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, 2021

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 stock	**LCTX**	**NYSE American**

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. ☐

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

As of June 30, 2021, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant was approximately $356.8 million.

The number of common shares outstanding as of March 4, 2022 was 169,709,292

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2022 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 Annual Report on Form 10-K (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. 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. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain. Forward-looking statements include statements about:

- statements relating to the collaboration and license agreement with Roche and Genentech and activities expected to occur thereunder, the upfront, milestone and royalty consideration payable to Lineage and Lineage's planned use of proceeds therefrom;
- our plans to research, develop and commercialize our product candidates;
- the initiation, progress, success, cost and timing of our clinical trials and product development activities;
- the therapeutic potential of our product candidates, and the disease indications for which we intend to develop our product candidates;
- our ability to manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;
- the performance of third parties in connection with the development and manufacture of our product candidates, including third parties conducting our clinical trials as well as third-party suppliers and manufacturers;
- the potential of our cell therapy platform, and our plans to apply our platform to research, develop and commercialize our product candidates;
- our ability to obtain funding for our operations, including funding necessary to initiate and complete clinical trials of our product candidates;
- 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;
- our ability, and the ability of our licensors, to obtain, maintain, defend and enforce intellectual property rights protecting our product candidates, and our ability to develop and commercialize our product candidates without infringing the proprietary rights of third parties;
- our ability to recruit and retain key personnel;
- the effects of the COVID-19 pandemic on our operations; and
- other risks and uncertainties, including those described under Part I, Item 1A. Risk Factors of this Report.

You should refer to “Item 1A. Risk Factors” in this Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this Report represent our views as of the date of this Report. We anticipate that subsequent events and developments may cause our views to change. However, while we may elect to update these forward-looking statements 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 subsequent to 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 results 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 are 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 the context requires otherwise, references in this report to “Lineage,” “we,” “us,” and “our” refer 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 (“Commission”) before making investment decisions regarding our common shares.

- We have incurred operating losses since inception, and we do not know if or when we will attain profitability.
- 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 useful in medicine.
- The amount and pace of research and development work that we can do or sponsor, and our ability to commence and complete clinical trials required to obtain regulatory approval to market our therapeutic and medical device products, depends upon the amount of funds we have.
- We are dependent on our third-party collaboration with Roche to develop and commercialize OpRegen. If Roche is not successful in developing and commercializing OpRegen, we will lose a significant source of potential revenue.
- We will need to issue additional equity or debt securities in order to raise capital needed to pay our operating expenses.

- 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.

- If we do not receive regulatory approvals, we will not be permitted to sell our therapeutic and medical device products.

- 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.

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

- Clinical studies are costly, time consuming and are subject to risks that could delay or prevent commercialization of our current or future product candidates.

- Clinical and preclinical drug development involves a lengthy and expensive process with an uncertain outcome. The results of early preclinical trials and 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, if any, or receive regulatory approval on a timely basis, if at all.

- Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

- The ongoing COVID-19 pandemic has affected and may adversely affect our operations, including the conduct of our current or future clinical trials, as well as the operations of third-party partners on whom we rely.

- Our intellectual property may be insufficient to protect our products.

- 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.

- 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.

- Because we are engaged in the development of pharmaceutical and cell therapy products, the price of our common shares may rise and fall rapidly.

- Current economic and stock market conditions may adversely affect the price of our common shares.

- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy and security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could negatively affect our operating results and business.

ITEM 1. BUSINESS

Overview

Lineage Cell Therapeutics, Inc. ("Lineage," "we," "us," or "our") is a clinical-stage biotechnology company developing novel cell therapies to address unmet medical needs. Our programs are based on our proprietary cell-based technology and associated development and manufacturing capabilities. From this platform, we design, develop, and manufacture specialized human cells with anatomical and physiological functions which are similar or identical to cells found naturally in the human body. These cells which we manufacture are created by developmental differentiation protocols applied to established and well-characterized, pluripotent, and self-renewing cell lines. These functional cells are transplanted into patients to either replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury, or are administered as a means of helping the body mount a more robust and effective immune response to cancer or infectious diseases.

Our strategy is to efficiently leverage our technology platform and manufacturing capabilities to develop and advance our programs internally or in conjunction with strategic partners to further enhance their value. As one example, on December 17, 2021, we entered into a Collaboration and License Agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively, "Roche"), wherein Lineage granted to Roche exclusive worldwide rights to develop and commercialize retinal pigment epithelium cell therapies, including its proprietary cell therapy known as OpRegen®, for the treatment of ocular disorders, including advanced dry age-related macular degeneration with geographic atrophy. Roche has paid Lineage a $50.0 million upfront payment under this alliance and Lineage is eligible to receive up to an additional $620.0 million in certain developmental, regulatory, and commercialization milestone payments. Lineage also is eligible for tiered double-digit percentage royalties on net sales of OpRegen.

Currently, Lineage is working with Roche in support of the dry age-related macular degeneration (OpRegen) program and is clinically testing therapies to treat spinal cord injuries and non-small cell lung cancer, as well as conducting research and preclinical development activities intended to advance our pipeline into other therapeutic indications and target tissues or organs.

Product Candidates & Other Programs

We have several allogeneic, or "off-the-shelf," cell therapy programs in development:

- *OpRegen*®, a retinal pigment epithelium ("RPE") cell replacement therapy currently in a Phase 1/2a multicenter clinical trial for the treatment of advanced dry age-related macular degeneration ("AMD") with geographic atrophy ("GA") (also known as atrophic AMD). There are currently no therapies approved by the U.S. Food and Drug Administration ("FDA") for dry AMD. As of December 17, 2021 this program has been partnered with Roche for further clinical development and commercialization.

- *OPC1*, an oligodendrocyte progenitor cell therapy currently in long-term follow-up for a Phase 1/2a multicenter clinical trial for spinal cord injuries ("SCI"). This clinical trial has been partially funded by the California Institute for Regenerative Medicine ("CIRM").

- *VAC*, an allogeneic cancer immunotherapy of antigen-presenting dendritic cells. One of the VAC product candidates, VAC2, is currently in a Phase 1 clinical trial in non-small cell lung cancer ("NSCLC"). This clinical trial is being funded and conducted by Cancer Research UK ("CRUK"), one of the world's largest independent cancer research charities. We also have another VAC-based product candidate in preclinical development with our partner, Immunomic Therapeutics, Inc. ("ITI"), for the treatment of glioblastoma multiforme ("GBM").

- *Other.* We have other product candidates in preclinical development covering a range of therapeutic areas and target tissues or organs. Generally, these candidates are based on the same pluripotent platform technology and employ a similar guided cell differentiation and transplant approach as our current clinical-stage products.

In addition to seeking to create value for shareholders by developing product candidates and other technologies through our clinical development programs, we also seek to create value from our technologies through partnering and strategic transactions. We founded two companies that later became publicly traded companies: OncoCyte Corporation ("OncoCyte") and AgeX Therapeutics, Inc. ("AgeX"). We continue to hold common stock in OncoCyte as of December 31, 2021.

During the year ended December 31, 2021, we received approximately $10.1 million in gross proceeds in connection with our sale of shares of OncoCyte. In August 2020, we also received $24.6 million from Juvenescence Limited ("Juvenescence"), representing principal and accrued interest under a promissory note we received in connection with our sale of AgeX shares to Juvenescence in August 2018.

Corporate Information

Lineage is incorporated 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 +1- (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. Lineage routinely uses its website as a means of disclosing material non-public information and for complying with its 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 Securities and Exchange Commission.

2021 Chronological Highlights

We achieved numerous strategic accomplishments during 2021, including advancing clinical trials and product development in several key programs.

- In February 2021, we announced an agreement with Neurgain Technologies to evaluate a novel delivery system for OPC1 to treat spinal cord injury, with the goal of eventually supporting a larger-scale clinical trial.

- In March 2021, we announced the achievement of significant improvements to OPC1 manufacturing, including to process, purity, and scale.

- In April 2021, we announced a worldwide license and development collaboration agreement with ITI, for the development and commercialization of novel cancer immunotherapy agents derived from the VAC platform utilizing antigens provided by ITI.

- In June 2021, we announced the second and third known findings of retinal tissue restoration in dry-AMD patients who received OpRegen RPE cell transplant therapy.

- In November 2021, we announced the fourth known finding of retinal tissue restoration in a dry-AMD patient who received OpRegen RPE cell transplant therapy.

- In December 2021, we announced a collaboration and license agreement with Roche, pursuant to which we granted Roche exclusive worldwide rights to develop and commercialize RPE cell therapies, including OpRegen, for the treatment of ocular disorders, including advanced dry AMD with GA.

Business Strategy

Our goal is to address unmet medical needs by developing and advancing allogeneic, or "off-the-shelf," treatments comprised of functional cells derived by differentiation of pluripotent cells from established and self-renewing cell lines. We direct pluripotent cells to become specific cell types and use those differentiated cells as treatments to restore diseased or diminished functions, such as impaired vision, loss of movement and sensation, or to increase immune response to tumors or infectious agents. Significant near-term activities that underlie our business strategy include:

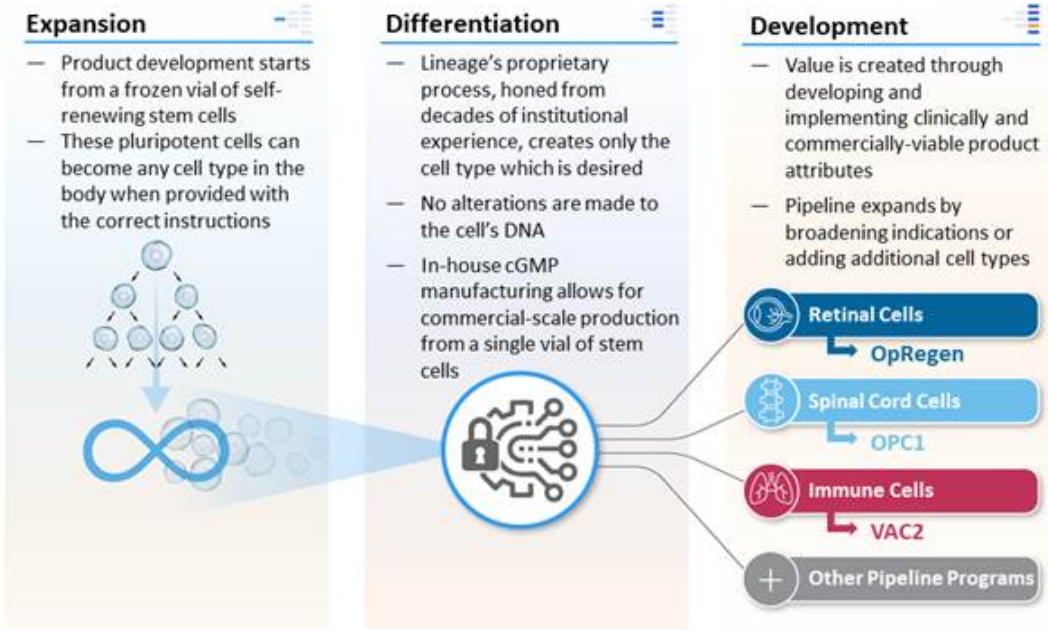
- Providing continuing OpRegen data from the ongoing Phase 1/2a clinical study, which is in the long-term follow-up phase, to our partner Roche;

- Supplying OpRegen to support our partner, Roche, in initiating a new clinical study for OpRegen;

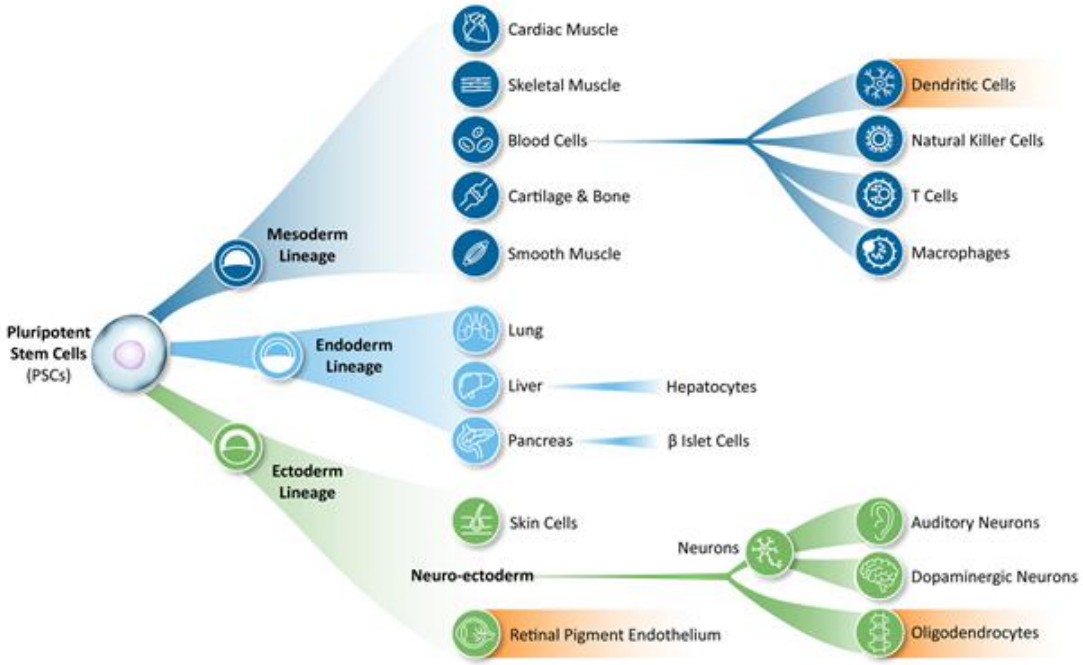
- Completing GMP production of OPC1 through an improved and larger-scale manufacturing process and a new thaw-and-inject formulation;
- Multiple FDA interactions to discuss further development of the OPC1 program, including manufacturing improvements, the novel Parenchymal Spinal Delivery (PSD) device, and a late-stage clinical study;
- Initiating clinical performance and safety testing of the novel PSD device for OPC1, with an anticipated amended Investigational New Drug (IND) submission;
- Analyzing data from the ongoing Phase 1 VAC2 clinical study for the treatment of non-small cell lung cancer;
- Initiating a clinical study of VAC2, with an anticipated IND submission;
- Continuing development of a dendritic cell-based therapeutic for GBM with our strategic partner;
- Evaluating opportunities for new VAC product candidates based on internally identified or partnered tumor antigens/neoantigens;
- Evaluating partnership opportunities and expansion of existing collaborations and identification of new collaborations for OPC1 and the VAC platform, and
- Evaluating new programs for the implementation of our directed cell differentiation technology and expertise into adjacent or new therapeutic areas and tissues or organs.

