused by the loss or dysfunction of a specific cell type. Each of our product candidates is allogeneic and utilizes a single, carefully selected and cultured cell line for the life of the product, which eliminates donor variability and reduces regulatory and clinical risk. Our work is grounded in the conviction that replacing lost or dysfunctional cells can restore function and fundamentally reshape many treatment paradigms.

Our lead program, OpRegen, is being developed under a worldwide collaboration with Roche and Genentech for the treatment of GA secondary to dry-AMD and is currently in a phase 2a clinical study. Our second clinical-stage program, OPC1, is an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury. One of our preclinical programs, ReSonance (ANP1), is an allogeneic auditory

neuron progenitor cell transplant therapy currently in preclinical development under collaboration with WDI for the treatment of auditory neuropathy. We also recently launched a research initiative focused on addressing the issue of large-scale production of undifferentiated pluripotent cells, which if successful could be evaluated for the production of islet cells to support a potential treatment of T1D, and we have several additional indications being evaluated for future development.

Our core technology, including our AlloSCOPE platform, generates assets which share essential traits in common. Those assets are based foremost on the directed differentiation of pluripotent cells into discrete and scalable cell types of the human body. And while each product candidate is intended for a different condition, and each cell line behaves in a unique manner, the early and necessary steps of process development, namely control, scale, and purity, are largely common features in the way they are applied under the AlloSCOPE platform, which allows us to expand the scope of our pipeline in a focused manner and potentially without requiring an excessive amount of capital investment. Adapting or initiating each program on the same process development modality under the AlloSCOPE platform also may allow us to generate more shots on goal per dollar invested.

Our business strategy is to efficiently leverage our AlloSCOPE platform and our development and manufacturing capabilities to create a pipeline of cell-based assets, some of which we might advance internally and some of which we might seek to partner in order to further enhance their value and probability of success, but all of which rely on our core technology and platform, and which utilize our extensive expertise in the directed differentiation and scalable production of pluripotent cells into discrete cell types of the human body.

Cell Therapy Technology Platform

AlloSCOPE (Allogeneic, Scalable, Consistent, Off-the-shelf, Pluripotent Cell Engineering) Platform

We believe we are a leader in pluripotent, cell-based non-oncology product development, as evidenced by our proprietary directed differentiation processes for multiple cellular lineages, cell manufacturing capabilities, corporate alliances, and stage of clinical development across multiple programs.

All our programs are based on our proprietary, cell-based technology platform, AlloSCOPE, which is supported by our development, formulation, manufacturing and delivery capabilities, and serves as the source of our pluripotent cell-based product candidates. 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. The AlloSCOPE platform describes in particular a differentiation and production modality, from which we believe we can manufacture millions of doses of an allogeneic, cell-based product derived from a single initial and pluripotent cell line, conferring consistent, cost-effective, and scalable cell-based production. Importantly, the AlloSCOPE platform can be applied across multiple programs and highlights the key attributes of our in-house technology, which we believe are necessary to create a commercially successful, “off the shelf” allogeneic cell therapy.

Our product candidates consist of functional cells that may be able to replace faulty or absent cells, attenuate disease progression, or facilitate tissue repair. Based on our AlloSCOPE platform, we develop, manufacture, and test specialized human cells with anatomical and physiological functions similar or identical to cells found naturally in the human body. The cells we manufacture are produced by applying directed differentiation processes to established, well-characterized, and self-renewing pluripotent cell lines. These processes are based on specific developmental lineages and generate cells with desired characteristics. Functional cells developed from such lineages and which are relevant to the underlying condition are transplanted into patients in an effort to (a) replace or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and (b) by that restore or enhance the patient's functional activity.

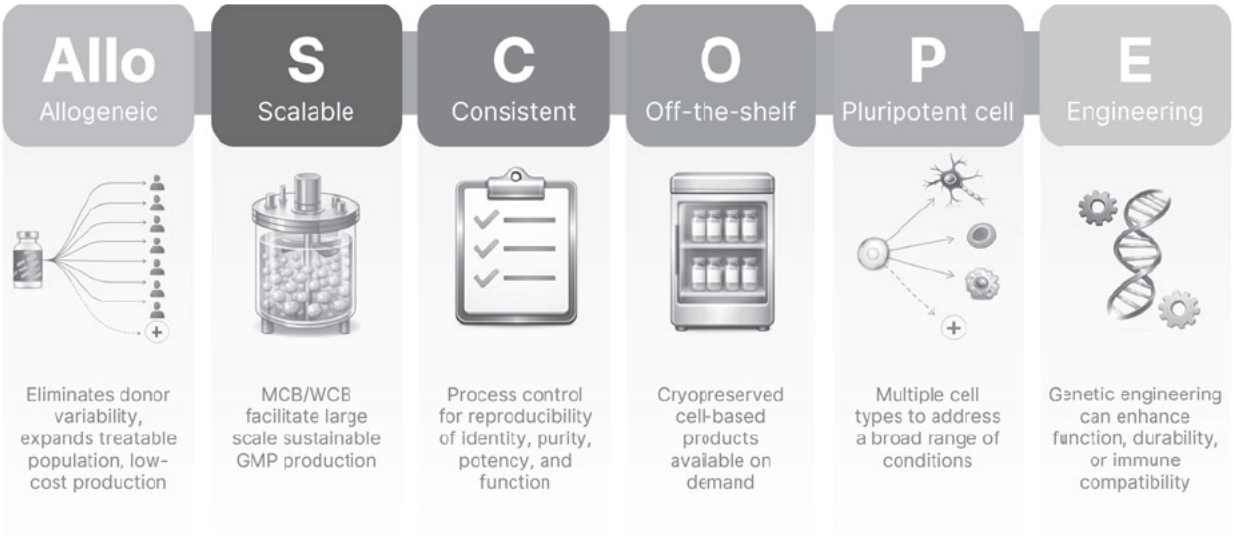
A key advantage of our approach is that we have demonstrated the ability to rapidly develop new programs without the extensive and costly steps traditionally required to develop a small molecule agonist or antagonist. Small molecule product development typically requires selection and validation of a drug target, followed by screening millions of molecules (e.g., a “library”) to identify hits, followed by chemical modification to develop a hit into a potent lead. The process of developing a new cell therapy from pluripotent lines may be comparatively faster in regards to product identification because the target cell type is clearly linked to a condition and may already

generally be "validated", insofar as it is normally well-established in the literature as being the cell type which is dysfunctional or deficient in the patient and for which its identity and disease-related functional properties can be imitated.

A significant challenge facing the cell therapy field is the ability to create a stable cell product with the purity, control, reproducibility, potency and other vital manufacturing attributes, and to do so at the scale and cost needed to adequately and profitably supply the addressable market population with broad penetration. We believe these features are vital to creating a successful allogeneic cell transplant product.

We believe one of our key advantages is the progress we have made toward demonstrating these capabilities in a cGMP environment and releasing actual production lots for clinical use, which to our knowledge has not been achieved by most of our competitors. To date, we have successfully completed a current cGMP production run from our two-tiered cell banking system for two of our product candidates. In at least one instance, they have been utilized in an FDA cleared clinical trial in 2025. This demonstrates our ability to scale pluripotent cells with the purity, potency, and, regulatory quality required for clinical use, a standard which we believe is currently beyond the reach of many companies, and which can become a valuable competitive differentiator for Lineage.

Figure 2. The AlloSCOPE Platform: Enabling commercially viable, next-generation cell therapies



MCB = Master cell bank; WCB = Working cell bank

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

Clinical Stage Cell Transplant Programs

OpRegen Program for Dry-AMD with Geographic Atrophy

Our lead cell therapy program, OpRegen, serves as a critical case study for our approach to cell transplantation. OpRegen (also known as RG6501) is a suspension of human allogeneic retinal pigment epithelial (RPE) cells and is being developed for the treatment of ocular disorders, including GA secondary to dry-AMD under our global Collaboration and License Agreement with Roche entered into in December 2021 (the "Roche Agreement").

Under the terms of the Roche Agreement, we received a $50.0 million upfront payment in January 2022 and in December 2025, we received the first development milestone for $5 million which was achieved based on manufacturing and clinical advancements related to the OpRegen cell therapy program. We remain eligible to receive as much as an additional $615.0 million in other developmental, regulatory, and commercialization milestone payments in addition to tiered double-digit percentage royalties on net sales of OpRegen in the U.S. and other major markets. Payments received under the Roche Agreement are subject to downstream payment obligations to the IIA and Hadasit. In May 2024, we entered into an additional agreement with Genentech, pursuant to which we agreed to provide Genentech with supplemental clinical, technical, training, manufacturing, and procurement services to support the ongoing advancement of the OpRegen program in exchange for certain payments See "Collaborations—Roche Collaboration Agreement," below.

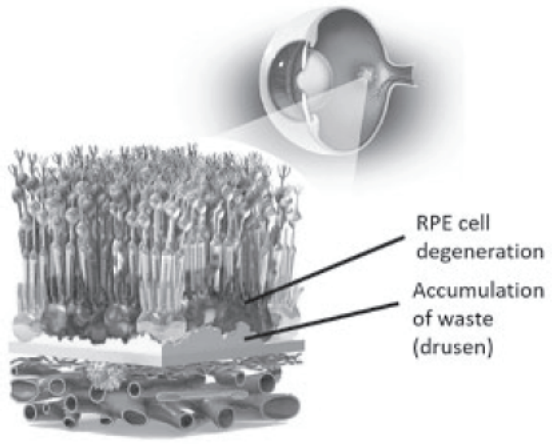
Age-Related Macular Degeneration (AMD) Overview and Treatments

AMD is a gradual, progressive, deterioration of the macula, the small sensitive area in the center of the retina that provides clear, high-definition central vision. It is a leading cause of vision loss in people over the age of 65 in the developed world. According to a 2022 report in JAMA Ophthalmology, 18.34 million individuals in the U.S. 40 years and older (11.64%) were living with early-stage AMD and 1.49 million (0.94%) were living with late-stage AMD in 2019. As the area of atrophy begins to include the fovea (the center of the macula), patients may lose their central vision, making facial recognition, reading, and driving difficult or impossible, and may ultimately become legally blind. The exact cause of GA secondary to AMD is unknown, but is thought to result from multiple factors, such as genetics, age, smoking history, and environmental effects.

There are two clinical presentations of AMD, the dry form, and the wet, or neovascular form (growth of abnormal new blood vessels). Dry AMD typically advances slowly toward GA as RPE cells and photoreceptors become dysfunctional and deteriorate over time. RPE cells support and nourish the retina by metabolizing waste by-products and producing a number of components essential for photoreceptor health and function. If the metabolic waste products accumulate, lesions known as drusen may result.

Approximately 85-90% of AMD patients suffer from the dry form of AMD, for which there are only two FDA approved therapeutic options at this time, pegcetacoplan injection (SYFOVRE®) and avacincaptad pegol intravitreal solution (IZERVAY™). Both approved products are complement inhibitors, administered either monthly or every other month, and neither has clinically demonstrated improved or restored vision to date, which means patients are likely to experience gradual continued vision decline while on treatment.

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.



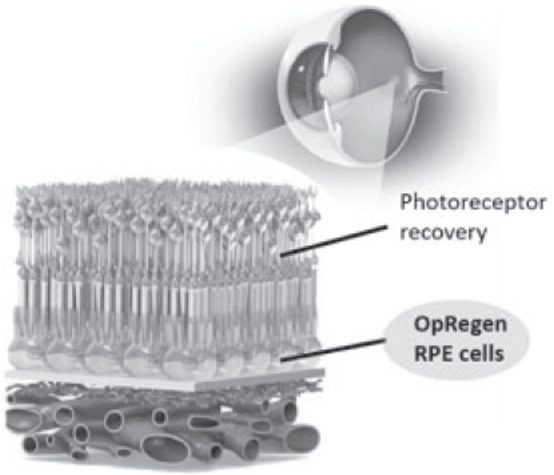


Figure 3. Dry AMD involves the loss of retina cells, creating an area of GA, which causes impaired vision and blindness	Figure 4. OpRegen is an injection of RPE cells delivered to the retina, with the potential to replace lost retinal cells and/or preserve or restore vision

Mechanism of Action

Our approach, which we believe is one of the most promising options 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, and extensively cover the area of geographic atrophy.

OpRegen is a cell replacement therapy derived from our AlloSCOPE manufacturing platform in which our proprietary directed-differentiation methods convert pluripotent stem cells into nearly pure populations of RPE cells. Using this method, OpRegen is grown free of any animal products and consists of human RPE cells with high yield and purity that can be transplanted directly into the patient's eye, where the patient's own RPE cells are missing or dysfunctional.

The goal of the OpRegen therapeutic approach is to slow or halt disease progression and to preserve and/or restore visual function in patients affected by dry-AMD. OpRegen has been granted Fast Track and Regenerative Medicine Advanced Therapy (RMAT) designations from the FDA, which includes an expedited regulatory path with the ability for increased interfacing with the FDA during the clinical development process.

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 administered every several years. This approach differs 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.

Clinical Data and Development

Phase 1/2a Clinical Study Overview

In a Phase 1/2a clinical trial, OpRegen has demonstrated the potential to slow, stop or reverse disease progression in GA secondary to AMD and these results, which were present at 12 months, have persisted through 24 and 36 months following a single administration of OpRegen.

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.

In June 2025, 36-month visual acuity results from patients enrolled in the Phase 1/2a clinical trial were presented by Roche and Genentech. Highlights include:

- Improvement in visual acuity in patients in Cohort 4 (less advanced GA than in other cohorts) present at 12 months (primary endpoint), 24 months, and persisted through 36 months.
- Gains in BCVA in patients in Cohort 4 (less advanced GA) measured at month 12 remain evident through month 36 following subretinal administration of OpRegen cell therapy.
- Mean change in BCVA among treated eyes for patients (n=10) completing 3-year follow up was +6.2 letters (compared to +5.5 letters at 24 months) (Early Treatment Diabetic Retinopathy Study (ETDRS) assessment).
- Improvement in BCVA and outer retinal structure in patients with extensive OpRegen bleb coverage of their GA area was greater than in patients with limited coverage and persisted through month 36.
- Effects were greater on average in the five (5) patients with extensive OpRegen cell therapy coverage of atrophic areas at the time of surgical delivery.
- Sustained evidence of retinal structural improvement by a quantitative Optical Coherence Tomography (OCT) analysis through 36 months was observed in treated eyes of Cohort 4 patients (less advanced GA than in other cohorts) following a single subretinal administration of OpRegen cell therapy.
- At month 36, sustained evidence of retinal structure improvements in external limiting membrane (ELM) and RPE drusen complex (RPEDC) layers on OCT was observed in the subgroup of five patients in Cohort 4 with extensive OpRegen cell therapy bleb coverage of atrophic areas at the time of surgical delivery.
- These data suggest that OpRegen cell therapy may counteract RPE cell dysfunction and loss in GA by providing support to the remaining retinal cells within atrophic areas, and these effects appear durable through at least 36 months after a single administration.

Phase 2a Clinical Study ("GAlette") Overview

OpRegen is currently being evaluated by our partners Roche and Genentech in a Phase 2a multicenter clinical trial in patients with GA secondary to dry-AMD, the "GAlette" study, which is currently enrolling up to 60 patients at 17 clinical sites across the U.S. and Israel.

The study is intended to optimize subretinal surgical delivery and evaluate biological activity of OpRegen in up to 60 patients with GA secondary to dry-AMD. The primary objectives of the study are to evaluate (i) the success of subretinal surgical delivery of OpRegen as measured by the proportion of patients with subretinal surgical delivery of OpRegen to target regions under the retina, and (ii) the safety of subretinal surgical delivery of OpRegen as measured by the incidence and severity of procedure-related adverse events at 3 months following surgery. The secondary objective is to evaluate the biological activity of OpRegen measured by the proportion of patients with qualitative improvement in retinal structure, as determined by Optical Coherence Tomography (SD-OCT) imaging, within 3 months following surgery. Genentech currently plans to also evaluate two proprietary surgical delivery devices that have potential advantages over available off-the-shelf devices in the ongoing GAlette study.

OPC1 Program for Spinal Cord Injury

Our most advanced, internally owned product candidate is OPC1, an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury. Improved functional activity can lead to greater mobility and enhanced quality of life for those affected by a SCI and significant cost-savings for caregivers and payors. Importantly, elevations in functional improvement can be reasonably expected to be retained for long periods, including the lifetime of the patient, enhancing the value of any gains of function that are achieved by a patient. OPC1 is currently being tested in a phase 1 safety study of a novel delivery device, and in parallel, we are working on the design of a larger comparative clinical study.

OPC1 has an extensive long-term safety profile based on two clinical trials conducted to date. See "—Clinical Data and Development—Phase 1 Thoracic Study and Phase 1/2a Cervical Study," below.

OPC1 has received RMAT designation and Orphan Drug designation from the FDA.

Spinal Cord Injury (SCI) Overview

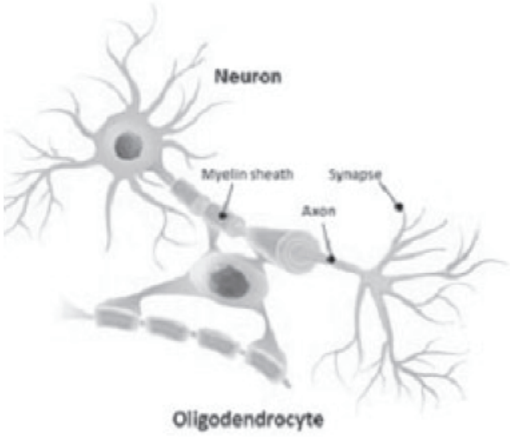
SCI occurs when the spinal cord is subjected to a severe crush or contusion injury, such as that caused by a car or motorcycle accident, and typically results in severe functional impairment, including limb paralysis, aberrant pain signaling, and loss of bladder and/or sexual function.

There are approximately 18,000 new spinal cord injuries annually in the U.S. (NSCIC SCI Facts and Figures at a Glance (2025)), 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.

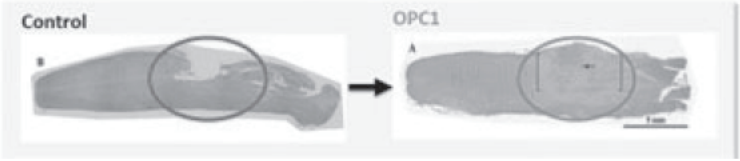


Mechanism of Action

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 after thawing. Based on preclinical studies, when OPC1 is transplanted into the injured spinal cord, the cells undergo further maturation to generate a replacement population of oligodendrocytes at the injury site that are capable of remyelinating denuded and newly formed nerve axons.

Based on preclinical studies, prior to their maturation, the transplanted oligodendrocyte progenitor cells are believed to stimulate additional reparative processes, including promotion of neuron survival and nerve axon outgrowth, and induction of blood vessel formation in and around the injury site. In addition, OPC1 cells can migrate from the injection point to the injury site where they generate a supportive tissue matrix and suppress cavitation (Figure 6). Cavitation is a destructive process that occurs within the spinal cord following SCI, and typically results in permanent loss of motor and sensory function. A patient with cavitation can develop a condition known as syringomyelia, which results in additional neurological and functional damage to the patient and can result in chronic pain. Based on the multiple reparative properties associated with OPC1, we believe this candidate cell therapy product is ideally suited to treat neurological conditions such as SCI and other demyelination disorders of the CNS.

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



Clinical Data and Development

Phase 1 Thoracic Study and Phase 1/2a Cervical Study

To date, two clinical trials of OPC1 have been completed: a Phase 1 clinical safety trial in 5 patients with thoracic SCI, where all active participants have been followed for at least 14 years, and a Phase 1/2a multicenter dose-escalation clinical trial in 25 patients with cervical SCI, where all active participants were evaluated for at least 8 years.

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

OPC1 Thoracic & Cervical Clinical Trials Overview

- **Thoracic phase 1 clinical trial (N=5)**
  - All active subjects followed for at least 14 years
  - Results published in Journal of Neurosurgery Spine (*Vol 37, Issue 3, 2022*)
    - No unexpected serious adverse events attributable to the OPC1 transplant:
      - No evidence of neurological decline
      - No enlarging masses
      - No further spinal cord damage

- **Cervical phase 1/2a clinical trial (N=25)**
  - All active subjects evaluated for at least 8 years
  - Results published in Journal of Neurosurgery Spine (*Vol 37, Issue 6, 2022*)
    - 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)

DOSED (Delivery of Oligodendrocyte Progenitor Cells for Spinal Cord Injury: Evaluation of a Novel Device) Clinical Study

In February 2025, we announced that we were initiating our "DOSED" clinical study to evaluate the safety and utility of a novel spinal cord delivery device designed to administer OPC1 to the spinal parenchyma in both subacute (between 21 to 42 days following injury) and chronic (between 1 to 5 years following injury) spinal cord injury. The DOSED study is the first study of OPC1 to include participants with a chronic injury, a condition which comprises most individuals affected by SCI. If the novel delivery system is determined to be satisfactory for its purpose, we expect the device will enable future studies which will aim to demonstrate OPC1's ability to impact functional outcomes.

In July 2025, the first chronic SCI participant, with a neurologically complete SCI injury was treated in the DOSED study at UC San Diego Health, and the novel delivery system successfully administered a one-time injection of OPC1. No significant safety events have been reported through 180 days post treatment in the first treated chronic SCI participant in the DOSED study.

In February 2026, our second clinical site in the DOSED study, Rancho Research Institute, in conjunction with Rancho Los Amigos National Rehabilitation Center, opened for enrollment.

Manufacturing and Delivery Improvements

All cGMP manufacturing processes, including the establishment of cell banks and the production of OPC1, are conducted at CCN, our subsidiary and manufacturing site. Improvements to the OPC1 starting material and manufacturing process were completed at CCN, leading to significant increases in scale and purity. CCN also

developed a ready-to-use thaw-and-inject formulation of OPC1, which simplifies logistics and handling at the point of care and eliminates 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 any larger-scale clinical trials we may conduct.

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 continue to evaluate the Neurgain device, including in the DOSED Study.

Preclinical and Research Cell Transplant Programs

ReSonance Program for Hearing Loss

Our second most advanced internally owned product candidate is ReSonance (ANP1), an allogeneic auditory neuron progenitor cell transplant, currently in preclinical development for the treatment of sensorineural hearing loss.

In August 2025, we announced that we entered into a research collaboration agreement with William Demant Invest 2 Aps ("WDI") to advance the preclinical development of ReSonance for the treatment of hearing loss. WDI will fund up to $12 million in planned research collaboration costs over the approximate three-year term of the agreement.

The main objective of the agreement is for the parties to complete a preclinical development plan leading to readiness to progress to human clinical trials under one or more separate clinical agreements, the terms of which would be negotiated in good faith before the expiration of the agreement. Development activities will be jointly conducted and managed by Lineage and scientists from Eriksholm Research Centre, part of Oticon A/S, which is a subsidiary of the Demant Group. See Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information.

Islet Cell Transplant Research Initiative

In September 2025, we announced the launch of a new cell therapy research initiative focused on addressing the issue of large-scale production of undifferentiated pluripotent cells, which if successful could support the production of islet cells to support a potential treatment of Type 1 Diabetes (T1D).

We believe there are three areas of emphasis for a cell transplantation that could lead to a commercially feasible, functional cure for T1D patients. The first area, mechanism of action, has already been demonstrated, with multiple independent reports showing that an islet cell transplant from cadaveric or pluripotent cell sources can achieve insulin independence for diabetics. The second area is the reduction or prevention of immunological rejection of transplanted cells, as lifetime immunosuppression is not a feasible solution for most patients. Multiple attempts to eliminate the need for immunosuppression have been explored, such as encapsulation, but recent evidence from genetically edited "hypoimmune" cells may offer a successful approach. The third area is the production scale required for a commercially viable cell therapy for T1D patients. Cadavers are not a sustainable or consistent source of islet cells, but pluripotent cells are self-renewing, so they may be able to address the scale deficiencies. Since the current anticipated dose levels of a cell therapy transplant for T1D patients may be as high as a billion cells per patient, a large-scale production process will be required to address the issue of commercially viable production of islet cells.

Under our T1D cell therapy research initiative, we plan to deploy our AlloSCOPE manufacturing capabilities to address the issue of large-scale production of undifferentiated pluripotent cells, with the initial goal of establishing a production modality that can support the entire production process through differentiation in a dynamic culturing system, which if successful, could potentially solve a major hurdle to commercialization of eventual islet cell therapy product candidates.

An initial objective for this initiative is to demonstrate a scalable process for undifferentiated pluripotent cells using one of our proprietary and in house cell lines. This initial work has been successful at a small scale (0.5 liter) and supports further development into a larger scale. If successful at larger scale, we may thereafter seek to demonstrate AlloSCOPE platform scalability with an internally or externally sourced, hypo-immune cell line, one suitable to support eventual islet cell differentiation for a potential clinical campaign in T1D, or we may proceed with a larger or optimized process with our non hypoimmune line. Importantly, we expect we can apply insights and process improvements we have learned or will learn through this process to our other cell transplant programs, including programs we may launch in the future.

Overall, if we are successful in developing a commercially viable production modality for undifferentiated pluripotent cells, and we then differentiate those into islet cells, we believe it will create a compelling product profile, as well as provide options to license this technology to a partner or enter the diabetes field directly.

RND1 Research Initiative

RND1 is a novel hypoimmune iPSC cell line being evaluated in collaboration with our gene editing partner Factor Biosciences for the development of a cell transplant candidate for the potential treatment of an undisclosed indication.

In February 2023, we entered into an option and license agreement with Factor (as assigned from Eterna) to develop engineered hypoimmune iPSC line that we will evaluate for differentiation into cell transplant product candidates for CNS diseases and certain indications, including RND1. In September 2023, we announced the initiation of certain development activities to generate a novel iPSC line with Factor and our selection of specific gene edits for the initial product candidate to be developed by Factor. The edits include: the targeted deletion of the B2M gene, designed to reduce the immunogenicity of product candidates derived from the lines by inhibiting rejection by CD8+ T cells; the targeted insertion of the HLA-E gene, designed to overexpress HLA-E and prevent the allogeneic NK cell response; and a third undisclosed edit intended to confer clinical differentiation and a competitive advantage in the applicable indications. We expect that these edits may expand the edited cell lines' overall utility, including for non-immune privileged or non-human leukocyte antigen (HLA) matched indications and may further differentiate the cell line from others currently in use by competitors.

In January 2026, we announced the receipt of the novel iPSC line with Factor. Acceptance of the line triggered a success payment from Lineage to Factor as reimbursement for Factor's development efforts. Factor remains eligible for an additional payment from Lineage subject to Lineage's entry into an exclusive license to utilize the line. Lineage's decision to proceed with the RND1 program will be based on further performance criteria and the outcome of additional testing, including the evaluation of the novel cell line for its ability to adapt to Lineage's AlloSCOPE platform.

We believe this collaboration allows us to leverage our expertise by capitalizing our directed cell differentiation and manufacturing capabilities with externally-sourced gene editing technology. This is reflective of a portion of our corporate strategy which aims to capitalize on our process development capabilities by combining them with cell engineering and editing technologies to produce novel cell therapies with potentially superior product profiles compared to currently marketed therapies, if any.

PNC1 Research Initiative

Our photoreceptor research initiative, 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 aims to replace damaged photoreceptors regardless of the cause of degeneration.

Other Programs and Technologies

The pluripotent cells underlying our platform are by definition, capable of becoming any cell type of the human body. We therefore maintain a list of additional potential product candidates which we may consider for development or partnership in the future, and which altogether cover a range of therapeutic areas and conditions. Generally, we expect that these potential product candidates will be based on the same AlloSCOPE platform technology and would employ a similar guided cell differentiation and transplant approach as our current product candidates, and in some cases may also include genetic modifications designed to enhance efficacy and/or safety profiles. We currently have more than one additional undisclosed cell type receiving initial research & development and/or business development internal resources, and we expect to share updates on one or more of these new initiatives during 2026. We also may elect not to develop, terminate the development of, or not partner any of these product candidates.

Collaborations

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

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.

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 another $5.0 million milestone payment (which was received in December 2025). Lineage is eligible to receive up to an additional $615.0 million in developmental, regulatory and commercialization milestone payments. Lineage is also eligible for tiered double-digit percentage royalties on net sales of OpRegen. All milestone payments, and royalty payments, due under the Roche Agreement are subject to the existence of certain intellectual property rights that cover OpRegen at the time such payments would otherwise become due, and the royalties on net sales of OpRegen are subject to financial offsets based on the existence of competing products.

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

Based on the intercompany relationship between Lineage and CCN, Lineage is responsible for payment to the IIA (as defined below) approximately 24.1% of the upfront payment and of any future payments Lineage receives under the Roche Agreement, up to an aggregate cap on all payments to IIA, such cap growing over time via interest

accrual until paid in full. As of December 31, 2025, the aggregate cap amount was $96.2 million. In addition, pursuant to the Second Amended and Restated License Agreement, dated June 15, 2017, CCN, and Hadasit Medical Research and Development Ltd. ("Hadasit"), as amended, and a letter agreement entered into between CCN and Hadasit on December 17, 2021, Lineage is responsible for payment to Hadasit (i) a maximum of 21.5% of the upfront payment (subject to certain reductions) and of any milestone payments Lineage receives from Roche under the Roche Agreement, and (ii) up to 50% of all royalty payments (subject to a maximum payment of 5% of net sales of products) Lineage receives from Roche under the Roche Agreement. In accordance with the foregoing obligations, from the $50.0 million upfront payment Lineage received from Roche in January 2022, Lineage paid $12.1 million to the IIA and $8.9 million to Hadasit, and from the $5.0 million milestone payment Lineage received from Roche in December 2025, Lineage paid $1.2 million to the IIA and accrued $1.1 million payable to Hadasit. See "Grants from Government Entities," below, and Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information related to our obligations to the IIA and Hadasit.

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

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"). 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").

Effective June 30, 2025, Lineage elected to cease development and commercialization of all products under the CRT License Agreement. Upon notice, and in conjunction therewith, CRT notified Lineage of CRT's termination of the CRT License Agreement. Further, Lineage notified Immunomic Therapeutics, Inc. ("ITI") of the termination of the collaboration agreement that Lineage had entered into with ITI in April 2021 (the "ITI Agreement") in accordance with its terms. As of June 30, 2025, the Company has abandoned all future development efforts and will no longer prosecute any of the pending patent applications or issued patents related to the VAC platform. See Note 6 (Goodwill and Intangible Assets, Net) to our consolidated financial statements included in this report for additional information.