Cell Therapy Technology Platform

We believe we are a leader in pluripotent, cell-based asset development based on directed derivation protocols of cellular lineages and whole cell manufacturing capabilities. Pluripotent cells, which are widely published as capable of becoming any human cell type, have potential applications in many areas of medicine with large unmet patient needs, including certain age-related degenerative diseases and degenerative conditions for which there presently are no cures. We are currently in clinical development for various pluripotent cell-derived product candidates such as RPE cells, oligodendrocyte progenitor cells and dendritic cells. In addition, we are exploring the differentiation of pluripotent cells into other cell types that may have therapeutic benefit in other areas of unmet medical need.



Examples of Cell Types Which Can Be Derived from Pluripotent Stem Cells



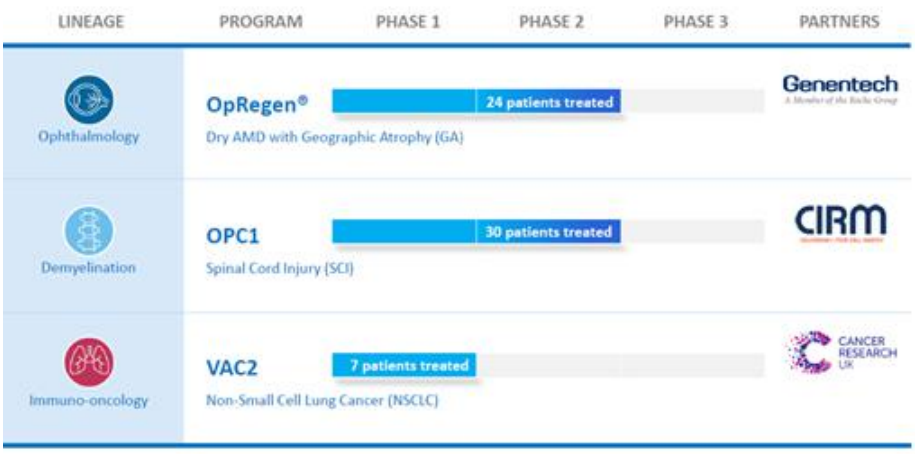
Highlighted cell types indicate currently active clinical programs of Lineage

Cellular therapies are often aimed at regenerating or replacing entire affected cells or tissues and therefore, may have more durable, broader, or more suitable applicability than many traditional pharmaceutical products which are aimed to influence a single molecular target or group of biological pathways. Small molecules and biologic therapies that require systemic delivery into the body often have unexpected side effects that can limit their usefulness. When cell replacement is locally administered, particularly to a specific anatomical compartment, systemic side effects are usually minimal and well-tolerated. Cell therapy more closely resembles that of transplant medicine, being focused on whether the transplanted cells are retained or rejected by the body and whether the cells function as expected, rather than causing intolerable or dose limiting side effects.

A key advantage of our approach is that it provides us the opportunity to rapidly develop new programs without the extensive and costly steps traditionally required to develop a new small molecule. Whereas small molecule product development typically requires selection or validation of a drug target, followed by screening millions of molecules to identify a series of hits, followed by chemical modification known as structure-activity relationship or "SAR" to develop a hit into a more potent lead, the process of developing a new cell therapy from pluripotent lines can be comparatively faster because the target cell type is already known and fully "validated", insofar as it is well-established in the literature as being the cell type which is dysfunctional or deficient in the patient. The most critical step in developing a new cell therapy is the establishment of a proprietary and commercially feasible differentiation protocol which can create the needed cells, a process which avoids mass screening campaigns and is more readily accomplished via the combination of literature reviews and in-house experience with pluripotent cell differentiation. This approach can facilitate our pipeline expansion faster and at a lower cost than traditional methods.

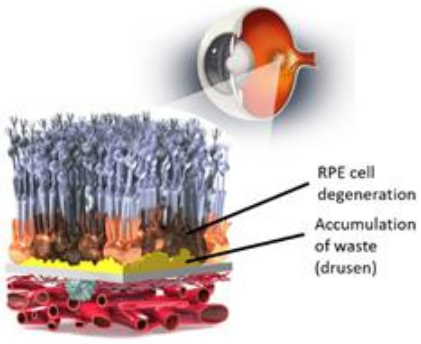
In addition to our corporate headquarters located in San Diego, CA, we have a modern and innovative manufacturing facility in the Bio Park on the campus of the Hadassah University Hospital in Jerusalem, Israel. The facility includes process development laboratories and a state-of-the-art, current good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

Novel Clinical Cell Therapy Pipeline



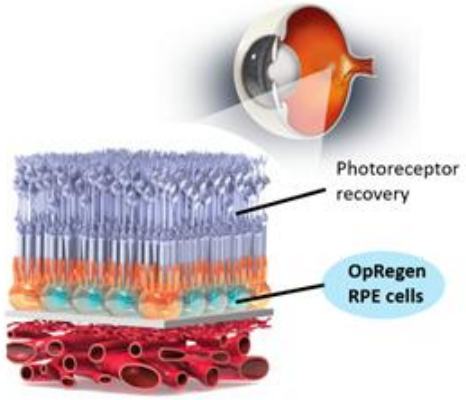
OpRegen

OpRegen is an ophthalmic product candidate (currently in a Phase 1/2a clinical trial) for the treatment of advanced dry AMD with GA. 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. AMD affects over 30 million people worldwide and approximately 1.6 million people are diagnosed annually in the United States. It is a leading cause of vision loss in people over the age of 65 in the developed world. As the area of atrophy begins to include the fovea (the center of the macula), patients lose their central vision, making facial recognition, reading and driving difficult or impossible, and often resulting in legal blindness. The exact cause of dry AMD is unknown, but is thought to result from multiple factors, such as genetics, age, and environmental effects. There are two clinical presentations of AMD, the dry form and the wet form, or neovascular form (growth of abnormal new blood vessels). Dry AMD typically advances slowly toward GA in which RPE cells and photoreceptors deteriorate over time. RPE cells support and nourish the retina by metabolizing waste by-products and producing a number of components useful for photoreceptor health and function. If the metabolic waste products accumulate, lesions known as drusen are generated. Approximately 85-90% of AMD patients suffer from dry AMD, for which there is no FDA-approved medical therapies. Dry AMD may also lead to wet AMD, a condition for which there are several FDA-approved treatments administered locally to inhibit the growth of new blood vessels, but these treatments are not effective nor approved for the treatment of dry AMD. 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 below show a representation of the process of drusen formation and the goal of cell replacement therapy.



Dry AMD involves the loss of retina cells, creating an area of geographic atrophy (GA), which causes impaired vision and blindness

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



OpRegen is an injection of RPE cells delivered to the retina, to replace lost retinal cells and preserve or restore vision

OpRegen is intended to be an allogeneic, or "off-the-shelf," product provided to retinal surgeons in an "easy-to-use" form for transplantation. We believe OpRegen could have a lasting benefit from a single administration, or once every several years. This approach differs from other investigational drugs for dry AMD and approved agents currently marketed for wet AMD, such as ranibizumab (Lucentis®) and aflibercept (Eylea®), that require repeated, frequent intravitreal injections into the eye.

The patients in our ongoing Phase 1/2a clinical trial are 50 years of age or older, whose dry AMD has advanced to the GA stage, with absence of additional concomitant ocular disorders. The trial includes 24 subjects. The first 12 subjects (Cohorts 1-3) were legally blind at the outset of the trial, with significant progression of GA. Cohort 4 consists of 12 patients with less advanced disease, smaller areas of GA, and better baseline visual acuity at the outset of the trial. In all 24 subjects, the eye in which the disease has progressed the most is treated, while their other, untreated eye serves as a measure of disease progression. Following injection, the patients are followed for 12 months at specified intervals to evaluate the safety and tolerability of OpRegen.

Following the initial 12-month period, patients are evaluated at longer intervals for up to a total of five years following administration. A secondary objective of the clinical trial is to examine the ability of transplanted OpRegen to engraft, survive, and modulate disease progression in the patients. In addition to thorough characterization of visual function, several vision tests are used to quantify stabilization or improvements in visual function. We also perform anatomical evaluation imaging to assess the restoration of the structure of the retina.

Interim data have been encouraging and suggest that OpRegen RPE cells are generally well-tolerated when administered by subretinal injection in patients with GA. Findings on clinical examination by different imaging modalities show improvements in retinal structure and decreases in drusen, which are collections of waste deposits associated with AMD, as well as durable engraftment of OpRegen cells now extending to more than five years in the earliest treated patients. Across the study, a trend toward slower GA progression in treated compared to untreated eyes continues to be present. Of particular note, four subjects in Cohort 4 have shown evidence of retinal tissue restoration, evidenced by a reduction in size or no growth in the area of atrophy at least 12 months post-treatment and the presence of key retinal cells that were not observable at baseline study entry. This anatomical effect was accompanied by improvements in visual acuity in all four subjects. Furthermore, differences in visual acuity between treated and untreated eyes remains statistically significant across Cohort 4 patients at 15 months post-treatment.

Importantly, in the safety-focused aspect of the trial, no unexpected ocular adverse events have been observed and those events expected to occur based on the procedures involved in OpRegen administration, such as vitrectomy, have been predominately mild in severity. The majority of these subjects had pre-existing epiretinal membranes (“ERMs”) at the time of trial enrollment and in most cases, experienced new or worsening ERMs following the surgical procedure, which is believed to be partially attributable to the route of administration via pars plana vitrectomy (“PPV”) and retinotomy. The majority were mild to moderate in severity, though three patients with severe ERM were successfully treated via a routine surgical procedure where the ERM was removed. These subjects are being monitored during trial follow-up. Two instances of retinal detachment were reported among all patients, one of which occurred in a patient who was legally blind prior to treatment. The event was not assigned as related to treatment, procedure or to the combination. The patient continued for a period of time in the trial following successful surgical repair but has since withdrawn due to other unrelated health issues. The second case, also successfully repaired, took place in an area of the retina away from the site of the OpRegen transplant and was thought by the investigators and other reviewers to be related to an existing retinal tear in the patient. The independent data safety monitoring board (“DSMB”) approved moving to Cohort 4 based on the safety data from the Cohorts 1-3. Cohort 4 incorporated an additional variety of objective and subjective assessments to look for signs of potential efficacy as well as potential anatomical changes indicative of OpRegen cell function following implantation.

We completed enrollment in Cohorts 1-3 (12 patients) in the middle of 2018 and as previously reported, OpRegen was well tolerated with no unexpected systemic serious adverse events (“SAEs”) or ocular adverse events (“AEs”). Importantly, there were several patients that exhibited improved retinal structure, reduction in drusen, alterations in the pattern of GA progression and indications of long-term survival of the OpRegen cells. We began enrollment of Cohort 4 shortly thereafter and treated three patients via the traditional route of administration. In 2019, we amended our clinical protocol to incorporate the Gyroscope Therapeutics, Ltd. Orbit Subretinal Delivery System (“Orbit SDS”), a single use vitrectomy-free delivery device designed to deliver products to the subretinal space through a sclerotomy and suprachoroidal approach, and our new thaw and inject formulation into our Phase1/2a clinical trial. In February 2020, we announced that after reviewing promising preliminary data from the ongoing OpRegen Phase 1/2a clinical trial, our independent data safety monitoring board removed the protocol-mandated treatment stagger. The COVID pandemic slowed the rate of patient accrual, but study enrollment was completed on November 10, 2020, with the treatment of the twelfth Cohort 4 patient, seven via the Orbit SDS and five via PPV/retinotomy. Five different surgeons at four centers successfully delivered OpRegen using the Orbit SDS and there were no unexpected AEs. Encouraging structural and clinical changes were observed in these better vision patients, including better visual acuity and increased reading speed.

In June 2020, we were able to report the first known example of retinal restoration following OpRegen administration in a Cohort 4 patient who was treated via the PPV/retinotomy route, with the findings confirmed by several independent reviewers. It is hypothesized that photoreceptor cells in the transition areas at the boundary of the GA are dysfunctional and dying, but not completely lost. The addition of new RPE cells may restore the microenvironment in surrounding tissue and contribute to the possibility of restoring function to existing cells that otherwise, if left untreated, would inevitably progress to further expansion of the atrophic region. Specifically, in this patient, the area of GA assessed at nine months following OpRegen treatment was approximately 25% smaller than the patient's pre-treatment baseline. As reported in November at the 2020 American Academy of Ophthalmology ("AAO") Annual Meeting, this patient continued to show signs of a smaller area of GA and improved visual acuity. Further, as reported throughout 2021, this patient continued to show zero progression of atrophy growth for three full years after treatment. This unprecedented finding supports the view that dry AMD is not an irreversible, degenerative condition and that some portion of diseased retinal tissue may be recoverable in atrophic end-stage disease patients.

In May 2021, we reported at the Association for Research in Vision and Ophthalmology Annual Meeting ("ARVO") that 83% of all Cohort 4 patients were at or above baseline visual acuity, based on per protocol scheduled visits ranging from 4.5 months to approximately three years post-transplant. In contrast, 83% of the patients' untreated eyes were below baseline entry values at the same time points. As well, previously reported structural improvements in the retina, decreases in drusen density, and a trend toward slower GA progression in treated compared to untreated eyes continued.

In June 2021, we reported that retinal restoration was observed in two additional Cohort 4 patients, evidenced by optical coherence tomography ("OCT"), bringing the total to three observed cases of retinal tissue restoration. These findings continue to suggest integration of new RPE cells with functional photoreceptors in areas that previously showed no presence of any of these cells. In addition to the observed anatomical changes, all three patients' visual acuity increased above baseline levels.

In September 2021, it was reported at the Annual Retina Society Meeting that updated interim results of our Phase 1/2a study showed a statistically significant difference in visual acuity between treated and untreated eyes across Cohort 4 patients, at month nine as well as months 12 and 15 post-transplant. These results, when combined with the previous evidence of retinal restoration in areas previously considered to be atrophic, suggest that both a structural and functional benefit is possible with OpRegen therapy. Additionally, it was reported that OpRegen continues to be well tolerated, with no new, unexpected ocular or systemic AEs or SAEs.

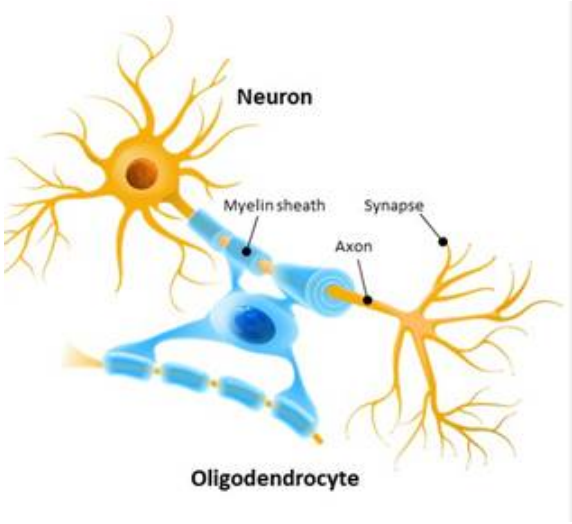
In November 2021, we reported that evidence of retinal restoration was observed in a fourth patient enrolled in the Phase 1/2a clinical study of OpRegen. Importantly, reduction or no progression for at least one-year post-transplant, was observed in the total area of GA in all four of these better-vision Cohort 4 patients. In addition, all four retinal restoration patients reported improvements in their visual acuity, which has been maintained for at least 12 months in all cases. This new and additive finding continues to support our view that atrophic AMD is not an irreversible, degenerative condition and that some portion of diseased retinal tissue may be recoverable.

In December 2021, we entered into an exclusive worldwide collaboration and license agreement with Roche, for the development and commercialization of OpRegen. Roche paid us a $50.0 million upfront payment and we are eligible to receive up to $620.0 million in additional development, approval, and sales milestone payments, in addition to tiered double-digit royalties. See Note 14 to our consolidated financial statements included elsewhere in this Report for discussion on the Roche collaboration agreement.

OPC1

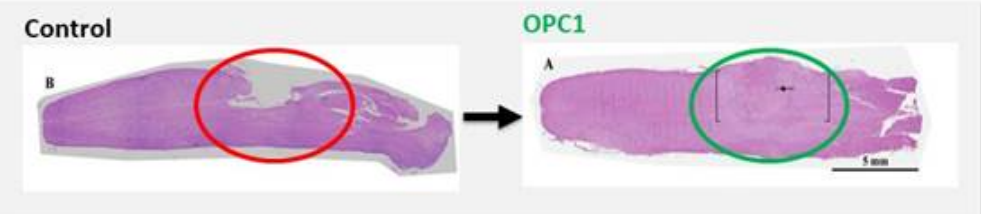
OPC1 is our lead product candidate for the treatment of SCI. SCI occurs when the spinal cord is subjected to a severe crush or contusion injury, such as that caused by a car or motorcycle accident and typically results in severe functional impairment, including limb paralysis, aberrant pain signaling, and loss of bladder and sexual function. There are approximately 18,000 new spinal cord injuries annually in the U.S. (NSCIC SCI Facts and Figures at a Glance (2019)), 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. It is believed that to effect substantial benefit in treating this complex injury, multiple mechanisms of action are required, such as introduction of 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 key 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 conduction of electrical impulses throughout the central nervous system ("CNS").

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



OPC1 is an oligodendrocyte progenitor cell therapy derived from our pluripotent cell technology under cGMP conditions using a directed differentiation method. These cells are stored frozen until ready for use and prepared for direct administration into the injured spinal cord. Based on preclinical studies, when OPC1 is transplanted into the injured spinal cord, the cells undergo further maturation to generate a replacement population of oligodendrocytes at the injury site that are capable of remyelinating denuded and newly formed nerve axons. Based on preclinical studies, prior to their maturation the transplanted oligodendrocyte progenitor cells are believed to stimulate additional reparative processes, including promotion of neuron survival and nerve axon outgrowth, and induction of blood vessel formation in and around the injury site. In addition, OPC1 cells rapidly migrate from the injection point to the injury site where they generate a supportive tissue matrix and suppress cavitation. 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.

Suppression of spinal cavitation in a rat contusion model.



Under a grant for clinical development, the development of OPC1 has been supported by $14.3 million in funds from CIRM, from 2014 through the date of this Report. We are eligible for and may seek to apply for additional grants from CIRM for the program's continued development.

Prior to its acquisition, Asterias Biotherapeutics, Inc. ("Asterias") was testing OPC1 in two clinical trials: a five patient Phase 1 safety trial and a 25-patient Phase 1/2a dose escalation trial, which we call the SCiStar trial. The SCiStar trial is an open-label, single-arm trial testing three sequential escalating doses of OPC1 administered at up to 20 million OPC1 cells with subacute, C-4 to C-7, motor complete (AIS-A or AIS-B) cervical SCI. These individuals have essentially lost all movement below their injury site and experience severe paralysis of the upper and lower limbs. AIS-A patients have lost all motor and sensory function below their injury site, while AIS-B patients have lost all motor function but may retain some minimal sensory function below their injury site. OPC1 was administered 21 to 42 days post-injury. Patients continue to be followed by neurological exams and imaging procedures to assess the safety and activity of the product. Enrollment consisted of five cohorts:

Cohort	Injury Type; OPC1 Dose	# of Patients
Cohort 1	AIS-A; 2 million OPC1 cells (low dose for safety evaluation)	3
Cohort 2	AIS-A; 10 million OPC1 cells	6
Cohort 3	AIS-A; 20 million OPC1 cells*	6
Cohort 4	AIS-B; 10 million OPC1 cells	6
Cohort 5	AIS-B; 20 million OPC1 cells*	4

* One patient from Cohort 3 and one patient from Cohort 5 were administered 10 million cells.

In January 2019, top-line 12-month data from the SCiStar trial were announced by Asterias, which included the following key findings:

- Positive Safety Profile. Magnetic resonance imaging ("MRI") scans at 12 months post-injection of OPC1 showed no evidence of adverse changes in any of the 25 patients.

- Cell Engraftment. All three patients in Cohort 1 and 21 of the 22 patients in Cohorts 2-5 had MRI scans at 12 months consistent with the formation of a tissue matrix at the injury site, which is encouraging evidence that OPC1 cells had engrafted at the injury site and helped to prevent cavitation.

- Improved Motor Function. At 12 months, 21 of the 22 patients who were administered either 10 million or 20 million cells of OPC1 (Cohorts 2-5) recovered at least one motor level on at least one side, and seven of the 22 patients recovered two or more motor levels on at least one side. Motor level recovery was based on the upper extremity motor score ("UEMS"), as measured by the International Standards for Neurological Classification of Spinal Cord Injury ("ISNCSCI"). None of these patients saw decreased motor function following administration of OPC1, and patients consistently retained the motor function recovery seen through six months or saw further motor function recovery from six to 12 months.

In November 2019, we provided an update on the SCiStar trial that highlighted, among other things:

- Positive Safety Profile. For the 21 SCiStar trial patients who had follow-up visits at 24 months post-injection of OPC1, MRI scans showed no evidence of adverse changes, and none of the patients had a decline in their motor function from their 12-month follow-up visit. There were no unexpected serious adverse events to date in any of these patients.

- Improved Motor Function. All 3 Cohort 1 patients continued to be stable 2-4 years post treatment. At 24 months, five of the six Cohort 2 patients recovered at least two motor levels on at least one side, and one Cohort 2 patient recovered three motor levels, which has been maintained through that patient's 36-month follow-up visit. Motor level recovery was based on the UEMS as measured by the ISNCSCI.

In November 2020, the formal clinical study report (CSR) for the SCiStar study with the above supporting data was submitted to the FDA.

The FDA designated OPC1 as a Regenerative Medicine Advanced Therapy ("RMAT"), for the treatment of subacute SCI. RMAT is an accelerated development pathway and includes the ability for increased interfacing with the FDA during clinical development, and granted OPC1 Orphan Drug Designation, providing a pathway to possible market exclusivity.

In 2019, we transferred all cGMP manufacturing processes, including the establishment of cell banks and the OPC1 process development and manufacturing for clinical studies, to our cell therapy manufacturing facility in Jerusalem, Israel. Improvements to the manufacturing process were completed to include enhancements to the production process to ensure robust, controlled, reproducible and commercially viable scale, and purity of OPC1. We also developed a thaw and inject formulation of OPC1 to facilitate logistics and handling at the point of care with the elimination of the dose preparation at the clinical site. An information amendment describing the new process, an improved analytical plan, and a proposed comparability plan was filed with the FDA. Throughout 2021, we manufactured clinical batches based on the improved process in a thaw and inject formulation in preparation for a larger-scale, late-stage clinical trial.

In February 2021, we announced an exclusive agreement with Neurgain Technologies, Inc. ("Neurgain") to evaluate a novel delivery system for OPC1. Preliminary assessment of prototypes revealed promising compatibility with OPC1 product while simplifying the surgical procedure by providing surgeons with an instrument that is small, simple to use and would not require stopping the patient's ventilator to perform the injection, allowing far more flexibility for accurate delivery to the injury site. We continued to evaluate the Neurgain device throughout 2021 and intend to submit an IND amendment during the third quarter of 2022 for a human safety clinical study to validate the device and which is intended to support use of the device in a late-stage clinical study to follow.

We continue work to expand our partnerships with SCI advocacy and support organizations to support their mission to accelerate stem cell treatments to patients with unmet medical needs and fast-track the development of the most promising stem cell technologies.

VAC Platform

VAC is our immuno-oncology platform using dendritic cells loaded with antigens for the treatment of cancer. Cancer afflicts millions worldwide and is one of the largest unmet clinical needs with current treatment options providing limited efficacy and a wide range of debilitating side effects. As the most potent type of antigen-presenting cell in the body, dendritic cells instruct our body's immune system to attack and eliminate harmful pathogens and unwanted cells, including cancer cells.

Specifically, to provide a more effective and targeted treatment of non-small cell lung cancer, we are currently developing VAC2 as an allogeneic, or non-patient specific, cancer vaccine candidate designed to stimulate patient immune responses to an antigen hTERT, which is commonly expressed in cancerous cells but not in normal adult cells. VAC2 is produced by our pluripotent cell technology using a directed differentiation method and is comprised of a population of mature dendritic cells to which the hTERT antigen was introduced. To target cancerous cells, VAC2 is engineered to express the tumor-selective antigen telomerase, which is found in over 85% of all cancers. The tumor antigen is loaded exogenously into the dendritic cells. The VAC1 autologous program, which preceded VAC2, serves as an effective and encouraging proof of concept behind our approach to dendritic cell vaccines targeting telomerase, which is the backbone of the VAC2 program.

Using pluripotent cells as the starting material for VAC production adds several additional advantages to this therapeutic candidate. Compared to technologies that rely on the use of a patient's own blood, our pluripotent cell technology provides a scalable system for production of a large number of vaccine doses in a single lot, lower manufacturing costs, greater product consistency, and more notably, off-the-shelf availability to provide broader and immediate access to patients. In addition, we believe that as an allogeneic therapy, VAC has the potential to stimulate a more robust immune response through an adjuvant effect resulting from the partial immune mismatch between the VAC cells and patients receiving the therapy. We believe that VAC can be used as a platform technology that can be modified to carry any antigen, including patient-specific tumor neo-antigens.

In September 2014, Asterias initiated clinical development of VAC2 by entering into a Clinical Trial and Option Agreement (the "CRUK Agreement") with CRUK and Cancer Research Technology Limited ("CRT"), a wholly owned subsidiary of CRUK, under which CRUK agreed to fund Phase 1 clinical development of VAC2 in NSCLC. CRUK was responsible, at its own cost, for manufacturing clinical grade VAC2 and for carrying out the Phase 1 clinical trial of VAC2. Patient enrollment began in June 2018, and as of December 31, 2021 seven patients have now completed dosing in the initial aspect of the trial.

In October 2020, we reported preliminary results of the ongoing Phase 1 clinical study of VAC 2 in non-small cell lung cancer. As reported, VAC2 demonstrated remarkable potent induction of immune response in all patients dosed to date, with high levels of peripheral antigen-specific immunogenicity observed at multiple time points. As well, VAC2 appeared to be well tolerated with no unexpected adverse events.

In April 2021, Lineage entered into a worldwide license and development collaboration agreement with ITI. Lineage licensed to ITI patents and materials for the development and commercialization of a novel cancer immunotherapy agent derived from the VAC platform utilizing an antigen provided by ITI, for the treatment of GBM. Under the terms of this agreement, Lineage is entitled to upfront licensing fees totaling $2.0 million paid over the first year, and up to $67.0 million in development and commercial milestones across multiple indications. Lineage will also be eligible to receive royalties of up to 10% on net sales of future products.

We completed the transfer of all cGMP manufacturing processes, including the establishment of cell banks and the VAC2 process development and manufacturing for clinical studies, to our cell therapy manufacturing facility in Jerusalem, Israel.

Throughout 2021 and early into 2022, we focused on updating and optimizing the manufacturing process for VAC to ensure reliable supply for future clinical studies and possible commercial development. An improved VAC manufacturing process will be the subject of a key interaction with FDA in the future to introduce VAC in an IND. We also continue to evaluate additional opportunities for the introduction of new VAC candidates based on internally identified or partnered tumor antigens to expand the VAC platform.

Collaboration Agreements

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

One key principle of our approach to collaborations is to share rewards and risks of conducting large-scale clinical trials and commercializing a product, but also to provide the broadest patient population the earliest access to our therapies. Significant on-going collaboration agreements include the following:

- Roche, for the development and commercialization of OpRegen a RPE cell therapy for the treatment of advanced dry age-related macular degeneration with geographic atrophy, currently in Phase 1/2a, as well as for the use in other ocular disorders; and
- ITI, for the development and commercialization of a novel cancer immunotherapy agent based on the VAC platform for the treatment of glioblastoma multiforme.