William Demant Invest Collaboration Agreement

On August 22, 2025, Lineage and WDI entered into a research collaboration agreement (the RCA) to advance the preclinical development of ReSonance (ANP1) for the treatment of hearing loss (the Project). WDI will fund up to $12 million in planned research collaboration costs over the approximate three-year term of the RCA. The main objective of the RCA is for the parties to complete a preclinical phase achieving readiness to potentially progress to human clinical trials under one or more separate clinical agreements, the terms of which would be negotiated in good faith before the expiration of the RCA.

All intellectual property owned by a party prior to the date of the RCA will remain such party's sole and exclusive property. The parties will jointly own all results, data, reports, know-how and patent(s) conceived or otherwise generated in the course of and resulting from the Project, other than discoveries or developments relating to Lineage's proprietary platform technology.

If a party (the "abandoning party") informs the other party (the "continuing party") that it will not continue the research with the other party under a clinical agreement, the continuing party may purchase the abandoning party's

ownership interest in the intellectual property resulting from the Project for exploitation for the treatment of hearing loss and a license to the abandoning party's background intellectual property to the extent necessary for such exploitation for an amount and on terms to be determined by the mutual agreement of the parties, and if such mutual agreement is not reached, by an independent third-party.

Grants from Government Entities

Grants from the Israeli Innovation Authority

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

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

The know-how developed within the framework of the Innovation Law plan may not be transferred to third parties outside Israel without the prior approval of a governmental committee chartered under the Innovation Law. The IIA approval to transfer know-how created, in whole or in part, in connection with an IIA-funded project to a third party outside Israel where the transferring company remains an operating Israeli entity is subject to payment of a redemption fee to the IIA calculated according to a formula provided under the Innovation Law that is based, in general, on the ratio between the aggregate IIA grants to the company's aggregate investments in the project that was funded by these IIA grants, multiplied by the transaction consideration. The transfer of such know-how to a party outside Israel where the transferring company ceases to exist as an Israeli entity is subject to a redemption fee. The redemption fee in case of transfer of know-how to a party outside Israel is generally based on the ratio between the aggregate IIA grants received by the transferring company and the transferring company's aggregate research and development expenses, multiplied by the transaction consideration. The maximum amount payable to the IIA in case of transfer of know-how outside Israel will not exceed six times the value of the grants received plus interest. In the event that the grant recipient ceases to be an Israeli corporation such payment shall not exceed six times the value of the grants received plus interest, with a possibility to reduce such payment to up to three times the value of the grants received plus interest if the research and development activity remains in Israel for a period of three years after payment to the IIA.

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

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

Grants from the California Institute for Regenerative Medicine

The clinical development of OPC1 was supported in part by $14.3 million 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 include 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 June 2025 we applied for a Clinical Trial (CLIN2) award (the "CIRM Grant") from CIRM for approximately $7.0 million to support continued clinical development of OPC1 for the treatment of SCI. On November 28, 2025, the Company elected to withdraw its application for the CIRM Grant following comments to the application received by the Company from CIRM. Following discussions between the Company and CIRM representatives, on January 28, 2026, the Company submitted a revised application to address the feedback it received on its original application. Neither the withdrawal of the Company's current application nor the planned resubmission of a revised application impact the Company's current and planned development of OPC1 or the ongoing DOSED clinical study. No assurances can be given that Lineage will be awarded a grant or, if awarded, the amount or timing thereof.

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 and products with intellectual property through a variety of measures, including seeking and maintaining patents intended to cover our products, including compositions, their methods of use and processes for their manufacture, our platform technologies and any other inventions that are commercially important to the development of our business and, when appropriate, trade secret protection. We have sought, and intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the United States and internationally. We may also file additional patent applications, when appropriate, to cover improvements on our manufacturing processes, clinical products, clinical product candidates, and related technologies. From time to time, we assess our patents and pending applications covering our products and product candidates. If we determine that any patents or patent applications no longer provide adequate or necessary protection, we may assign or abandon such patents and patent applications to avoid incurring unnecessary costs.

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

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

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

OpRegen

We solely own and have rights to U.S. and international issued patents and pending patent applications relating to OpRegen, including those in-licensed from Hadasit. Our solely owned issued patents and pending patent applications include those relating to a cryopreserved thaw-and-inject formulation which have, or if issued, will have estimated patent expiration dates in 2038. Otherissued patents and pending patent applications, if issued, have expiration dates ranging from 2028 to 2042. Pursuant to the Roche Agreement, we have licensed these patent rights

to Roche to further develop and commercialize RPE cell therapies, including OpRegen (see "—Collaborations—Roche Collaboration Agreement" above).

OPC1

We own numerous U.S. and international issued patents and pending patent applications that are relevant to neural cells, such as oligodendrocyte progenitor cells, that are directed to the differentiation of pluripotent stem cells, including human embryonic stem ("hES") cells, into various neural cell types, as well as various culture and purification methods. These issued patents and pending patent applications include eight patent families directed to improved methods of producing oligodendrocyte progenitor cells, oligodendrocyte progenitor cell compositions, and methods of treatment of spinal cord injury using oligodendrocyte progenitor cells. These patent families include five U.S. patents directed to methods for producing oligodendrocyte progenitor cells, composition of oligodendrocyte progenitor cells and methods of treatment of spinal cord injury using oligodendrocyte progenitor cells. The estimated patent expiration dates of these nine patent families range from 2036 to 2045. The commercial success of OPC1 depends, in part, upon our ability to exclude competition for this product with the existing patent portfolio and new patent applications that may be filed, regulatory exclusivity, undisclosed know-how and/or trade secrets, or a combination of these exclusivity barriers to entry.

Auditory Neurons

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

Photoreceptors

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

General Risks Related to Obtaining and Enforcing Patent Protection

Because patent applications are confidential until a patent application is published or a patent is issued, we may not know if our competitors have filed patent applications for technology covered by our pending applications or if we were the first to invent or first to file an application directed toward the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents or other proprietary rights that block or compete with our products. In addition, if competitors file patent applications covering our technology, we may have to participate in interference/derivation proceedings or litigation to determine the right to a patent. Litigation and interference/derivation proceedings are unpredictable and expensive, such that, even if we are ultimately successful, our results of operations may be adversely affected by such events. Accordingly, there is a risk that any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and be declared invalid in view of third-party patent applications and/or patents or through other proceedings before the U.S. Patent and Trademark Office such as post-grant reviews, reexaminations, and inter partes' reviews, or oppositions and other comparable proceedings in foreign jurisdictions. Litigation, interferences, oppositions, inter partes' reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other

instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. We may also face challenges to our patent and regulatory protections covering our products by third parties, including manufacturers of generics and biosimilars that may choose to launch or attempt to launch their products before the expiration of our patent or regulatory exclusivity. Litigation, interference, oppositions, inter partes' reviews, administrative challenges or other similar types of proceedings are unpredictable and may be protracted, expensive and distracting to management. The outcome of such proceedings could adversely affect the validity and scope of our patent or other proprietary rights, hinder our ability to manufacture and market our products, require us to seek a license for the infringed product or technology or result in the assessment of significant monetary damages against us that may exceed any amounts that we may accrue on our financial statements as a reserve for contingent liabilities. An adverse determination in a judicial or administrative proceeding or a failure to obtain necessary licenses could prevent us from manufacturing or selling our products. Furthermore, payments under any licenses that we are able to obtain would reduce our profits derived from the covered products and services.

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

Employees

As of December 31, 2025, we had 77 employees, of which 22 were employed by Lineage and 55 were employed by CCN and work in Israel. Of the 77 employees, 72 were employed on a full-time basis and five were employed on a part-time basis. Twelve employees hold Ph.D. degrees in one or more fields of science or doctorates in medicine. None of our employees are covered by a collective bargaining agreement.

Manufacturing

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

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

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

Licensed Technology and Product Development Agreements

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

Second Amended and Restated License Agreement

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

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

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

The Hadasit License Agreement was amended on November 30, 2017 ("First Amendment") to update the original list of patent applications and issued patents for Licensed IP, and provide for reimbursement of certain costs associated with a patent not originally listed in the Hadasit License Agreement to CCN. The Hadasit License Agreement was amended on December 1, 2019 to replace PR Research Agreement with a new PR Research Agreement ("New PR Research Agreement") which included provisions with respect to the ownership of research results and intellectual property. The Hadasit License Agreement was further amended on December 17, 2021 by a letter agreement pursuant to which CCN is obligated to pay a maximum of 21.5% of any milestone payments Lineage receives under the Roche Agreement (subject to certain reductions, including for costs related to Lineage's performance obligations under the Roche Agreement) and up to 50% of all royalty payments (subject to a maximum payment of 5% of net sales of products), Lineage receives under the Roche Agreement. We removed the Photoreceptor Field from the scope of the Hadasit License Agreement, in April 2024.

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

WARF Agreements

We have rights to certain U.S. and international issued patents, pending patent applications, and stem cell lines from the Wisconsin Alumni Research Foundation ("WARF") under an Amended and Restated Non-Exclusive License Agreement we entered into with WARF on March 3, 2026. Until the time we entered into that agreement, such rights were granted to us under two agreements, one agreement between WARF and Asterias Biotherapeutics Incorporated, our wholly-owned subsidiary, entered into in 2013, and one between us and WARF entered into in 2008. See Item 9B. "Other Information," below for additional information.

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 biologics that are HCT/Ps are subject to all regulations applicable to drug/biologics, as well as HCT/P-specific regulations, including, but not limited to, current good tissue practices ("cGTP") and contagious disease prevention requirements. Certain proposed cell therapy products will be reviewed by the FDA staff in its Center for Biologics Evaluation and Research Office of Therapeutic Products. Drugs, biologics, and devices are also subject to other federal, state, and local statutes and regulations.

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

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

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA/BLA.

In addition, the Pediatric Research Equity Act ("PREA"), requires a sponsor to conduct pediatric clinical trials for most drugs and biologics, for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration. Under PREA, original NDAs/BLAs and supplements must contain a pediatric assessment unless the sponsor has received a deferral or waiver. The required assessment must evaluate the safety and efficacy, or safety, purity, and potency of the product for the claimed indications in all relevant pediatric subpopulations and support dosing and administration for each pediatric subpopulation for which the product is deemed safe and effective, or safe, pure, and potent. The sponsor may request or the FDA may grant a deferral of pediatric clinical trials for some or all of the pediatric subpopulations. A deferral may be granted for several reasons, including a finding that the drug is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The FDA

must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current, or fails to submit a request for approval of a pediatric formulation. 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 ("CRL") if it determines that the application does not provide an adequate basis for approval. A CRL indicates that the review cycle for the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the NDA/BLA identified by the FDA and may require additional clinical data, including additional clinical trials or other significant and time-consuming requirements related to clinical trials, nonclinical studies, or manufacturing. If a CRL is issued, the sponsor must resubmit the NDA/BLA addressing all of the deficiencies identified in the letter or withdraw the application. Even if such data and information are submitted, the FDA may decide that the resubmitted NDA/BLA does not satisfy the criteria for approval. FDA regulations also restrict the export of therapeutic products for clinical use prior to FDA approval. Under the Prescription Drug User Fee Act ("PDUFA") guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of an NDA/BLA for a new molecular entity to complete a standard review and act on the submission. This review typically takes twelve months from the date the NDA/BLA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured or perform an establishment file review of the site. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with the requirements of current Good Manufacturing Practices ("cGMPs") and adequate to assure consistent production of the product within required specifications including good tissue practices ("GTPs") to the extent applicable. FDA's cGMP regulations detail minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. FDA's GTP regulations and guidance documents govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require when applicable, evaluation of donors through screening and testing. To maintain compliance with cGMPs, GTPs, and good clinical practices ("GCPs"), an applicant must incur significant expenditure of time, money and effort in areas including, but not limited to, training, record keeping, production, and quality control.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. In addition, the FDA may require that contraindications, warnings or precautions be included in the product's labeling; require that post-approval studies be conducted to further assess the drug's safety or effectiveness; require testing and surveillance programs to monitor the safety of the commercialized product; or impose other conditions, including distribution restrictions or other risk management mechanisms, including a risk evaluation and mitigation strategy ("REMS") to assure safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA/BLA must submit a proposed REMS, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA will not approve the NDA/BLA without an approved REMS, if required. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products.

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

The FDA offers several programs to expedite development of products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments. Such programs include (i) Fast Track designation; (ii) Breakthrough Therapy designation; (iii) Accelerated Approval pathway; (iv) Priority Review designation; and (v) Regenerative Medicine Advanced Therapy ("RMAT") designation.

Drugs/biologics awarded Fast Track designation give the sponsor additional opportunities to interact with FDA reviewers during the drug development and review process. Early and frequent communication with FDA can address questions and issues which can lead to faster approval. An additional feature of Fast Track designation is rolling review which allows FDA to review portions of a drug/biologic sponsor's NDA or BLA before the complete application is submitted. Eligible Fast Track drugs must treat a serious condition and nonclinical or clinical data must demonstrate the potential to address unmet medical need. Dru/biologic sponsors can request Fast Track designation during the drug development process, generally before submitting an NDA or BLA.

Drugs awarded Breakthrough Therapy designation have all features of Fast Track designation plus organizational commitment from FDA senior managers to interact and provide intensive guidance on drug development during the clinical phases. Eligible Breakthrough Therapy drugs must treat a serious condition and preliminary clinical evidence indicates that the drug/biologic may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. Drug/biologic sponsors can request Breakthrough Therapy designation no later than the end of phase II clinical trial meetings with FDA. Alternatively, FDA may suggest the sponsor request Breakthrough Therapy designation if the Agency believes the drug/biologic is eligible and can benefit from the designation.

A drug/biologic in the Accelerated Approval pathway is approved based on a surrogate endpoint or intermediate endpoint that is reasonably likely to predict a drug's clinical benefit, such as decreased morbidity and mortality. Because it can often take years to measure primary outcomes like survival, surrogate or intermediate endpoints (e.g. decreasing biomarker levels, imaging results) can serve as a proxy for clinical benefit. Eligible Accelerated Approval drugs/biologics must treat a serious condition, provide a meaningful advantage over available therapies, and demonstrate a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity and mortality or other clinical benefit. Sponsors generally explore the possibility of Accelerated Approval with FDA early in the development process (e.g. during the design of clinical trials).

For drugs with Priority Review designation, FDA's goal is to act on a drug sponsor's marketing application within six months rather than the usual 10 months for a standard review process. Eligible Priority Review drugs must treat a serious condition and provide a significant improvement in safety or effectiveness over existing treatments. Drug sponsors can request Priority Review when they submit either an NDA or BLA. Another method for a drug sponsor to obtain Priority Review designation is through a Priority Review Voucher. If a drug sponsor develops a treatment for a neglected tropical disease, rare pediatric disease, or medical countermeasure it can be awarded a Priority Review Voucher which can be redeemed at the drug sponsor's discretion to obtain Priority Review or sold to another sponsor to use for the same purpose. A drug sponsor with a Priority Review Voucher will inform FDA of its intent to use the voucher when it submits either an NDA or BLA. Priority Review Vouchers can be awarded for drugs/biologics intended to treat tropical diseases, rare pediatric diseases, or material threat countermeasures. Additionally, in June 2025, the FDA launched the Commissioner's National Priority Voucher ("CNPV") pilot program, offering drug manufacturers an expedited 30 to 60-day review by proposing plans to advance five stated priorities, which include addressing public health crises, delivering innovative cures, meeting unmet medical needs, strengthening supply chains through onshore drug manufacturing, and increasing affordability. The FDA cites examples that include developing novel medicines for obesity, PTSD, other chronic diseases, or creating universal flu vaccines. Proposals may also include domestic manufacturing expansions and commitments for the firm to implement "most favored nation" pricing models on some of their drugs. Proposals are not required to address all five priority areas, but more comprehensive plans are likely to be favored in the selection process.

A drug is eligible for RMAT designation if: the drug is a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product or any combination product using such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act and part 1271 of Title 21, Code of Federal Regulations;; the drug is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition; and preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition.

Exclusivity Programs

Additionally, FDA administers several statutory marketing exclusivity programs for drugs and biologics that operate independently of patent protection and prevent FDA from approving (or, in some cases, even accepting)

certain competing applications for defined periods. Key programs include 3-year clinical investigation exclusivity (for new indications or changes supported by new clinical studies), pediatric exclusivity (a 6-month add-on to existing exclusivities and patents), 12-year reference product exclusivity for biologics under the Biologics Price Competition and Innovation Act ("BPCIA"), and – most notably for our purposes – Orphan Drug Designation exclusivity (7 years for the approved rare-disease indication). These exclusivities differ in scope, trigger, and blocking effect (e.g., approval block vs. filing block), and may run concurrently or sequentially depending on the product's regulatory pathway.

The FDCA provides three years of non-patent exclusivity for an NDA/BLA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval based on the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to, all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to an existing period of regulatory exclusivity or available patent term if a sponsor conducts clinical trials in children in response to a "written request" from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials, and the FDA's grant of pediatric exclusivity does not require the FDA to approve labeling containing information on pediatric use based on the studies conducted.

The BPCIA grants 12 years of exclusivity for brand-name biologics (subject to an approved BLA) from the date of first licensure, preventing FDA approval of biosimilars during this period. It includes 4 years of data exclusivity (no biosimilar application submission) and 8 years of marketing exclusivity, with 1 year of extra, separate exclusivity for the first-approved interchangeable biosimilar.

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, as codified by the Consolidated Appropriations Act of 2026, 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 approved use or indication within such rare disease or condition" for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the NDA or BLA application fee. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Combination Products

Combination products are defined by the FDA to include products comprised of two or more regulated components or parts such as a biologic and a device. Combination products may be reviewed in a single application

or in separate applications for the constituent parts. Whether the constituent parts (e.g., a biologic and a device) are reviewed together as a combination product or separately under two different marketing applications, each constituent part must meet the regulatory requirements applicable to that constituent part (e.g., biologic-specific regulations for the biologic constituent part and device-specific regulations for the device constituent part). Further, 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, like the Federal Trade Commission (“FTC”), 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.

Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties.

Increased scrutiny over direct-to-consumer (“DTC”) drug advertising has been a priority of this administration, particularly the U.S. Department of Health and Human Services (“HHS”). On September 9, 2025, the FDA announced a crackdown on deceptive drug advertising, sending thousands of letters warning pharmaceutical companies to remove misleading ads, and issuing many enforcement letters to companies with deceptive ads. We expect that the administration will continue to closely monitor and enforce against DTC advertising of drug and biologic products.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing

processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of requirements for post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on ongoing or planned clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

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

Prior to January 2026, the use of hES cells in federally funded research was governed primarily by the 2009 National Institute of Health ("NIH") policy, which required 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. However, on January 22, 2026, NIH announced a new policy, effective immediately, that NIH funds will no longer be used to support research involving hES from elective abortions – which provides an additional layer of restriction for hES use in federally funded research on top of the 2009 policy. The new policy applies across the NIH Intramural Research Program and all NIH-supported extramural research, including grants, cooperative agreements, other transaction awards, and research and development contracts.

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

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

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

The Health Insurance Portability and Accountability Act ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act ("HITECH"), and their respective implementing regulations impose obligations on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose, access, or otherwise process individually identifiable protected health information, with respect to protecting the privacy, security, and transmission of protected health information. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for covered health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties. Additionally, HITECH created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, certain state and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Privacy and Data Security Laws

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

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

There is a growing trend towards required public disclosure of clinical trial data in the EU which adds to the complexity of obligations relating to processing health data from clinical trials. Failing to comply with these obligations could lead to government enforcement actions and significant penalties against the Company, harm to its

reputation, and adversely impact its business and operating results. The uncertainty regarding the interplay between different regulatory frameworks further adds to the complexity that the Company faces with regard to data protection regulation. In addition, Israel's Protection of Privacy Law 5741-1981 and the regulations promulgated thereunder impose certain obligations with respect to the manner personal data is processed, and government regulators may issue fines or sanctions for non-compliance.

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

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

Federal and State Fraud and Abuse Laws

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

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

codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

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

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

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

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

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

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

Coverage and Reimbursement

Patients generally rely on third-party payors to reimburse part or all of the costs associated with medical products. Accordingly, market acceptance of medical products can depend on the extent to which third-party

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

Outside of the United States, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

Healthcare Reform

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

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

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, except for a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic, unless additional Congressional action is taken. Under

current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Congress is considering additional health reform measures.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of the rule was delayed until 2032 by the Inflation Reduction Act of 2022. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. The Most Favored Nation regulations mandate participation by identified Medicare Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021 CMS published a final rule that rescinds the Most Favored Nation model interim final rule. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to President Biden's executive order, on September 9, 2021, the HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles and considerable uncertainty exists regarding how federal government policy and budget decisions will unfold with respect to drug pricing under the Trump administration.

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

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

Major Sources of Revenues

The following table shows our major sources of revenues, as a percentage of total revenues, that were recognized during the years ended December 31, 2025 and 2024:

	Year ended December 31,	
Sources of Revenues	2025	2024
Collaboration revenues	93.5%	85.8%
Royalties, license and other revenues	6.5%	14.2%

Our collaboration revenues for the year ended December 31, 2025 are related primarily to collaboration revenues from Roche and WDI, and in the prior year the revenues were primarily attributable to Roche. Our royalties, license and other revenues for the years ended December 31, 2025 and 2024 represent cash flows generated under patent families that Asterias acquired from Geron and the Services Agreement with Genentech. See Note 3 (Revenue) and Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information.

For the year ended December 31, 2025 based on the location of our customers, $2.5 million of our revenues were attributed to countries outside of the United States. For the year ended December 31, 2024, there were no revenues generated outside of the United States.

Marketing

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

Competition

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

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

Corporate Information

Lineage was incorporated on November 30, 1990 in the State of California. Our common shares trade on the NYSE American and the Tel Aviv Stock Exchange under the symbol "LCTX." Our principal executive offices are at 2173 Salk Avenue, Suite 200, Carlsbad, CA 92008, USA, and our phone number at that address is (442) 287-

8990. Our website address is www.lineagecell.com. The information on, or that can be accessed through our website, is not part of this report. We routinely use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. We also make available, free of charge through our website, our most recent annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports as soon as reasonably practicable after the reports are electronically filed with or furnished to the SEC.

ITEM 1A. RISK FACTORS

An investment in our common shares involves a high degree of risk. You should carefully consider all the risk factors described below, as well as the other information in this report, when evaluating our business and before deciding whether to purchase, hold or sell our common shares. Each of these risk factors, as well as additional risks not presently known to us or that we currently consider immaterial, could harm our business, financial condition, results of operations and/or growth prospects, as well as adversely affect the market price of our common shares, in which case you may lose all or part of your investment. The matters described below reflect our beliefs and views as to factors, events or contingencies that could materially and adversely affect our business, financial condition, results of operations, and growth prospects, and/or the price of our common shares in the future. References in this section to past events or conditions are provided by way of example only and are not intended to be a complete listing or a representation as to whether or not the factors, events or contingencies discussed below have occurred in the past or their likelihood of occurring in the future.

Risks Related to Our Business Operations and Capital Requirements

We are dependent on our third-party collaboration with Roche to develop and commercialize OpRegen. If Roche is not successful and/or terminates the collaboration, we will lose a significant source of potential revenue, further development of OpRegen may be significantly delayed or terminated and its commercial potential could be significantly diminished. Additionally, if OpRegen is not successful, prospects for our other product candidates and our business could be significantly harmed.

OpRegen is our lead cell therapy program. 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 epithelial ("RPE") cell therapies, including OpRegen (the "Licensed Products"), for the treatment of ocular disorders, including age-related macular degeneration with geographic atrophy. Roche is obligated to pay us milestone payments upon the achievement of specified developmental, regulatory and commercialization milestones. In addition, Roche is obligated to pay us royalties upon sales of the Licensed Products, if any. All regulatory and commercial milestone payments and royalty payments are subject to the existence of certain intellectual property rights that cover OpRegen at the time such payments would otherwise become due, and the royalties on net sales of OpRegen are subject to financial offsets based on the existence of competing products.

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

Roche's degree of control of the collaboration, clinical development and commercialization efforts may impact the payment amounts that we receive under the Roche Agreement. For example, Roche may suspend development of OpRegen or other product candidates covered by the Roche Agreement or decide not to pursue commercialization of OpRegen or such other product candidates at all, or it may agree to pay royalties to third parties or adopt a pricing model that reduces the amount of royalties we might otherwise expect.

In recent years, the pharmaceutical industry has experienced a significant trend toward strategic portfolio rationalization—commonly referred to as "pipeline pruning"—in which large pharmaceutical companies have increasingly discontinued, divested, or deprioritized development programs that do not meet internal return-on-investment thresholds, in favor of concentrating resources on a smaller number of high-value or near-term commercial assets. For example, in recent years, Roche has announced that it decided to halt the development of certain programs on the basis that such programs did not provide sufficient grounds for Roche to continue investing in the program. More broadly, Roche has undertaken substantial reductions in its development pipeline in recent years, which illustrates how large pharmaceutical companies may prioritize return on investment and near-term commercial prospects over breadth of pipeline and early-stage or platform-based collaborations of the type we are

seeking to enter into or expand. No assurances can be given that Roche will dedicate the resources necessary to carry OpRegen through clinical development, regulatory approval, or commercialization.

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

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

- delays in development, manufacture or clinical supply of OpRegen (see the risk factor titled, "The manufacture of our cell therapy product candidates is complex, highly regulated and subject to a multitude of risks. We have limited experience manufacturing our product candidates on a clinical scale and no experience manufacturing on a commercial scale. Roche also has limited experience manufacturing OpRegen in a research and development setting, and no experience manufacturing it on a clinical or commercial scale. Any failure to manufacture our product candidates in sufficient quantities in accordance with applicable quality standards and regulatory requirements and at acceptable costs, may result in significant clinical development delays or impair our ability, or that of a strategic collaborator, to obtain approval for or commercialize our product candidates," below);
- Roche may conclude that clinical supply of OpRegen does not meet its internal standards;
- Roche may believe that data generated in clinical trials for OpRegen may be negative, inconclusive, or do not otherwise demonstrate adequate safety, efficacy or clinical benefit to warrant further development or commercialization;
- Roche may not dedicate the resources necessary to carry OpRegen through clinical development, regulatory approval, or commercialization;
- Roche may conclude, prior to completion of clinical development of OpRegen, that the commercial landscape in GA secondary to AMD has changed in a manner that would significantly limit the commercial potential of OpRegen;
- 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;
- Roche may determine to find or develop, and subsequently seek regulatory approval for, a surgical device for OpRegen, and Roche may not be able to do so in a commercially viable and timely manner, or at all;
- Roche controls patent prosecution and could make decisions to abandon one or more patent applications or patents; or
- the loss or impairment of intellectual property rights related to OpRegen.

If Roche terminates the collaboration:

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

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

In addition, we are required under the Roche Agreement to transfer certain manufacturing process know-how to Roche to facilitate manufacture of OpRegen and other potential Licensed Products for clinical trials and commercialization. Transferring manufacturing testing and processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. We have never completed such transfer and we can give no assurances that we will be successful in doing so. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We and Roche will need to conduct significant development work to transfer these processes. In addition, the cells generated by Roche will need to be demonstrated to be comparable to the cells we previously produced and used in testing. See the risk factor below titled, "Changes in or disruptions to our manufacturing operations could materially and adversely affect our business." Any failure or delay in the successful transfer of manufacturing process know-how to Roche or the inability of Roche to manufacture comparable cells could halt or delay the continued development of OpRegen and other potential Licensed Products.

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

Our total operating losses for the fiscal years ended December 31, 2025 and 2024 were $36.6 million and $21.5 million, respectively, and we had an accumulated deficit of $467.0 million as of December 31, 2025. 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. In addition, our current strategy includes further investment in our AlloSCOPE manufacturing platform and leveraging that platform and our other technology and know-how to expand our product candidate pipeline. Any new development program will likewise require substantial additional time and resources by us and/or a collaborator before we or any collaborator would be able to apply for marketing approval, and likewise be subject to significant uncertainty. 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 and we and our collaborators must overcome significant challenges to develop, manufacture, and commercialize our product candidates. 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 directed differentiation processes to established pluripotent cell lines. The cells we manufacture must be transplanted into patients in an effort to replace or support cells that are absent or dysfunctional due to degenerative disease, aging, or traumatic injury, and restore or enhance the patient's functional activity. Allogeneic cell therapy is still an emerging area of therapeutic medical intervention, and as such, it is difficult to accurately predict the type and scope of challenges we and our collaborators may face during the identification and development of our product candidates. To date, there is only one FDA-approved allogeneic RPE cell-based product and it is an encapsulated cell-based gene therapy; it does not integrate into the retina. Although there are clinical trials of other pluripotent stem cell-derived therapeutic candidates ongoing, we do not believe that the FDA has granted marketing approval to any pluripotent stem cell-based therapeutic product, and we are not aware of any regulatory approvals of any iPSC-derived therapeutic candidate anywhere in the world other than conditional and time-limited approvals granted in February 2026 by a committee of Japan's Ministry of Health, Labor and Welfare's Pharmaceutical Affairs Council for Reheart and Amchepry. Those conditional and time-limited approvals were based on the likelihood of the efficacy of these candidate therapeutics, allowing them to be sold provisionally; further testing will be needed to demonstrate safety and efficacy. These candidate therapeutics were only presumed to be effective by the committee of Japan's Ministry of Health, Labor and Welfare's Pharmaceutical Affairs Council, with trials observing symptom improvement in four of six Parkinson's patients and in all eight heart failure patients, but with no comparisons against patients who did not receive the treatments. Accordingly, these conditional approvals should not be construed as establishing confirmed safety or efficacy of iPSC-derived therapies, and the framework under which they were granted is not equivalent to the full marketing authorization process that our product candidates would need to satisfy to be commercialized in the United States or other major markets, including generating substantially more clinical data—including from large, controlled trials with direct comparator arms.