Roche Collaboration Agreement

On December 17, 2021, Lineage and its subsidiary, Cell Cure Neurosciences Ltd. ("Cell Cure") entered into a Collaboration and License Agreement (the "Roche Agreement") with Roche, pursuant to which Lineage granted to Roche exclusive worldwide rights to develop and commercialize retinal pigment epithelium 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 will assume responsibility for further clinical development and commercialization of OpRegen, which currently is being evaluated in a Phase 1/2a open-label, dose escalation clinical safety and efficacy study in patients with advanced dry AMD with GA. Lineage will be responsible for completing activities related to the ongoing clinical study, for which enrollment is complete, and performing certain manufacturing and process development activities.

Roche paid Lineage a $50.0 million upfront payment and Lineage is eligible to receive up to an additional $620.0 million in certain developmental, regulatory and commercialization milestone payments. Lineage is also eligible for tiered double-digit percentage royalties on net sales of OpRegen. 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.

The OpRegen program has been supported in part with contributions made by Hadasit Medical Research Services and Development Ltd. ("Hadasit"), the technology transfer company of Hadassah Medical Center, and the Israel Innovation Authority (the "IIA"), an independent agency created to address the needs of global innovation ecosystems. A significant portion of early development on the OpRegen program occurred at Cell Cure, which was established by the Hadassah Medical Center, where the intellectual property underlying the differentiation and manufacture of RPE cells originated. In addition, significant monetary support for the OpRegen program was provided by the IIA through a series of separate research grants, beginning in 2007. Each of these parties' contributions began when the OpRegen program was in its earliest stages of development. As a result, and subject to the terms of contracts among the applicable parties and applicable law, Lineage is obligated to pay Hadasit and the IIA a portion of the upfront, milestone, and royalty payments which may be received from Roche under the Agreement. Lineage is obligated to pay approximately 24.3% of the upfront payment and any future payments it receives from Roche to the IIA, up to an aggregate cap on all payments to IIA, which currently stands at approximately $102.7 million.

In addition, pursuant to that certain Second Amended and Restated License Agreement, dated June 15, 2017, between Cell Cure and Hadasit, as amended (the "Hadasit License)", and a certain letter agreement entered into on December 17, 2021, by and between Cell Cure and Hadasit (the "Hadasit Letter Agreement"), Cell Cure is obligated to pay to Hadasit a maximum of 21.5% of the upfront payment (subject to certain reductions) and any milestone payments, and up to 50% of all royalty payments (subject to a maximum payment of 5% of net sales of products), Lineage receives from Roche. The Hadasit Letter Agreement generally terminates upon the termination of the Roche Agreement.

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 advance 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.

In January 2022, Lineage received the $50.0 million upfront payment from Roche. Lineage made a subsequent payment of $12.1 million to the IIA, pursuant to Lineage's obligations under the Innovation Law. Additionally, Lineage made a subsequent payment of $8.9 million to Hadasit, pursuant to Lineage's obligations under the Hadasit License.

ITI Collaboration Agreement

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

Under terms of the ITI Agreement, Lineage is entitled to upfront licensing fees totaling $2.0 million paid over the first year, and up to $67.0 million in development and commercial milestones across multiple indications. Lineage will also be eligible to receive royalties of up to 10% on net sales of future products.

Research Programs

Vision restoration

In 2017, we expanded our ophthalmology portfolio by acquiring exclusive global rights to technology that allows the generation of three-dimensional human retinal tissue derived from human pluripotent cells. This tissue contains all the cell types and layers of the human retina and has shown evidence of functional integration in proof of concept animal models for advanced retinal degeneration. The technology is being developed to potentially treat or prevent a variety of retinal degenerative diseases and injuries. In 2017, the National Institutes of Health ("NIH") awarded us a grant of up to $1.6 million to further develop this innovative, next generation vision restoration program for retinal diseases and injuries. We completed work under this grant in 2020 and submitted final reports to the NIH.

Demyelination

OPC1 exhibits multiple reparative properties that may have broad applicability to neurological injury and disease, particularly as a treatment for demyelination. Past research efforts investigated the potential development of OPC1 as a candidate treatment for certain forms of ischemic stroke and multiple sclerosis ("MS"), two severely debilitating conditions for which demyelination is a central component to their pathology.

While we are not actively pursuing OPC1 for MS or ischemic stroke at this time, we may use the results of these studies to guide further preclinical development of OPC1 for these or other conditions of demyelination or wherever there is depletion or disfunction of myelinated neurons.

Other Programs

We have other product candidates in preclinical development covering a range of therapeutic areas and target tissues or organs. Generally, these candidates are based on the same pluripotent platform technology and employ a similar guided cell differentiation and transplant approach as our current clinical-stage products.

Other Products

We also have rights to HyStem, a patented biomaterial that mimics naturally occurring extracellular matrix, the structural network of molecules surrounding cells in organs and tissues essential to cellular function and tissue structure. HyStem may be useful as a scaffold for cell replacement and retention. We sold HyStem-related assets and licensed the applicable technology in late 2019, but retained the rights for other uses, including for Renevia®, our facial aesthetics product, which received a Conformité Européenne (CE) Mark in September 2019.

Investments and subsidiaries:

The following tables show the companies in which we have a direct or indirect ownership, their respective principal fields of business, our percentage ownership as of December 31, 2021, and the country where their principal business is located.

Investments:

Company	Field of Business	Lineage Ownership	Country
OncoCyte Corporation[1]	Cancer diagnostics	~1%	USA
Hadasit Bio-Holdings Ltd.[1]	Owns a portfolio of R&D based companies	<2%	Israel

Subsidiaries:

Company	Field of Business	Lineage Ownership	Country
Cell Cure Neurosciences Ltd.	Manufacturing of Lineage's cell replacement platform technology	99%[2]	Israel
Asterias Biotherapeutics, Inc.[3]	Cell based therapeutics to treat neurological conditions and cancer	100%	USA
ES Cell International Pte. Ltd[4]	Research and clinical grade cell lines	100%	Singapore
OrthoCyte Corporation[4]	Research in orthopedic diseases and injuries	99.8%	USA

(1) These are publicly traded companies. See Notes to Consolidated Financial Statements: Note 4. Marketable Equity Securities.

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

(3) Asterias was acquired by Lineage in March 2019.

(4) The operating activities and fields of business listed under these subsidiaries are conducted primarily by Lineage as the parent company.

Patents and Trade Secrets

We seek to protect and rely on our proprietary cell-based therapy platform and associated development and manufacturing capabilities and derived product candidates through a variety of methods, including seeking and maintaining patents intended to cover our products and compositions, their methods of use and processes for their manufacture, our platform technologies and any other inventions that are commercially important to the development of our business. We also rely on contractual obligations with employees and third parties to protect our proprietary rights. For example, in addition to protecting our proprietary rights with patents, we rely on unpatented trade secrets, improvements, know-how and innovation, and we take steps necessary to protect these rights, including through confidentiality agreements with our corporate partners, employees, consultants and vendors. We have sought, and intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the United States and internationally. We may also file additional patent applications, when appropriate, to cover improvements on our clinical products, clinical product candidates, and related technologies. There are no assurances that any of our intellectual property rights will guarantee complete or adequate protection or market exclusivity for our products and product candidates. We also enter into collaborative and other similar 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, to protect and enforce our intellectual property rights and to operate without infringing any intellectual property rights of others. From time to time, we assess our patents and pending applications covering our products and product candidates. If we determine that any patents or patent applications no longer provide adequate or necessary protection, we may transfer or abandon such patents and patent applications to avoid incurring unnecessary costs.

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

OpRegen

We and our subsidiary, Cell Cure, have rights to issued U.S. and international patents and pending patent applications covering OpRegen. The issued patents have expiration dates ranging from 2028 to 2036. The pending applications, if issued, will have estimated expiration dates ranging from 2028 to 2041. These U.S. and international issued patents and pending applications also include those in-licensed from Hadasit, the commercial arm and a wholly owned subsidiary of Hadassah Medical Organization. We also solely own pending U.S. and Patent Cooperation Treaty ("PCT") patent applications relating to cryopreserving the cell population and then shipping it to the clinical trial site so the cells can be immediately thawed and delivered to the patient without further processing. The U.S. patent applications, and any filed international patent applications based on the PCT applications, if issued, will have estimated expiration dates in 2038. Pursuant to the Roche Agreement, we have licensed these patent rights to Roche to further develop and commercialize RPE cell therapies, including OpRegen (see "Roche Collaboration Agreement" description above).

OPC1

We have numerous U.S. and international issued patents and pending patent applications that are relevant to neural cells, such as oligodendrocyte progenitor cells, including patent families acquired from Geron Corporation ("Geron") that are directed to the differentiation of pluripotent stem cells, including human embryonic stem ("hES") cells, into various neural cell types, as well as various culture and purification methods. These U.S. and international issued patents and pending patent applications also include those in-licensed from the Regents of the University of California. Additionally, there are four patent families with pending patent applications owned by us directed to improved methods of producing oligodendrocyte progenitor cells, oligodendrocyte progenitor cell compositions and methods of treatment of spinal cord injury using oligodendrocyte progenitor cells. There is also a patent family directed to improved methods of producing oligodendrocyte progenitor cells, oligodendrocyte progenitor cell compositions and methods for the treatment of stroke using oligodendrocyte progenitor cells which is jointly owned with the Regents of the University of California. The expiration dates of the patents and pending patent applications acquired from Geron and in-licensed from the Regents of the University of California range from 2023 to 2036. The estimated expiration dates of the four patent families with pending applications owned by us range from 2036 to 2042. The commercial success of OPC1 depends, in part, upon our ability to exclude competition for this product with the existing patent portfolio, regulatory exclusivity, undisclosed know-how and/or trade secrets, or a combination of these barriers to entry.

VAC Platform

We have numerous U.S. and international issued patents and pending patent applications that are relevant to dendritic cells, including patent families acquired from Geron or in-licensed from third parties that are directed to the differentiation of pluripotent stem cells, including hES cells, into hematopoietic progenitor cells and immature and mature dendritic cells. In addition, these patent rights include a patent family with claims directed to immunogenic compositions comprising antigen-presenting dendritic cells and methods of eliciting an anti-telomerase immune response in a subject by administering to the subject such compositions. The expiration dates of the patents, and the estimated expiration dates of the pending applications, acquired from Geron or in-licensed to us range from 2022 to 2041. The commercial success of VAC products depends, in part, upon our ability to exclude competition in these products with this patent portfolio, regulatory exclusivity, undisclosed know-how and/or trade secrets, or a combination of these barriers to entry.

General Risks Related to Obtaining and Enforcing Patent Protection

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

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

Employees

As of December 31, 2021, we had 61 employees, of which 18 were Lineage employees and 43 were employees of our subsidiary, Cell Cure in Israel and of which 57 were employed on a full-time basis and four were employed on a part-time basis. Eleven 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

We maintain an innovative cell therapy manufacturing facility in the Bio Park on the campus of the Hadassah University Hospital in Jerusalem, Israel. The facility includes process development laboratories and a state-of-the-art, cGMP manufacturing facility. It 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. All cGMP manufacturing processes, including cell banks and product manufacturing for our cell therapy product candidates are conducted in this facility.

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

Licensed Technology and Product Development Agreements

Lineage has obtained the right to use technology that we believe has 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 Amendment to Clinical Trial and Option Agreement and License Agreement with Cancer Research UK

On May 6, 2020, Lineage and its wholly owned subsidiary Asterias entered into a Second Amendment to Clinical Trial and Option Agreement (the "CTOA Amendment") with CRUK and Cancer Research Technology Limited ("CRT"), which amends the Clinical Trial and Option Agreement entered into between Asterias, CRUK and CRT dated September 8, 2014, as amended September 8, 2014. Pursuant to the CTOA Amendment, Lineage assumed all obligations of Asterias and exercised early its option to acquire data generated in the Phase 1 clinical trial of VAC2 in non-small cell lung cancer being conducted by CRUK. CRUK is continuing to conduct the VAC2 study.

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

WARF Agreements

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

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

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

Royalty Agreement with Geron

In connection with Asterias's acquisition of Geron's stem cell assets, in October 2013, we entered into a royalty agreement with Geron (the "Royalty Agreement") pursuant to which we agreed to pay Geron a 4% royalty on net sales (as defined in the Royalty Agreement) by us or any of our affiliates or sales agents of any products that we develop and commercialize that are covered by the patents Geron contributed to us. In the case of sales of such products by a person other than us or one of our affiliates or sales agents, we will be required to pay Geron 50% of all royalties and cash payments received by us or by our affiliate in respect of a product sale. Royalty payments will be subject to proration in the event that a product covered by a patent acquired from Geron is sold in combination with another product that is not covered by a patent acquired from Geron. The Royalty Agreement will terminate at the expiration or termination date of the last issued patent contributed by Geron under the Royalty Agreement. We estimate that the latest patent expiration date will be in 2033.

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, 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 and biologics under the Federal Food, Drug and Cosmetic Act ("FDCA"), the Public Health Service Act ("PHSA"), and implementing regulations. In addition, establishments that manufacture human cells, tissues, and HCT/Ps are subject to additional registration and listing requirements, including current good tissue practice regulations. Certain cell therapy proposed products will be reviewed by the FDA staff in its Center for Biologics Evaluation and Research Office of Tissues and Advanced Therapies.

Our domestic human drug and biologic products will be subject to rigorous FDA review and approval procedures. 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 optimal use, 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. 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, multi-center, comparative trials and are conducted with patients afflicted with the target disease or condition in order to provide enough data to demonstrate the efficacy and safety required by the FDA. The FDA closely monitors the progress of each of the three phases of clinical testing and may, at its discretion, re-evaluate, alter, suspend or terminate the clinical trial based upon the data which have been accumulated to that point and its assessment of the risk/benefit ratio to the intended patient population. All adverse events must be reported to the FDA. Monitoring of all aspects of the trial to minimize risks is a continuing process.

No action can be taken to market any therapeutic product in the U.S. until an appropriate New Drug Application ("NDA") or Biologics License Application ("BLA") 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, the FDA may grant marketing approval, or deny the application by way of a Complete Response Letter if it determines that the application does not provide an adequate basis for approval. FDA regulations also restrict the export of therapeutic products for clinical use prior to FDA approval. Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications including gene therapy products ("GTPs") to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps. The primary intent of the GTP requirements is to ensure that cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require HCT/P establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To maintain compliance with cGMPs, GTPs, and GCPs, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

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

The FDA offers several programs to expedite development of products that treat serious or life-threatening illnesses and that provide meaningful therapeutic benefits to patients over existing treatments. A drug is eligible for designation as an RMAT if: the drug is a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product or any combination product using such therapies or products, except for those regulated solely under certain other sections; 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. Some of our current and future products may be eligible for RMAT designation.