If any cell therapies that have received conditional, accelerated, or other non-traditional regulatory approvals in Japan or other jurisdictions subsequently experience serious adverse events ("SAEs") or adverse events ("AEs"), clinical trial halts, regulatory enforcement actions, product withdrawals, or the imposition of additional restrictions, such developments could have significant negative consequences for us, even if our product candidates are not implicated in the underlying events. For example, adverse safety events in other conditionally approved or investigational cell therapies could cause the FDA or other regulatory authorities to adopt more conservative regulatory positions, impose additional preclinical requirements, increase evidentiary expectations for clinical development, require more extensive manufacturing controls or long-term follow-up studies, or impose additional post-marketing conditions for cell therapy programs broadly. Any such changes could increase our development costs, extend our development timelines, or reduce the likelihood or timing of approval for our product candidates.

In addition, negative developments involving cell therapies — whether our product candidates or those of third parties — can reduce investor confidence in the cell therapy sector broadly, adversely affect the market price of cell therapy companies' securities, and impair the ability of companies in our industry to access capital, and adverse safety signals or negative public perception arising from SAEs in other cell therapy programs could cause potential collaboration partners to reduce their interest in cell therapy programs more broadly, demand more extensive safety data before entering into collaborations, or seek more favorable terms reflecting perceived sector-wide risk.

Because cell therapy remains a nascent and rapidly evolving field, and the regulatory framework for the approval of pluripotent stem cell-derived and iPSC-derived therapies has limited established precedent in major markets, we and our collaborators face heightened challenges and uncertainties and potentially a longer regulatory approval process for our product candidates compared with therapeutic candidates with more established clinical development and regulatory approval pathways. We and our collaborators face significant challenges and uncertainties associated with the identification, manufacture, preclinical and clinical development, regulatory approval pathway, and third-party payor coverage and reimbursement of our product candidates required for successful commercialization, including:

- successfully identifying potential product candidates;
- manufacturing our product candidates to our internal standards and those of our collaborators, as applicable, as well as to applicable regulatory specifications, in a timely manner, and on the scale necessary to support larger-scale clinical trials, and, if approved, commercialization;
- understanding and addressing variability in our cell manufacturing processes, which could affect our ability, or the ability of our collaborators, as applicable, to produce clinical trial material and, if approved, commercial product in a reliable and consistent manner;
- designing and completing clinical trials of our product candidates that will demonstrate their safe and effective use to treat the targeted disease or other medical condition;
- sourcing clinical and, if approved, commercial supplies of key components required for the manufacture of our product candidates;
- developing formulations of our cells that reduce or eliminate dose preparation or other complexities of handling and administration of our product candidates at the point of care;
- identifying and developing the appropriate hypoimmune strategies to prevent or reduce immune rejection of our cell-based product candidates;
- 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 therapy products and products created with gene-editing technology 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 meaningful intellectual property protection for our product candidates, the process 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 and our collaborators are not successful in addressing key challenges in development and commercialization of our cell therapy product candidates, or if our product candidates and technologies do not prove to be safe or effective for the indications for which they are being developed, our business prospects and revenue opportunities will be materially limited.

We will continue to spend a substantial amount of our capital on research and development, but we might not succeed in identifying or developing product candidates that are safe and effective for their target indications or are 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 $17.7 million and $12.5 million during the fiscal years ended December 31, 2025 and 2024, respectively, and we expect to continue to incur substantial research and development expenses. If we successfully identify and develop a new technology or product candidates, refinement of the new technology or product and definition of the practical applications and limitations of the technology or product may take years and require large sums of money. Clinical trials of new therapeutic products, particularly those products that are regulated as biologics, drugs, or devices, such as our product candidates, are very expensive and take years to complete. Only a small percentage of therapeutic product candidates that enter the development process ever receive marketing approval. Even with substantial spending on research and development of our product candidates, they might not prove to be safe or efficacious in the human medical applications for which they are being developed, or they may prove too expensive to manufacture or otherwise fail to gain sufficient market acceptance to be commercially viable.

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

We believe that our cash, cash equivalents and marketable securities as of December 31, 2025 will be sufficient to fund our planned operations for at least twelve months after the issuance date of our consolidated financial statements included elsewhere in this report; however, these resources will not be sufficient to fund our product candidates through regulatory approval, and we will need to raise substantial additional capital to complete the development and seek regulatory approval of our product candidates and to commercialize products approved for marketing, if any. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our planned operations.

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

being developed by third parties could have a negative effect on potential investor or strategic collaborator sentiment for our technologies and product candidates.

As discussed elsewhere in this report, we issued warrants to purchase our common shares in connection with our November 2024 registered direct offering. As of the filing date of this report, warrants to purchase up to approximately 35.2 million common shares remain outstanding and, if those warrants are exercised in full on a cash basis, we would receive $32.1 million in gross proceeds. However, no assurances can be given that all or any portion of such warrants will be exercised, or if exercised, that they will be exercised on a cash basis. See also the risk factor below titled "The issuance of common shares upon exercise of warrants will cause immediate and substantial dilution to existing shareholders."

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

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

- number, 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 and the delivery systems or other tools required for transplant of the cells, including but not limited to clinical trial and manufacturing requirements for approval;
- our decisions to initiate additional clinical trials, not to initiate any clinical trial or to terminate an existing clinical trial;
- the cost of obtaining and the availability of materials, equipment and devices that are necessary for the production or administration of our product candidates;
- our ability to maintain existing development and commercialization collaborations and whether we decide to enter into new third-party collaborations for development or commercialization of our product candidates and the terms of any such collaboration;
- the cost and timing of establishing and validating new manufacturing processes or facilities for our product candidates and any approved products or of transferring manufacturing responsibilities to a collaborator; and
- additions or departures of key management or scientific personnel.

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

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

We may seek additional capital through a variety of means, including equity offerings, debt financings or other third-party funding, including grants or new strategic alliances and licensing or collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Any debt capital financing may involve covenants that restrict our operations, including limitations on additional borrowing and on the use of our assets and may also include equity components, such as warrants, which could cause your ownership interests to be diluted. If we raise capital through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates and technology or grant licenses on terms that are not favorable to us compared to if we developed and commercialized a product candidate without a strategic collaboration. Any such arrangements may be dilutive to our ownership or economic interest in the products we develop, and we might have to accept royalty payments on product sales rather than receiving the gross revenues from product sales. See, for example, the terms of our agreements with Roche to develop and commercialize OpRegen and with William Demant Invest 2 Aps (WDI) to advance preclinical development of ReSonance. Grants from third parties may involve covenants that restrict our operations, require us to relinquish valuable rights in our products, technology and other intellectual property and may be dilutive to our economic interest in products and technologies we develop with such funding. For example, as discussed in Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report, pursuant to the terms of grants received by CCN from the Israeli government, there are limitations on our ability to manufacture products and transfer or license technologies outside of Israel and considerable contingent financial obligations to the IIA with respect to products, technologies and intellectual property developed with the support of IIA grant funding, which includes the OpRegen program, and, as discussed below in this Risk Factors section, pursuant to the terms of a grant we received from CIRM in support of clinical development of OPC1, we have royalty payment obligations to CIRM based on net sales of products developed with the support of CIRM funding, if any.

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

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

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

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

We have multiple cell therapy programs in development and limited resources. In addition, we maintain a list of additional undisclosed product candidates which may be considered for development or partnership in the future, and which altogether cover a range of therapeutic areas and conditions. We have and may continue to expand our research and development efforts into therapeutic areas and conditions outside of our initial focus in neurology and ophthalmology and where we have limited experience. We also have contractual commitments to conduct certain manufacturing and development activities, and do not have unilateral discretion to vary from such efforts. As a result, we may forego or delay pursuit of existing or new development opportunities that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. For example, we may invest our resources in a limited number of more advanced programs in the shorter term and reduce our investment in promising earlier stage programs. Such decisions would require us to limit the breadth and diversity of our product candidate pipeline, which could potentially limit the long-term growth of our product portfolio and subject us to greater risk that the failure of any such programs would harm our prospects. Alternately, we may delay or abandon more advanced programs to increase investment in promising earlier stage programs. Our spending on current and future research and development programs, manufacturing technology, 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 preclinical or 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 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 as well as cell lines 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 fail to enter into new strategic relationships or may not realize the benefits of any strategic relationships that we have entered into, either of which could materially adversely affect our business, financial condition, commercialization prospects, and results of operations.

Collaborative models are central to our business strategy. Our product development programs, the potential commercialization of our product candidates, and diversification and expansion of our pipeline will require substantial additional funding. Therefore, as we have done with OpRegen and certain of our preclinical programs, we have decided or may decide to form or seek strategic alliances, collaborations, or similar arrangements with pharmaceutical or biotechnology companies or other third parties that we believe will complement or augment our development and potential commercialization efforts with respect to such product candidates, including in territories outside the United States or for certain indications. We may also pursue alternative strategies or relationships, such as spin-outs, joint ventures, or investments in complementary businesses that align with our strategy, which may pose risks similar to those described elsewhere in this Risk Factors section with respect to collaborations, as well as additional risks unique to these types of relationships. To the extent we enter into strategic relationships involving parties located outside the United States, we are subject to similar risks to those described elsewhere in this Risk Factors section with respect to foreign acquisitions and licensing arrangements. For example, in August 2025, we entered into a multi-year research collaboration agreement with WDI, a Danish company, to advance preclinical

development of ReSonance for the treatment of hearing loss, and development activities are jointly conducted and managed by us and scientists from the from Eriksholm Research Centre, which is located in Denmark and part of Oticon A/S, which is a subsidiary of the Demant Group.

We face significant challenges, including competition, in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may not be successful in our efforts to establish a collaboration or other alternative arrangements for our product candidates or technologies on acceptable terms or at all, including because our product candidates or technologies may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate success in clinical trials and ultimately obtain regulatory approval. We may incur costs to continue developing one or more of our product candidates or technologies to establish or support an appropriate collaboration, which costs may outweigh the benefit of any such collaboration, if we are able to enter into a collaboration at all. Additionally, there have been a significant number of recent business combinations among large pharmaceutical companies that have reduced the number of potential future collaborators and changed the strategies of the resulting combined companies. In addition, under the terms of certain license agreements applicable to our product candidates and technologies, we may be restricted from entering into collaboration or similar agreements relating to those product candidates or technologies on certain terms or at all, and when we collaborate with a third party for development and commercialization of a product candidate, we expect that we may have to relinquish some or all of the control over the future success of that product candidate to the third party. See "Item 1. Business— Collaborations," above. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator's evaluation of our technologies, product candidates, and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and could determine that such other collaboration is more attractive than a collaboration with us for our product candidate or technologies. Similar risks exist with respect to any joint ventures we may pursue, as well as risks and uncertainties related to the costs, time, and other resources required to manage and gain the benefit of any such joint venture, and any potential liabilities we may incur in connection with a joint venture.

In instances where we enter into collaborations, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects, and financial results and condition:

- collaborators may have significant discretion in determining the efforts and resources that they will apply to a collaboration and may not commit sufficient efforts, funding, and other resources to the development or marketing programs for collaboration product candidates or may misapply those efforts, funding, or resources;
- collaborators may have significant discretion in determining to discontinue programs, to terminate or suspend development of programs, reprioritize internal resources, or decline to exercise options for additional programs, in each case without our consent and potentially at commercially critical times;
- collaborators may experience financial difficulties, including those that could negatively impact their ability to perform their obligations pursuant to the collaboration agreement, such as funding and development obligations;
- collaborators may not pursue development and commercialization of collaboration product candidates or may elect not to continue or renew development or commercialization programs based on preclinical or clinical study results or changes in their strategic focus;
- collaborators may decide or may be required by regulatory authorities to delay clinical trials, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, address delivery device concerns, including the development of new devices, or require a new formulation of a product candidate for clinical testing;
- we may be required to relinquish important rights to our product candidates or technologies, such as marketing, distribution, and intellectual property rights;
- we may be required to agree to exclusivity, non-competition, or other terms that restrict our ability to research, develop, or commercialize certain existing or potential future product candidates or technologies, including

our ability to develop our product candidates in certain indications or geographic regions or combine our product candidates or technologies with certain third-party products or technologies;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property rights or proprietary information or expose us to potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may acquire outside of the collaboration or develop, independently or in collaboration with third parties, including our competitors, products that compete directly or indirectly with our product candidates and may decide to advance such product candidates instead of ours;
- collaborators may own or co-own intellectual property rights covering the product candidates or technologies that result from our collaboration, and in such cases, we may not have the exclusive right to commercialize such product candidates or technologies;
- we and our collaborators may disagree regarding the development plan for a collaboration product candidate, including, for example, with respect to target indications, inclusion or exclusion criteria for a clinical trial, or the decision to seek approval as front-line therapy versus second-, third-, or fourth-line therapy;
- disputes may arise with our collaborators that could result in the delay or termination of the research, development, or commercialization of the applicable product candidates or costly litigation or arbitration that diverts management attention and resources;
- business combinations or significant changes in a collaborator's business strategy may adversely affect our or the collaborator's willingness to complete our or such collaborator's obligations under the collaboration;
- collaborations may be terminated, which may require us to obtain additional capital to pursue further development or commercialization of the applicable product candidates or technologies; or
- we may not achieve the revenue, specific net income, or other anticipated benefits that justify our having entered into, or otherwise led us to enter into, the collaboration.

If our strategic collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone, royalty, or other payments under the collaboration. Moreover, our initial estimates of the potential revenue we are eligible to receive under our strategic collaborations may include potential payments related to therapeutic programs for which our collaborators may discontinue development. If we are unable to enter into strategic collaborations, or if any of the other events described in this Risk Factor section occur after we enter into a collaboration, we may have to curtail the development of a particular product candidate, reduce or delay the development program for such product candidate or one or more of our other product candidates, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

Our decisions regarding whether to advance our programs internally or through strategic relationships may not maximize the value of our pipeline for our shareholders, and misjudgments in these decisions could materially adversely affect our business.

We evaluate strategic alternatives for programs in our pipeline, including whether to continue internal development or enter into strategic alliances, collaborations, or similar arrangements with pharmaceutical or biotechnology companies or other third parties. As we have done with OpRegen and certain of our preclinical programs, we expect to continue to pursue collaborations and other strategic transactions as part of our value creation strategy. These decisions involve complex and inherently uncertain judgments regarding scientific and clinical risk, manufacturing feasibility, regulatory pathway and timeline, competitive dynamics, capital and resource

requirements, and the timing and nature of potential value inflection points. There can be no assurance that we will correctly assess the optimal timing, structure, or counterparty for any collaboration or other strategic transaction.

If we out-license or partner a program at an early stage when internal advancement might have generated substantially greater value, we may forego a significant portion of the potential upside of that program. Conversely, if we retain a program internally for too long or attempt to advance it without a partner when a collaboration might have increased the probability of success or reduced capital consumption, we may incur substantial additional costs, experience delays, or ultimately be unable to fund continued development on acceptable terms.

Any of the foregoing could materially adversely affect our business, financial condition, results of operations, and prospects, as well as the market price of our common shares.

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

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

In addition, we may not be able to successfully integrate any acquired personnel, operations and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could harm our operating results. We also face risk of shareholder lawsuits in connection with acquisitions that can divert management's focus from operating our business and result in significant legal and other expenses, which could harm our operating results and financial condition. For example, in 2023, we settled a putative shareholder class action lawsuit relating to our acquisition of Asterias after more than three years of litigation. See Note 13 (Commitments and Contingencies) to our consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 10, 2025. 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.

In addition, foreign acquisitions and licensing arrangements are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations, and the particular economic, political, regulatory, and compliance risks associated with specific countries. The occurrence of any of these risks or uncertainties may preclude us from realizing the anticipated benefit of any acquisition or licensing arrangement, and our financial condition may be harmed.

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

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

We, or our collaborators, suppliers, CROs, other service providers, or other third parties on which we rely, may experience interruptions that could significantly disrupt or harm our operations, including the conduct of our research and development programs, clinical trials, and manufacturing operations, due to natural disasters, public health emergencies, geopolitical conflicts, political and economic instability, acts of terrorism, or hardware, software, telecommunication or electrical failures.

Currently, all of our cGMP manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, are conducted by our subsidiary, CCN, at its facility in Jerusalem, Israel, and more than two-thirds of our workforce are CCN employees who are based in the same facility. In addition, certain of the clinical trial sites for the OpRegen GAlette study are in Israel.

The recent escalation of conflict and hostilities in the Middle East—including the strikes by Israel and the United States on Iran that began on February 28, 2026 and the retaliatory attacks thereto— has increased the risk of broader regional military escalation, cyberattacks, disruptions to transportation and logistics infrastructure, interruption of utility and communications services, and other events that could directly disrupt our operations in Jerusalem and our ability to source and ship materials and supplies to and from Israel, and the clinical trial sites for the OpRegen GAlette study in Israel. Any such disruption could increase our costs, delay our development timelines, or render us unable to manufacture clinical material in sufficient quantities or on required timelines and otherwise materially adversely affect our business and results of operations. The situation continues to rapidly evolve, and it is currently not possible to predict the scope, duration or severity of present or future regional instability or its effects on our operations, financial condition or operating results, on our ability to raise additional capital, as well as the overall economy in Israel and the value of the New Israeli Shekel.

As a result of safety concerns and in response to government-imposed restrictions on movement and travel and other precautions taken to address the Israeli regional conflict that began in October 2023, our operations at our CCN facility in Jerusalem were temporarily impacted in the past. In light of the recent escalation of hostilities and conflict in the Middle East, we expect that similar government-imposed restrictions on movement and travel and other precautions will be implemented, which could materially and adversely affect the operations at our Jerusalem facility. Further, a number of our CCN employees in Israel are members of the military reserves and subject to immediate call-up in response to regional instability. Male Israeli citizens are obligated to perform several days, and in some cases more, of annual military reserve duty each year until they reach the age of 40 (or older, for reservists who are military officers or who have certain occupations) and, in the event of a military conflict, may be called to active duty. Several employees in Israel, including CCN's chief executive officer, were activated for military duty in the past, and they and other employees may be activated for military duty in the future, particularly in light of the

recent escalation of hostilities and conflict in the Middle East, which could disrupt our operations. In addition, the general impact on employees operating in a region of conflict could adversely impact our operations. Although we have business continuity plans in place to address medium- or long-term disruptions that could result from regional instability, those plans are limited and do not account for every possible scenario, and in addition, any long-term closure of our CCN facility, or if that facility were damaged, or if hostilities otherwise disrupt the ongoing operations at that 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.

The regional conflict and instability could adversely affect the operations of the clinical trial sites for the OpRegen GAlette study in Israel, including their ability to enroll patients, administer doses, monitor patients, or collect and verify data at those sites. Any such disruption could delay or halt enrollment, require the modification of trial protocols, impair the completeness or integrity of clinical data, any of which could materially delay development of OpRegen.

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

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. 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. Israel faces threats from its neighbors, in particular, Iran and Iran-backed militia groups, which have heightened since the escalation of hostilities in the Middle East. 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.

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

and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences."

We have historically relied on equity financings and other capital market transactions to fund our operations, and geopolitical conflicts, wars, and other macroeconomic events outside our control can contribute to capital markets volatility and reduce risk appetite for small-capitalization biotechnology issuers. The escalation of hostilities in the Middle East could contribute to broader macroeconomic uncertainty, equity market volatility, and reduced investor appetite for companies with operations in the Middle East, which could adversely affect our ability to raise additional capital on acceptable terms, if at all.

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

CCN has received Israeli government grants for certain of its research and development activities, including grants under the Innovation Law for OpRegen and our photoreceptor research initiative, PNC1. 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 the IIA, such cap growing over time via interest accrual until paid in full. In accordance with obligations under the Innovation Law, Lineage continues to fund CCN to pay the downstream obligation to the IIA. As of December 31, 2025, the aggregate cap amount was approximately $96.2 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 the IIA, or limit the economic benefit that we might derive under such agreements. We cannot be certain that any approval of the IIA will be obtained on terms that are acceptable to us, or at all. We may not receive the required approvals should we wish to transfer or license IIA-funded know-how, manufacturing and/or development outside of Israel in the future. Furthermore, in the event that we undertake a transaction involving the transfer to a non-Israeli entity of know-how developed with IIA funding pursuant to a merger or similar transaction, the consideration available to our shareholders may be significantly reduced by the amounts we are required to pay to the IIA. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with the requirements under the Innovation Law may subject CCN to mandatory repayment of grants received by it (together with interest and penalties), as well as expose its directors and management to criminal proceedings. In addition, the IIA may from time-to-time conduct royalty audits.

Clinical development of OPC1 has been supported in part by grant funding from CIRM. We may not be able to timely obtain additional CIRM funding, which could negatively impact our ongoing clinical trial and 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 in part by $14.3 million of funding from CIRM, a state agency established to fund stem cell research and development of new stem cell-based treatments. In June 2025, we applied for approximately $7.0 million of additional funding from CIRM to support continued clinical development of OPC1 for the treatment of SCI. In November 2025, we elected to withdraw that application following comments we received from CIRM to the application. There were no specific content deficiencies identified by CIRM in the application. We submitted a revised application in January 2026, which we believe responds to feedback we received from CIRM in November 2025. However, CIRM may determine not to accept our application for review or, even if our application is accepted, CIRM may decline to award any additional funding or may award significantly less additional funding than we applied for. Moreover, we expect that any CIRM funding will only be

applicable to expenses we incur after the date of receipt of an appliable grant and that expenses incurred by us prior to the receipt of any such grant will not be eligible for CIRM funding. If we are unable to timely obtain another CIRM grant or if the amount of grant funding we receive from CIRM, if any, is significantly less than we applied for , the timeline for the DOSED clinical study may be adversely affected and we may be unable to complete the study or we may need to raise funds through other means to continue clinical development of OPC1, which could have a higher cost of capital, cause dilution to our shareholders, restrict our operations or require us to relinquish rights on unfavorable terms.

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

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

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

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

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

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

The administration of our cell therapy product candidates requires surgical transplantation, which exposes us to additional regulatory, clinical, operational and commercial risks that could materially adversely affect our business, results of operations and prospects.

Our product candidates are administered via surgical procedures, which depend on the use of specialized instruments and other tools, such as needles, catheters, cannulas, injectors, imaging-guided systems. For some of our product candidates, we or our collaborators plan or may seek to investigate the administration of our product candidates utilizing novel, specialized delivery systems or devices. These tools may be used to deliver our cells to precise anatomical locations and may be deemed integral to achieving the intended therapeutic effect. As a result, our business is subject to a number of added risks, including that:

- a product candidate could be regulated as biologic-device combination product or otherwise require compliance with device-specific regulatory requirements, which could increase the complexity, cost and timeline for its development and regulatory approval;
- the use of invasive or technically complex transplantation procedures increases the risk of adverse events, including those unrelated to the cells themselves, such as tissue injury, bleeding, infection, ophthalmological damage, neurological damage, off-target cell placement, or other serious adverse outcomes, and, even if caused primarily by the delivery tool or procedure, such events may be attributed to our product candidate in clinical trials or post-marketing surveillance, which could result in clinical holds, delays, additional study requirements, labeling restrictions, reputational harm, or product liability claims;
- inconsistent or imprecise transplantation of our cell therapies may adversely affect clinical outcomes and trial results, particularly where the therapeutic effect of a cell therapy may depend on precise placement, injection depth, dosing, or handling during administration;
- delivery tools may adversely affect cell viability, potency, or stability, which could adversely affect clinical outcomes and trial results and require additional preclinical and clinical studies,
- we or our collaborators may be dependent on third parties over whom we have limited control for supply of delivery tools and these third parties may fail to perform as expected, including by discontinuing products, experiencing quality or regulatory compliance issues, increasing pricing, failing to supply adequate quantities, declining to support our intended use, or exposing us to intellectual property infringement claims, and disruption in access to necessary delivery tools could delay clinical trials or commercialization efforts and force us or our collaborators to adopt alternative devices that require additional validation and testing and may be less effective;
- complex or invasive administration may require highly trained clinicians, specialized facilities, or longer procedure times, which could limit use to select healthcare centers and reduce physician or hospital willingness to adopt our therapies;
- third-party payors may be reluctant to reimburse therapies that require costly procedures or equipment, which could adversely affect commercial uptake and revenue potential of our product candidates; and
- disputes may arise in the event of patient injury claims regarding whether harm was caused by the cells, the delivery tools, the procedure, or inadequate instructions or training, and such disputes could complicate indemnification arrangements, increase litigation costs, and expose us to significant financial and reputational harm.

See also the discussion in this Risk Factors section under, "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," and "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."

If we or our collaborators are unable to effectively manage risks related to the tools and procedures used to administer our cell therapies, prospects for successful clinical development, regulatory approval, and commercialization of our product candidates, and our overall business could be materially adversely affected.

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

We believe that our continued success depends to a significant extent upon our efforts and ability to retain highly qualified personnel. All of our officers and other employees, including CCN employees, are at-will employees and may terminate their employment with us at any time with no advance notice. Given the novel and specialized nature of our cell manufacturing technology and the fact that we are operating in an emerging field, there is an inherent scarcity of personnel with the requisite experience to fill the roles in our organization as our business expands. The loss of the services of key personnel could delay or otherwise impact our cell manufacturing and other research and development activities, for example, through loss of institutional knowledge, capabilities, or subject matter expertise, or otherwise disrupt our operations and our ability to conduct our business. The replacement of any of key personnel would likely involve significant time and costs and may significantly delay or prevent the achievement of our business and clinical objectives and would harm our business.

In addition, we could experience difficulties attracting qualified employees in the future. For example, competition for qualified personnel in the biotechnology and medical device field is intense due to the limited number of individuals who possess the skills and experience required by our industry and our cell therapy business in particular. Further, for some key positions at CCN, candidates will need to be already living in or willing to relocate to Israel, which further limits the pool of potential candidates. We will need to hire additional personnel as we continue developing our technology and product candidates and building our pipeline, including personnel with specialized and/or program-specific medical, scientific, or technical qualifications and experience. We may not be able to attract quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information or that their former employers own their research output.

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances to which we are subject in the U.S. or Israel could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances to which we are subject in the U.S. or Israel could be interpreted, changed, modified or applied adversely to us. For example, the One Big Beautiful Bill Act ("OBBBA") was signed into law in July 2025 and made significant changes to U.S. federal tax law, including reinstatement of 100% bonus depreciation, allowing domestic research cost expensing, and modifies the business interest expense limitation. The OBBBA permits the deduction of certain expenditures incurred for research and development performed in the U.S. in tax years beginning on or after January 1, 2025, but expenditures attributable to research and development conducted outside of the U.S. must continue to be capitalized and amortized over a 15-year period. A material portion of our research and development activities are conducted in Israel. It cannot be predicted whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued that could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. or Israeli tax expense or require changes in the manner in which we operate to minimize or mitigate any adverse effects of changes in tax law.

The Organization for Economic Co-operation and Development (OECD) has a framework to implement a global minimum corporate tax of 15% for companies with global revenue and profits above certain thresholds (referred to as Pillar 2). Although the U.S. has not enacted legislation to implement Pillar 2, certain countries in which we operate have adopted legislation, and other countries are in the process of introducing legislation to implement Pillar 2. The OECD issued new administrative guidance on January 5, 2026, with respect to Pillar 2 which modifies key aspects of the framework for countries to enact in their own laws. Pillar 2 did not have an impact on the Company's 2025 financial statements because the Company does not currently meet the 750 million Euro sales threshold but it could in future years.

Our ability to use our net operating losses and other tax attributes to offset future taxable income or taxes may be limited, which may effectively increase our future income tax obligations.

As of December 31, 2025, 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 2045. Our federal research and development tax credit carryforwards expire in varying amounts between 2024 and 2045, the California research and development tax credit carryforwards have no expiration date. See Note 12 (Income Taxes) to our consolidated financial statements included in this report for additional information. NOL carryforwards and research and development and other tax credits that expire unused will be unavailable to offset future income tax liabilities. Under federal income tax law, federal NOL carryforwards generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOL carryforwards is limited to 80% of taxable income. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We have experienced ownership changes in the past and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. As a result, our ability to use our pre-change NOL carryforwards and tax credits to offset post-change taxable income, if any, could be subject to significant limitations. Similar provisions of state tax law may also apply. In addition, the state of California suspended the use of the NOL deduction for tax years 2024 through 2026 if their California taxable income is greater than or equal to $1 million. Accordingly, we may not be able to offset taxable income with our NOL carryforwards during these years. The state of California also limited the use of their research and development credits to $5 million for tax years 2024 through 2026, which could accelerate or permanently increase state taxes owed. As a result of limitations on our ability to use our NOL carryforwards and tax credits, we may be unable to gain the benefit of a material portion of our NOL carryforwards and tax credits, which could harm our future operating results by effectively increasing our future income tax obligations.

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

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

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

Our reporting and functional currency is the United States Dollar, but a material portion of our research and development and other operating expenses are incurred in Israeli New Shekels through our subsidiary CCN. As a result, we are exposed to some currency fluctuation risks. We do not currently manage our foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. For example, we do not

engage in any active hedging techniques, and we do not employ any derivative instruments. Unfavorable fluctuations in the exchange rate between Israeli New Shekels and U.S. dollar may adversely affect our comprehensive loss and cash flows.

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

The ability of the FDA to review and approve new product applications and take action with respect to other regulatory matters can be affected by a variety of factors, including the U.S. federal government budget and funding levels, government shutdowns, public health crises, leadership changes, statutory, regulatory and policy changes, federal government policy actions, including reduction-in-force initiatives, ability to hire and retain key personnel, ability to accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years. In 2025, as a result of initiatives of the new presidential administration, the FDA experienced leadership turnover, significant workforce cuts and voluntary departures, requirements to reduce regulation, shifts in scientific and regulatory priorities, and political pressure to increase scrutiny of certain products. These and other factors increased the uncertainties associated with interpreting the FDA's guidance and predicting its areas of focus and responses to various issues. In addition, companies experienced reduced engagement with review divisions and reported slower reviews and missed review deadlines. Changes and disruptions at the FDA that have occurred or may occur in the future may make it more difficult or costly to progress the development of our product candidates by resulting in delayed meetings and other communications with agency staff, slower application acceptances and reviews, and increased unpredictability in review outcomes for applications to commence clinical studies or to market a new product in the U.S. In addition, government funding of the FDA and other government agencies, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable and could lead to changes in agency funding that make it more difficult or costly to operate our business. For example, recent actions by the current presidential administration and National Institutes of Health may adversely impact research and development of new biologics products, and we cannot predict how and the extent to which such action may impact our business.

The failure of the U.S. Congress to pass a new appropriations bill or continuing resolution to temporarily extend funding by the applicable legislative deadline or the occurrence of a public health crisis may cause federal agencies to reduce or halt non-essential operations, which could prevent or delay staff at federal agencies from performing key functions and may adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities to the extent they are not funded by existing available user fees. For further 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, disruptions at the SEC could prevent or delay SEC staff from performing key functions, including, for example, granting acceleration requests for registration statements, declaring registration statements or amendments thereto effective and providing interpretive guidance or no-action letters. If a prolonged government shutdown, public health crisis, or other event or condition occurs that prevents or significantly delays the FDA, SEC or other regulatory agencies from hiring and retaining personnel and conducting their regular activities, or if an agency is restructured or experiences significant reduction in funding, leadership changes or employee turnover, it could significantly impact the ability of these agencies to timely review and process our regulatory submissions and may impede our access to the public markets and ability to obtain additional capital needed to maintain or expand our operations or to complete important acquisitions or other transactions, which could have a material adverse effect on our business.

Risks Related to Government Regulation

If we or our strategic collaborators are unable to obtain FDA or comparable foreign regulatory authority approvals for our product candidates on a timely basis, or at all, our product candidates may not be marketed or sold and our business will be substantially harmed.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other activities we may engage in relating to our product candidates are subject to extensive regulation. No action can be taken to market any therapeutic biologics product in the U.S. until a BLA has been approved by the FDA. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing, and controls. Outside the United States, many comparable foreign regulatory authorities employ similar approval processes. Any issues encountered by such regulatory authorities could delay or otherwise negatively impact the development and commercialization of our product candidates. For example, changes in leadership, loss of key personnel, and staffing shortages and furloughs, lapses in government appropriations or funding, government shutdowns, or other disruptions could increase the time required for interactions with regulatory authorities, including with respect to the review, acceptance, or approval of regulatory applications or other correspondence or submissions related to our product candidates, as well as our patent or other intellectual property applications, and could also result in delays in the interpretation and implementation of important laws and regulations relevant to our business. In addition, there is uncertainty regarding how the FDA and other government agencies may evolve in the coming years, as well as with respect to the regulatory approval process for biopharmaceutical products. For example, in January 2025, an executive order entitled "Unleashing Prosperity Through Deregulation," which is applicable to the FDA, called for at least ten existing regulations to be repealed whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation. There have also been numerous recent developments at the FDA, including implementation of a generative artificial intelligence tool, referred to as Elsa, across all centers at the FDA, announcement of a plan to phase out animal testing for certain drugs, announcement of a plan to expand its use of unannounced inspections of foreign manufacturing facilities that produce medicines and other medical products intended for U.S. patients and consumers, establishment of a program designed to facilitate new U.S. drug manufacturing facilities, and the rollout of a new Commissioner's National Priority Voucher pilot program to accelerate the development and review of products that align with U.S. national health priorities and interests. We cannot fully predict how developments such as those described above, including any future developments, will impact our business.

To date, neither we nor any collaborator has submitted a BLA to the FDA or similar applications to comparable foreign regulatory authorities for any of our cell therapy product candidates, and we cannot be certain that any of our product candidates will receive regulatory approval once a BLA or similar application has been submitted. The process of obtaining regulatory approval is expensive, uncertain, often takes many years following the commencement of clinical trials, and can vary substantially based upon the type, complexity, and novelty of the product candidates involved, as well as the target indications, patient population, and regulatory authority involved. As a company, we have no experience with the preparation and submission of a BLA. Further, the FDA has not yet granted approval for any pluripotent stem cell-based or iPSC-derived therapeutic candidate, which we believe may increase the complexity, uncertainty, and length of the regulatory approval process for our product candidates. In addition, the FDA has the authority to require a Risk Evaluation and Mitigation Strategy (REMS) plan as part of a BLA approval or after BLA approval, which may impose further requirements or restrictions on the distribution or use of an approved biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria, and requiring treated patients to enroll in a registry. Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate satisfies the FDA's or such comparable foreign regulatory authorities' legal standards with respect to safety, purity, and potency, or efficacy, for its intended patient population;

- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials may not be sufficient to support the submission of a BLA or other comparable foreign submission or to obtain regulatory approval in the U.S. or elsewhere, or regulatory authorities may not accept a submission due to, among other reasons, the content or formatting of the submission;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities for a product candidate;
- FDA requirements with respect to HCT/Ps are still evolving, and FDA could increase and/or expand requirements for keeping and/or maintaining marketing approval; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change in a manner that renders our clinical data insufficient for approval, including, for example, as a result of positive or negative data from third parties regarding other cell-based products or product candidates.

The lengthy approval process, as well as the unpredictability of clinical trial results, may prevent us or a collaborator from obtaining regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining whether and when regulatory approval will be granted for any product candidates, including those that we may submit for approval in the future. For example, regulatory authorities in various jurisdictions have in the past had, and may in the future have, differing requirements for, interpretations of, and opinions on preclinical and clinical data, and certain regulatory authorities may more closely scrutinize our data, including our processes for maintaining the integrity of and disseminating such data, in particular, as our product candidates advance into later stages of development. We or our collaborator may be required to conduct additional preclinical studies, alter proposed clinical trial designs, or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which we hope to conduct clinical trials and develop and, if approved, market our products. In addition, from time to time, the FDA and other governmental or regulatory authorities across jurisdictions may adopt or promulgate laws, regulations, guidance, standards, or policies, or issue communications in areas applicable to various aspects of our research and development programs. Our efforts to comply with or address such laws, regulations, guidance, standards, policies, or communications could increase the time and expense required, or make it more difficult, to complete development activities and ultimately obtain regulatory approval for our product candidates. Further, certain of such laws, regulations, guidance, standards, policies, or communications may be subject to varying interpretations, which may increase our risk of potential noncompliance. Additionally, as discussed elsewhere in these Risk Factors, the FDA's "real-time" release of newly issued CRLs, if received for any of our product candidates, could materially harm our business. In such a case, the deficiencies in the BLA for our product candidate may be publicly disclosed before we or our collaborator have an opportunity to fully evaluate or address them, and even if a CRL contains redactions, our confidential or proprietary information may be revealed, which could harm our intellectual property strategy and competitive position, trigger disclosure requirements, and increase our exposure to potential litigation.

In addition, even if we obtain approval for any of our product candidates, regulatory authorities may grant such approval for fewer or more limited indications than we request, may not approve the price we intend to charge for such product, may grant approval contingent on the performance of costly post-marketing clinical trials, may require lengthy post-treatment follow-up, or may approve such product with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

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. However, 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. Further, However, on January 22, 2026, NIH announced a new policy, effective immediately, that NIH funds will no longer be used to support research involving hES from elective abortions – which provides an additional layer of restriction for hES use in federally funded research on top of the 2009 policy. Additionally, 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. Federal and or state regulations may change unexpectedly which could adversely affect our current or future hES cell development. Moreover, 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 product candidates, and/or our ability to supply them.

Our reliance on pluripotent cell lines that may be exempt from certain donor eligibility requirements could create regulatory, labeling, and commercialization constraints, and could require us to undertake additional steps that delay, limit, or prevent commercialization of one or more product candidates.

Our product candidates are subject to extensive regulation by the FDA and other regulatory authorities, including requirements applicable to HCT/Ps that are intended to prevent the introduction, transmission, and spread of communicable disease. Where applicable, these requirements include donor screening and testing and may give rise to labeling conditions or other restrictions as a condition of approval.

Certain of our programs are based on hES cell lines, including OpRegen, OPC1 and ANP1, which were derived from embryos created for IVF purposes and donated for research prior to adoption of certain current requirements under 21 CFR Part 1271 governing donor eligibility. Because these lines were derived prior to the effective date of current donor eligibility requirements, they may qualify as exempt from certain contemporaneous donor screening and testing obligations that would apply to HCT/P donor material sourced today. Notwithstanding any such exemption, upon commercialization of a product derived from any such exempt cell line, we may be required to label the product to reflect its exempt donor eligibility status, and regulatory authorities may impose additional risk-based conditions, post-market requirements, or use limitations as part of the approval process. //

Our iPSC line was derived under donor screening and testing practices that were consistent with 21 CFR Part 1271 requirements applicable at the time of donation and derivation. However, scientific understanding of infectious disease risk and donor eligibility standards continues to evolve, and future changes in regulatory expectations, advances in testing science, or identification of new infectious agents or transmission pathways could lead regulatory authorities to reassess the sufficiency of historical donor screening or testing information for iPSC-derived products, potentially requiring additional characterization, testing, or disclosure.

Any of these outcomes could require us to modify product labeling, conduct additional preclinical or clinical studies, implement additional manufacturing controls, or discontinue development of one or more product candidates derived from an affected cell line. Because our allogeneic product candidates are generally derived from a single master cell line for the life of the product, any regulatory constraint that applies to a foundational cell line could affect the entire dependent program. These events could materially and adversely affect our business, financial condition, results of operations, and development prospects.

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

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

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

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

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

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

We face similar issues outside of the United States. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing

arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally tend to be significantly lower.

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

Certain of the clinical sites for the GAlette study are outside of the United States and we or our collaborators may in the future conduct certain of our clinical trials for one or more of our product candidates outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business.

OpRegen is currently being evaluated by our partners Roche and Genentech in the GAlette study, which is currently at clinical sites across the U.S. and Israel, and we or our collaborators may in the future conduct one or more of our clinical trials for our product candidates outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the United States population and United States medical practice; the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the relevant study was not conducted pursuant to an IND, the FDA will not accept the data as support for a marketing application unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. There can be no assurance the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept data from our clinical trials of our product candidates, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

A party conducting a clinical trial outside the United States also exposes such party to additional risks, including risks associated with: additional foreign regulatory requirements; foreign exchange fluctuations; compliance with foreign manufacturing, customs, shipment, and storage requirements; inconsistent standards for reporting and evaluating clinical data and adverse events; diminished protection of intellectual property in some countries; public health concerns or political instability, civil unrest, war, or similar events that may jeopardize our ability to commence, conduct, or complete a clinical trial and evaluate resulting data; challenges with enrolling enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs; and political and economic risks, including war, relevant to such foreign countries.

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

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. As an example, in August 2022, Congress passed the Inflation Reduction Act of 2022, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all

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

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

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

- created the branded prescription pharmaceutical manufacturers and importers annual fee;
- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price. However, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap for single source and innovator multiple source drugs, beginning January 1, 2024;
- created new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics that are inhaled, infused, instilled, implanted or injected;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded the entities eligible for discounts under the Public Health program;
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and
- created a licensure framework for follow on biologic products.

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties for not complying with the ACA's individual mandate to carry health insurance, and eliminating the implementation of certain ACA-mandated fees. In June 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the

"individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Moreover, prior to the United States Supreme Court ruling, in January 2021, President Biden issued an executive order that, among other things, instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, other litigation, and the healthcare reform measures of the Biden administration will impact the ACA.

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

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, in 2020 the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020, providing pathways for states to build and submit importation plans for drugs from Canada. Further, in November 2020, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed until 2032 by the Inflation Reduction Act of 2022. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which has been delayed until 2032 by the Inflation Reduction Act of 2022. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. The Most Favored Nation regulations mandate participation by identified Medicare Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. As a result of litigation challenging the Most Favored Nation model, in December 2021, CMS published a final rule that rescinds the Most Favored Nation model interim final rule. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to President Biden's executive order, in September 2021, the HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In January 2025, the new U.S. presidential

administration issued Executive Order 14148, which rescinded the prior U.S. presidential administration Executive Order 14087, which had built upon a July 2021 Executive Order by setting out the policy to have the HHS Secretary test healthcare payment and delivery models to lower drug costs. Considerable uncertainty exists regarding how the new U.S. presidential administration will reform the Inflation Reduction Act and other drug pricing policies.

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

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

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

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, pricing or marketing practices, compliance with wage and hour laws and other employment practices, method of delivery, payment for healthcare products and services, compliance with health information and data privacy and security laws and regulations, tracking and reporting payments and other transfers of value made to physicians and teaching hospitals, extensive anti-bribery and anti-corruption prohibitions, product serialization and labeling requirements and used product take-back requirements;
- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;
- as a result of the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language, which has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays or changes;
- requirements that provide for increased transparency of clinical trial results and quality data, such as the EMA's clinical transparency policy, which could impact our ability to protect trade secrets and competitively sensitive information contained in approval applications or could be misinterpreted leading to reputational damage, misperception or legal action which could harm our business;
- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products; and
- changes the new U.S. presidential administration may institute to federal regulatory agencies including the FDA, including reductions in funding levels or restructuring of such agencies.

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

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

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

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

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

We have orphan drug designation from the FDA for OPC1 for the treatment of acute SCIs and we may seek orphan drug designation for other product candidates. As discussed in more detail in Item 1. "Business—Government Regulation—FDA and Foreign Regulation of Therapeutic Products," above, generally, if a biologic with orphan drug designation from the FDA subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to seven years of marketing exclusivity in the United States. Other benefits of an orphan drug designation may include a waiver of the marketing application fee. However, the orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

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

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

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

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

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

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

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

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws, including the federal False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- HIPAA, which created new federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;
- HIPAA, as amended by HITECH and their implementing regulations, which imposes certain requirements on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose, access, or otherwise process individually identifiable protected health information, relating to the privacy, security, and transmission of individually identifiable health information;
- The Physician Payments Sunshine Act, which requires manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS, information related to payments and other

transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payors, including commercial insurers, state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures, or drug pricing, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

Risks Related to the Development and Clinical Testing of Our Product Candidates

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

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

- inability to generate satisfactory preclinical, toxicology, or other in vivo or in vitro data or diagnostics to support the initiation or continuation of clinical studies necessary for product approval;
- delays in identifying, developing or securing rights to use, and testing delivery systems or other methods for administration of our potential cell therapies;
- delays in securing clinical investigators and agreeing on acceptable terms with contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among CROs and clinical trial sites;
- delays in obtaining required institutional review board ("IRB") or ethics committee ("EC") approval at each clinical trial site;
- failure of IRB to follow FDA protocols or procedures;
- delays in or 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);
- enrolled patients dropping out of our clinical studies before completing all follow-up visits;
- 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 SAEs or 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, including safety or tolerability concerns that arise during the course of a clinical trial that could cause us or governmental authorities to impose a clinical hold or terminate a clinical trial;
- 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;
- clinical trial sites dropping out of a trial and delays caused by the addition of new investigators or clinical trial sites;
- inadequate supply or quality of clinical trial materials or other supplies necessary for the conduct of our clinical trials;
- changes to the manufacturing protocols, processes, materials or facilities of the product candidate or its delivery system or other tools required for the transplantation procedure that require additional regulatory review, clearance or approval;
- 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.

Some of the factors that may cause, or lead to, a delay in the commencement or completion of a clinical trial may also ultimately lead to the denial of regulatory approval of the applicable product candidate. 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. 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 of a product candidate could result in additional costs to us, impair our ability to generate revenue and harm our financial condition.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or, as applicable, comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or, as applicable, comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or, as applicable, a comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

If we or our collaborators experience delays or difficulties enrolling or retaining patients in clinical trials of our product candidates, our research and development efforts and business, financial condition, and results of operations could be materially adversely affected.

Successful and timely initiation and completion of clinical trials of our product candidates will require timely enrollment and retention of a sufficient number of patients. As discussed elsewhere in this Risk Factors section, clinical trials may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal, or the occurrence of adverse events. These types of developments could cause us or our collaborator to delay the trial or halt further development of the product candidate being studied. If patients drop out of a clinical trial or a trial is disrupted due to unforeseen circumstances, such as previously occurred as a result of the COVID-19 pandemic, the integrity of data from the trial may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

Patient enrollment and retention in clinical trials depend on many factors, including:

- the size and nature of the patient population;
- the severity of the disease or condition under investigation, including patients' prior lines of therapy and treatment;
- eligibility and exclusion criteria for the trial;
- the number and location of clinical trial sites;
- the proximity of patients to clinical sites;
- the design of the clinical protocol;
- the ability to obtain and maintain patient consents;
- competition with other sponsors or clinical trials for clinical trial sites or patients;
- clinicians' and patients' perceptions as to the risks and benefits of the product candidate being studied, in relation to the risks and benefits associated with other products or product candidates that may be perceived to be similar to the product candidate being studied or that are approved or in development for the indication the clinical trial is evaluating;
- the ability to recruit and availability of clinical trial investigators and sites with the appropriate competencies, experience, and resources;
- the risk that enrolled patients will drop out of the trial before administration of the product candidate or completing all follow-up visits;
- the availability of patients resulting from the impact of any pandemic, epidemic, or disease outbreak; and
- the availability of, and clinicians' and patients' satisfaction with, existing and new therapies approved for the indication the clinical trial is investigating.

Some of clinical trials of our product candidates may compete with other clinical trials that are in the same therapeutic areas as our product candidates. In addition, because the number of qualified clinical investigators and

clinical trial sites is limited, we may conduct some of our clinical trials at the same sites as those used by our competitors. Competition with other clinical trials may further reduce the number and types of patients available to participate in our trials, as some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. In addition, if there is an accepted standard of care or other approved options for the disease or condition for which our product candidate is being studied, enrolling patients in our clinical trial could prove more challenging. Moreover, our product candidates represent a novel treatment approach for the diseases or conditions for which they are being studied, and as a consequence, may encounter difficulty in gaining acceptance of clinicians and the applicable patient community. Failure to enroll and retain patients in clinical trials of our product candidates would extend development timelines or increase costs for our programs.

The circumstances described above and elsewhere in this Risk Factors section may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. If we are unable to timely recruit and enroll patients for our clinical trials, enroll a sufficient number of patients to complete our clinical trials as planned, or retain patients in our clinical trials, we may be required to change our trial design, recruit and enroll a different population of patients than we anticipated, or recruit and enroll patients in geographies that are more challenging. We may not be fully prepared to address such challenges, and even if we are able to address such challenges, the results of our clinical trials may be negatively impacted. Delays in the completion of any clinical trial we may conduct will increase our costs, slow down the development and approval process, and delay or potentially jeopardize our ability or that of a collaborator to commence product sales and generate revenue for the relevant product candidate.

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:

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

For example, positive data from the Phase 1/2a clinical trial of OpRegen 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 yet know how OpRegen will perform in that Phase 2a trial or future clinical trials.

Even if prior, current and planned clinical trials of our product candidates are successful, additional clinical trials, 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, review and/or verification procedures that could result in final clinical data that is materially different and unfavorable.

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

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

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

The manufacture and supply of our cell therapy product candidates involve novel processes that are generally more complex than those required for example for small molecule or antibody-based drugs and accordingly present significant challenges and are subject to multiple risks. These complex processes involve the expansion of pluripotent stem cells to produce a master cell bank from which a working cell bank can be obtained. Cells from a working cell bank will then undergo differentiation in order to produce the desired cell product candidate. Reprograming pluripotent cells or establishing a line of pluripotent cells from embryonic stem cells which is genetically stable and can proliferate without differentiating and remain well characterized, including being free of potentially deleterious genetic mutations, is challenging and requires a significant amount of time and resources. The process requires significant expertise and capital investment, including in the development and validation of advanced manufacturing techniques and specific quality assurance and quality control procedures. We have limited experience manufacturing our product candidates on a clinical scale and no experience manufacturing on a commercial scale. Roche also has limited experience manufacturing OpRegen and there can be no guarantee that Roche will be able to manufacture OpRegen for clinical use or commercial scale.

As a result of the complexities involved, the cost to manufacture human cell-based products is generally higher than for traditional therapies and the manufacturing process is less reliable and more difficult to reproduce. In addition, our cost of goods development is at an early stage. The actual cost to manufacture and supply our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates. Excessive manufacturing costs could make our product candidates too expensive to compete with alternative products or therapies, or might result in third-party payors declining to cover our products or setting coverage levels too low for us or a strategic collaborator to earn a profit from the commercialization of one or more of our products.

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

In addition, we will need to continue to invest in greater manufacturing capabilities 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 to whom we can transfer the production process and are 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. Though we have previously completed a cGMP production run for each of OpRegen and OPC1 from a customized two-tiered cGMP compliant cell banking system which we believe will be capable of large scale production, we have not produced sufficient amounts of our product candidates to support a

product launch. None of our manufacturing processes have been validated for commercial production of our product candidates. We may face multiple challenges as we continue to 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, batch 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 produce 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. See also the discussion in this Risk Factors section under "No assurances can be given that we will be able to continue to consistently manufacture clinical quantities of our product candidates in accordance with cGMP from a master and working cell bank system, or at a cost-effective or commercially viable scale, for one or more of our product candidates."

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

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

No assurances can be given that we will be able to continue to consistently manufacture clinical quantities of our product candidates in accordance with cGMP from a master and working cell bank system, or at a cost-effective or commercially viable scale, for one or more of our product candidates.

Consistent, scalable, and cost-effective manufacturing is a significant hurdle to overcome for cell therapy companies. from our AlloSCOPE platform, we previously completed a cGMP production run for each of OpRegen and OPC1 from a customized, two-tiered cGMP compliant cell banking system. However, at this time, no assurances can be given that we will be able to consistently continue to produce production lots in the future in compliance with cGMP or do so at a cost-effective or commercially viable scale, or that we will be able to produce production lots that are greater in scale than what we have previously produced. For example, one of our cell therapy research initiatives is focused on the issue of large-scale production of islet cells and we are in the early stages of that initiative. If we are unable to consistently manufacture clinical quantities of a product candidate in compliance with applicable laws and regulations, including cGMPs, or at a cost-effective or commercially viable scale, clinical development may be significantly delayed, commercial potential may be significantly diminished, and we or a collaborator may be unable to continue development of the applicable product candidate at all.

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

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

Currently, as described elsewhere in this Risk Factors section, we are entirely dependent on our subsidiary CCN and its manufacturing facility located in Israel for the manufacture and supply of our cell therapy product candidates, and events or conditions that disrupt operations at that facility could materially and adversely affect our business. As we grow our business, we plan to expand our manufacturing capabilities and may do so by establishing additional manufacturing facilities, including in California. Utilization of any new facility for cGMP manufacturing of our product candidates would 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 a new manufacturing facility, we will need to conduct significant development work to transfer our manufacturing processes to enable manufacturing of any product candidate in a new 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 are working 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. Additionally, the FDA or foreign regulators may deem clinical materials to ultimately not be comparable, in which case we, or our partner, may be required to file a new application which may require repeating non-clinical and earlier clinical work previously completed. Any inability to manufacture comparable material by us, a collaborator, or any third-party manufacturer we may engage, or any determination of non comparability by a regulatory agency, 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, the FDA or comparable foreign regulatory authority may not approve a marketing application until the deficiencies are corrected or we or a collaborator replace the manufacturer in our application with a manufacturer that is in compliance, which may not be feasible on a timely basis at a reasonable cost, or at all. If we or any future third-party manufacturer fails to comply with applicable regulatory requirements, we or a collaborator may ultimately be unable to manufacture the product candidate. Any such failure could be the basis for the FDA to issue a warning letter or an untitled letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of supplies of the product candidate, total or partial suspension of production, suspension of then-ongoing clinical trials, refusal to approve then-pending applications or supplemental applications, detention of product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties. The occurrence of any of these issues could result in product liability claims, delay or failure to commence or complete clinical development, obtain regulatory approval of or commercialize our product candidates.

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

Emerging, unknown, or previously unidentified infectious agents could affect one or more of our foundational cell lines or cell banks, require abandonment of a cell line, and materially delay or halt development of all product candidates dependent on that line.

Scientific understanding of infectious disease risk and pathogen identification continues to evolve, and new infectious agents, novel modes of transmission, or previously unrecognized risks associated with existing agents may be identified in the future. The implications of such advances for cell-based therapeutic products — including products derived from pluripotent cell lines — are difficult to predict and may create regulatory, manufacturing, and clinical challenges that cannot be fully addressed with existing testing and mitigation tools.

For certain hES cell lines used in our programs, including lines derived from IVF donations made prior to the adoption of current donor eligibility requirements, contemporaneous donor history information and biological samples from the original donors may be incomplete or unavailable. As a result, it may not be possible to perform

the retroactive donor testing that would otherwise be expected for newly sourced donor material. While risk assessment and characterization of the existing cell bank serve as the primary available mitigation for such exempt lines, risk assessment cannot fully substitute for contemporaneous donor testing in all circumstances, particularly with respect to pathogens — including prions, novel viruses, and other emerging agents — for which no validated, commercially available, or regulator-accepted test methods currently exist or may exist at the time of any future regulatory review.

For our iPSC line, which was derived under donor screening and testing practices consistent with then-current 21 CFR Part 1271 requirements, future identification of new infectious agents, new transmission vectors, or new regulatory standards could similarly implicate the line and call into question whether the historical screening was sufficient to identify and assess all relevant risks.

Our product candidates are susceptible to quality issues including those due to contamination, and discovery of problems including contamination could require us to withdraw product from clinical trials, discard product inventory, or interrupt supply, any of which would harm our business. If a regulatory authority were to determine that a cell line or cell bank used in our programs presents an unacceptable or unmitigable risk of transmitting an infectious agent — whether identified before or after the time of derivation — we or our collaborators could be required to suspend manufacturing activities, place clinical trials on clinical hold, modify or terminate clinical protocols, implement additional labeling, or discontinue development of one or more product candidates.

Because our product candidates are manufactured from master and working cell banks derived from a single initial cell line, any disruption or required abandonment of a foundational cell line or associated cell bank could have a severe and disproportionate impact on our manufacturing capabilities and development programs. Any required abandonment of a cell line would halt development of all product candidates dependent on that line, require generation of a replacement cell line from a new and potentially unproven donor source, and would require new regulatory submissions and likely additional clinical development. Such an outcome could require substantial additional time and capital, result in significant delays, or render certain programs non-viable, each of which could materially and adversely affect our business, financial condition, results of operations, and prospects.

Our cell lines, cell banks, and product candidates may be affected by contaminants associated with animal- or human-derived materials used historically during IVF, derivation, or early expansion, and there can be no assurance that all such contaminants can be identified, tested for, or ruled out.

Manufacturing cell therapy products is complex and subject to numerous risks, including challenges associated with ensuring the absence of contamination, maintaining process robustness, and complying with applicable cGMP and current Good Tissue Practice requirements. Certain pluripotent cell lines used in our programs, including certain hES lines and our iPSC line, were exposed to animal-derived and/or human-derived materials — such as fetal bovine serum, human serum, and human serum albumin — during the IVF process, initial derivation, or early expansion phases of cell line establishment. The standards applicable to such materials at the time of derivation may differ from requirements applicable today, and certain risks associated with animal- or human-derived biological materials may not have been fully characterized at the time of use.

Our product candidates are susceptible to quality issues that could arise as a result of defects in raw materials or contamination, and discovery of any such problems or contaminants could require us to withdraw product from clinical trials, discard product inventory, delay our development programs, face regulatory action, or suffer supply interruptions, any of which would harm our business.

If previously unknown contaminants, adventitious agents, transmissible spongiform encephalopathy-related materials, or other impurities were later discovered to be associated with materials used during the derivation or early handling of our cell lines, we could be required to conduct additional testing, implement additional manufacturing controls, develop new risk mitigation strategies, repeat preclinical or clinical studies, or generate new cell banks derived from alternative starting materials. Each of these steps could be costly, time-consuming, technically complex, and potentially infeasible depending on the nature of the contaminant and the availability of validated testing methods.

Moreover, even with extensive testing, there can be no assurance that all potential contaminants can be detected, characterized, or excluded. Certain biological contaminants — including prions and novel viral or sub-viral agents — may not be testable using currently available or regulator-accepted assay methods, and our ability to provide definitive assurances regarding the absence of such agents may be limited in ways that are outside our control.

If contamination or suspected contamination is identified in, or associated with, a cell line, cell bank, raw material, or manufactured product lot used in our programs, we or our collaborators could experience lot failures, be required to discard materials, suspend manufacturing operations, delay or halt clinical trials, or be unable to obtain or maintain regulatory approval for an affected product candidate. Any such event could materially and adversely affect our business, financial condition, results of operations, and development prospects.

Our pluripotent stem cell-derived product candidates may acquire genetic or epigenetic abnormalities, exhibit clonal selection or phenotypic drift, or contain residual undifferentiated cells, any of which could create safety risks (including tumorigenicity), reduce efficacy, complicate regulatory review, and require us to abandon or replace a foundational cell bank.

Our product candidates are derived from pluripotent cell sources, including hES cell lines and an iPSC line, and depend on multi-step processes such as cell expansion, banking, differentiation, purification, cryopreservation and thaw, each of which may contribute to genetic instability, epigenetic changes, or selection of cell subpopulations over time. Pluripotent cells and their differentiated progeny may acquire chromosomal abnormalities (including aneuploidy), copy number variants, structural variants, point mutations, or other alterations during derivation, reprogramming, expansion, or extended culture, including changes that confer a growth advantage and may therefore become enriched in a cell bank or manufacturing process. In addition, even in the absence of detectable genetic abnormalities, cell populations may undergo phenotypic drift (including altered differentiation propensity, maturity state, function, or secretory profile) that could affect product potency, durability, or safety.

Certain genetic or phenotypic changes could increase the risk that administered cells proliferate in an uncontrolled manner, form ectopic tissue, or otherwise contribute to tumor formation, and residual undifferentiated pluripotent cells in a final product may present a risk of teratoma or other tumorigenic outcomes. Although we employ qualification, in-process controls, and release testing, no testing strategy can provide absolute assurance that all potentially harmful genetic variants, rare subclonal populations, or tumorigenic cells will be detected, particularly where such variants are present below assay detection limits or arise after testing is performed. If a clinically relevant abnormality or tumorigenic potential were suspected or identified, we or our collaborators could be required to halt manufacturing, place clinical trials on hold, conduct additional preclinical studies (including tumorigenicity assessments), implement new analytical methods, modify dosing or administration, impose additional patient monitoring and long-term follow-up, narrow intended patient populations, implement risk management measures, or discontinue development of an affected product candidate.