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 must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product may be entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the 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

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

FDA Regulation of Manufacturing

The FDA regulates the manufacturing process of pharmaceutical products, human tissue and cell products, and medical devices, requiring that they be produced in compliance with cGMP. See “Manufacturing.” 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 those inspections, 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 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.

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

Foreign Regulation

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

Federal Funding and State Regulations

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

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

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

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

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

Privacy and Data Security Laws

In the ordinary course of our business, we may process personal data and other sensitive information. Accordingly, we are, or may become, subject to numerous data privacy and security obligations, including federal, state, local, and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such obligations may include, without limitation, the Federal Trade Commission Act, the California Consumer Privacy Act of 2018 ("CCPA"), Israel's Protection of Privacy Law 5741-1981 ("PPL"), the European Union's General Data Protection Regulation 2016/679 ("EU GDPR"), the EU GDPR as it forms part of United Kingdom ("UK") law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"), and the ePrivacy Directive. In addition, several states within the United States have enacted or proposed data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act.

The CCPA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business's collection, use, and disclosure of personal data and a requirement to respond to certain requests from California residents related to their personal data (for example, requests to know of the business's personal data processing activities, to delete the individual's personal data, and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties and a private right of action for certain data breaches. In addition, the California Privacy Rights Act of 2020 ("CPRA"), effective January 1, 2023, will expand the CCPA. The CPRA will, among other things, give California residents the ability to limit use of certain sensitive personal data, establish restrictions on personal data retention, expand the types of data breaches that are subject to the CCPA's private right of action, and establish a new California Privacy Protection Agency to implement and enforce the new law. U.S. federal and state consumer protection laws require us to publish statements that accurately and fairly describe how we handle personal data and choices individuals may have about the way we handle their personal data

Foreign data privacy and security laws (including but not limited to the EU GDPR and UK GDPR) impose significant and complex compliance obligations on entities that are subject to those laws. As one example, the EU GDPR applies to any company established in the EEA and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. These obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances.

Federal and State Fraud and Abuse Laws

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

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, to induce or in return for either the referral of an individual, or the furnishing, recommending, or arranging for the purchase, lease or order of any healthcare item or service reimbursable, in whole or in part, under a federal healthcare program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, ownership interests and providing anything at less than its fair market value. Recognizing that the federal Anti- Kickback Statute is broad and may prohibit certain common activities within the healthcare industry, the Office of Inspector General for HHS has issued a series of statutory exceptions and regulatory "safe harbors." However, these exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection from prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution 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 which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

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

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

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

Coverage and Reimbursement

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

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

Healthcare Reform

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

In March 2010, the ACA was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States, and significantly affected the pharmaceutical industry. The ACA contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs. Since its enactment, there have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA. For example, legislation enacted in 2017, informally known as the Tax Cuts and Jobs Act (the "2017 Tax Act"), among other things, removes penalties for not complying with ACA's individual mandate to carry health insurance. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the individual mandate was repealed by Congress. Thus, the ACA will remain in effect in its current form. Moreover, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and other litigation, and the healthcare reform measures of the Biden administration will impact the ACA.

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

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. 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 have also been delayed by the Biden administration until January 1, 2023. 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. 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. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Major Customers and Sources of Revenues

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, 2021 and 2020:

	Year Ended December 31,	
Sources of Revenues	**2021**	**2020**
Royalties	63.9%	42.3%
Collaboration revenues	25.8%	-%
IIA grant income (Cell Cure Neurosciences Ltd, Israel)	10.3%	36.5%
NIH grant income	-%	21.2%

Geographic Area

	Year Ended December 31,	
	2021	**2020**
United States	$ 3,895	$ 1,160
Foreign[(1)]	446	666
Total revenues	$ 4,341	$ 1,826

(1) Foreign revenues are primarily generated from grants in Israel.

Marketing

Therapeutic Products and Medical Devices

Because our therapeutic product candidates and medical devices are still in the research and development stage, we will not initially need to have our own marketing personnel. If we or our subsidiaries are successful in developing marketable therapeutic products and medical devices, we will need to build our own marketing and distribution capability for those products, which would require the investment of significant financial and management resources, or we and our subsidiaries will need to find collaborative marketing partners, independent sales representatives, or wholesale distributors for the commercial sale of those products.

If we market products through arrangements with third parties, we may pay sales commissions to sales representatives or we may sell or consign products to distributors at wholesale prices. This means that our gross profit from product sales may be less than would be the case if we were to sell our products directly to end users at retail prices through our own sales force. On the other hand, selling to distributors or through independent sales representatives would allow us to avoid the cost of hiring and training our own sales employees. There can be no assurance we will be able to negotiate distribution or sales agreements with third parties on favorable terms to justify our investment in our products or achieve sufficient revenues to support our operations.

Competition

We face substantial competition in all fields of business in which we engage. That competition is likely to intensify as new products and technologies reach the market. Superior new products are likely to sell for higher prices and generate higher profit margins if acceptance by the medical community is achieved. Those companies that are successful at being the first to introduce new products and technologies to the market may gain significant economic advantages over their competitors in the establishment of a customer base and track record for the performance of their products and technologies. Such companies will also benefit from revenues from sales that could be used to strengthen their research and development, production, and marketing resources. Companies engaged in the medical products industry face the risk of obsolescence of their products and technologies as more advanced or cost-effective products and technologies are developed by competitors. As the industry matures, companies will compete based upon the performance and cost-effectiveness of their products.

Products for Regenerative Medicine

The cell therapy industry is characterized by rapidly evolving technology and intense competition. Our competitors include major multinational pharmaceutical companies, specialty biotechnology companies, and chemical and medical products companies operating in the fields of regenerative medicine, cell therapy, tissue engineering, and tissue regeneration. Many of these companies are well established and possess technical, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, certain smaller biotech companies have formed strategic collaborations, partnerships, and other types of joint ventures with larger, well-established industry competitors that afford the smaller companies' potential research and development as well as commercialization advantages. Academic institutions, governmental agencies, and other public and private research organizations are also conducting and financing research activities, which may produce products directly competitive to those we are developing.

We believe that some of our competitors are trying to develop pluripotent cells and human embryonic progenitor cell-based technologies and products that may compete with our stem cell products based on efficacy, safety, cost, and intellectual property positions.

We may also face competition from companies that have filed patent applications relating to the propagation and differentiation of stem cells. We may be required to seek licenses from these competitors to commercialize certain products proposed by us, and such licenses may not be granted.

ITEM 1A. RISK FACTORS

An investment in our common shares involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Report, before deciding whether to purchase, hold or sell our common shares. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business.

Risks Related to Our Business Operations and Capital Requirements

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

Our total operating losses for the fiscal years ended December 31, 2021 and 2020 were $49.2 million and $26.4 million, respectively, and we had an accumulated deficit of $337.1 million as of December 31, 2021. Since inception, we have incurred significant operating losses and have funded our operations primarily through sales of our equity securities and the equity securities of former subsidiaries, receipt of research grants, royalties on product sales, license revenues, sales of research products, and revenues from subscription fees and advertising revenue from database products of a former subsidiary. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize any of our product candidates and seek to identify, assess, acquire, in-license or develop additional product candidates.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and preclinical trials of our product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. In addition, we are attempting to develop new medical products and technology. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve 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 useful in medicine.

We are attempting to develop new medical products and technology. These new products and technologies might not prove to be safe and efficacious in the human medical applications for which they are being developed. Our research and development activities are costly, time consuming, and their results are uncertain. We incurred research and development expenses amounting to approximately $33.9 million and $12.3 million during the fiscal years ended December 31, 2021 and 2020, respectively. If we successfully develop a new technology or product, refinement of the new technology or product and definition of the practical applications and limitations of the technology or product may take years and require large sums of money. Clinical trials of new therapeutic products, particularly those products that are regulated as biologics, drugs, or devices, are very expensive and take years to complete. We may not have the financial resources to fund clinical trials on our own and we may have to enter into licensing or collaborative arrangements with others. 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. In addition, we may discontinue one or more of the research or product development programs. Our product and technology development programs may be delayed or discontinued should adequate funding on acceptable terms not be available.

The amount and pace of research and development work that we can do or sponsor, and our ability to commence and complete clinical trials required to obtain regulatory approval to market our therapeutic and medical device products, depends upon the amount of funds we have.

At December 31, 2021, we had $58.4 million of cash, cash equivalents and marketable equity securities. There can be no assurance that we will be able to raise additional funds on favorable terms or at all, or that any funds raised will be sufficient to permit us to develop and market our products and technology, if and when approved. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. Unless we are able to generate sufficient revenue or raise additional funds when needed, it is likely that we will be unable to continue our planned activities, even if we make progress in our research and development projects. We may have to postpone or limit the pace of our research and development work and planned clinical trials of our product candidates unless our cash resources increase through a growth in revenues, royalties, license fees, equity financings or borrowings.

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

We currently have a collaboration and license agreement with Roche, pursuant to which we license to Roche rights to develop and commercialize our retinal pigment epithelium cell therapies, including OpRegen (the “Licensed Products”), for the treatment of ocular disorders, including age-related macular degeneration with geographic atrophy. Roche is obligated to pay us milestone payments upon the achievement of specified developmental, regulatory and commercialization milestones. In addition, Roche is obligated to pay us royalties upon sales of the Licensed Products. 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 relying on Roche to develop and commercialize the Licensed Products, and if Roche is not able to develop and commercialize the Licensed Products, determines not to continue to pursue development and commercialization of the Licensed Products, or determines to terminate the collaboration at any time in its sole discretion, we will not receive any future milestone or royalty payments under the agreement which would harm our business, business prospects, financial condition and results of operations.

Roche may determine not to pursue development and commercialization and/or terminate the collaboration for many reasons, including: delays in development, manufacture or clinical supply of OpRegen; Roche may believe that data generated in clinical trials for OpRegen may be negative, inconclusive, or do not otherwise demonstrate adequate efficacy or clinical benefit to warrant further development or commercialization; Roche may not dedicate the resources necessary to carry OpRegen through clinical development; 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 more highly 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 commercially viable formulation and/or manufacturing process for OpRegen; 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; and 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. As a result, any loss or termination of rights under the collaboration will cause us to lose a significant source of potential revenue, which would have a material and adverse effect on our company, financial condition and results of operations.

We will need to issue additional equity or debt securities in order to raise additional capital needed to pay our operating expenses.

We expect to continue to incur substantial research and product development expenses and will need to raise additional capital to pay operating expenses until we are able to generate sufficient revenues from product sales, royalties and license fees. Our ability to raise additional equity or debt capital will depend, not only on progress made in developing new products and technologies, but also on access to capital and conditions in the capital markets. We believe that our cash, cash equivalents and marketable securities as of December 31, 2021 will be sufficient to fund our planned operations for at least the next 12 months after the issuance of this Report. We have based these estimates on assumptions that may prove to be wrong, and we may use our capital resources sooner than we currently expect. Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned. Any equity capital raise could result in the dilution of the interests of shareholders or may otherwise limit our ability to finance further in the future, which may negatively impact our business and operations. Any debt capital financing may involve covenants that restrict our operations, including limitations on additional borrowing and on the use of our assets. If we raise capital through licensing arrangements, it may be necessary to grant licenses on terms that are not favorable to us. There can be no assurance that we will be able to raise capital on favorable terms, or at all, or at times and in amounts needed to successfully finance product development, clinical trials, and general operations.

Lawsuits have been filed and other lawsuits may be filed against Lineage and certain members of the Lineage and Asterias boards of directors relating to our acquisition of Asterias (the "Asterias Merger"). An adverse ruling in any such lawsuit may result in additional payments and costs.

A putative class action lawsuit alleging breach of fiduciary duties in connection with the Asterias Merger is pending in the Delaware Chancery Court. The defendants are certain former members of Asterias' board of directors and our company's board of directors. The complaint alleges that the merger process was conflicted, that the consideration was inadequate, and that the proxy statement filed by Asterias was misleading. The complaint seeks, among other things, certification of a class, rescission of the merger or monetary damages, and attorneys' fees and costs. The parties are currently engaged in discovery. A five-day trial before the Delaware Chancery Court is currently scheduled for October 17-21, 2022.

Lineage believes the allegations in the action lack merit and intends to vigorously defend the claims asserted. It is impossible at this time to assess whether the outcome of this proceeding will have a material adverse effect on Lineage's results of operations, cash flows or financial position. Additional lawsuits arising out of or relating to the merger agreement and/or the merger may be filed in the future.

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

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the Biden administration and Congress have proposed various U.S. federal tax law changes, which if enacted could have a material impact on our business, cash flow, financial condition or results of operations. In addition, it is uncertain if and to what extent various states will conform to the federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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

As of December 31, 2021, we had net operating loss ("NOL") carryforwards for U.S. federal and state tax purposes of approximately $155.6 million and $151.8 million, respectively. In addition, the Company has U.S. federal and California research and development (R&D) credit carryforwards of $3.7 million and $5.8 million, respectively. Included in these amounts are NOLs and R&D credits acquired through the merger with Asterias (see below). A portion of the federal and state NOL carryforwards will begin to expire, if not utilized, in varying amounts between 2032 and 2037. NOLs that expire unused will be unavailable to offset future income tax liabilities. Under federal income tax law, federal NOLs incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOLs in tax years beginning after December 31, 2021, is limited to 80% of taxable income. The federal R&D credits expire in varying amounts between 2021 and 2041, the California credits have no expiration date. It is uncertain if and to what extent various states that we may operate in will conform to the federal tax law. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We 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. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited,

which could accelerate or permanently increase state taxes owed. For example, in 2020 California enacted A.B. 85 which imposed limits on the usability of California state net operating losses and certain tax credits in tax years beginning after 2019 and before 2023.