Because our allogeneic programs generally rely on a limited number of master and working cell banks derived from a single foundational line, the discovery of a material genetic abnormality, phenotypic drift, or tumorigenicity signal in a foundational line or bank could require us to discard existing inventories and cell banks, generate and qualify replacement banks, and demonstrate comparability to prior material. Any such replacement or comparability effort may require additional regulatory submissions and could require new or repeated clinical studies. These events could materially and adversely affect our business, financial condition, results of operations, and development prospects.

The manufacturing, storage, and distribution of our cell therapy product candidates are vulnerable to cross-contamination, mix-ups, and sterility assurance failures, and any such event could lead to product loss, clinical holds, regulatory action, patient injury, reputational harm, and delays or inability to commercialize.

Cell therapy manufacturing requires stringent aseptic processing and control of raw materials, equipment, facilities, personnel practices, and logistics, and is susceptible to failures that may not be fully preventable. Our manufacturing activities and those of our collaborators and contract manufacturers may be affected by microbial contamination (including bacteria, fungi, and mycoplasma), endotoxin or bioburden excursions, or contamination introduced through raw materials, single-use assemblies, facility utilities, or environmental conditions. Mycoplasma

contamination, in particular, can be difficult to detect and may alter cell growth characteristics and product attributes without obvious signs, and sterility tests have inherent limitations, including the potential for false negatives and the inability to detect certain organisms or low-level contamination in all circumstances.

In addition, cell therapy operations present risks of cross-contamination or misidentification, including inadvertent introduction of other cell lines, unintended cell types, or residual process-associated cells, as well as chain-of-identity or chain-of-custody errors, labeling errors, mix-ups, or recordkeeping failures. Such events may not be discoverable until after product has been distributed or administered and could require patient notification, product retrieval or recall, clinical protocol amendments, additional monitoring, and could adversely affect the integrity of clinical data.

Further, our product candidates may be particularly sensitive to cryopreservation, storage, shipping, and handling conditions, including temperature excursions, container closure integrity failures, thawing errors, extended hold times, or other deviations that could reduce viability, alter product attributes, or increase the risk of contamination. Any contamination, suspected contamination, mix-up, or sterility assurance failure could lead to lot failures, destruction of product, interruption of clinical supply, increased cost of goods, regulatory inspections or enforcement actions, refusal to accept or approve regulatory submissions, imposition of additional CMC requirements, or inability to maintain regulatory approvals. Any of these outcomes could materially and adversely affect our business, financial condition, results of operations, and prospects.

Risks Related to Commercialization of our Product Candidates

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, prior to 2023, there were no FDA-approved therapies for the treatment of GA secondary to AMD, and in 2023, the FDA approved two such therapies, Apellis Pharmaceuticals, Inc.'s SYFOVRE® (pegcetacoplan injection) and Astellas Pharma'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. Since 2023, dry AMD with GA has become an increasingly established indication with an educated patient population, and we are aware of the proliferation of new therapies in development, including RPE cell therapies. We expect OpRegen, if approved, will face increasingly intense competition. During 2025, three privately held companies pursuing RPE cell therapies for dry AMD or GA with dry AMD reported positive early-stage clinical data. In addition, Astellas is pursuing development of an RPE cell therapy candidate for GA secondary to AMD, which is in Phase 1 clinical development.

Other products in development for patients with GA due to AMD include a subretinal photovoltaic implant intended to operate as an array of artificial photoreceptors and, paired with specialized glasses, restore functional vision. In addition, new therapies that demonstrate an ability to lower the incidence of new-onset GA could reduce the potential market for OpRegen if they are successful. For example, in 2024, the FDA authorized marketing of LumiThera, Inc.'s noninvasive Valeda® photobiomodulation device for the treatment of early and intermediate dry AMD and a subset of late dry AMD (non-central involving GA) to improve vision and it became available to patients in the U.S. LumiThera was acquired by Alcon in September 2025, and Alcon announced plans to expand Valeda office-based treatment in approved markets. Regulatory approval and/or the achievement of clinical or commercial success of one or more competing products or product candidates may reduce or eliminate the market for our product candidates. For additional information regarding our competition, see "Business—Competition" in Item 1 above. In addition, if one or more competing products fail to obtain regulatory approval or achieve clinical or commercial success and are perceived by regulators, healthcare providers, third-party payors or potential patients as comparable to our product candidates, our regulatory strategy could be impaired, our ability, or that of a collaborator, to obtain regulatory approval for our product candidates could be delayed or prevented, or the market for our product candidates may be reduced or eliminated.

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

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

We face the risk of incurring liabilities to clinical trial patients if they are injured as a result of their participation in clinical trials of our product candidates or products. We also face potential product liability for use or misuse of our products that obtain regulatory approval and are commercialized. In 2023, we settled a product liability lawsuit, which we determined was not material, relating to the use in a clinical trial of a product candidate that we are no longer developing and have no plans to pursue, and that is not related to the cell therapy candidates we currently are developing. See Note 13 (Commitments and Contingencies) to our consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 10, 2025 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 and seeking patent protection for our own technology and that of our subsidiaries, we have licensed patents and patent applications for certain stem cell technologies, human pluripotent stem cells, and hES cell lines, and other technologies from other companies and institutions. We own or license, directly or through our subsidiaries, patent families that include several hundred U.S. and international patents and patent applications. We cannot be certain that issued patents will be enforceable or provide adequate protection or that pending applications will result in issued patents. In addition to the loss of patent protection due to expiration, from time to time, we assess our patents and pending applications covering our products and product candidates as well as our manufacturing processes, and if we determine that any patents or patent applications no longer provide adequate or necessary protection, we abandon such patents and patent applications to avoid incurring unnecessary costs. Moreover, establishing and maintaining robust patent portfolios is expensive and we have limited resources. If we are unable to adequately fund our patent prosecution and maintenance, or if the costs of defending our patents against third-party challenges become prohibitive, our competitive position could be weakened.

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

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

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

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

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

product candidates, we may, at times, share trade secrets with them, which increases the possibility that our trade secrets will be misappropriated or disclosed.

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

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

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

Our success will depend in part on our ability to obtain and enforce patents and maintain trade secrets in the United States and in other countries. If we are unsuccessful at obtaining and enforcing patents or maintaining trade secrets, our competitors could use our unpatented technology or trade secrets and create products that compete with our products, without paying license fees or royalties to us. The preparation, filing, prosecution and maintenance of patent applications and patents is costly and time consuming. Our limited financial resources may not permit us to pursue patent protection for all of our technology and products in all key markets. Our strategy is to pursue patent protection for technologies that meet our corporate and business development priorities balanced against timing and costs. For example, we may choose to seek only composition of matter patent protection, or no patent protection, for technologies that do not necessarily align with these considerations, and instead rely on available trade secret protection. Similarly, because we periodically assess this balance, we may abandon filed patent applications. 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 and trade secret rights to protect our technology and products against infringers.

We may not have the financial resources to finance the litigation required to preserve our patent and trade secret rights. Litigation, interferences, oppositions, inter partes reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third

parties to be pertinent to the manufacture, use or sale of our products. This means that patents owned or licensed by us, or our trade secrets, may be lost if the outcome of a proceeding is unfavorable to us.

Additionally, in July 2025, the FDA announced its intent to increase transparency by publicly releasing CRLs issued to drug and biologic sponsors, and subsequently announced it would release in "real time" newly issued CRLs. CRLs, which are issued when an application for marketing approval of a new drug or biologic product cannot be accepted in its current form, outline the reasons for non-approval and may contain confidential or proprietary information relating to the applicant's product, including clinical trial, manufacturing, and technical information, including specific observations about study design and clinical endpoints. Although the FDA has stated that confidential information will be redacted, it remains unclear how such disclosures will be implemented. Any public release of a CRL issued to us or a collaborator could result in the unintentional disclosure of information that competitors may use to infer proprietary aspects of our or our licensor's technologies, which could compromise our confidential and proprietary information, including our trade secrets and know-how, or facilitate third-party efforts to design around or challenge the validity, enforceability, or scope of our patents, or accelerate the development of biosimilars. If we are required to modify or limit the information shared with the FDA to mitigate such risks, it could increase our costs, slow our regulatory interactions, or delay our product approval timelines. Accordingly, evolving laws, regulations, and policies in the U.S. and other countries may adversely affect our ability to maintain trade secrets and our and our licensors' ability to obtain new patents or to enforce existing patents, and may facilitate third-party challenges to our owned or licensed intellectual property.

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

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

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

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

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

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

We enter into agreements with our employees pursuant to which they agree that any inventions created in the scope of their employment are assigned to us or owned exclusively by us, without the employee retaining any rights.

A significant portion of our intellectual property has been developed by our employees and CCN's employees in the course of their employment. Under the Israeli Patent Law, 5727-1967 (the "Patent Law"), inventions conceived by an employee during the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee, a body constituted under the Patent Law, shall determine whether the employee is entitled to remuneration for his or her inventions. Previous decisions by the Israeli Compensation and Royalties Committee have created uncertainty in this area regarding whether the right to receive remuneration for service inventions can be voluntarily waived by an employee and whether such waiver is enforceable. In addition, the Committee determined that even if such right to receive compensation and royalties for service inventions may be waived, the waiver should be specific. Subsequent court cases have not provided significant clarity on these matters.

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

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

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

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

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.

As discussed elsewhere in this Risk Factors section, we may enter into various kinds of collaborative research and development and product marketing agreements to develop and commercialize our product candidates. 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. For example, ReSonance is currently in preclinical development under a collaboration with WDI, and our RND1 program is currently being developed through a gene editing collaboration with Factor Biosciences. 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.

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. See also the discussion in this Risk Factors section under "We are dependent on our third-party collaboration with Roche to develop and commercialize OpRegen. If Roche is not successful and/or terminates the collaboration, we will lose a significant source of potential revenue, further development of OpRegen may be significantly delayed or terminated and its commercial potential could be significantly diminished. Additionally, if OpRegen is not successful, prospects for our other product candidates and our business could be significantly harmed," and "We may fail to enter into new strategic relationships or may not realize the benefits of any strategic relationships that we have entered into, either of which could materially adversely affect our business, financial condition, commercialization prospects, and results of operations."

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 preclinical or clinical protocols, regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, our costs could increase, 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 meet certain quality standards, 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 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 cell therapy 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 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 or unacceptable product quality. 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 reagents, 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 would 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 reagents, materials and equipment that are necessary to manufacture our product candidates, including certain consumables such as sterile bags, tissue flasks, and pipettes, which has affected and may continue to affect our ability 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. 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, and if approved, ultimately commercialization, 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 and/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/or 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 or will require complex invasive surgical procedures. We or our collaborators 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 are evaluating the safety and utility of the device to deliver OPC1 in the DOSED clinical study. To the extent we collaborate with third parties for specialized delivery systems or devices for administration of our product candidates, we may become dependent on those third parties and their contract manufacturers and suppliers not only for rights to use those systems or devices, but also for the manufacture and supply of those systems or devices in sufficient quantities and at acceptable quality levels and costs for our clinical trials, and ultimately to potentially market and sell them with our product candidates, if approved. Our dependence on such third parties is subject to a multitude of risks, including these risks:

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

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

Risks Related to Ownership of 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 shares may be influenced by a variety of factors, some of which are beyond our control, including:

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

- significant lawsuits, including intellectual property, product liability or shareholder litigation;
- publication of research reports about us or our industry, or cell therapies in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- actual or potential suspension of trading or delisting of our common shares by stock exchanges.
- inclusion or exclusion of our common shares in or from stock indices such as the Russell 3000® Index;
- significant business disruptions caused by natural or man-made disasters, prolonged public health emergencies, wars and other armed conflicts, and regional instability, particularly significant disruptions to our manufacturing operations in Israel;
- market conditions in the biotechnology sector and general political and economic conditions; and
- other factors described in this Risk Factors section.

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

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

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

Our largest shareholder, who is affiliated with a member of our board of directors, owns a significant percentage of our common shares and will be able to exert substantial influence over the election of directors and matters subject to shareholder approval, including potential change of control transactions.

Our largest shareholder, Broadwood Partners, L.P. ("Broadwood Partners") and its affiliates, including Neal Bradsher, a member of our board of directors, owned approximately 20.4% and 19.9% of our outstanding common shares as of each of December 31, 2025 and March 5, 2026, respectively. As a result, Broadwood Partners and its affiliates, acting on their own, will be able to exert substantial influence on matters requiring shareholder action, including the election of directors, amendments to our organizational documents, the approval of capital raising transactions, and the approval of mergers, acquisitions, sales of assets, or other major corporate 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. In addition, Broadwood Partners holds warrants to purchase up to approximately 7.9 million of our common shares at an exercise price of $0.91 per share. Such warrants are exercisable at any time, and although we have warrants outstanding to purchase an aggregate of up to 33.2 million of our common shares at an exercise price of $0.91 per share (including those held by Broadwood Partners), Broadwood Partners could exercise all or a significant portion of the warrants it holds before all or a significant portion of our other outstanding warrants are exercised, thereby increasing its percentage of ownership of our outstanding common shares.

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

We and our subsidiaries may issue additional common shares or other securities convertible into or exercisable for common shares to raise additional capital or to hire or retain employees or consultants, or in connection with future acquisitions of companies or licenses to technology or rights, in settlement of lawsuits, or for

other business purposes. The issuance of additional securities may be dilutive to our shareholders and may create downward pressure on the trading price of our common shares. For example, in November 2024 we announced a registered direct offering of 39,473,688 of our common shares and accompanying warrants to purchase an aggregate of up to 39,473,688 of our common shares, of which 33,202,635 remain outstanding. That offering closed in two tranches: one in November 2024 and another in January 2025.

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

As of December 31, 2025, we had 31,152,641 common shares reserved for issuance upon the exercise of outstanding options and 315,105 common shares reserved for issuance upon the vesting and settlement of restricted stock units awarded under our equity incentive plans. The exercise of outstanding options and vesting and settlement of outstanding restricted stock units would be dilutive to our existing shareholders.

We have used "at the market" ("ATM") offerings of our common shares to raise substantial capital. For information regarding such sales of our common shares see "At the Market ('ATM') Offering" in Note 10 (Shareholders' Equity) to our consolidated financial statements included in this report. We may continue to use ATM offerings to fund our operations. As of March 5, 2026, $17.4 million was available for sale under our ATM offering program. Additional sales of our common shares in our ATM offering may result in substantial dilution to our existing shareholders and such sales, or the anticipation of such sales, may cause the market price of our common shares to decline.

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

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

As discussed elsewhere in this report, we issued warrants to purchase an aggregate of up to 41,447,372 of our common shares in connection with our November 2024 registered direct offering. Of those warrants, as of the filing date of this report, warrants to purchase up to 33,202,635 of our common shares with an exercise price of $0.91 per share were outstanding and warrants to purchase up to 1,973,684 of our common shares with an exercise price of $0.95 per share were outstanding, in each case, the exercise price is subject to customary adjustments. The warrants became exercisable on May 21, 2025 and will expire on the earlier of (a) May 21, 2028 and (b) the 90th day following the date of the public disclosure of the intent to advance OpRegen® (also known as RG6501) into a multi-center phase 2 or 3 clinical trial which includes a control or comparator arm, with such 90-day period subject to extension if certain conditions, including equity conditions, some of which are outside of our control, are not satisfied. The warrants also provide for cashless exercise in certain circumstances, including if the shares issuable upon exercise thereof are not covered by an effective registration statement.

The issuance of common shares upon exercise of these warrants will result in dilution to the ownership interests of other shareholders. Although warrants to purchase up to the remaining 27,281,582 of our common shares have a beneficial ownership limitation provision providing that the holder may not exercise any portion of its warrant if the holder, together with its affiliates, would beneficially own in excess of 4.99% (or 9.99% if the holder so elected prior to the issuance of the warrant) of the number of our common shares outstanding immediately after giving effect to such exercise, this provision does not prevent such holder from exercising a portion of their

warrants, selling those shares, and then exercising additional portions of their warrants, while still staying below the beneficial ownership cap percentage. By doing so, the holder could sell more of our common shares than the beneficial ownership cap percentage. In addition, upon 61 days' prior notice to us, the warrant holder may increase or decrease the beneficial ownership cap percentage, provided that the beneficial ownership limitation percentage may not exceed 9.99%. Furthermore, the operation of the beneficial ownership limitation provision may not allow a warrant to be exercised in full at a time when it would otherwise be required to be exercised in full.

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

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

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

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

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

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

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

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

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

General Risk Factors

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

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

Our employees may use generative artificial intelligence technologies to perform their work, and the disclosure and use of personal data in generative artificial intelligence technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative artificial intelligence. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits.

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

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

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

Cyberattacks, malicious internet-based activity, and online and offline fraud are increasing in frequency, persistence, sophistication and intensity. These threats come from a variety of sources, including traditional computer "hackers," threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors engage and are expected to continue to engage in cyberattacks, including, without limitation, nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyberattacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. In particular, the Israeli regional conflict has and may continue to 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), attacks enhanced or facilitated by artificial intelligence technologies, 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 U.S. 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.

Additionally, artificial intelligence-based platforms are increasingly being used in the pharmaceutical and biotechnology industries and we are expanding the use of artificial intelligence-based platforms in our operations for data analysis, summarization and automation, which subjects us to a variety of risks, including potential cybersecurity vulnerabilities, breaches of data privacy and the potential for inadvertent or unauthorized disclosure of our confidential information and intellectual property. Our use, or the use by our suppliers and service providers

with access to our proprietary and confidential information, including trade secrets, may lead to the release of our proprietary and confidential information, which may negatively impact our company, including our ability to realize the benefit of our intellectual property.

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.

The use of social media platforms present risks and challenges.

Social media is increasingly being used to communicate information about us, our programs and the diseases or conditions our product candidates are being developed to treat. Social media practices in the pharmaceutical and biotechnology industries are evolving, and applicable regulations and guidance are not always clear. This creates uncertainty and risk of noncompliance with laws and regulations applicable to our business, such as those governing marketing, communications, and clinical trial disclosures, which could result in regulatory actions, litigation, or heightened scrutiny by the FDA, SEC, and other regulators. For example, patients, family members of patients or persons otherwise associated with patients, may use social media platforms or similar mediums to comment on their experiences in an ongoing clinical trial or to report an alleged adverse event, which could result in reporting obligations or other consequences for us, negatively impact trial enrollment, and/or materially impact our stock price. In addition, misinformation disseminated by bad actors impersonating us or our employees or impersonating patients or close relatives of patients in clinical studies of our product candidates could have similar effects. Although the impact of these incidents has not been material to date, we have been the target of incidents of this nature and expect additional incidents may occur in the future. Further, the accidental or intentional disclosure of non-public information by our workforce or others through social media platforms could lead to information loss. In addition, there is a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us or our product candidates on any social media platform or a risk that a post by any of our employees or agents may be construed as inappropriate promotion. The nature of social media prevents us from having real-time control over postings about us and our product candidates on social media. We may not be able to reverse damage to our reputation from negative publicity or adverse information posted on social media platforms or similar mediums. If any of these events were to occur or we otherwise fail to comply with application regulations, we could incur liability, face restrictive regulatory actions or incur other harm to our business.

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

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

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

subject to investigations by the NYSE American, the SEC, and other regulatory authorities, which could require additional financial and management resources.

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

Our results of operations are affected by prevailing economic and political conditions and other factors beyond our control, including tariffs and trade barriers, the recent shutdown of the U.S. federal government and the resulting effects on its regulatory agencies, geopolitical tensions, and military conflicts. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, inflation and interest rates, debt and equity capital markets, liquidity of the global financial markets, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our manufacturers and suppliers, and our collaborators operate. A weak or declining global economy due to geopolitical tensions or tariffs and trade barriers could also strain our suppliers and manufacturers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Regional instability in and around Israel and Ukraine, and the uncertain nature, magnitude, and duration of those conflicts and the potential effect of sanctions and other measures being imposed in response thereto have contributed to increased levels of economic and political uncertainty, which could have an adverse impact on macroeconomic factors that affect the financial markets, the global economy and our business and operations. See also the risk titled, "All of our manufacturing operations currently are conducted at our facility in Jerusalem, Israel. Accordingly, political and economic conditions in Israel and war, cyberattacks, terrorist attacks or other armed conflicts involving Israel and the broader region could directly affect our business. Any event or condition that significantly disrupts our ordinary course of operations at our Jerusalem facility could harm our business and materially and adversely affect our financial condition and operating results." above.

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 materially and adversely affected in the future by the effects of a public health crisis.

Disease outbreaks, epidemics and pandemics, particularly in regions where our product candidates are manufactured or where clinical trial sites or other business operations are concentrated, could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of third parties upon whom we rely, including strategic collaborators, clinical trial sites, CROs, suppliers and other vendors. A public health crisis may have negative impacts on our ability, or that of a strategic collaborator, to initiate new clinical trial sites, enroll new patients and to maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delay in our ability, or that of a strategic collaborator, to obtain regulatory approvals of our product candidates, if at all. For example, the COVID-19 pandemic and actions taken to reduce its spread disrupted our normal course of business operations and delayed patient enrollment in our OpRegen

Phase 1/2a clinical trial. Additionally, some enrolled patients in that trial decided not to participate in follow-up visits on schedule or at all.

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

- delays or difficulties in clinical trial site initiation, including difficulties in recruiting clinical site investigators and staff,
- delays or difficulties in enrolling patients or conducting follow-up visits with patients in clinical trials of our product candidates, particularly patients who may be at higher risk of complications from the infection or other health condition;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting the infection or other health conditions or being forced to quarantine;
- diversion of healthcare resources away from the conduct of clinical trials, including at hospitals or other facilities serving as our clinical trial sites;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel;
- limitations on employee or other resources that would otherwise be focused on the conduct of clinical trials of our product candidates and preclinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, school closures or mass transit disruptions;
- manufacturing delays and difficulties for us and our suppliers of raw materials, consumables or equipment caused by business closures, operational restrictions or labor shortages;
- delays in the shipment or receipt of our products;
- 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 negatively impacted by environmental, social and corporate governance (“ESG”) matters or our reporting of such matters.

Certain investors, employees, collaborators, and other stakeholders are focused on ESG matters. Moreover, certain governmental authorities have proposed or adopted, and may continue to propose or adopt, certain mandated ESG reporting requirements, which, to the extent adopted, could significantly increase our compliance and reporting

costs. At the same time, anti-ESG sentiment has gained momentum across the United States, with several states having enacted or proposed “anti-ESG” policies or legislation. We may be perceived to be not acting responsibly in connection with these matters or, on the other hand, we may be criticized or perceived as not prioritizing returns to our shareholders by those who criticize a company’s focus on ESG matters, either of which could negatively impact us and adversely affect the price of our common shares.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Risk Management and Strategy

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

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

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

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

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

Governance

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

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

ITEM 2. PROPERTIES

General

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

Lineage Facilities

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

CCN Facilities

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

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

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

Holders

As of March 5, 2026, there were approximately 337 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, 2025, there were no unregistered sales of equity securities by us during the year ended December 31, 2025.

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, 2025, 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, 2025 as compared to the year ended December 31, 2024. 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 cell replacement therapies to treat serious medical conditions. Certain diseases and medical events can arise from the loss of critical cellular activity and lead to devastating or difficult-to-treat conditions or impairments. Our work is grounded in the emerging evidence that replacing or supporting those cells that have become dysfunctional or "lost" (destroyed or dead) can restore or replenish normal function and improve treatment and recovery paradigms. We call this approach "Replace and Restore". We believe cellular therapies aimed at entirely replacing dysfunctional or destroyed cells may have more durable, broader, or suitable applicability than traditional pharmaceutical products, which often seek to affect just a single molecular target or group of biological pathways. Transplantation of replacement cells represents an emerging branch of medicine, and we believe we are uniquely positioned to capitalize on its opportunities by demonstrating the value of administering mature, differentiated cells to patients. We are developing a portfolio of assets based on this mechanism and our most clinically-advanced program to date is OpRegen (RG6501), an allogeneic retinal pigmented epithelial (RPE) cell replacement therapy currently in Phase 2a development under a worldwide collaboration with F. Hoffman-La Roche Ltd. and Genentech, Inc., a member of the Roche Group (collectively or individually, "Roche" or "Genentech"), for the treatment of geographic atrophy (GA) secondary to dry-AMD.

Our programs are based on our proprietary, in-house, cell-based manufacturing platform, which we call AlloSCOPE™ (Allogeneic, Scalable, Consistent, Off-the-shelf, Pluripotent Cell Engineering), and supported by our associated development, formulation, manufacturing, and delivery capabilities. To date, we have successfully completed a current cGMP production run from our two-tiered cell banking system for two of our product candidates, one of which was used in a clinical trial in 2025.

Our business strategy aims to efficiently leverage our AlloSCOPE platform and our development and manufacturing expertise to create a pipeline of related but discrete cell-based assets, some of which we may advance internally toward commercialization and some of which we may seek to partner during early or late development, if we believe doing so will enhance their value to us and probability of success and value to Lineage and our shareholders.

Our lead program, OpRegen, an allogeneic RPE cell replacement therapy, is currently in Phase 2a development under a worldwide collaboration with Roche, for the treatment of geographic atrophy (GA) secondary to dry-AMD. Our second clinical-stage program, OPC1, is an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury. One of our preclinical programs, ReSonance (ANP1), is an allogeneic auditory neuron progenitor cell transplant therapy currently in preclinical development under collaboration with William Demant Invest 2 Aps (WDI) for the treatment of auditory neuropathy.

In addition, we have a pipeline of allogeneic cell therapy research initiatives, and are evaluating a novel hypoimmune induced pluripotent stem cell line under a gene editing partnership with Factor Biosciences Limited.

In addition to the collaboration agreements mentioned above with Roche and WDI, we have received grants from governmental agencies that have supported the development of OpRegen and OPC1.

For additional information regarding our clinical programs, business strategy, AlloSCOPE platform, pipeline of preclinical programs and research initiatives, our collaborations and the grants we have received from governmental entities, see "Item 1. Business," above.

Israeli Regional Conflict

All of our manufacturing processes, including cell banking and product manufacturing for our cell therapy product candidates, are conducted by our subsidiary, CCN, at its facility in Jerusalem, Israel, and more than two-thirds of our workforce are CCN employees based in that facility. In addition, certain of the clinical trial sites for the OpRegen GAlette study are in Israel.

The recent escalation of conflict and hostilities in the Middle East—including the strikes by Israel and the United States on Iran that began on February 28, 2026 and the retaliatory attacks thereto— has increased the risk of broader regional military escalation, cyberattacks, disruptions to transportation and logistics infrastructure, interruption of utility and communications services, and other events that could directly disrupt our operations in Jerusalem and the clinical trial sites for the OpRegen GAlette study in Israel. As of the date of the filing of this report, our operations in Jerusalem have not been materially or adversely disrupted, and we are not aware of any material disruption to the clinical trial sites for the OpRegen GAlette study in Israel. The situation continues to rapidly evolve, and it is currently not possible to predict the scope, duration or severity of present or future regional instability or its effects on our operations in Jerusalem or on the clinical trial sites for the OpRegen GAlette study in Israel. See the risk factor in Item 1A. Risk Factors in Part I of this report titled, "All of our manufacturing operations currently are conducted at our facility in Jerusalem, Israel. Accordingly, political and economic conditions in Israel and war, cyberattacks, terrorist attacks or other armed conflicts involving Israel and the broader region could directly affect our business. Any event or condition that significantly disrupts our ordinary course of operations at our Jerusalem facility could harm our business and materially and adversely affect our financial condition and operating results."

As a result of safety concerns and in response to government-imposed restrictions on movement and travel and other precautions taken to address the Israeli regional conflict that began in October 2023, our operations at our CCN facility in Jerusalem were temporarily impacted in the past. In light of the recent escalation of hostilities and conflict in the Middle East, we expect that similar government-imposed restrictions on movement and travel and other precautions will be implemented, which could materially and adversely affect the operations at our Jerusalem facility. Further, a number of our CCN employees in Israel are members of the military reserves and subject to immediate call-up in response to regional instability. Male Israeli citizens are obligated to perform several days, and in some cases more, of annual military reserve duty each year until they reach the age of 40 (or older, for reservists who are military officers or who have certain occupations) and, in the event of a military conflict, may be called to active duty. Several employees in Israel, including CCN's chief executive officer, were activated for military duty in the past, and they and other employees may be activated for military duty in the future, particularly in light of the recent escalation of hostilities and conflict in the Middle East, which could disrupt our operations. In addition, the general impact on employees operating in a region of conflict could adversely impact our operations. Although we have business continuity plans in place to address medium- or long-term disruptions that could result from regional instability, those plans are limited and do not account for every possible scenario, and in addition, any long-term closure of our CCN facility, or if that facility were damaged, or if hostilities otherwise disrupt the ongoing operations at that 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.

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.

Macroeconomic, Political, and Regulatory Environment Considerations

Our business, financial condition, operating results, stock price, and our ability to raise additional capital may be adversely affected by evolving macroeconomic, political, and regulatory developments and conditions, such as inflation, trade disruptions and restrictive measures, including tariffs, high interest rates, slowed economic growth or recession, uncertainty with respect to the federal budget and debt ceiling, potential or prolonged U.S. government shutdowns, volatility in financial markets, liquidity concerns at financial institutions, supply chain disruptions, changes in the regulatory landscape in the U.S., including due to significant reductions in funding and staffing of federal agencies and changes in leadership, and geopolitical factors. Further, third parties with whom we have business relationships, including clinical investigative sites, financial institutions, and our collaborators, may be adversely affected by the foregoing risks, which could directly impact our ability to achieve our operating goals within planned timelines and budgets.

In addition, there may be significant future effects on the pharmaceutical and biopharmaceutical industries as a result of federal policy and regulatory changes under the current U.S. presidential administration, including in areas relating to regulatory framework and oversight, research and development funding, drug pricing reform, global trade policy and tariffs, and others. Recent initiatives have resulted in significant reductions in staffing levels at the FDA and other governmental agencies. The foregoing could impact agencies' ability to retain remaining key personnel and hire additional personnel, which may disrupt their ability to perform routine activities or function in the normal course. For example, with respect to the FDA, this may result in delays or limitations on our ability to obtain guidance from agency staff and slow review times for applications we submit with respect to clinical studies, any of which could negatively impact the cost and timelines for developing and obtaining regulatory approval of our product candidates. Moreover, the current U.S. presidential administration has taken and may take additional future actions to freeze or reduce federal funding for medical research, which could decrease the ability of facilities that rely on such funding to conduct clinical trials or increase the costs to us of conducting clinical trials at those facilities. Given the high level of uncertainty regarding federal policy, enforcement and regulatory changes, and that circumstances are rapidly evolving, we cannot reasonably predict the potential impact on our business at this time.

Critical Accounting Policies and Estimates

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

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

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

Revenue Recognition Under Collaborative Agreements

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

arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants.

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

Impairment of Intangible Assets

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

Goodwill is calculated as the difference between the acquisition date fair value of the consideration transferred and the values assigned to the assets acquired and liabilities assumed in the acquisition transaction. Goodwill is tested for impairment in accordance with Accounting Standards Update ("ASU") 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. In-process research and development ("IPR&D") assets are indefinite-lived intangible assets until the completion or abandonment of the associated research and development ("R&D") efforts. Once the R&D efforts are completed or abandoned, the IPR&D will either be amortized over the asset's estimated life as a finite-lived intangible asset or be impaired, respectively, in accordance with ASC Topic 350, *Intangibles – Goodwill and Other* ("ASC 350"). In accordance with ASC 350, goodwill and acquired IPR&D are determined to have indefinite lives and, therefore, are not amortized. Instead, they are tested for impairment at least annually and between annual tests if we become aware of an event or a change in circumstances that would indicate the asset may be impaired. For further information, see Note 6 (Goodwill and Intangible Assets, Net) and Note 13 (Commitments and Contingencies) in the accompanying notes to the consolidated financial statements included in this report.

Income Taxes

We account 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. We file a U.S. federal income tax return as well as California combined and foreign income tax returns. Our 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 our assumptions, and consequently the estimates, change in the future with respect to our own deferred tax assets and liabilities, the valuation allowance may be

increased or decreased, which may have a material impact on our 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, 2025 and 2024. 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, 2025 and 2024. For further information, see Note 12 (Income Taxes) in the accompanying notes to the consolidated financial statements included in this report.

Warrants

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

Results of Operations

Comparison of Years Ended December 31, 2025 and 2024

Revenues

The following table shows our revenues for the years ended December 31, 2025 and 2024 (amounts in thousands except percentages).

	Year Ended December 31,		Dollar Increase	Percent Increase
	2025	2024	(Decrease)	(Decrease)
Collaboration revenues	$ 13,609	$ 8,149	$ 5,460	67%
Royalties, license and other revenues	947	1,350	(403)	(30)%
Total revenues	$ 14,556	$ 9,499	$ 5,057	53%

For the twelve months ended December 31, 2025, the $5.1 million increase in total revenues as compared to the prior year was primarily attributable to the $5.5 million increase in collaboration revenues, partially offset by a decrease of approximately $0.4 million in royalty revenue. The $5.5 million increase in collaboration revenue was driven by: (i) the achievement of the first milestone under the Roche Agreement in the amount of $5.0 million whereby $4.6 million was recognized as revenue in 2025; (ii) $2.5 million in revenue from our research collaboration agreement with WDI signed in 2025; (iii) an approximate $0.7 million increase in revenue related to the remaining deferred revenue recognized upon the termination of the license agreement with Immunomic Therapeutics, Inc. in 2025, partially offset by (iv) approximately $2.4 million in lower revenue recognized from deferred revenue under the Roche Agreement. See Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information.

Collaboration revenues may fluctuate from period to period based on changes in estimated costs to support the performance obligations. Under the collaboration agreements with Roche and WDI, delivery is determined to be over time and revenue is recognized utilizing an input method of costs incurred over total estimated costs to complete the performance obligation. See Note 3 (Revenue) to our consolidated financial statements included in this report for additional information.

Operating Expenses

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

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

Research and development expenses. These expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct expenses and indirect research-related overhead expenses including compensation and related benefits, stock-based compensation, consulting fees, research and laboratory fees, rent of research facilities, amortization of intangible assets, and license fees paid to third parties to acquire patents or licenses to use patents and other technology. Research and development costs with no future benefit or alternative use are expensed as incurred. Research and development expenses incurred and reimbursed by grants from third parties approximate the grant income recognized in our consolidated statements of operations. Royalties and sublicensing fees are recorded as research and development expenses, unless they are associated with product royalties, which we classify as cost of royalties 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, 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, 2025 and 2024 (amounts in thousands, except percentages).

	Year Ended December 31,		Dollar Increase (Decrease)	Percent Increase (Decrease)
	2025	2024		
Cost of royalties	$ 146	$ 334	$ (188)	(56)%
Research and development	17,729	12,472	5,257	42%
General and administrative	18,460	18,171	289	2%
Loss on impairment of intangible asset	14,840	—	14,840	100%
Total operating expenses	$ 51,175	$ 30,977	$ 20,198	65%

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	
	2025	2024	2025	2024
OpRegen®	$ 7,653	$ 6,081	43%	49%
OPC1	3,681	3,491	21%	28%
ANP1	2,883	2,200	16%	18%
PNC1	-	156	0%	1%
RND1	2,425	394	14%	3%
Other programs and non-program expenses	1,087	150	6%	1%
Total research and development expenses	$ 17,729	$ 12,472	100%	100%

Research and development expenses. For the twelve months ended December 31, 2025, the $5.3 million year-over-year increase in total research and development expenses is mainly attributable to: (i) a $1.6 million increase

for our OpRegen program; (ii) a $0.7 million increase for our ANP1 program; (iii) a $0.2 million increase for our OPC1 program; and (iv) a $2.8 million increase for our preclinical and other undisclosed programs.

General and administrative expenses. For the twelve months ended December 31, 2025, the $0.3 million year-over-year increase in general and administrative expenses was primarily attributable to: (i) a $0.2 million increase in personnel costs and (ii) a $0.1 million overall increase for services provided by third parties.

Loss on impairment of intangible asset. In 2025, we abandoned the VAC platform and its related research and development efforts, and concluded the IPR&D asset had no alternative future use. Consequently, we derecognized the intangible asset and recorded a non-cash pre-tax impairment charge of $14.8 million within total operating expenses of the consolidated statement of operations. See Note 6 (Goodwill and Intangible Assets, net) and Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information.

Other Income and Expenses, Net

The following table shows the amount of other income (expenses), net, during the year ended December 31, 2025 and 2024 (in thousands):

Other income (expenses)	Year Ended December 31, 2025	Year Ended December 31, 2024	Dollar Increase (Decrease)	Percent Increase (Decrease)
Interest income, net	$ 1,691	$ 1,715	$ (24)	(1)%
Loss on marketable equity securities, net	(8)	(8)	—	0%
Change in fair value of warrant liability	(35,727)	2,128	(37,855)	(1779)%
Foreign currency transaction gain (loss), net	2,148	(269)	2,417	899%
Other income (expenses), net	(132)	(670)	538	80%
Total other income (expenses)	$ (32,028)	$ 2,896	$ (34,924)	(1206)%

Interest income, net. For the twelve months ended December 31, 2025 as compared to the prior year, the change in interest income, net, was de minimis.

Loss on marketable equity securities, net. We expect our net gain or loss on marketable equitable securities to fluctuate each reporting period based on the changes in the market price of marketable equitable securities held by us which could impact our net income or loss reported in our consolidated statements of operations for a particular reporting period. These marketable equitable securities are carried at fair market value on our consolidated balance sheet. See Note 4 (Marketable Securities) to our consolidated financial statements included in this report for additional information regarding our marketable equity securities. For the twelve months ended December 31, 2025 as compared to the prior year, the change in the values of our marketable equity securities was de minimis.

Change in fair value of warrant liability. The liability-classified warrants issued in November 2024 and January 2025 in connection with the November 2024 registered direct offering ("November 2024 RDO") are valued at issuance, at each reporting period end date while the warrants are outstanding, and at the time of each warrant exercise, using a Black-Scholes option pricing model that maximizes the use of observable inputs and minimizes the use of unobservable inputs to the extent possible. A significant increase or decrease in these inputs could result in significantly higher or lower fair value measurements. The changes in fair value of the liability-classified warrants are non-cash adjustments recorded in the consolidated statements of operations and we expect this fair value to fluctuate each reporting period. For the twelve months ended December 31, 2025 as compared to the prior year, the change in the fair value of the warrants was primarily driven by fluctuations in the Company's common share price during the period.

Foreign currency transaction gain(loss), net. Foreign currency transaction gain (loss), net, for each of the years ended December 31, 2025 and 2024 consisted of net foreign currency transaction gains and losses primarily recognized by our subsidiaries CCN and ES Cell International Pte. Ltd. ("ESI"). The functional currency of CCN and ESI is the Israeli New Shekel ("ILS") and the Singapore Dollar ("SGD"), respectively. The majority of the net foreign currency transaction gains (losses) were generated by CCN's intercompany notes payable and notes

receivable with Lineage, which is U.S. dollar-denominated. The year-over-year net increase in foreign currency transaction gain was the result of the combined impact of: (i) changes in intercompany balances in 2025 as compared to 2024, and (ii) volatility of the ILS and SGD as compared to the U.S. dollar during 2025 and 2024.

Other income (expenses), net. For the twelve months ended December 31, 2025 as compared to the prior year, the change in other expenses was primarily related to the transaction costs for warrants issued in connection with the first closing of the November 2024 RDO and its second closing in January 2025. Transaction costs in the first closing were $0.7 million, while transaction costs in the second closing were $0.2 million and driven by lower quantity of warrants issued.

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. Since inception, we've had a full valuation allowance due to the uncertainty of realizing future tax benefits from our deferred tax assets. During the year ended December 31, 2025, based on sustained profitability and other positive evidence related to the Israel subsidiary, the Company released the valuation allowance associated with the Israel subsidiary's deferred tax assets. The Company recorded a deferred tax benefit of $5.3 million in 2025,which was primarily related to the release of the valuation allowance on the Israel subsidiary's deferred tax assets. The Company continues to maintain a valuation allowance against the U.S. and Singapore deferred tax assets.

Liquidity and Capital Resources

Overview

As of December 31, 2025, we had $55.8 million in cash, cash equivalents and marketable securities and our accumulated deficit was $467.0 million. For the year ended December 31, 2025, we incurred a loss from operations of $36.6 million and had negative cash flow from operations of $18.9 million. Since inception, we have incurred significant operating losses and we expect to continue to incur significant operating losses for the foreseeable future.

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.

Cash Flows

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024
Cash provided by (used in):		
Operating activities	$ (18,919)	$ (23,092)
Investing activities	(13,457)	(2,308)
Financing activities	26,950	35,857
Effect of exchange rate changes on cash, cash equivalents and restricted cash	396	(95)
Net (decrease) increase in cash, cash equivalents, and restricted cash	$ (5,030)	$ 10,362

Cash Used In Operating Activities

Net cash used in operating activities in 2025 was $18.9 million and consisted of a net loss attributable to Lineage of $63.5 million plus the net changes in operating assets and liabilities of approximately $4.1 million, partially offset by $48.6 million in non-cash adjustments. The net changes in operating assets and liabilities were primarily due to a $6.1 million reduction in deferred revenues, partially offset by a $2.3 million increase in accounts payable and accrued liabilities. The non-cash adjustments were primarily due to a $35.7 million change in the fair value of the warrant liability, a $14.8 million loss on impairment of our IPR&D intangible asset related to the VAC platform, and $4.8 million in stock-based compensation partially offset by a $5.3 million deferred tax benefit.

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

Cash Used In Investing Activities

Cash used in investing activities for the year ended December 31, 2025 was $13.5 million and primarily consisted of cash used to purchase U.S. Treasury securities, net of proceeds from maturities of U.S. Treasury securities.

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

Cash Provided by Financing Activities

Cash provided by financing activities for the year ended December 31, 2025 was $27.0 million and consisted of net proceeds from the sale of common shares under our at-the-market offering program, net proceeds from the sale of our common shares and warrants in the November 2024 RDO, as well as proceeds from the exercise of options and warrants. These cash inflows were partially offset by principal payments related to our financed insurance liability and finance lease liabilities.

Cash provided by financing activities for the year ended December 31, 2024 was $35.9 million and primarily consisted of net proceeds from the sale of our common shares and warrants in the November 2024 RDO and from

the sale of our common shares in a registered direct offering we closed in February 2024, and from the sale of our common shares under our at-the-market offering program.

The purchase and sale of our common shares and warrants in the November 2024 RDO was made pursuant to the registration statement on Form S-3 (File No. 333-277758), filed with the SEC on March 7, 2024 and declared effective on May 14, 2024.

The purchase and sale of our common shares in the registered direct offering we closed in February 2024 was made pursuant to the registration statement on Form S-3 (File No. 333-254167), filed with the SEC on March 5, 2021 and declared effective on March 19, 2021.

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 Israel Innovation Authority ("IIA"), obligations under vendor contracts for research services and other purchase commitments with suppliers.

As discussed in "Part I—Item 1. Business—Grants from Government Entities," above, we have received grants under the Innovation Law and are required to pay royalties to the IIA from the revenues generated from the sale of product candidates and related services developed, in whole or in part pursuant to, or as a result of, a research and development program funded by the IIA. Under the Innovation Law, we are also required to pay redemption fees to the IIA. To date, through a series of separate grants beginning in 2007, CCN has received a total of $15.4 million from the IIA to support the OpRegen program. We are obligated to pay approximately 24.1% of any future payments we may receive under the Roche Agreement to the IIA, up to an aggregate cap on all payments to IIA, such cap growing over time via interest accrual until paid in full. In December 2025, Lineage funded CCN to pay the IIA 24.1% of the $5.0 million received from Roche upon the achievement of the first milestone under the Agreement. As of December 31, 2025, the aggregate cap amount was approximately $96.2 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, 2025, we have not included any future financial obligations due to the IIA under the Innovation Law in the accompanying consolidated balance sheet because the achievement and timing of the events that would require future payments to the IIA under the Innovation Law is not fixed and determinable. See Note 13 (Commitments and Contingencies) to our consolidated financial statements included in this report for additional information.

Our obligations to licensors under license agreements and to other government entities under the terms of grants we have received require us to make future payments relating to sublicense fees, developmental, regulatory and/or commercial 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 developmental, regulatory and/or commercial milestones. Royalties are payable to licensors or government entities based on a percentage of net sales of licensed products or of products covered by the in-licensed intellectual property, including those related to the Roche Agreement. In December 2025, CCN accrued a payment obligation to be funded by Lineage due to Hadasit for 21.5% of the $5.0 million received from Roche upon the achievement of the first milestone under the Roche Agreement. Patent maintenance costs are payable to licensors as reimbursement for the cost of maintaining licensed patents. Due to the contingent nature of the payments, the amounts and timing of payments to licensors under our in-license agreements and to government entities under the terms of grants we have received are uncertain and may fluctuate significantly from period to period. As of December 31, 2025, we have not included these future commitments on our consolidated balance sheet because the achievement and timing of these events are not fixed and determinable.

As of December 31, 2025, under the terms of the leases for the facilities from which CCN and Lineage operate, a total of $2.3 million of rent payments will become due, of which $0.9 million will become due in 2026.

In the normal course of business, we enter into services agreements with contract research organizations, contract manufacturing organizations and other third parties. Generally, these agreements provide for termination

upon notice, with specified amounts due upon termination based on the timing of termination and the terms of the agreement. The amounts and timing of payments under these agreements are uncertain and contingent upon the initiation and completion of the services to be provided.

Future Funding Requirements and Potential Sources

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

In March 2026, we received $5.4 million in gross proceeds from the exercise of warrants issued under our November 2024 RDO. We may receive up to an additional $30.2 million in gross proceeds upon the full cash exercise of the warrants we issued to the investors in the November 2024 RDO. We have received $5.7 million through the filing date of this report. However, no assurances can be given as to the extent to which additional warrants will be exercised. As of December 31, 2025, $17.4 million remained available for sale under our at-the-market offering program. See Note 10 (Shareholders' Equity) to our consolidated financial statements included in this report for additional information regarding our at-the-market offering program.

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, political and economic uncertainty, geopolitical conflicts, rising inflation and interest rates, and other macroeconomic factors.

We believe that our $55.8 million in cash, cash equivalents and marketable securities at December 31, 2025, will be sufficient to fund our planned operations through at least twelve months from the issuance date of our consolidated financial statements included elsewhere in this report. We believe we will meet our longer-term expected future cash requirements and obligations with our current cash and cash equivalents, marketable securities, milestone and other payments we expect to receive under our collaboration agreements, and proceeds we receive from sales of our common shares under our at-the-market offering program.

Off-Balance Sheet Arrangements

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Lineage Cell Therapeutics, Inc. and Subsidiaries (the "Company") as of December 31, 2025 and 2024, the related consolidated statements of operations, comprehensive loss, shareholders' equity and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2025 and 2024, and the consolidated results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our 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 audit included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures to respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our 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 audit provides a reasonable basis for our opinion.

Critical Audit Matter

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

Revenue recognition based on a cost input measure of progress

Critical Audit matter Description

As described in Note 3 to the consolidated financial statements, the Company recorded total deferred revenue of $15.7 million as of December 31, 2025 and revenue of $13.6 million for the year ended December 31, 2025 from collaboration agreements. The Company concluded the grant of licenses for the Company's technology or programs,

research and development services, and services or obligations in connection with participation in research or steering committees represent a combined performance obligation for which the Company recognizes collaboration revenues as the services are performed over time. The Company used a cost-based input method to measure progress toward completion of the performance obligation for each collaboration agreement and to calculate the corresponding revenue to recognize each period.

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

How we Addressed the Matter in Our Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. Our audit procedures related to total estimated contract costs and estimated progress toward completion included the following, among others:

- Inspecting, on a test basis, supporting documentation for costs incurred which are used to measure progress toward completion and to calculate revenue recognition.
- For new collaboration agreements executed in the current year or existing collaboration agreements with milestones achieved, reviewing the collaboration agreements and management's related analysis, with the assistance of a subject matter expert on technical accounting matters, to evaluate the reasonableness of management's accounting conclusion to recognize revenue each period based on a cost-based input method to measure progress toward completion.
- Inquiring with research and development personnel to evaluate factors related to the nature of the work to be performed and their impact on the total contract costs to be incurred, including progress to date and the estimate of remaining contract costs.
- Performing a retrospective review to assess the Company's historical estimates of remaining costs to complete the research and development services by comparing the total actual project expenses to the forecasted amounts for the same period for consistency of the estimates prepared for the current period and period immediately following the year-end based on information available during fieldwork.
- Recalculating the corresponding revenue recognized each period based on the cost-based input method to measure progress toward completion of the performance obligation for each collaboration agreement.

/s/ Baker Tilly US, LLP

San Diego, California
March 5, 2026

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

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

	December 31, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 40,791	$ 45,789
Marketable securities	14,990	2,016
Accounts receivable	891	638
Prepaid expenses and other current assets	2,485	2,554
Total current assets	59,157	50,997
NONCURRENT ASSETS		
Property and equipment, net	2,566	2,251
Operating lease right-of-use assets	2,131	2,144
Deposits and other long-term assets	558	614
Goodwill	10,672	10,672
Intangible assets, net	31,700	46,540
Deferred tax asset, net	5,800	—
TOTAL ASSETS	$ 112,584	$ 113,218
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 7,181	$ 5,437
Operating lease liabilities, current portion	816	1,097
Finance lease liabilities, current portion	37	55
Deferred revenues, current portion	3,333	7,388
Total current liabilities	11,367	13,977
LONG-TERM LIABILITIES		
Deferred tax liability, net	22	273
Deferred revenues, net of current portion	12,377	14,433
Operating lease liabilities, net of current portion	1,534	1,295
Finance lease liabilities, net of current portion	32	67
Warrant liabilities	43,906	6,161
TOTAL LIABILITIES	69,238	36,206
Commitments and contingencies (Note 13)		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of December 31, 2025 and 2024	—	—
Common shares, no par value, 450,000 shares authorized as of December 31, 2025 and 2024; 243,122 and 220,416 shares issued and outstanding as of December 31, 2025 and 2024, respectively	515,467	484,722
Accumulated other comprehensive loss	(3,920)	(2,876)
Accumulated deficit	(466,998)	(403,465)
Lineage's shareholders' equity	44,549	78,381
Noncontrolling deficit	(1,203)	(1,369)
Total shareholders' equity	43,346	77,012
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 112,584	$ 113,218

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,	
	2025	2024
REVENUES:		
Collaboration revenues	$ 13,609	$ 8,149
Royalties, license and other revenues	947	1,350
Total revenues	14,556	9,499
OPERATING EXPENSES:		
Cost of royalties	146	334
Research and development	17,729	12,472
General and administrative	18,460	18,171
Loss on impairment of intangible asset (Note 6 and Note 13)	14,840	—
Total operating expenses	51,175	30,977
Loss from operations	(36,619)	(21,478)
OTHER INCOME (EXPENSES):		
Interest income, net	1,691	1,715
Loss on marketable equity securities, net	(8)	(8)
Change in fair value of warrant liability	(35,727)	2,128
Foreign currency transaction gain (loss), net	2,148	(269)
Other income (expense), net	(132)	(670)
Total other income (expenses)	(32,028)	2,896
LOSS BEFORE INCOME TAXES	(68,647)	(18,582)
Income tax benefit	5,280	—
NET LOSS	(63,367)	(18,582)
Net (income) loss attributable to noncontrolling interest	(166)	(27)
NET LOSS ATTRIBUTABLE TO LINEAGE	$ (63,533)	$ (18,609)
Net loss per common share attributable to Lineage basic and diluted	$ (0.28)	$ (0.09)
Weighted-average common shares used to compute basic and diluted net loss per common share	230,116	200,193

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,	
	2025	2024
NET LOSS	$ (63,367)	$ (18,582)
Other comprehensive loss:		
Foreign currency translation adjustment, net of tax	(1,046)	189
Unrealized gain on marketable debt securities	2	3
COMPREHENSIVE LOSS	(64,411)	(18,390)
Comprehensive (income) loss attributable to noncontrolling interest	(166)	(27)
COMPREHENSIVE LOSS ATTRIBUTABLE TO LINEAGE COMMON SHAREHOLDERS	$ (64,577)	$ (18,417)

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, 2023	**174,987**	**$ 451,343**	**$ (384,856)**	**$ (1,396)**	**$ (3,068)**	**$ 62,023**
Shares issued through registered direct financings	45,041	29,711	—	—	—	29,711
Shares issued through ATM financing	56	70	—	—	—	70
Financing related fees	—	(1,685)	—	—	—	(1,685)
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	45	(23)	—	—	—	(23)
Shares issued upon exercise of stock options	287	229	—	—	—	229
Stock-based compensation	—	5,077	—	—	—	5,077
Unrealized gain on marketable debt securities	—	—	—	—	3	3
Foreign currency translation adjustment, net of tax	—	—	—	—	189	189
Net income (loss)	—	—	(18,609)	27	—	(18,582)
BALANCE - December 31, 2024	**220,416**	**$ 484,722**	**$ (403,465)**	**$ (1,369)**	**$ (2,876)**	**$ 77,012**
Shares issued through registered direct financing	7,895	3,795	—	—	—	3,795
Shares issued through ATM financing	13,133	22,550	—	—	—	22,550
Financing related fees	—	(2,092)	—	—	—	(2,092)
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	63	(16)	—	—	—	(16)
Shares issued upon exercise of stock options	1,265	1,250	—	—	—	1,250
Shares issued upon exercise of warrants	350	319	—	—	—	319
Derivative warrant liability reclassified to share capital upon exercise of warrants	—	187	—	—	—	187
Stock-based compensation	—	4,752	—	—	—	4,752
Unrealized gain on marketable debt securities	—	—	—	—	2	2
Foreign currency translation adjustment, net of tax	—	—	—	—	(1,046)	(1,046)
Net income (loss)	—	—	(63,533)	166	—	(63,367)
BALANCE - December 31, 2025	**243,122**	**$ 515,467**	**$ (466,998)**	**$ (1,203)**	**$ (3,920)**	**$ 43,346**

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	$ (63,533)	$ (18,609)
Net income (loss) attributable to noncontrolling interest	166	27
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities:		
Issuance costs for common stock warrant liabilities	183	688
Loss on impairment of intangible asset	14,840	—
Loss on marketable equity securities, net	8	8
Accretion of income on marketable debt securities	(44)	(229)
Depreciation and amortization expense	699	587
Change in right-of-use assets and liabilities	(58)	(42)
Amortization of intangible assets	—	22
Stock-based compensation	4,752	5,077
Change in fair value of warrant liability	35,727	(2,128)
Deferred income tax benefit	(5,280)	—
Foreign currency remeasurement	(2,269)	273
Changes in operating assets and liabilities:		
Accounts receivable	(316)	106
Prepaid expenses and other current assets	46	489
Accounts payable and accrued liabilities	2,271	(1,681)
Deferred revenue	(6,111)	(7,680)
Net cash used in operating activities	(18,919)	(23,092)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of marketable equity securities	—	18
Purchases of marketable debt securities	(14,935)	(8,761)
Maturities of marketable debt securities	2,000	7,000
Purchase of equipment	(522)	(565)
Net cash used in investing activities	(13,457)	(2,308)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	1,250	229
Proceeds from exercise of warrants	319	—
Common shares received and retired for employee taxes paid	(16)	(23)
Proceeds from sale of common shares under ATM, net of offering costs	20,908	68
Proceeds from sale of common shares under registered direct financing, net of offering costs	—	13,889
Proceeds from sale of common shares with warrants under registered direct financing, net of offering costs	5,232	21,919
Payment of financed insurance premium	(684)	(171)
Payment of finance lease liabilities	(59)	(54)
Net cash provided by financing activities	26,950	35,857
Effect of exchange rate changes on cash, cash equivalents and restricted cash	396	(95)
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(5,030)	10,362
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	46,354	35,992
At end of the period	$ 41,324	$ 46,354
SUPPLEMENTAL DISCLOSURES:		
Cash paid for interest	$ 29	$ 9
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:		
Financing costs in accounts payable and accrued liabilities	$ 3	$ 179
Fair value of warrant liability recognized upon issuance in registered direct financing	$ 2,205	$ 8,289
Derivative warrant liability reclassified to equity on exercise of warrants	$ 187	$ —
Financed insurance premium	$ —	$ 855
Reconciliation of cash, cash equivalents and restricted cash, end of period:		
Cash and cash equivalents	$ 40,791	$ 45,789
Restricted cash included in deposits and other long-term assets (see Note 13 (Commitments and Contingencies))	533	565
Total cash, cash equivalents, and restricted cash	$ 41,324	$ 46,354

See accompanying notes to the consolidated financial statements.

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

1. Organization, Basis of Presentation and Liquidity

We are a clinical-stage biotechnology company developing cell replacement therapies to treat serious medical conditions. Our programs are based on our proprietary, in-house, cell-based manufacturing platform, which we call AlloSCOPE™ (Allogeneic, Scalable, Consistent, Off-the-shelf, Pluripotent Cell Engineering), and supported by our associated development, formulation, manufacturing, and delivery capabilities.

Our lead program, OpRegen, an allogeneic retinal pigmented epithelial (RPE) cell replacement therapy, is currently in Phase 2a development under a worldwide collaboration with F. Hoffman-La Roche Ltd. and Genentech, Inc., a member of the Roche Group (collectively or individually, "Roche" or "Genentech"), for the treatment of geographic atrophy (GA) secondary to dry-AMD. Our second clinical-stage program, OPC1, is an allogeneic oligodendrocyte progenitor cell therapy designed to improve recovery following a spinal cord injury. One of our preclinical programs, ReSonance (ANP1), is an allogeneic auditory neuron progenitor cell transplant therapy currently in preclinical development under collaboration with William Demant Invest 2 Aps (WDI) for the treatment of auditory neuropathy.

Use of Estimates

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

Segments and Principles of Consolidation

Our chief operating decision maker ("CODM"), our Chief Executive Officer, manages our business activities as a single operating and reportable segment at the consolidated level. The information in our consolidated financial statements is the only financial information regularly provided to our CODM and there are no other significant expense categories regularly reviewed by our CODM. Accordingly, our CODM uses consolidated net loss to measure segment profit or loss, allocate resources and assess performance. Further, our CODM reviews and utilizes revenue and functional expenses (cost of royalties, research and development, general and administrative, and loss on impairment of intangible asset) at the consolidated level to manage our operations. Other segment items included in consolidated net loss are interest income, loss on marketable equity securities, change in fair value of warrant liability, foreign currency transaction gain (loss), and other income (expense), and the provision for income tax benefit, which are reflected in the consolidated statements of operations

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, 2025.

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

(1) Includes shares owned by Lineage and ESI.

All material intercompany accounts and transactions have been eliminated in consolidation. Lineage consolidates its direct and indirect wholly owned or majority-owned subsidiaries because Lineage has the ability to

control their operating and financial decisions and policies through its ownership, and the noncontrolling interest is reflected as a separate element of shareholders' equity on Lineage's consolidated balance sheets.

Liquidity

On December 31, 2025, we had $55.8 million of cash, cash equivalents and marketable securities. Based on our current operating plan, we believe that our cash, cash equivalents and marketable securities will be sufficient to enable us to carry out our planned operations through at least twelve months from the issuance date of our consolidated financial statements.

Capital Resources

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

As of December 31, 2025, we had $25.3 million of marketable securities, of which $10.3 million is classified as cash equivalents. We may use our marketable securities for liquidity as necessary and as market conditions allow. The market value of our marketable securities may not represent the amount that could be realized in a sale of such securities due to various market and regulatory factors, including trading volume, prevailing market conditions and prices at the time of any sale and subsequent sales of securities by the entities. In addition, the value of our marketable securities may be significantly and adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from pandemics, geopolitical conflicts, political and economic instability, rising inflation and interest rates, and other macroeconomic factors.