As part of the merger with Asterias, we acquired various tax attribute carryforwards. As the merger triggered an ownership change, the acquired net operating loss carryforwards and credit are subject to limitation under Section 382 of the Internal Revenue Service Code. Accordingly, Lineage will only be able to utilize federal and California NOLs of $52.8 million and $41.9 million, respectively, as well as California research and development credits of $2.4 million. Because of the annual limitation, the total amount of these NOLs is not immediately available to offset future income. The California research and development credit of $2.4 million has no expiration date.

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

We are organized in the United States, and currently have subsidiaries in Israel and Singapore. If we succeed in growing our business, we expect to conduct increased operations through subsidiaries in various tax jurisdictions pursuant to transfer pricing arrangements between us and our subsidiaries. If two or more affiliated companies are located in different countries, the tax laws or regulations of each country generally will require that such arrangements be priced the same as those between unrelated companies dealing at arm's length and that appropriate documentation is maintained to support the value of such arrangements. Our transfer pricing policies were formulated with the assistance of third-party experts. We are in the process of obtaining a formal transfer pricing report. However, after we receive such report, we do not intend to amend our returns for prior years. Whether we obtain a formal transfer pricing study with outside experts or not, our transfer pricing procedures will not be binding on applicable tax authorities.

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, it would increase our tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Our business and operations could suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters including earthquakes and tsunamis, terrorism, war, and telecommunication and electrical failures. Such events could cause significant interruption of our operations and development programs. For example, the loss of data for our product candidates could result in delays in our regulatory filings and development efforts and significantly increase our costs. To the extent that any disruption or security breach was to result in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the development of our product candidates could be delayed.

In addition, our product candidates are manufactured by starting with cells that are stored in a cryopreserved master cell bank. While we believe we have adequate backup should any cell bank be lost in a catastrophic event, we or our third-party suppliers and manufacturers could lose multiple cell banks, which would severely affect our manufacturing activities. We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates or products will not occur in the future. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls or other interruptions in the supply of our product candidates or products. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products and could have an adverse effect on our business, prospects, financial condition and results of operations.

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 senior management and key scientific personnel.

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

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

The value of our investments in public companies fluctuates based on their respective stock prices and could be negatively affected by business, regulatory and other risks applicable to them.

As of December 31, 2021, we had an equity investment in OncoCyte, a U.S. publicly traded company. As of December 31, 2021, the value of our investment in OncoCyte was approximately $2.4 million based on its closing stock price as of that date. If OncoCyte were to have delays in clinical trials or commercialization activities or otherwise realize the specific business, regulatory and other risks applicable to them, the value of its common stock and the valuation of our investment could be negatively affected. If OncoCyte were to fail and ultimately cease operations, we may lose the entire value of our investment. In addition, the value of our marketable equity securities may be significantly and adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

Risks Related to Government Regulation

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

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

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

- federal civil and criminal false claims laws, including the federal False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- HIPAA, which created new federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters;

- HIPAA, as amended by HITECH and their implementing regulations, which imposes certain requirements on "covered entities," including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective "business associates" that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, and their subcontractors that use, disclose, access, or otherwise process individually identifiable protected health information, relating to the privacy, security, and transmission of individually identifiable health information;

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

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

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

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

If we do not receive regulatory approvals, we will not be permitted to sell our therapeutic and medical device products.

The therapeutic and medical device products that we and our subsidiaries develop cannot be sold until the FDA and corresponding foreign regulatory authorities approve the products for medical use. The need to obtain regulatory approval to market a new product means that:

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

- Clinical trials and the regulatory approval process for a pharmaceutical or cell-based product can take several years to complete. As a result, we will incur the expense and delay inherent in seeking FDA and foreign regulatory approval of new products, even if the results of clinical trials are favorable.

- Data obtained from preclinical and clinical studies is susceptible to varying interpretations and regulatory changes that could delay, limit, or prevent regulatory agency approvals.

- Because the therapeutic products we are developing with pluripotent stem cell technology involve the application of new technologies and approaches to medicine, the FDA or foreign regulatory agencies may subject those products to additional or more stringent review than drugs or biologics derived from other technologies.

- A product that is approved may be subject to restrictions on use.

- The FDA can recall or withdraw approval of a product, if it deems necessary.

- We will face similar regulatory issues in foreign countries.

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

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

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

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could negatively impact our business.

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

Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, FDA inspections were interrupted and restarted on a risk-based basis. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, and eliminating the implementation of certain ACA-mandated fees. For example, on June 17, 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, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, other litigation, and the healthcare reform measures of the Biden administration will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, Congress is considering additional health reform measures.

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent presidential executive orders, congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, 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 U.S. Department of Health & Human Services ("HHS") finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. 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 have also been delayed by the Biden administration until January 1, 2023. 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. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

In addition, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

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

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

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

- new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, pricing or marketing practices, compliance with wage and hour laws and other employment practices, method of delivery, payment for healthcare products and services, compliance with health information and data privacy and security laws and regulations, tracking and reporting payments and other transfers of value made to physicians and teaching hospitals, extensive anti-bribery and anti-corruption prohibitions, product serialization and labeling requirements and used product take-back requirements;

- changes in the FDA and foreign regulatory approval processes that may delay or prevent the approval of new products and result in lost market opportunity;

- requirements that provide for increased transparency of clinical trial results and quality data, such as the EMA's clinical transparency policy, which could impact our ability to protect trade secrets and competitively sensitive information contained in approval applications or could be misinterpreted leading to reputational damage, misperception or legal action which could harm our business; and

- changes in FDA and foreign regulations that may require additional safety monitoring, labeling changes, restrictions on product distribution or use, or other measures after the introduction of our products to market, which could increase our costs of doing business, adversely affect the future permitted uses of approved products, or otherwise adversely affect the market for our products.

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

Even if we receive approval for our products, we may be subject to extensive regulatory obligations in order to commercialize our products.

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

If we are deemed to be an investment company, we may have to institute burdensome compliance requirements and our activities may be restricted.

An entity that, among other things, is or holds itself out as being engaged primarily, or proposes to engage primarily, in the business of investing, reinvesting, owning, trading or holding certain types of securities would be deemed an investment company under the Investment Company Act of 1940, as amended (the "1940 Act"). Based on the securities we hold, including our equity ownership in publicly traded companies, we may not meet the requirements for an exemption promulgated under the 1940 Act. If we are deemed to be an investment company under the 1940 Act, we would be subject to additional limitations on operating our business, including limitations on the issuance of securities, which may make it difficult for us to raise capital.

Risks Related to Our Clinical Development and Commercial Operations

Clinical studies are costly, time consuming and are subject to risks that could delay or prevent commercialization of our current or future product candidates.

We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of development. Events that may prevent successful or timely completion of clinical development 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 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 IRB approval at each clinical trial site;
- failure to obtain 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 (including as a result of actual or threatened public health emergencies and outbreaks of disease such as the current COVID-19 pandemic), failing to reach the targeted number of patients due to competition for patients from other trials, or patients dropping out of our clinical studies once enrolled;
- failure by clinical sites or our CROs or other third parties to adhere to clinical trial requirements or report complete findings;
- failure to perform the clinical studies in accordance with the FDA's good clinical practices requirements or applicable foreign regulatory guidelines;
- occurrence of adverse events associated with our product candidates or with product candidates of third parties that may have characteristics similar to or perceived to be similar to our product candidates;

- negative or inconclusive results from our clinical trials which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or to curtail or abandon development programs for a product candidate;

- unforeseen 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 investigator or patient compliance with the trial protocols;

- inability or unwillingness of medical investigators to follow our clinical protocols;

- unavailability of clinical trial supplies;

- inability to use clinical trial results from foreign jurisdictions to support U.S. regulatory approval;

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;

- the cost of clinical studies of our product candidates; and

- delays in agreeing on acceptable terms with third-party manufacturers and the time for manufacture of sufficient quantities of our product candidates for use in clinical studies.

Any inability to successfully complete clinical development and obtain regulatory approval could result in additional costs to us or impair our ability to generate revenue. 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 business and results of operations.

Clinical and preclinical drug development involves a lengthy and expensive process with an uncertain outcome. The results of early preclinical trials and 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, if any, or receive regulatory approval on a timely basis, if at all.

Clinical and preclinical drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. Our clinical trials may not be conducted as planned or completed on schedule, if at all, and failure can occur at any time during the preclinical or clinical trial process. 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. Although we may from time to time disclose results from preclinical testing or preliminary data or interim results from our clinical studies of our product candidates, and earlier clinical studies, including clinical studies with similar product candidates, these are not necessarily predictive of future results, including clinical trial results. The historical failure rate for product candidates in our industry is high.

The results of our current and future clinical trials may differ from results achieved in earlier preclinical and clinical studies for a variety of reasons, including:

- we may not demonstrate the potency and efficacy benefits observed in previous studies;

- our efforts to improve, standardize and automate the manufacture of our product candidates, including *OpRegen*®, OPC1 and VAC2, and any resulting deviations in the manufacture of our product candidates, may adversely affect the safety, purity, potency or efficacy of such product candidates;

- differences in trial design, including differences in size, eligibility criteria, and patient populations;
- advancements in the standard of care may affect our ability to demonstrate efficacy or achieve trial endpoints in our current or future clinical trials;
- safety issues or adverse events in patients that enroll in our current or future clinical trials; and
- results in preclinical and clinical tests may not be repeated in subsequent tests or be predictive of future results.

In September 2021, we provided updates to the fully enrolled 24 patient Phase 1/2a open-label trial for OpRegen. Data presented showed that restoration of retinal tissue previously reported in three patients had been maintained for up to nine months in the two most recent restoration patients and for up to 33 months in the first case of restoration. These three patients exhibited optical coherence tomography (OCT) evidence of newly integrated RPE cells, and layers of retinal tissue (i.e., outer plexiform, outer nuclear layer, ellipsoid zone) in areas that previously showed no presence of these structures at baseline. All three of these patient's visual acuities increased above baseline levels within 6 months post-transplant. Overall, the best corrected visual acuity of the better vision Cohort 4 patients has improved or remained stable in 8/12 (67%) OpRegen treated eyes while decreasing in 9/12 (75%) of their respective fellow eyes. All of these patients are being closely monitored for additional evidence of clinical benefit.

Specifically, additional data presented showed that as patients continued to progress into post-operative follow-up, eyes receiving OpRegen trended toward improvement in visual acuity, a secondary objective under the study, while their untreated eyes typically lost visual acuity, as expected with this progressive disease. As additional patients have reached longer periods post-treatment, differences in visual acuity between treated and untreated eyes across Cohort 4 patients became statistically significant beginning at month 9 ($P = 0.0085$), as well as months 12 ($P = 0.0220$) and 15 ($P = 0.0273$) as determined via 2-sided Wilcoxon Signed Rank (using NCSS, LLC statistical software). These results, when combined with the OCT findings, suggest that both a structural and functional benefit is possible with OpRegen therapy. The totality of these findings supports the view that atrophic AMD is not an irreversible degenerative condition. OpRegen has been well tolerated with no unexpected adverse events, and evidence of durable engraftment of OpRegen RPE cells have extended to more than five years post-transplant in earliest treated patients. However, we do not know how OpRegen will perform in future clinical trials.

It is not uncommon to observe results in clinical trials that are unexpected based on preclinical trials and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. Moreover, preclinical and clinical data may be susceptible to varying interpretations and analyses. Several companies in the biotechnology industry have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

Further, as a result of the COVID-19 pandemic, if patients drop out of our clinical trials, miss scheduled doses or follow-up visits or otherwise fail to follow clinical trial protocols, or if our clinical trials are otherwise disrupted due to COVID-19 or actions taken to slow its spread, the integrity of data from our clinical trials may be compromised or not accepted by the FDA or other regulatory authorities, which would represent a significant setback for the applicable program.

Even if our current and planned clinical trials are successful, we will need to conduct 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, before we 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 to meet the requirements to support marketing approval for our product candidates in our ongoing and future clinical trials would substantially harm our business and prospects. For the foregoing reasons, our ongoing and planned clinical trials may not be successful, which could have a material adverse effect on our business, financial condition and results of operations.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our 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, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete 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 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 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 choose 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 determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine 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 that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Because we have multiple cell therapy programs in clinical development, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

We have three cell therapy programs in clinical development. OpRegen is currently in a Phase 1/2a multicenter clinical trial for the treatment of dry AMD, OPC-1 is currently in a Phase 1/2a clinical trial for subacute spinal cord injuries, and VAC2 is in a Phase 1 clinical trial in non-small cell lung cancer. As a result of these and other future clinical trials for these product candidates or any of our future product candidates it may make our decision as to which product candidates to focus on more difficult and we may forgo or delay pursuit of opportunities with other product candidates that could have had greater commercial potential or likelihood of success.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through future collaborations, licenses and other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

Additionally, we may pursue additional in-licenses or acquisitions of development-stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment.

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 we bring to the market may not gain market acceptance by such parties. The degree of market acceptance of any of our products 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 the disease and 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;
- the cost of treatment, particularly as additive to existing 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 authorities.

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 products 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 are smaller than we believe and estimate they are, we may not meet our revenue expectations and our business may suffer.

Our projections of the number of potential users in the markets we are attempting to address are based on our beliefs 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 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, any which could adversely affect our results of operations and our business.

Sales of the products we may develop will be adversely affected by the availability of competing products.

Our products and product candidates will face substantial competition, whether through the development of safer and more effective alternatives to our products, lower costs to administer than our products or other forms of competition such as more favorable distribution, reimbursement and pricing or formulary and healthcare provider acceptance.

The cell therapy industry is characterized by rapidly evolving technology and intense competition. Our competitors include major multinational pharmaceutical companies, specialty biotechnology companies, and chemical and medical products companies operating in the fields of regenerative medicine, cell therapy, tissue engineering, and tissue regeneration. Many of these companies are well established and possess technical, research and development, financial, and sales and marketing resources significantly greater than ours. In addition, certain smaller biotechnology companies have formed strategic collaborations, partnerships, and other types of joint ventures with larger, well-established industry competitors that afford the smaller companies' potential research and development as well as commercialization advantages. Academic institutions, governmental agencies, and other public and private research organizations are also conducting and financing research activities, which may produce products directly competitive to those we are developing.

We believe that some of our competitors are trying to develop pluripotent cells and human embryonic progenitor cell ("hEPC") based technologies and products that may compete with our stem cell products based on efficacy, safety, cost, and intellectual property positions. Ocata, which was acquired by a subsidiary of Astellas Pharma Inc., and Retinal Patch Technologies Inc. are conducting clinical trials of hES cell products designed to treat age-related macular degeneration. If their products are proven to be safe and effective, they may reach the market ahead of OpRegen.