Additional Capital Requirements

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

Our obligations to licensors under license agreements and our obligations related to grants received from government entities require us to make future payments, such as sublicense fees, milestone payments, redemption fees, royalty fees and patent maintenance fees. Sublicense fees are payable to licensors or government entities when we sublicense the applicable intellectual property to third parties; the fees are based on a percentage of the license-related revenue we receive from sublicensees. Milestone payments, including those related to the worldwide collaboration with Roche (Roche Agreement), are due to licensors or government entities upon achievement of commercial, development and regulatory milestones. Redemption fees due to the IIA under the Innovation Law are due upon receipt of milestone payments and royalties received under the Roche Agreement. See Note 13 (Commitments and Contingencies) for additional information. Royalties, including those related to royalties we may receive under the Roche Agreement, are payable to licensors or government entities based on a percentage of net sales of licensed products. Patent maintenance fees are payable to licensors as reimbursement for the cost of maintaining license patents. Due to the contingent nature of the payments, the amounts and timing of payments to licensors under our in-license agreements are uncertain and may fluctuate significantly from period to period. As of December 31, 2025, we had not included these commitments on our consolidated balance sheet because the achievement of events that would trigger our payment obligations and the timing thereof were not fixed and determinable.

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

2. Significant Accounting Policies

Cash and cash equivalents – Lineage considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Restricted cash – At December 31, 2025 and 2024, CCN had restricted cash related to its office lease. See Note 13 (Commitments and contingencies).

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

Any unrealized losses attributable to current expected credit loss ("CECL") would be recorded through an allowance for credit losses, limited to the amount by which the fair value is below amortized cost, with the offsetting amount recorded in other income or expense in the consolidated statement of operations. To date, no such credit losses have occurred or have been recorded. See Note 4 (Marketable Securities) for additional information.

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

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

Accounts receivable - Accounts receivable are recorded at the net invoice value and are non-interest bearing. Lineage establishes an allowance for credit losses based on the evaluation of the collectability of its receivables using a variety of factors, including the length of time receivables are past due, significant events that may impair the customer's ability to pay, such as a bankruptcy filing or deterioration in the customers operating results or financial position, and historical experience. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted. Lineage has deemed the risk of customer default to be low, as the receivable amounts: i) are from creditworthy customers, ii) have not historically been impacted by macro-economic uncertainties (i.e., interest rates, inflation, GDP growth) as it relates to collectability, and iii) with respect to royalties, are based on estimates and/or reports directly communicated by its sublicensees. As such, a credit loss allowance per the provisions of CECL is not determined to be necessary and no reserves have been recorded as of December 31, 2025 or 2024. The Company reevaluates such reserves on a quarterly basis and adjusts its reserves as needed. Once a receivable is deemed to be uncollectible, such balance is charged against the reserve.

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

any losses on such accounts. Lineage mitigates its credit exposure on marketable debt securities by investing in short term U.S. Treasuries securities.

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

For the year ended December 31, 2025, the Company's top two customers collectively represented 92% of the Company's total revenue. For the year ended December 31, 2024, the Company's top single customer represented 92% of the Company's total revenue.

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

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

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

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

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

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

Accounting for warrants - The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in FASB ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC Topic 815, *Derivatives and Hedging* ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's common shares, whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance. Liability and equity-classified warrants are valued using a Black-Scholes option pricing model at issuance, and for liability-classified warrants, upon warrant exercise, and at each reporting period end date while the warrants are outstanding. Changes in fair value of liability-classified warrants are recorded in the consolidated statements of operations, and reflected as an adjustment to reconcile net loss to net cash used in operating activities in the consolidated statements of cash flows. See Note 8 (Fair Value Measurements) and Note 10 (Shareholders' Equity) for additional information on the warrants.

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

Foreign currency translation adjustments and other comprehensive income or loss - In countries in which Lineage operates where the functional currency is other than the U.S. dollar, assets and liabilities are translated using published exchange rates in effect at the consolidated balance sheet date. Revenues and expenses and cash flows are translated using an approximate weighted average exchange rate for the period. Resulting foreign currency translation adjustments are recorded as other comprehensive income or loss, net of tax, in the consolidated statements of comprehensive income or loss and included as a component of accumulated other comprehensive income or loss on the consolidated balance sheets. Foreign currency translation adjustments are primarily attributable to CCN and ESI, Lineage's consolidated foreign subsidiaries. For the years ended December 31, 2025 and 2024, the total comprehensive loss includes foreign currency translation adjustment losses of $1.0 million and foreign currency translation adjustment gains of $0.2 million, respectively, net of tax. As of December 31, 2025 and 2024, we had cumulative translation adjustments of $3.9 million and $2.9 million, respectively, net of tax.

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

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

directly for each reporting period. Actual revenues ultimately received may differ from those estimates recorded and are adjusted in the period when information on actuals is available to Lineage. Other revenues are generated from service agreements and are recognized as revenue in the period earned.

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

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

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

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

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

- *Upfront fees* - If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize collaboration revenues from the transaction price allocated to the license when the license is transferred to the licensee, and the licensee is able to use and benefit from the license. When the license is determined to be non-distinct, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time, and, if over time, the appropriate method of measuring progress for purposes of recognizing collaboration revenue from the allocated transaction price. For example, when we receive upfront fees for the performance of research

and development services, or when research and development services are not considered to be distinct from a license, we recognize collaboration revenue for those units of account over time using a measure of progress. We evaluate the measure of progress at each reporting period and, if necessary, adjust the measure of performance and related revenue as a change in estimate.

- *Milestone payments* - At the inception of each collaboration agreement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the collaboration partner's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of milestones that are within our or the collaboration partner's control, such as operational developmental milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and net income (loss) in the period of adjustment. Revisions to our estimate of the transaction price may also result in negative collaboration revenues and net income (loss) in the period of adjustment.
- *Royalties* - For collaboration agreements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).
- *Reimbursement, cost-sharing payments* - Under certain collaborative agreements, we will receive reimbursement for a portion of our R&D expenses. Such reimbursements are reviewed for gross versus net reporting considerations and reflected either as a reduction of R&D expense or as reimbursement revenue in our consolidated statements of operations.

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

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

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

The Company recognizes share-based compensation for equity awards granted to employees, non-employee director and consultants as an expense on the consolidated statements of operations. Share-based compensation is recognized over the requisite service period of the individual awards using the straight-line attribution method,

which generally equals the vesting period. Employees stock options primarily have a ten-year life and generally vest 25% on the first anniversary of the grant and in 1/36th equal installments on each monthly anniversary thereafter, such that options are fully vested on the four-year anniversary of the date of grant. The exercisability and vesting periods of options granted to directors and consultants vary. Restricted stock units subject to time-based vesting generally vest in four equal annual installments beginning on the first anniversary of the grant date. Restricted stock units subject to performance-based vesting will vest in connection with the achievement of certain development milestones (see Note 11 (Stock-Based Awards) for additional details).

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

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

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

Income taxes - Lineage accounts for income taxes in accordance with ASC Topic 740, *Income Taxes* ("ASC 740"), which prescribe the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. ASC 740 guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. Lineage files a U.S. federal income tax return as well as California 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. During the year ended December 31, 2025, the Company released the valuation allowance related to its Israel subsidiary; a valuation allowance continues to be maintained against the Company's remaining deferred tax assets. 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, 2025 and 2024. 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, 2025 and 2024.

On July 4, 2025, the One Big Beautiful Bill Act (OBBBA) was enacted in the United States. The OBBBA makes permanent key elements of the Tax Cuts and Jobs Act, including 100% bonus depreciation, domestic research cost expensing, and the business interest expense limitation. ASC 740 requires the effects of changes in tax rates and laws on deferred tax balances to be recognized in the period in which the legislation is enacted. OBBBA contained U.S. corporate tax provisions under which the Company elected to expense U.S. incurred research or experimental

expenditures immediately. The enactment of OBBBA did not have a material impact on the financial statements for the year ended December 31, 2025.

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

For the years ended December 31, 2025 and 2024, 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,	
	2025	2024
Stock options	31,153	26,726
Restricted stock units	315	501
Warrants	41,097	33,158

Recently Adopted Accounting Pronouncements

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

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) - Improvements to Income Tax Disclosures. The new standard requires a company to expand its existing income tax disclosures, specifically related to the rate reconciliation and income taxes paid. The standard is effective for us beginning in fiscal year 2025. We adopted ASU 2023-09 prospectively for the year ended December 31, 2025 and applied the new disclosure requirements and its adoption did not have a significant impact on our consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

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

3. Revenue

Our revenue is primarily generated from our collaborative research and development agreements as well as royalty and other service agreement revenues.

Collaboration revenues

The following paragraphs provide information regarding the accounting treatment of the Company's most significant collaborative agreements, which are all within the scope of ASU 2014-09 – Revenue from Contracts with Customers (Topic 606).

For our collaboration agreements where revenue is recognized over time, an input method of costs incurred over total estimated costs to be incurred is used to measure progress toward completion of the performance obligation and to calculate the corresponding revenue to recognize each period. During each reporting period, we update our total estimated collaboration costs, and any resulting adjustments are recorded on a cumulative basis, which would affect revenue and deferred revenue (the latter, if applicable) in the period of adjustment. For our collaboration agreements where revenue is recognized over time, we believe the input methodology represents the most appropriate measure of progress towards satisfaction of the identified performance obligation.

Roche Agreement - From the inception of the December 2021 Roche Agreement through the quarter ending September 30, 2025 the total transaction price was equal to the $50.0 million upfront payment received and was allocated among two performance obligations. The license, technology transfer and related clinical deliverables were determined to be highly interdependent and interrelated and were combined as the first performance obligation. Delivery related to the first performance obligation is determined to be over time using the input methodology which we believe represents the most appropriate measure of progress towards satisfaction of the identified performance obligation. A material customer option for additional goods and services was included in this initial total transaction price, of which $12.0 million was allocated to a second performance obligation. This customer option will be recognized as revenue, as appropriate, when the customer exercises the option or when this option expires. Regulatory and development milestones within the agreement 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.

In the fourth quarter of 2025, the achievement of the first milestone under the agreement in the amount of $5.0 million resulted in a corresponding increase in the transaction price for the first performance obligation. Revenue recognized during 2025 from performance obligations satisfied in prior periods was $3.9 million, driven by the $5.0 million change in the transaction price. There were no further changes to the transaction price in the current year. See Note 13 (Commitments and Contingencies) for additional information.

WDI Agreement - In August 2025, the Company entered into a multi-year, multi-phase research collaboration agreement (the RCA) with WDI. During the RCA period, the parties will perform preclinical development activities to support a potential IND and/or clinical trial application (CTA) filing related to the Company's ReSonance (ANP1) program, for the treatment of hearing loss. The preclinical research activities assigned to Lineage were determined to be highly interdependent and interrelated and have been combined as one performance obligation. Delivery is determined to be overtime and revenue will be recognized utilizing an input method of costs incurred over total estimated costs to complete the performance obligation. We believe the input methodology represents the most appropriate measure of progress towards satisfaction of the identified performance obligation.

The initial transaction price for the RCA of $3.6 million includes a non-refundable upfront payment and variable consideration attributed to cost reimbursement for Lineage's costs incurred during the first phase of the research program. Based on the billing and payment terms of the arrangement, the Company's actual costs will be known each period and therefore the variable consideration will be recognized as revenue as these costs are incurred as there is no estimation uncertainty at such time. Additional variable consideration related to the second and third

phase of the research program are excluded from the initial transaction price until the uncertainty of progressing into these phases is resolved. As of December 31, 2025, the Company recognized $2.5 million from partial satisfaction of its first phase of the single performance obligation. See Note 13 (Commitments and Contingencies) for additional information.

Royalties, license and other revenues

Revenues from royalties, licenses and service agreements are recognized as revenue in the period earned and are generated from royalty and service agreements. Costs related to royalties are included within costs of royalties and costs from service agreements are included within research and development expenses in our consolidated statements of operations.

Our disaggregated revenues were as follows for the periods presented (in thousands):

	Year Ended December 31,	
	2025	2024
Revenues under collaborative agreements		
Upfront license fees [1]	$ 6,445	$ 8,149
Event-based milestones and other collaborative revenue [2]	7,164	—
Total revenues under collaborative agreements	13,609	8,149
Royalties, license and other revenues [3]	947	1,350
Total revenue	$ 14,556	$ 9,499

(1) All of the upfront license fee revenue recognized each period was included within deferred revenue as contract liabilities at the beginning of each period. Effective June 30, 2025, Lineage notified ITI of the termination of the ITI Agreement in accordance with its terms, which resulted in approximately $0.7 million in revenues recognized out of the remaining deferred revenues from this customer. See Note 13 (Commitments and contingencies) for additional information.

(2) None of the event-based milestones and other collaborative revenue recognized in 2025 was included within deferred revenues as contract liabilities as of the beginning of the period.

(3) Of the royalties, license and other revenues recognized each period, $45,000 and $30,000 was included within deferred revenues as contract liabilities as of January 1, 2025 and 2024, respectively.

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, 2025 was $18.4 million, of which $15.7 million is reported as deferred revenues. The $18.4 million is estimated to be substantially recognized as revenue by December 2027.

For the year ended December 31, 2025 based on the location of our customers, $2.5 million of our revenues were attributed to countries outside of the United States. For the year ended December 31, 2024, there were no revenues generated outside of the United States.

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

	December 31, 2025	December 31, 2024
Accounts receivable - beginning of the year	$ 638	$ 676
Accounts receivable - end of the period	$ 891	$ 638
Contract liabilities		
Deferred revenues - beginning of the year	$ 21,821	$ 29,501
Deferred revenues - end of the period	$ 15,710	$ 21,821

Contract assets, which consist of revenue recognized and performance obligations satisfied or partially satisfied in advance of customer billing were $671,000 and zero as of December 31, 2025 and 2024, respectively, and was included within prepaid expenses and other current assets on the consolidated balance sheet. There were no contract assets at the beginning of the twelve months ending December 31, 2025 or 2024.

4. Marketable Securities

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

	December 31, 2025	December 31, 2024
Marketable debt securities		
Included within cash and cash equivalents	$ 10,282	$ 17,432
Included within marketable securities	$ 14,973	$ 1,992
Marketable equity securities		
Included within marketable securities	$ 17	$ 24

Marketable Debt Securities

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

	December 31, 2025			
Financial Assets:	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasury securities	$ 25,248	$ 7	$ —	$ 25,255
Total	$ 25,248	$ 7	$ —	$ 25,255

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

The Company has not recognized an allowance for credit losses on any securities in an unrealized loss position as of December 31, 2025 and 2024. The Company believes that any individual unrealized losses represent temporary declines resulting from changes in interest rates, and do not reflect a deterioration of the credit quality of the issuer. The Company does not intend to sell these securities before their maturity, and does not anticipate that these securities will be required to be sold before recovery. The costs basis of the available-for-sale debt securities upon sale or maturity is determined using the specific identification method.

As of December 31, 2025, 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	$ 25,248	$ 25,255
Total available-for-sale debt securities	$ 25,248	$ 25,255

Marketable Equity Securities

Marketable equity securities with readily determinable fair values are reported at fair value with unrealized gains and losses related to mark-to-market adjustments included in income. Lineage's marketable equity securities are classified as trading securities and for the periods reported have consisted of shares of common stock of OCX and HBL. The value of marketable equity securities is based on the closing price of OCX and HBL common stock on the last trading day of the applicable quarter.

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

	Year Ended December 31,	
	2025	2024
Loss on marketable equity securities, net	$ (8)	$ (8)
Less: Loss recognized in earnings on marketable equity securities sold	—	4
Unrealized loss recognized on marketable equity securities held at end of period, net	$ (8)	$ (4)

5. Property and Equipment, Net

At December 31, 2025 and 2024, property and equipment, net was comprised of the following (in thousands):

	December 31, 2025	December 31, 2024
Equipment, furniture and fixtures	$ 5,280	$ 4,131
Leasehold improvements	2,749	2,300
Right-of-use assets - finance lease	221	204
Accumulated depreciation and amortization	(5,684)	(4,384)
Property and equipment, net	$ 2,566	$ 2,251

Depreciation and amortization expense was $699,000 and $587,000 for the years ended December 31, 2025 and 2024, respectively. These amounts include amortization expense for right-of-use finance lease assets of $59,000 and $55,000 for the years ended December 31, 2025 and 2024, respectively.

Geographic Area Information

The composition of Lineage's long-lived tangible assets, consisting of plant and equipment, net, and operating lease right-of-use assets between those in the United States and in foreign countries, as of December 31, 2025 and 2024, is set forth below (in thousands):

	Property and equipment, net		Operating lease right-of-use assets	
	December 31, 2025	December 31, 2024	December 31, 2025	December 31, 2024
United States	$ 61	$ 105	$ 888	$ 685
Foreign [1]	2,505	2,146	1,243	1,459
Total	$ 2,566	$ 2,251	$ 2,131	$ 2,144

(1) Assets in foreign countries are principally located at CCN in Israel.

6. Goodwill and Intangible Assets, Net

At December 31, 2025 and December 31, 2024, goodwill and intangible assets, net consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
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
	31,700	46,540
Intangible assets subject to amortization:		
Acquired patents	18,953	18,953
Acquired royalty contracts [3]	650	650
Accumulated amortization [4]	(19,603)	(19,603)
	—	—
Intangible assets, net	$ 31,700	$ 46,540

(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 connection with our acquisition of Asterias Biotherapeutics, Inc. ("Asterias") in March 2019 (the "Asterias Merger"). The Company conducted a qualitative goodwill assessment for the second quarter of 2025 and took into consideration the impairment of the VAC indefinite-lived intangible asset. After assessing the totality of relevant events and circumstances, there was no impairment to the goodwill carrying value as of June 30, 2025, and through December 31, 2025, the Company has 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. As of June 30, 2025, the VAC platform was deemed to be abandoned. As the Company has abandoned the VAC platform and its related research and development efforts, and the IPR&D asset has no alternative future use, the Company derecognized the intangible asset and recorded a non-cash pre-tax impairment charge during the quarter ending June 30, 2025 of $14.8 million, within total operating expenses of the consolidated statement of operations. See Note 13 (Commitments and Contingencies) for additional information.

(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 other acquired IPR&D intangible assets, and are considered to be separate intangible assets under ASC Topic 805, *Business Combinations*.

(4) Lineage recognized $22,000 in amortization expense of intangible assets during the three months ended March 31, 2024 and did not recognize any amortization expense in subsequent periods as the acquired patents and acquired royalty contracts were fully amortized as of March 31, 2024.

7. Accounts Payable and Accrued Liabilities

At December 31, 2025 and 2024, accounts payable and accrued liabilities consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Accounts payable	$ 2,341	$ 1,174
Accrued compensation	3,744	3,066
Accrued liabilities	1,096	1,197
Total	$ 7,181	$ 5,437

8. Fair Value Measurements

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

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

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, 2025 and 2024 (in thousands):

		Fair Value Measurements Using		
	Balance at December 31, 2025	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]	$ 20,693	$ 20,693	$ —	$ —
Marketable debt securities [1]	10,282	10,282	—	—
Marketable debt securities	14,973	14,973	—	—
Marketable equity securities [2]	17	17	—	—
Total assets measured at fair value	$ 45,965	$ 45,965	$ —	$ —
Liabilities:				
Warrant liabilities [3]	$ 43,906	$ —	$ —	$ 43,906
Total liabilities measured at fair value	$ 43,906	$ —	$ —	$ 43,906

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

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

(2) Lineage's marketable equity securities include the shares of stock of HBL which has a readily determinable fair value quoted on the TASE (Level 1). These securities are measured at fair value and reported as current assets on the accompanying consolidated balance sheet based on the closing trading price of the security as of the date being presented.

(3) Liability-classified warrants are valued at issuance, upon warrant exercise, and at each reporting period end date while the warrants are outstanding using a Black-Scholes option pricing model that maximizes the use of observable inputs and minimizes the use of unobservable inputs to the extent possible. Changes in the fair value of liability-classified warrants are recorded in the consolidated statements of operations, and reflected as an adjustment to reconcile net loss to net cash used in operating activities in the consolidated statements of cash flows. A significant increase or decrease in these Level 3 inputs could result in a significantly higher or lower fair value measurement. See Note 10 (Shareholders' Equity) for additional information on the warrants.

The following table sets forth a summary of changes to Level 3 fair value measurements (in thousands):

Common Share Warrant Liabilities	Year Ended December 31, 2025	Year Ended December 31, 2024
Balance - beginning of the year	$ 6,161	$ —
Issued	2,205	8,289
Change in fair value of warrant liability recognized in the consolidated statement of operations	35,727	(2,128)
Derivative warrant liability reclassified to equity upon exercise of warrants	(187)	—
Balance - end of the year	$ 43,906	$ 6,161

Level 3 inputs - Significant assumptions used in valuing the warrant liabilities were as follows:

	Year Ended December 31, 2025	Year Ended December 31, 2024
Expected stock price volatility	71.78% - 79.50%	69.70% - 71.18%
Risk-free interest rate	3.50% - 4.25%	4.27% - 4.30%
Expected dividend yield	—	—
Expected term (in years)	2.39 - 3.32	3.39 - 3.50

The expected stock price volatility assumption is determined using historical volatility of the Company's common stock. The risk-free interest rate assumption is based on the U.S. Treasury yield curve whose term is consistent with the expected term of the stock options. The expected dividend yield is 0% as the Company has not paid and does not anticipate paying dividends on its common stock. The expected term represents the period from the date of warrant issuance to May 21, 2028. At each reporting period end date, the expected term is reduced to reflect the remaining term of the warrants. Because the term of the warrants will expire earlier than May 21, 2028 upon the occurrence of a future event and subject to specified conditions being satisfied, the expected term could be shortened in subsequent periods. See Note 10 (Shareholders' Equity) for additional information regarding the warrants.

9. Related Party Transactions

In the February 2024 RDO (as such term is defined in Note 10 (Shareholders' Equity)), we sold 6,730,770 common shares to Broadwood Partners, L.P. ("Broadwood Partners"), an affiliate of Neal Bradsher, a member of our board of directors, and 96,155 common shares to Don Bailey, a member of our board of directors at the time of the February 2024 RDO. See Note 10 (Shareholders' Equity) for additional information regarding such offering.

In January 2025, we sold 7,894,737 common shares and an accompanying warrant to purchase up to 7,894,737 common shares to Broadwood Partners in the November 2024 RDO (as such term is defined in Note 10 (Shareholders' Equity)). See Note 10 (Shareholders' Equity) for additional information regarding such offering.

10. Shareholders' Equity

Preferred Shares

Lineage is authorized to issue 2,000,000 preferred shares. 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. There were no preferred shares issued or outstanding as of either December 31, 2025 or December 31, 2024.

Common Shares

Lineage is authorized to issue 450,000,000 common shares. As of December 31, 2025 and 2024, there were 243,121,801 and 220,416,326 common shares issued and outstanding, respectively.

At-The-Market Offering Program

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

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

During the year ended December 31, 2025, 13.1 million common shares were sold under the ATM program at a weighted average price per share of $1.72 for gross proceeds of $22.6 million. During the year ended December

31, 2024, 56,000 common shares were sold under the ATM program at a weighted average price per share of $1.26 for gross proceeds of $70,000.

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

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

Additionally, as part of the 12.0 million shares issued under the ATM program in November 2025 for gross proceeds of $21.0 million, Lineage paid H.C. Wainwright & Co., LLC ("Wainwright"), a 6% placement agent fee.

February 2024 Registered Direct Offering

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

November 2024 Registered Direct Offering

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

On November 21, 2024, we closed the first tranche of the offering and in connection therewith we issued to the unaffiliated healthcare focused institutional investors an aggregate of 31,578,951 common shares and accompanying warrants to purchase an aggregate of up to 31,578,951 of our common shares. The warrants have an exercise price of $0.91 per common share, have been exercisable since May 21, 2025 and will expire on the earlier of (a) May 21, 2028, and (b) the 90th day following the date of the public disclosure of the intent to advance OpRegen® (also known as RG6501) into a multi-center phase 2 or 3 clinical trial which includes a control or comparator arm, subject to extension if certain conditions, including equity conditions, some of which are outside of our control, are not satisfied. The warrants also provide for cashless exercise in certain circumstances, including if the shares issuable upon exercise thereof are not covered by an effective registration statement. The aggregate gross proceeds from this closing was $24 million, with $2.3 million for related issuance costs. The warrants issued at this closing had a fair value of approximately $7.9 million at issuance and are classified as warrant liabilities in the Company's consolidated financial statements. See Note 8 (Fair Value Measurements) for additional information.

The offering of the securities to Broadwood Partners in the November 2024 RDO was subject to obtaining shareholder approval to satisfy applicable NYSE American rules, which was obtained at our special meeting of shareholders on January 27, 2025. Following such meeting, we closed the second tranche of the offering and in connection therewith we issued to Broadwood Partners 7,894,737 common shares and an accompanying warrant to purchase up to 7,894,737 common shares. The terms of such warrant are substantially the same as those described above. The aggregate gross proceeds from this closing was $6.0 million, with approximately $0.6 million for related issuance costs. The warrant issued to Broadwood Partners at this closing had a fair value of approximately $2.1 million at issuance and is classified as a warrant liability in the Company's consolidated financial statements. See Note 8 (Fair Value Measurements) and Note 9 (Related Party Transactions) for additional information.

We entered into an engagement letter with H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which Wainwright agreed to serve as our exclusive placement agent, on a reasonable best efforts basis, in connection with the November 2024 RDO. Pursuant to the engagement letter, we paid Wainwright a cash fee equal to 7.0% and a management fee equal to 1.0%, in each case, of the aggregate gross proceeds we received at each closing. In addition, at each closing, we issued to Wainwright (or its designees) warrants to purchase our common shares with terms that are substantially similar to those described above except that the warrants issued to Wainwright (or its designees) have an exercise price of $0.95 per share. In the aggregate we issued to Wainwright (or its designees) warrants to purchase up to 1,973,684 of our common shares. The warrants issued to Wainwright (or its designees) in connection with the first and second closings had a fair value of approximately $0.4 million and $0.1 million, respectively, at issuance and are classified as warrant liabilities in the Company's consolidated financial statements. See Note 8 (Fair Value Measurements) for additional information.

Summary of Common Stock Warrant Activity and Outstanding

The following roll-forward presents the Company's common stock warrants outstanding as of December 31, 2025 and 2024 (in thousands, except per share amounts):

	Number of Warrants Outstanding (in thousands)	Weighted Average Exercise Price (per share)
Balance at December 31, 2023	—	—
Warrants issued	33,158	$ 0.91
Balance at December 31, 2024	33,158	$ 0.91
Warrants issued	8,289	$ 0.91
Warrants exercised	(350)	$ 0.91
Warrants expired/forfeited/cancelled	—	—
Balance at December 31, 2025	41,097	$ 0.91

See Note 8 (Fair Value Measurements) for additional information on the warrants. See Note 15 (Subsequent Events) for information regarding warrants exercised in March 2026.

11. Stock-Based Awards

Equity Incentive Plan Awards

In September 2021, our shareholders approved the Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan, and our shareholders approved amendments to increase the number of common shares that may be issued thereunder by 19,500,000 in September 2023 and by an additional 19,500,000 in June 2025 (as amended to date, the "2021 Plan"). The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, RSUs, and other stock awards. Generally, 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) 54,500,000 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 initially became effective in 2021 and are not issued because such awards expire or otherwise terminate. As a result of the approval of the 2021 Plan by our shareholders in 2021, no additional awards will be granted under the 2012 Plan. As of December 31, 2025, there were 35,837,519 shares available for grant under the 2021 Plan.

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

	Number of Options Outstanding (in thousands)	Weighted Average Exercise Price (per share)	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Balance at December 31, 2024	16,658	$ 1.30	8.23	$ —
Options granted	7,863	$ 0.56		
Options exercised	(479)	$ 1.20		
Options expired/forfeited/cancelled	(860)	$ 0.81		
Balance at December 31, 2025	23,182	$ 1.07	7.87	$ 13,898
Options exercisable at December 31, 2025	10,788	$ 1.34	6.99	$ 3,566
Options exercisable and expected to vest at December 31, 2025	23,182	$ 1.07	7.87	$ 13,898

	Number of RSUs Outstanding (in thousands)	Weighted Average Grant Date Fair Value (per share)
Balance at December 31, 2024	501	$ 1.24
RSUs forfeited	(100)	$ 0.21
RSUs vested	(86)	$ 1.50
Balance at December 31, 2025	315	$ 1.50

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, 2024	10,068	$ 1.84	4.58	$ —
Options exercised	(786)	$ 0.86		
Options expired/forfeited/cancelled	(1,311)	$ 2.33		
Balance at December 31, 2025	7,971	$ 1.86	4.21	$ 2,026
Options exercisable at December 31, 2025	7,971	$ 1.86	4.21	$ 2,026
Options exercisable and expected to vest at December 31, 2025	7,971	$ 1.86	4.21	$ 2,026

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,	
	2025	2024
Expected life (in years)	6.21	6.11
Risk-free interest rates	4.0%	4.2%
Volatility	80.3%	76.2%
Dividend yield	—	—

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

	Year Ended December 31,	
	2025	2024
Research and development	$ 676	$ 646
General and administrative	4,076	4,431
Total stock-based compensation expense	$ 4,752	$ 5,077

As of December 31, 2025, total unrecognized compensation costs related to unvested stock options and unvested RSUs under all equity plans, were $6.2 million, which is expected to be recognized as expense over a weighted average period of approximately 2.4 years for stock options and 0.5 years for RSUs. For the years ended December 31, 2025 and 2024, the weighted average grant-date fair value per share for options granted during the year under the 2021 Plan was $0.40 and $0.77, respectively. No RSUs were granted in the year ended December 31, 2025 or 2024. The total intrinsic value of options exercised during the years ended December 31, 2025 and 2024 was $800,000 and $135,000, respectively. The fair value of the options vested during the years ended December 31, 2025 and 2024 was $5,270,000 and $4,853,000, respectively.

12. Income Taxes

The domestic and foreign breakout of loss before income taxes was as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Domestic	$ (71,599)	$ (18,864)
Foreign	2,952	282
Loss before income taxes	$ (68,647)	$ (18,582)

Income taxes paid, net of refunds received, were $0 for the years ended December 31, 2025 and 2024, as the Company did not make any federal, state, or foreign income tax payments during the periods.

The provision (benefit) for income taxes consists of the following (in thousands):

	Year Ended December 31,	
	2025	2024
U.S. federal	$ (251)	$ —
U.S. state	—	—
Foreign	(5,029)	—
Total provision (benefit) for income taxes [1]	$ (5,280)	$ —

(1) There was no current or deferred income tax expense (benefit) for the year ended December 31, 2024. There was no current tax expense (benefit) for the year ended December 31, 2025. As a result, the income tax benefit for the year ended December 31, 2025 consists entirely of deferred tax adjustments.

During the year ended December 31, 2025, we adopted ASU 2023-09 to enhance the income tax disclosures regarding income taxes paid and the rate reconciliation disclosure. For the year ended December 31, 2025, the income tax provision (benefit) related to continuing operations differs from the amounts computed by applying the statutory income tax rate of 21% to pretax loss as follows (in thousands):

	Year Ended December 31, 2025	
U.S. federal statutory tax benefit and rate	$ (14,297)	21.00%
State income taxes, net of federal effect [1]	(37)	0.05%
Change in valuation allowance	6,608	(9.71)%
Nontaxable or nondeductible items;		
Fair market value adjustment on warrants liabilities	7,503	(11.02)%
Other nontaxable or nondeductible items	185	(0.27)%
Changes in tax laws or rates	—	—%
Tax credits	(486)	0.71%
Cross-border tax laws	374	(0.55)%
Worldwide changes in unrecognized tax benefits	154	(0.23)%
Other	365	(0.54)%
Foreign tax effects;		
Israel;		
Increase (decrease) valuation allowance	(5,847)	8.59%
Other Israel	236	(0.35)%
Other foreign jurisdictions	(38)	0.06%
Total income tax benefit and rate	$ (5,280)	7.74%

(1) California comprised all of the tax effect in this category for 2025.

A reconciliation between the statutory federal income tax expense and the Company's effective income tax expense for the year prior to the adoption of ASU 2023-09 is as follows:

	Year Ended December 31, 2024
Computed tax benefit at federal statutory rate	21%
Research and development and other credits	2%
Permanent differences	1%
Change in valuation allowance	(34)%
State tax benefit	10%
GILTI inclusion	—%
Income tax benefit (expense)	(0)%

Deferred Tax Assets and Liabilities

Deferred income taxes reflect the net tax effects of loss and credit carryforwards and temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of our deferred tax assets and liabilities for federal and state income taxes at December 31, 2025 and 2024 are as follows (in thousands):

	December 31, 2025	December 31, 2024
Deferred tax assets:		
Net operating loss carryforwards	$ 70,637	$ 68,180
Research and development and other credits	9,922	9,433
Capitalized research expense	10,275	8,441
Deferred revenue	4,225	—
Reserves and accruals	716	—
Stock-based compensation	3,941	3,841
Patents and licenses	1,361	1,612
Operating lease liability	267	233
Other	117	1,688
Section 481(a) - intangible amortization	8,061	—
Total deferred tax assets	109,522	93,428
Valuation allowance	(89,417)	(86,314)
Deferred tax assets, net of valuation allowance	20,105	7,114
Deferred tax liabilities:		
Operating lease ROU assets	(263)	(219)
Intangibles	(9,031)	(7,168)
Section 481(a) - deferred revenue	(5,033)	—
Total deferred tax liabilities	(14,327)	(7,387)
Net deferred tax assets	$ 5,778	$ (273)

Realization of our deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Because of our lack of U.S. earnings history, the net U.S. deferred tax assets have been fully offset by a valuation allowance. Based on sustained profitability and other positive evidence related to our Israel subsidiary, we released the valuation allowance associated with the Israel subsidiary's deferred tax assets during 2025. The valuation allowance increased by $3.1 million and $5.8 million during the years ended December 31, 2025 and 2024, respectively.

As required under ASU 2023-09, the Company has included only the portion of the valuation allowance related to federal deferred tax assets in the "change in valuation allowance" line of the rate reconciliation. The following table presents a reconciliation of the total change in the valuation allowance (in thousands):

	Year Ended December 31,	
	2025	2024
Beginning Balance	$ 86,314	$ 80,513
Change charged to income tax expense	3,389	5,803
Changes charged to other comprehensive income	(286)	(2)
Changed charged to goodwill	—	—
Ending Balance	$ 89,417	$ 86,314

Undistributed earnings of our foreign subsidiaries are considered to be permanently reinvested and accordingly, no deferred taxes have been provided thereon. Upon distribution of those earnings in the form of dividends or otherwise, we could be subject to various income and withholding taxes. At the present time it is not practicable to estimate the amount of taxes that might be payable if these earnings were repatriated.

Net Operating Loss and Tax Credit Carryforwards

As of December 31, 2025, we had a net operating loss carryforward for federal income tax purposes of approximately $187.3 million, of which $ 113.4 million is subject to expiration beginning in 2030. We had a total state net operating loss carryforward of approximately $214.6 million, which will begin to expire in 2030. Utilization of some of the federal and state net operating loss and credit carryforwards are subject to annual limitations due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitations may result in the expiration of net operating losses and credits before utilization.

We have federal credits of approximately $6.8 million, with various amounts expiring annually and state research credits of approximately $6.5 million which have no expiration date. These tax credits are subject to the same limitations discussed above.

Unrecognized Tax Benefits

Our policy is to include interest and penalties related to unrecognized tax benefits, if any, within the provision for taxes in the consolidated statements of operations. If we are eventually able to recognize our uncertain positions, our effective tax rate would be reduced. We currently have a full valuation allowance against out net U.S. deferred tax asset which would impact the timing of the effective tax rate benefit should any of these uncertain tax positions be favorably settled in the future. Any adjustments to our uncertain tax positions would result in an adjustment of our net operating loss or tax credit carry forwards rather than resulting in a cash outlay.

We have the following activity relating to unrecognized tax benefits (in thousands):

	Year Ended December 31,	
	2025	2024
Beginning balance	$ 3,153	$ 2,963
Gross increases - tax position in current period	162	190
Lapses in statutes of limitations	(8)	—
Ending balance	$ 3,307	$ 3,153

During the years ended December 31, 2025 and 2024, no interest or penalties were required to be recognized relating to unrecognized tax benefits. Due to our history of annual net operating losses, all of our previous tax years are open to examination by federal and state taxing authorities.

13. Commitments and Contingencies

Real Property Leases

Carlsbad Lease

In May 2019, Lineage entered into a lease for approximately 8,841 square feet of rentable space in an office park in Carlsbad, California. The lease was amended in December 2022 and again in September 2025. Under the amendment entered into in September 2025, the term of the lease was extended for 36 months commencing on April 1, 2026, and commencing on December 1, 2025, the monthly base rent was reduced from $26,700 to $24,800, subject to 3% annual increases and rent will be abated for April 2026 through July 2026. 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, 2025.

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

Carlsbad Sublease

In September 2022, Lineage entered into a sublease for approximately 4,500 square feet of rentable industrial space in Carlsbad, California for a term that commenced on October 1, 2022 and was originally set to expire on

March 31, 2024. In February 2024, Lineage extended the term of the sublease for 24 months through March 31, 2026 on similar terms. The base rent was $23,000 per month for the first twelve months of the extended term and is $23,500 for the remaining twelve months. As security for the performance of its obligations under the sublease, Lineage provided the landlord with a security deposit of $22,500, which is included in prepaid expenses and other current assets on the consolidated balance sheet as of December 31, 2025.

In December 2025, Lineage entered into a sublease for approximately 1,674 square feet of rentable industrial space in San Diego, California, for a 38-month term that will commence in the first quarter of 2026. The base rent will be $5,189 per month for the first twelve months with an annual increase of 3.5%. As security for the performance of its obligations under the sublease, Lineage will provide the landlord with a security deposit of $10,378.

CCN Leases

As of December 31, 2025, CCN leases approximately 2,096 square meters (approximately 22,600 square feet) of combined office and laboratory space in Jerusalem, Israel under a master lease, as amended, that expires December 31, 2027. Cumulative base rent and construction allowance payments are approximately 165,000 Israeli New Shekels ("ILS") per month (approximately $52,000 as of December 31, 2025), excluding any future rent escalations, and includes options to extend the lease term for five years. The U.S. dollar value of the ILS denominated base rent and construction allowance payments fluctuates based upon currency exchange rates. In addition to base rent, CCN pays a pro-rata share of real property taxes and certain costs related to the operation and maintenance of the building in which the leased premises are located, including parking usage fees. These pro-rata charges are expensed as incurred and excluded from the calculation of the ROU assets and lease liabilities.

CCN has security deposits denominated in ILS with the landlord for this master lease which is classified as restricted cash during the term of the lease. The U.S. dollar value of the ILS denominated security deposits fluctuates based upon currency exchange rates and was $533,000 as of December 31, 2025, which is included in deposits and other long-term assets on the consolidated balance sheet.

Supplemental Information – Leases

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

	Year Ended December 31,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 1,236	$ 1,218
Operating cash flows from finance leases	$ 7	$ 9
Financing cash flows from finance leases	$ 59	$ 54
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ 847	$ 597
Finance leases	$ —	$ 36

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

	December 31, 2025	December 31, 2024
Operating leases		
Right-of-use assets	$ 2,131	$ 2,144
Right-of-use lease liabilities, current	$ 816	$ 1,097
Right-of-use lease liabilities, noncurrent	1,534	1,295
Total operating lease liabilities	$ 2,350	$ 2,392
Finance leases		
Right-of-use assets	$ 221	$ 204
Accumulated amortization	(158)	(89)
Right-of-use assets, net	$ 63	$ 115
Right-of-use lease liabilities, current	$ 37	$ 55
Right-of-use lease liabilities, noncurrent	32	67
Total finance lease liabilities	$ 69	$ 122
Weighted average remaining lease term		
Operating leases	2.4 years	2.5 years
Finance leases	1.7 years	2.4 years
Weighted average discount rate		
Operating leases	6.0%	6.4%
Finance leases	7.2%	7.1%

Future minimum lease commitments are as follows as of December 31, 2025 (in thousands):

	Operating Leases	Finance Leases
Year Ending December 31,		
2026	$ 969	$ 42
2027	1,111	31
2028	355	—
2029	85	—
Total lease payments	2,520	73
Less imputed interest	(170)	(4)
Total	$ 2,350	$ 69

Operating lease expense was $1.2 million and $1.1 million for the twelve months ended December 31, 2025 and 2024, respectively.

Collaborations

Roche Agreement

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

Under the terms of the Roche Agreement, Roche paid Lineage a $50.0 million upfront payment (which was received in January 2022) and another $5.0 million milestone payment (which was received in December 2025). Lineage is eligible to receive up to an additional $615.0 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 its ongoing phase 1/2a 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.

Agreements with Hadasit and IIA

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

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

The terms of the grants under the Innovation Law generally require that the products developed as part of the programs under which the grants were given be manufactured in Israel. The know-how developed thereunder may not be transferred outside of Israel unless prior written approval is received from the IIA. Transfer of IIA-funded know-how outside of Israel is subject to approval and payment of a redemption fee to the IIA calculated according to formulas provided under the Innovation Law. In November 2021, the IIA research committee approved an application made by CCN with respect to the grant of an exclusive license and transfer of the technological know-how for OpRegen to Roche. Under the provisions for the redemption fee, Lineage paid the IIA approximately 24.1% of the upfront payment it received under the Roche Agreement, or $12.1 million, and is obligated to pay the IIA approximately 24.1% of any milestone and royalty payments which may be received under the Roche Agreement, up to an aggregate cap on all payments, such cap growing over time via interest accrual until paid in full. In accordance with obligations under the Innovation Law, Lineage continues to fund CCN to pay the downstream payments to the IIA. As of December 31, 2025, the aggregate cap amount was approximately $96.2 million.

Pursuant to the Second Amended and Restated License Agreement, dated June 15, 2017, between CCN and Hadasit, and a certain letter agreement entered into on December 17, 2021, CCN paid a sublicensing fee to Hadasit of $8.9 million or 21.5% of the $50.0 million upfront payment under the Roche Agreement (subject to certain reductions), and CCN is obligated to pay Hadasit (i) a maximum of 21.5% of all milestone payments Lineage receives under the Roche Agreement (subject to certain reductions, including for costs related to Lineage's performance obligations under the Roche Agreement), and (ii) up to 50% of all royalty payments (subject to a maximum payment of 5% of net sales of products), Lineage receives under the Roche Agreement. The letter agreement generally terminates upon the termination of the Roche Agreement. In accordance with the terms of these agreements, the initial sublicensing fee payment to Hadasit was reduced for costs related to Lineage's performance obligations under the Roche Agreement. To the extent such costs were not incurred within five years after the execution of the Roche Agreement, CCN would have been required to pay Hadasit 21.5% of the amount of costs not incurred; however to date, all such costs have been incurred. Under the terms of CCN's agreement with Hadasit, Lineage continues to fund CCN to pay the downstream payments to Hadasit, accordingly.

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).

Effective June 30, 2025, Lineage determined that it was no longer going to pursue the VAC2 program, and was going to cease development and commercialization of all products under the CRT License Agreement. In conjunction therewith, CRT notified Lineage of CRT's termination of the CRT License Agreement, which it had the right to do if Lineage ceased all development and commercialization of all products under the CRT License Agreement. Further, in conjunction therewith, Lineage notified Immunomic Therapeutics, Inc. ("ITI") of the termination of the collaboration agreement that Lineage had entered into with ITI in April 2021 (the "ITI Agreement") in accordance with its terms. The Company has abandoned all future development efforts and will no longer prosecute any of the issued patents related to the VAC platform. Accordingly, the Company performed an impairment assessment of the VAC platform IPR&D intangible asset which resulted in a non-cash, pre-tax impairment charge during the quarter ended June 30, 2025 of $14.8 million. Additionally, Lineage recognized the remaining deferred revenue amount of approximately $0.7 million, as of the June 30, 2025 effective date of the termination of the ITI Agreement, since Lineage had no remaining performance obligations under such agreement. See Note 6 (Goodwill and Intangible Assets, Net) to our consolidated financial statements included in this report for additional information.

WDI Collaboration

On August 22, 2025, Lineage and WDI entered into a research collaboration agreement (the "RCA") to advance the preclinical development of ReSonance (ANP1) for the treatment of hearing loss (the "Project"). WDI will fund up to $12 million in research collaboration costs over the approximate three-year term of the RCA. The main objective of the RCA is for the parties to complete a preclinical phase achieving readiness to potentially progress to human clinical trials under one or more separate clinical agreements, the terms of which would be negotiated in good faith before the expiration of the RCA.

All intellectual property owned by a party prior to the date of the RCA will remain such party's sole and exclusive property. The parties will jointly own all results, data, reports, know-how and patent(s) conceived or otherwise generated in the course of and resulting from the Project, other than discoveries or developments relating to Lineage's proprietary platform technology.

If a party (the "abandoning party") informs the other party (the "continuing party") that it will not continue the research with the other party under a clinical agreement, the continuing party may purchase the abandoning party's ownership interest in the intellectual property resulting from the Project for exploitation for the treatment of hearing loss and a license to the abandoning party's background intellectual property to the extent necessary for such exploitation for an amount and on terms to be determined by the mutual agreement of the parties, and if such mutual agreement is not reached, by an independent third-party.

Other Contingent Obligations

We have obligations under license agreements and grants received from government entities to make future payments to third parties, which become due and payable on the achievement of certain development, regulatory and commercial milestones or on the sublicense of our rights to another party. These commitments include sublicense fees, milestone payments, redemption fees and royalties. Sublicense fees are payable to licensors or government entities when we sublicense underlying intellectual property to third parties; the fees are based on a percentage of the license-related revenue we receive from sublicensees. Milestone payments are due to licensors or government entities upon the future achievement of certain development and regulatory milestones. Redemption fees due to the IIA under the Innovation Law are due upon receipt of any milestone or royalty payment received in respect of IIA-funded programs. Royalties are payable to licensors or government entities based on a percentage of net sales of licensed products. As of December 31, 2025, 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.

HBL Books and Records Request

On April 17, 2023, CCN received a motion for disclosure of documents pursuant to Section 198A of the Israeli Companies Law 5759-1999. The motion was filed in the district court in Tel Aviv-Yafo (the "Court") by HBL Hadasit Bio-Holdings Ltd. ("HBL"), currently an approximately 5% shareholder of CCN. According to the motion, the requested production of documents is intended to allow HBL to examine the possibility of pursuing a derivative action related to, among other things, the validity of an intercompany Collaboration and License Agreement (the "Intercompany Agreement") entered into between Lineage and CCN pursuant to which CCN conveyed certain rights and other assets to Lineage, and Lineage agreed to undertake certain liabilities and obligations of CCN relating to the OpRegen® program. In its motion, HBL alleges, among other things, that Lineage, in its capacity as CCN's controlling shareholder, and members of CCN's board of directors caused damage to CCN because the Intercompany Agreement was an interested party transaction that was not fairly priced and exploits CCN's resources for the benefit of Lineage. The motion seeks an order to compel CCN to disclose and deliver to HBL the documents described in the motion, such additional, cumulative, or alternative relief as the Court deems appropriate, and reimbursement of HBL's expenses, including attorneys' fees. The Court held a hearing on the motion on March 14, 2024 after which the Court proposed, and the parties agreed, to retain a third-party valuation firm to assess the fairness of the valuation that was performed in support of the Intercompany Agreement. In June 2025, the third party valuation firm delivered its report stating that in its opinion the consideration paid by Lineage to CCN under the Intercompany Agreement was insufficient. The Court subsequently notified the parties that they were to advise the Court whether they have settled the matter between themselves. On January 14, 2026 HBL notified the Court that the parties had failed to reach a settlement agreement and motioned to the Court to terminate the current proceedings in order to potentially initiate separate proceedings. CCN responded to HBL's motion on February 10, 2026 requesting that the Court deny HBL's motion. The parties are awaiting the Court's response to HBL's motion. It is not possible at this time to assess the likelihood of whether the outcome of this proceeding will have a material adverse effect on Lineage's consolidated results of operations, cash flows or financial position. Therefore, in accordance with ASC 450, *Contingencies*, Lineage has not recorded any accrual for a contingent liability associated with this legal proceeding based on its belief that a liability, while possible, is not probable nor estimable, and any range of potential contingent liability amounts cannot be reasonably estimated at this time. Lineage records legal expenses as incurred.

Employment Contracts

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

Indemnification

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

insurance policies that limit its financial exposure under the indemnification agreements described in this paragraph. Accordingly, Lineage has not recorded any liabilities for these agreements as of December 31, 2025 or December 31, 2024.

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 our research, development and commercialization activities, in exchange for which we have agreed to pay potential developmental, regulatory and/or commercial milestone payments and/or 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 royalties, respectively, in our consolidated statements of operations.

14. Employee Benefit Plan

We have a defined contribution 401(k) plan for all employees. Under the terms of the plan, employees may make voluntary contributions as a percentage or defined amount of compensation. We provide a safe harbor contribution of up to 5.0% of the employee's compensation, not to exceed eligible limits, and subject to employee participation. For each of the years ended December 31, 2025 and 2024, we incurred approximately $0.2 million in expenses related to the safe harbor contribution.

15. Subsequent Events

In March 2026, we received gross proceeds of $5.4 million from the exercise of warrants, which were issued in our November 2024 RDO, to purchase 5,921,053 common shares at an exercise price of $0.91 per share.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Exchange Act. Our management, including our principal executive officer and our principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. Following this review and evaluation, management collectively determined that our disclosure controls and procedures were effective as of December 31, 2025 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 2025 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, 2025, based on criteria established in the 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management believes that, as of that date, our internal control over financial reporting was effective.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. As a non-accelerated filer, we are not required to have, nor have we, engaged our independent registered public accounting firm to perform an audit of internal control over financial reporting pursuant to SEC rules that permit us to provide only management's report in this Annual Report on Form 10-K.

ITEM 9B. OTHER INFORMATION

(a) On March 3, 2026, we entered into an Amended and Restated Non-Exclusive License Agreement (the "A&R WARF License Agreement") with the Wisconsin Alumni Research Foundation ("WARF"). The A&R WARF License Agreement amends and restates the non-exclusive license agreement between WARF and Asterias Biotherapeutics Incorporated, our wholly-owned subsidiary, entered into in 2013, and terminates the license WARF granted to us in 2008, however the license granted to us in 2008 continues in effect under the terms of the A&R WARF License Agreement.

Under the A&R WARF License Agreement we were granted a worldwide non-exclusive license under certain WARF patents and WARF-owned embryonic stem cell lines to develop and commercialize therapeutic, diagnostic and research products. The licensed patents include patents covering methods for growth and differentiation of primate embryonic stem cells. The licensed stem cell lines include the H1, H7, H9, H13, and H14 hES cell lines.

Under the A&R WARF License Agreement we agreed to pay WARF (a) up to $3.0 million in the aggregate upon achievement certain developmental and regulatory milestones, (b) tiered royalties in low single-digits based on net sales of commercialized products, and (c) 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 A&R WARF License Agreement may be terminated by us at any time by giving WARF prior written notice, and by WARF if (a) payments of earned royalties, once begun, cease for a specified period of time, (b) we and any third parties collaborating or cooperating with us in the development of products using the licensed patents or stem cell lines fail to spend a specified minimum amount on research and development of products relating to the licensed patents or stem cell lines for a specified period of time, or (c) we breach the agreement or become bankrupt or insolvent or if any of the licensed patents or stem cell lines are offered to creditors. Unless earlier terminated in accordance with its terms, the term of the A&R WARF License Agreement with respect to licensed patents will continue until the expiration of the last to expire licensed patent.

Under the A&R WARF License Agreement we 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, or licensed stem cells, or inventions or materials developed or derived from the licensed patents or stem cell lines.

(b) During the period from October 1, 2025 to December 31, 2025, 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

Except as set forth below, 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, 2025, in connection with the solicitation of proxies for our 2026 annual meeting of shareholders (the "2026 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 2026 Proxy Statement and is incorporated herein by reference, except as to information disclosed in the 2026 Proxy Statement pursuant to Item 402(v) of Regulation S-K relating to pay versus performance.

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 2026 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 2026 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 2026 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:

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(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	Second Amended and Restated Bylaws	3.1(a)	8-K	June 13, 2024	001-12830
INSTRUMENTS DEFINING RIGHTS OF SECURITY HOLDERS					
4.01	Specimen of Common Share Certificate		S-1	December 18, 1991	033-44549
4.02	Description of Capital Stock of the Registrant	4.02	10-K	March 10, 2025	001-12830
4.03(a)	Form of Common Stock Purchase Warrant issued pursuant to the Securities Purchase Agreement dated November 19, 2024, between Lineage Cell Therapeutics, Inc. and the purchaser parties thereto	4.1	8-K	November 20, 2024	001-12830
4.03(b)	Form of Placement Agent Warrant	4.3	8-K	November 20, 2024	001-12830
4.03(c)	Warrant issued to Broadwood Partners, L.P. on January 27, 2025	4.03(c)	10-K	March 10, 2025	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
10.02(a)+	Amendment No. 1 to Employment Agreement entered into as of March 6, 2024 between Registrant and Brian M. Culley	10.1	10-Q	May 9, 2024	001-12830
10.03+	Amended and Restated Employment Agreement dated September 26, 2022 between Registrant and George A. Samuel III	10.3	10-Q	November 10, 2022	001-12830
10.03(a)+	Amendment No. 1 to Employment Agreement entered into as of March 6, 2024 between Registrant and George A. Samuel III	10.3	10-Q	May 9, 2024	001-12830
10.04+	Employment Agreement dated November 14, 2022 between Registrant and Jill A. Howe	10.7	10-K	March 9, 2023	001-12830
10.04(a)	Amendment No. 1 to Employment Agreement entered into as of March 6, 2024 between Registrant and Jill A. Howe	10.2	10-Q	May 9, 2024	001-12830
10.05+	Inducement Stock Option Agreement between Registrant and Brian Culley	10.18	10-K	March 14, 2019	001-12830
10.06+	Lineage Cell Therapeutics 2012 Equity Incentive Plan, as amended July 2015 ("2012 Plan")	4.1	S-8	July 15, 2015	333-205661
10.06(a)+	Amendment to 2012 Plan effective June 2017	4.2	S-8	July 7, 2017	333-219204
10.06(b)+	Amendment to 2012 Plan effective July 2019	99.3	S-8	August 8, 2019	333-233132
10.06(c)+	Amendment to 2012 Plan effective August 2019	10.1	10-Q	November 12, 2019	001-12830
10.06(d)+	2012 Plan Form of Employee Incentive Stock Option Agreement	10.7	10-Q	November 12, 2013	001-12830
10.06(e)+	2012 Plan Form of Non-employee Director Stock Option Agreement	10.8	10-Q	November 12, 2013	001-12830
10.06(f)+	2012 Plan Stock Option Grant Agreement	10.2	10-Q	November 12, 2019	000-12830
10.06(g)+	2012 Plan Form of Restricted Stock Unit	10.6	10-K	March 12, 2020	001-12830
10.07+	Lineage Cell Therapeutics 2021 Equity Incentive Plan, effective as of September 2021 ("2021 Plan")	10.1	8-K	September 15, 2021	001-12830
10.07(a)+	Amendment to 2021 Plan effective September 6, 2023	10.01	8-K	September 7, 2023	001-12830
10.07(b)+	Amendment No. 2 to the Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan	10.01	8-K	July 2, 2025	001-12830
10.07(c)+	2021 Plan Form of Stock Option Grant Notice and Agreement for Employees and Consultants	99.2	S-8	September 28, 2021	333-259853
10.07(d)+	2021 Plan Form of Stock Option Grant Notice and Agreement for Non-Employee Directors	99.3	S-8	September 28, 2021	333-259853
10.07(e)+	2021 Plan Form of Restricted Stock Unit Award Grant Notice and Agreement	99.4	S-8	September 28, 2021	333-259853
10.08+	Executive Performance Incentive Bonus Plan, adopted September 2022	10.5	10-Q	November 10, 2022	001-12830
COMMERCIAL AGREEMENTS					
10.09††*	Amended and Restated Non-Exclusive License Agreement between Registrant and the Wisconsin Alumni Research Foundation effective as of March 3, 2026				
10.10**	Second Amended and Restated License Agreement dated June 15, 2017, between Cell Cure Neurosciences, Ltd. and Hadasit Medical Research Services and Development Ltd. ("Hadasit License")	10.1	10-Q	August 8, 2024	001-12830
10.10(a)	Amendment to Hadasit License dated January 8, 2018	10.38	10-K	March 15, 2018	001-12830
10.10(b)††	Second Amendment to Hadasit License dated December 1, 2019	10.4(b)	10-K	March 10, 2022	001-12830

10.10(c)††	Side Letter Agreement dated December 17, 2021 between Hadasit Medical Research Services and Development Ltd., Cell Cure Neurosciences Ltd., Genentech, Inc. and F. Hoffmann-La Roche Ltd	10.4(c)	10-K	March 10, 2022	001-12830
10.10(d)††	Second Side Letter Agreement dated December 17, 2021 between Hadasit Medical Research Services and Development Ltd. and Cell Cure Neurosciences Ltd.	10.4(d)	10-K	March 10, 2022	001-12830
10.11†	Debt and Note Purchase Agreement dated June 16, 2017, as amended June 29, 2017, between Registrant and HBL-Hadasit Bio-Holdings Ltd.	10.3	10-Q	August 9, 2017	001-12830
10.12†	Share Purchase and Transfer Agreement dated June 16, 2017, by and among Registrant and HBL-Hadasit Bio-Holdings Ltd. and Cell Cure Neurosciences Ltd.	10.4	10-Q	August 9, 2017	001-12830
10.13	Form of Securities Purchase Agreement dated November 19, 2024, between Lineage Cell Therapeutics, Inc. and the purchaser parties thereto	10.1	8-K	November 20, 2024	001-12830
10.14	Form of Securities Purchase Agreement dated November 19, 2024, between Lineage Cell Therapeutics, Inc. and Broadwood Partners, L.P.	10.2	8-K	November 20, 2024	001-12830
10.15††	Collaboration and License Agreement dated December 17, 2021, between F. Hoffmann-La Roche Ltd, Genentech, Inc., Cell Cure Neurosciences Ltd., and Registrant	10.13	10-K	March 10, 2022	001-12830
19.01	Insider Trading Policy effective June 11, 2024	19.01	10-K	March 10, 2025	001-12830
OTHER EXHIBITS					
21.01*	List of Subsidiaries of the Registrant				
23.01*	Consent of Baker Tilly US, LLP				
31.01*	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002				
31.02*	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002				
32.01#	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
97	Lineage Cell Therapeutics, Inc. Clawback Policy	97	10-K	March 7, 2024	001-12830
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)				

^ The schedules and exhibits to the merger agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished to the Securities and Exchange Commission upon request.
* Filed herewith.
# Furnished herewith.
+ Indicates management contract or compensatory plan or arrangement.
† Portions of this exhibit have been omitted pursuant to a request for confidential treatment.
†† Certain information in this exhibit has been omitted pursuant to Item 601 of Regulation S-K.
** This exhibit previously was filed as Exhibit 10.2 to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2017 with certain information omitted pursuant to an order issued by the SEC on September 12, 2017 granting confidential treatment under the Securities Exchange Act of 1934 for such omitted information through August 9, 2024. In accordance with CF Disclosure Guidance: Topic No. 7, the Company is electing to transition to compliance with the requirements set out in Regulation S-K Item 601(b)(10), and, accordingly is

refiling this exhibit with portions of it redacted in compliance with Regulation S-K Item 601(b)(10) as indicated therein.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 5, 2026

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 5, 2026
/s/ Jill Ann Howe JILL ANN HOWE	Chief Financial Officer (Principal Financial and Accounting Officer)	March 5, 2026
/s/ Deborah Andrews DEBORAH ANDREWS	Director	March 5, 2026
/s/ Dipti Amin DIPTI AMIN	Director	March 5, 2026
/s/ Neal C. Bradsher NEAL C. BRADSHER	Director	March 5, 2026
/s/ Anula Jayasuriya ANULA JAYASURIYA	Director	March 5, 2026
/s/ Michael H. Mulroy MICHAEL H. MULROY	Director	March 5, 2026
/s/ Angus C. Russell ANGUS C. RUSSELL	Director	March 5, 2026