We may also face competition from companies that have filed patent applications relating to the propagation and differentiation of stem cells. Those companies include Ocata, which in 2015 had certain U.S. patents issue with claims directed to methods of producing RPE cells and isolating and purifying such cells. We may be required to seek licenses from these competitors in order to commercialize certain products proposed by us, and such licenses may not be granted.

Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

We will face risks related to our own manufacturing capabilities and those related to our reliance on third parties to manufacture products, including those related to product acquisition costs, production delays, and supply shortages that could impair our ability to complete the development and commercialization of our product candidates.

The manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Although we have manufacturing capability through Cell Cure for OpRegen, OPC1, and VAC2 in Israel, we will need greater manufacturing capacity if we are to successfully commercialize our products. Unless we can raise the capital required to construct our own commercial scale manufacturing facilities and can develop the expertise to manage and operate a manufacturing facility of our own, we may need to rely on third-party manufacturers to manufacture any products we develop. There is no assurance that we will be able to identify manufacturers on acceptable terms or at all. Regardless of whether we do our own manufacturing or rely on third parties to manufacture products for us, we will face risks related to the manufacture of our products including these risks:

- We or any third-party manufacturers might not timely formulate and manufacture our products or produce the quantity and quality required to meet our clinical and commercial needs, if any.

- We or any third-party manufacturers may not execute our manufacturing procedures appropriately.

- Any third-party manufacturers we engage may not perform as agreed 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 our products on a commercial scale.

- We or any third-party manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP, and other government regulations and corresponding foreign standards. We will not have control over third-party manufacturers' compliance with applicable regulations and standards.

- We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates.

- We may not obtain licenses for third-party intellectual property rights needed by manufacturers to produce our products.

- Third-party manufacturers could breach or terminate their agreements with us.

- We or third-party manufacturers may experience manufacturing difficulties as a result of resource constraints, labor disputes, unstable political environments, natural disasters, public health crises such as pandemics and epidemics, political crises such as terrorism, war, political insecurity or other conflict, or other events outside of our or our third-party manufacturers control (including as a result of actual or threatened public health emergencies and outbreaks of disease such as the current COVID-19 pandemic). This may result in business closures that affect us and our third-party manufacturers.

In addition, we may rely on third parties to perform release testing on our product candidates prior to delivery to patients. If these tests are not appropriately conducted and test data are not reliable, patients could be put at risk of serious harm which could result in product liability suits.

If we or any third-party manufacturers we may engage were to encounter any of these difficulties, our ability to provide our product candidates to patients in clinical trials or to the medical marketplace would be jeopardized. 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 commence new clinical trials at additional expense or terminate clinical trials completely. Each risk could delay our clinical trials, any 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.

Any cell-based products that receive regulatory approval may be difficult and expensive to manufacture profitably.

Cell-based products are among the more expensive biologic products to manufacture in accordance with cGMP. We do not yet have sufficient information to reliably estimate the cost of commercially manufacturing any of our product candidates. Excessive manufacturing costs could make our product candidates too expensive to compete in the medical marketplace with alternative products manufactured by our competitors or might result in third party payors such as health insurers and Medicare, declining to cover our products or setting reimbursement levels too low for us to earn a profit from the commercialization of one or more of our products.

The ongoing COVID-19 pandemic has affected and may adversely affect our operations, including the conduct of our current or future clinical trials, as well as the operations of third-party partners on whom we rely.

In December 2019, a novel strain of coronavirus and the resulting illness known as COVID-19 emerged in Wuhan, China. The outbreak has now spread to other countries and has been declared a pandemic by the World Health Organization.

The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including a California executive order and several other state and local orders across the country, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. In response to these public health directives and orders, we have implemented work-from-home policies for our employees. The effects of the executive order, the shelter-in-place order and our work-from-home policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

As COVID-19 continues to impact the United States and Israel, we have experienced and may continue to experience disruptions that could adversely affect our operations and clinical trials, including:

- delays or difficulties in conducting follow-up visits with patients in our clinical trials, particularly patients for our OpRegen Phase 1/2a clinical trial, who are older and who may be at higher risk of complications from COVID-19;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and staff;
- diversion of healthcare resources away from the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel;
- limited availability of our employees and the staff of our current clinical sites due to sickness or social distancing measures;
- manufacturing difficulties for us and our suppliers of raw materials caused by business closures;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials will acquire COVID-19 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.

These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition. The extent to which the COVID-19 pandemic affects our operations will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the pandemic, and the actions that may be required to contain the COVID-19 pandemic or treat its impact.

Our clinical trials have been, and may in the future be, affected by the COVID-19 pandemic. In particular, some sites paused enrollment to focus on, and direct resources to, the COVID-19 pandemic or adhere to national or local guidelines, while at other sites, patients may decide not to enroll or continue participating in follow-up visits as part of the ongoing clinical trial, as a result of the pandemic. We are unable to predict with confidence the duration of such patient enrollment delays or missed study visits, as the COVID-19 pandemic continues or gets worse. If patient enrollment or study follow-up is delayed for an extended period of time, our clinical trials could be delayed or otherwise adversely affected. Our inability to enroll or follow a sufficient number of patients for any of our current or future clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether.

Our ongoing or planned clinical trials may also be impacted by interruptions or delays in the operations of the FDA and comparable foreign regulatory agencies.

In addition, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at our CROs or third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our product candidates. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the COVID-19 pandemic, our ability to continue meeting clinical supply demand for our product candidates or otherwise advancing development of our product candidates may become impaired.

The spread of COVID-19 and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other biotechnology companies have been volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common shares or such sales may be on unfavorable terms.

COVID-19 and actions taken to reduce its spread continue to rapidly evolve. The extent to which COVID-19 may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this ‘‘Risk Factors’’ section.

The withdrawal of the United Kingdom (the “U.K.”) from the EU, commonly referred to as “Brexit,” may adversely impact our ability to obtain regulatory approvals of our product candidates in the EU and the U.K., result in restrictions or imposition of taxes and duties for importing our product candidates into the EU and the U.K., and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU and the U.K.

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the EU, the U.K. was subject to a transition period until December 31, 2020 (the “Transition Period”) during which EU rules continued to apply. A trade and cooperation agreement (the “Trade and Cooperation Agreement”) that outlines the future trading relationship between the United Kingdom and the European Union provisionally applied from January 1, 2021, and formally entered into force on May 1, 2021.

Since a significant proportion of the regulatory framework in the U.K. applicable to our business and our product candidates is derived from EU directives and regulations, Brexit has had, and will continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU (to the extent any development or manufacture of our product candidates takes place in the U.K.). For example, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the European Medicines Agency and a separate process for authorization of drug products, including our product candidates, will be required in Great Britain. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the U.K. and restrict our ability to generate revenue and achieve and sustain profitability. For medical devices, such as Renevia, CE marking remains applicable in Northern Ireland and will continue to be recognized in the rest of the United Kingdom (i.e., Great Britain) until 30 June 2023. Any devices placed on the market in Great Britain must be registered with the MHRA. The United Kingdom has also adopted a new UK Conformity Assessment (“UKCA”), mark, which may be used in Great Britain on a voluntary basis until June 30, 2023 and will be mandatory thereafter. The requirements for the UKCA for medical devices are based on the requirements set out in the EU Medical Devices Directive (93/42/EEC), rather than the Medical Devices Regulation that applies in the European Union and has repealed the directive.

While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the U.K. and the EU, there may be additional non-tariff costs to such trade which did not exist prior to the end of the Transition Period. Further, should the U.K. diverge from the EU from a regulatory perspective, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to the position prior to the end of the Transition Period) to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the affected nations and the U.K.

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, 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 our clinical trials. In the event we commercialize Renevia in the EU or in other countries that recognize the CE Mark, we will also face product liability risks associated with the use of Renevia by consumers. 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.

The use or misuse of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, including Renevia, exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. There is a risk that our product candidates may induce adverse events. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- 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 commercialize our product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions; and
- decreased demand for our product candidates, if approved for commercial sale.

We believe our current product liability insurance coverage is appropriate in light of our clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to increase our insurance coverage to include the sale of commercial products; however, we may be unable to obtain 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 our stock price to decline and, if the amount of damages exceeds our insurance coverage, could adversely affect our results of operations and business.

Cell Cure has received Israeli government grants for certain of its research and development activities. The terms of these grants may require Cell Cure 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, Cell Cure will be required to pay penalties in addition to the repayment of the grants. Such grants are applied for on a yearly basis and may not be available or only partially granted in the future, which would increase our costs.

Cell Cure has received Israeli government grants for certain of its research and development activities. 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.

Under the Encouragement of Research, Development and Technological Innovation in the Industry Law 5744-1984 (formerly known as the Law for the Encouragement of Research and Development in Industry 5744-1984), and the regulations, guidelines, rules, procedures and benefit tracks thereunder (collectively, the "Innovation Law"), annual research and development programs that meet specified criteria and are approved by a committee of the IIA are eligible for grants. The grants awarded are 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. A company that receives a grant from the IIA (a "Grant Recipient"), is typically required to pay royalties to the IIA on income generated from products incorporating know-how developed using such grants (including income derived from services associated with such products) or on all revenues of the Grant Recipient (depending upon the terms of the approval letters issued by the IIA), until 100% of the U.S. dollar-linked grant plus annual LIBOR interest is repaid. In general, the rate of such royalties varies between 3% to 5%.

The obligation to pay royalties is contingent on actual revenues being generated from such products and services or actual revenues being generated by the Grant Recipient in general (as the case may be). In the absence of such revenues, no payment of royalties is required. It should be noted that the restrictions under the Innovation Law will continue to apply even after the repayment of such royalties in full by the Grant Recipient 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.

The terms of the grants under the Innovation Law also (generally) require that the products developed as part of the programs under which the grants were given be manufactured in Israel and that the know-how developed thereunder may not be transferred outside of Israel, unless prior written approval is received from the IIA (such approval is not required for the transfer of a portion of the manufacturing capacity which does not exceed, in the aggregate, 10% of the portion declared to be manufactured outside of Israel in the applications for funding (in which case only notification is required), and additional payments are required to be made to IIA). It should be noted that this does not restrict the export of products that incorporate the funded know-how.

The Innovation Law restricts the ability to transfer or license know-how funded by IIA outside of Israel. Transfer of IIA-funded know-how outside of Israel requires prior approval and is subject to approval and payment of a redemption fee, which can be substantial, to the IIA calculated according to the relevant formulas provided under the Innovation Law. A transfer or license for the purpose of the Innovation Law is generally interpreted very broadly and include, inter alia, any actual sale or assignment of the IIA-funded know-how, any license to further develop or otherwise exploit the IIA-funded know-how or the products resulting from such IIA-funded know-how or any other transaction, which, in essence, constitutes a transfer of the IIA-funded know-how. Generally, a mere license solely to market or distribute products resulting from the IIA-funded know-how would not be deemed a transfer or license for the purpose of the Innovation Law.

Part of Cell Cure's research and development efforts have been financed, partially, through grants that it has received from the IIA and when we acquired our holdings in Cell Cure, we undertook in writing, vis-à-vis the IIA, to abide by, and to ensure the abidance of Cell Cure to, the Innovation Law. We therefore must comply with the requirements of the Innovation Law and related regulations.

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 are obligated to pay the IIA a portion of the upfront, milestone, and royalty payments which may be received from Roche under the Roche Agreement. Lineage is obligated to pay approximately 24.3% of the upfront payment and any future payments it receives from Roche to the IIA, up to an aggregate cap on all payments to IIA, which currently stands at approximately $102.7 million. In January 2022, we received the $50.0 million upfront payment from Roche. We made a subsequent payment of $12.1 million to the IIA, pursuant to our obligations under the Innovation Law.

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

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

Cell Cure is our 99% owned subsidiary located in Jerusalem, Israel. OpRegen is currently manufactured at Cell Cure and we anticipate transitioning some or all of the manufacturing of OPC1 and VAC2 to Cell Cure as well. A portion of our OpRegen Phase 1/2a clinical trial has been conducted at sites in Israel. Conducting operations internationally involves a number of risks, including:

- difficulty in staffing and managing foreign operations;
- failure by us to obtain the appropriate regulatory approvals;
- logistics and regulations associated with shipping drug product or patient samples, including infrastructure conditions and transportation delays;
- financial risks, such as longer payment cycles and exposure to foreign currency exchange rate fluctuations;
- subject to tax on Global Intangible Low Tax Income ("GILTI") earned by foreign subsidiaries;
- political and economic instability, including wars, terrorism, and political unrest, 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, 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.

Our international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, production, pricing, reimbursement and marketing of tests, as well as by inter-governmental disputes. Any of these changes could adversely affect our business.

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 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.

Risks Related to our Intellectual Property

Our intellectual property may be insufficient to protect our products.

Our patents and patent applications are directed to compositions of matter, formulations, methods of use and/or methods of manufacturing, as appropriate. In addition to patenting our own technology and that of our subsidiaries, we have licensed patents and patent applications for certain stem cell technology, hEPC, and hES cell lines, hydrogel technology and other technology from other companies.

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

- the claims of any patents that are issued may not provide meaningful protection, may not provide a basis for commercially viable products or may not provide us with any competitive advantages;
- our patents may be challenged by third parties;
- others may have patents 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;
- the pending patent applications to which we have rights may not result in issued patents;
- our patents may have terms that are inadequate to protect our competitive position on our products;
- 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. As an example, Astellas' patent portfolio with respect to the manufacture of its RPE products could adversely impact our rights to manufacture OpRegen. Moreover, we could incur substantial costs in litigation if we have to defend ourselves in patent lawsuits brought by third parties or if we initiate such lawsuits.

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

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

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

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

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

A Patent Cooperation Treaty patent application related to OpRegen was filed on May 25, 2021, directed to the restoration of the anatomy or functionality of a retina with OpRegen. As with all patent applications, there is no certainty that this or any of our other pending or future patent applications will result in the issuance of patents.

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

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

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, to operate without infringing upon the proprietary rights of others, or, when necessary, our ability to obtain enabling licenses.

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

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

Risks Related to our Dependence on Third Parties

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

We may enter into various kinds of collaborative research and development and product marketing agreements to develop and commercialize our products. 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.

There is a risk we could become dependent upon one or more collaborative arrangements. A collaborative arrangement upon which we might depend might be terminated by our collaboration partner or a partner might determine not to actively pursue the development or commercialization of our products. A collaboration partner also may not be precluded from independently pursuing competing products and drug delivery approaches or technologies.

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

We do not have the ability to independently conduct clinical trials required to obtain regulatory approvals for our product candidates.

We will need to rely on third parties, such as CROs, data management companies, contract clinical research associates, medical institutions, clinical investigators and contract laboratories to conduct any clinical trials we may undertake for our product candidates. We may also rely on third parties to assist with preclinical development of our product candidates. If we outsource clinical trials, we may not directly control the timing, conduct and expense of our clinical trials. If we enlist third parties to conduct clinical trials and they fail to perform their contractual duties or regulatory obligations or fail to meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to failing to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not obtain regulatory approval for or successfully commercialize our product candidates.

In addition, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at these third parties, which could disrupt our clinical timelines, which could have a material adverse impact on our business, prospects, financial condition and results of operations.

We have relied on CIRM to fund past clinical trials of OPC1 and we do not know if they will provide additional funding for future studies of OPC1.

We received $14.3 million of funding from CIRM to support clinical development of OPC1. We intend to apply for additional CIRM grants, if available; however, we cannot provide any assurance that such grants will be awarded. If we are unable to obtain another CIRM grant, we will need to raise funds through other mechanisms to support future clinical studies of OPC1, which may take additional time and effort. If capital is not immediately available, this may force us to amend, delay, or discontinue the clinical trial and development work for OPC1 until funding is secured.

We may need to rely on marketing partners or contract sales companies.

If we are able to develop our product candidates and obtain necessary regulatory approvals, we may need to rely on marketing, selling or distributing partners. If we do not partner for commercial services, we will depend on our ability to build our own marketing, selling and distribution capabilities, which would require the investment of significant financial and management resources, or we will need to find collaborative marketing partners, sales representatives or wholesale distributors for the commercial sale of our products.

If we market products through arrangements with third parties, we may pay sales commissions to sales representatives or we may sell or consign products to distributors at wholesale prices. As a result, our gross profit from product sales may be lower than it would be if we sold our products directly to end users at retail prices through our own sales force. There can be no assurance we will be able to negotiate distribution or sales agreements with third parties on favorable terms to justify our investment in our products or achieve sufficient revenues to support our operations.

Risks Pertaining to Our Common Shares

Because we are engaged in the development of pharmaceutical and stem cell therapy products, the price of our common shares may rise and fall rapidly.

The market price of our common shares, like that of the shares of many biotechnology companies, has been highly volatile. The price of our common shares may rise rapidly in response to certain events, such as the commencement of clinical trials of an experimental new therapy, even though the outcome of those trials and the likelihood of ultimate FDA approval of a therapeutic product remain uncertain. Similarly, prices of our common shares may fall rapidly in response to certain events such as unfavorable results of clinical trials or a delay or failure to obtain FDA approval. For example, from January 1, 2021 through March 4, 2022 the closing price of our common shares has ranged between $1.26 and $3.10 per share. In addition, the failure of our earnings to meet analysts' expectations could result in a significant rapid decline in the market price of our common shares.

Because we do not 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 our common shares may not be a suitable investment for anyone who needs to earn income from their investments.

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

Our directors, executive officers and their affiliates, in the aggregate, owned approximately 24.5% of our outstanding common shares as of December 31, 2021. As a result, these shareholders, if acting together, will be able to heavily influence or control matters requiring approval by our shareholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree, and which may be averse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deter certain public investors from purchasing our common shares and might ultimately affect the market price of our common shares.

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

We and our subsidiaries may issue additional common shares or other securities convertible into or exercisable for common shares to raise additional capital or to hire or retain employees or consultants, or in connection with future acquisitions of companies or licenses to technology or rights, or for other business purposes. The future issuance of additional securities may be dilutive to our shareholders and may create downward pressure on the trading price of our common shares.

We are currently authorized to issue an aggregate of 252,000,000 shares of capital stock consisting of 250,000,000 common shares and 2,000,000 "blank check" preferred shares, which means we may issue, without shareholder approval, one or more series of preferred stock 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 stock and any qualifications, limitations or restrictions thereof, as our board of directors may determine. The terms of one or more series of preferred stock 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, 2021, Lineage had 169,477,347 common shares outstanding, 14,883,344 common shares reserved for issuance upon the exercise of outstanding options under our employee stock option plans, and 30,900 common shares reserved for issuance upon the vesting and settlement of restricted stock units under our equity incentive plan.

On May 1, 2020, Lineage entered into the Sales Agreement, pursuant to which Lineage may offer and sell, from time to time, through Cantor Fitzgerald, common shares of Lineage ("ATM Shares") having an aggregate offering price of up to $25.0 million. Lineage is not obligated to sell any ATM Shares. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald has agreed to use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations, and the rules of the NYSE American, to sell the ATM Shares from time to time based upon Lineage's instructions, including any price, time or size limits specified by Lineage. Under the Sales Agreement, Cantor Fitzgerald may sell the ATM Shares by any method deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or by any other method permitted by law, including in privately negotiated transactions. Cantor Fitzgerald's obligations to sell the ATM Shares are subject to satisfaction of certain conditions, including the continued effectiveness of Lineage's Registration Statement on Form S-3 (File No. 333-237975), which was filed with the Commission on May 1, 2020 and was declared effective on May 8, 2020. The Sales Agreement replaced the previous sales agreement with Cantor that had been entered into in April 2017.

On March 5, 2021, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of an additional $25.0 million of common shares under the Sales Agreement increasing the total offering to $50.0 million. As of December 21, 2021, $14.1 million remained available for sale under the Sales Agreement. On December 21, 2021, Lineage filed a prospectus supplement with the SEC in connection with the offering and sale of up to $64.1 million of common shares (the "New Sales Agreement"), with Cantor Fitzgerald as the sales agent, no additional sales will be made under the Sales Agreement. The $64.1 million under the New Sales Agreement which may be issued are registered pursuant to Lineage's effective shelf registration on Form S-3 (File No. 333-237975), as filed with the SEC on May 1, 2020 and declared effective on May 8, 2020 (the "May 2020 Registration Statement"), and Lineage's effective shelf registration statement on Form S-3 (File No. 333-254167), which was filed with the SEC on March 5, 2021 and declared effective on March 19, 2021. As of December 31, 2021, under the Sales Agreement, Lineage had issued 14,908,735 common shares at a weighted average price per share of $2.41 for gross proceeds of $35.9 million. As of December 31, 2021, under the New Sales Agreement, Lineage had issued 108,200 common shares at a weighted average price per share of $2.55 for gross proceeds of $0.3 million (which includes $0.2 million of cash in transit related to a 2021 transaction that settled in early 2022). As a result, as of December 31, 2021, $63.9 million remained available for issuance under the New Sales Agreement.

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 shareholder's ownership interests in our consolidated enterprise. Certain of our subsidiaries also have their own stock option plans and the exercise of stock options or the sale of restricted stock under those plans would also reduce our ownership interest in the applicable subsidiary, with a resulting dilutive effect on the ownership interest of our shareholders in our consolidated enterprise.

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 proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In addition, the CCPA imposes obligations on covered businesses. These obligations include, but are not limited to, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation) and includes a private right of action for certain data breaches. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. In addition, it is anticipated that the CPRA, effective January 1, 2023, will expand the CCPA. The CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other states have enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. In addition, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the EU GDPR and the UK GDPR impose strict requirements for processing personal data. Under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to processing of their personal data. In addition, Israel's PPL and the regulations promulgated thereunder impose certain obligations with respect to the manner personal data is processed. Under the PPL, government regulators may issue fines or sanctions.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EU or in other foreign jurisdictions). Existing mechanisms that facilitate cross-border personal data transfers may change or be invalidated. For example, absent appropriate safeguards or other circumstances, the EU GDPR generally restricts the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, that the European Commission does not consider to provide an adequate level of data privacy and security. The European Commission released a set of "Standard Contractual Clauses" ("SCCs"), that are designed to be a valid mechanism to facilitate personal data transfers out of the EEA to these jurisdictions. Currently, these SCCs are a valid mechanism to transfer personal data outside of the EEA, but there exists some uncertainty regarding whether the SCCs will remain a valid mechanism. Additionally, the SCCs impose additional compliance burdens, such as conducting transfer impact assessments to determine whether additional security measures are necessary to protect the at-issue personal data. In addition, 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, any of which could increase the cost and complexity of doing business.

If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expense.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations 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. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third-party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others.

If we fail, or are perceived to have failed, to address or comply with data privacy and security obligations, 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.

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 are increasingly 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). It is critical that we do so in a secure manner to maintain the confidentiality, integrity and availability of such 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 now engage and are expected to continue to engage in cyber-attacks, 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 cyber-attacks that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our products. We and the third parties upon which we rely may be subject to a variety of evolving threats, including, but not limited to, malware (including as a result of persistent threat intrusions), malicious code (such as viruses and worms), ransomware attacks, denial-of-service attacks (such as credential stuffing), social engineering attacks (including phishing attacks), personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other technology assets, adware, telecommunication failures, earthquakes, fires, floods, and other similar threats. Although the aggregate impact on our operations and financial condition has not been material to date, we have been the target of events of this nature and expect them to continue.

Ransomware attacks, including by organized criminal threat actors, nation-states, and nation-state-supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. 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. Additionally, the COVID-19 pandemic and our remote workforce poses increased risks to our information technology systems and data, as more of our employees work from home, utilizing network connections outside our premises. Moreover, the prevalent use of mobile devices to access confidential information increase 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. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our 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.

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, industry-standard or reasonable security measures to protect our information technology systems 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 security incidents 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 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); 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 data for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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. Operating our business through subsidiaries, some of which are located in foreign countries, 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 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 Securities and Exchange Commission, and other regulatory authorities, which could require additional financial and management resources.

Current economic and stock market conditions may adversely affect the price of our common shares.

The stock market has been experiencing extreme price and volume fluctuations which have affected the market price of the equity securities without regard to the operating performance of the issuing companies. Broad market fluctuations, as well as general economic, political and other conditions (such as the recent coronavirus outbreak), may adversely affect the market price of our common shares.

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 stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. 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 team 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 business 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 business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the 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 our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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. There is no guarantee that securities analysts will cover our common shares. If securities analysts do not cover our common shares, the lack of research coverage may adversely affect the market price of those shares. If securities analysts do cover 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 prices could decline as a result of the report. If one or more of these analysts does not initiate coverage, ceases to cover our common shares or fails to publish regular reports on our business, we could lose visibility in the financial markets, which could cause our share prices or trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

General

In general, we believe that our properties are well-maintained, adequate and suitable for their current requirements and for our operations in the foreseeable future. See Note 14 to our consolidated financial statements included elsewhere in this Report.

Lineage Facilities

Our corporate headquarters comprise 8,841 square feet of rentable space in an office park in Carlsbad, California. We also sublease 2,432 square feet of space in Alameda, California.

Cell Cure Facilities

Cell Cure leases 728.5 square meters (approximately 7,842 square feet) of office and laboratory space in the Bio Park on the campus of the Hadassah University Hospital in Jerusalem, Israel under a lease that expires on December 31, 2025. We have an option to extend the term for an additional 5 years.

In January 2018, Cell Cure entered into another lease for an additional 934 square meters (approximately 10,054 square feet) of office space in the same facility in Jerusalem, Israel under a lease that expires on December 31, 2025, with two five-year extension options. The term of this lease commenced on April 1, 2018 and includes a leasehold improvement construction allowance of up to NIS 4,000,000 (approximately up to $1.1 million) from the landlord. The leasehold improvements were substantially completed by December 31, 2018 and the construction allowance was fully utilized.

In November 2021, Cell Cure entered into a lease agreement for an additional 133 square meters (approximately 1,432 square feet) of office space in the same facility in Jerusalem, Israel under a lease that expires on December 31, 2025, with one five-year and one approximate three-year extension options (the “November 2021 Lease”), the term of this lease commenced on December 1, 2021.

ITEM 3. LEGAL PROCEEDINGS

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. Except as described below, we are not currently subject to any pending material litigation, other than ordinary routine litigation incidental to our business, as described above.

On October 14, 2019, a putative class action lawsuit was filed challenging the Asterias Merger. This action (captioned *Ross v. Lineage Cell Therapeutics, Inc., et al.*, C.A. No. 2019-0822) was filed in Delaware Chancery Court and names Lineage, the Asterias board of directors, one member of Lineage's board of directors, and certain stockholders of both Lineage and Asterias as defendants. The action was brought by a purported stockholder of Asterias, on behalf of a putative class of Asterias stockholders, and asserts breach of fiduciary duty and aiding and abetting claims under Delaware law. The complaint alleges, among other things, that the process leading up to the Asterias Merger was conflicted, that the Asterias Merger consideration was inadequate, and that the proxy statement filed by Asterias with the Commission omitted certain material information, which allegedly rendered the information disclosed materially misleading. The complaint seeks, among other things, that a class be certified, the recovery of monetary damages, and attorneys' fees and costs. On December 20, 2019, the defendants moved to dismiss the complaint. On February 10, 2020, the plaintiff filed an opposition. Defendants filed their replies on March 13, 2020. On June 23, 2020, a hearing on the motions to dismiss occurred. On September 21, 2020, the Chancery Court denied the motion to dismiss as to Lineage and certain members of the Asterias board of directors, and it granted the motion to dismiss as to all other defendants. On October 30, 2020, the remaining defendants filed an answer to the complaint. The parties are currently engaged in discovery. A five-day trial before the Chancery Court is currently scheduled for October 17-21, 2022.

Lineage believes the allegations in the action lack merit and intends to vigorously defend the claims asserted. It is impossible at this time to assess whether the outcome of this proceeding will have a material adverse effect on Lineage's consolidated results of operations, cash flows or financial position.

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 trade on the NYSE American and on the Tel Aviv Stock Exchange under the ticker symbol LCTX.

Holders

As of March 1, 2022, there were 375 record holders of our common shares. The number of beneficial owners 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 dividends on our common shares. We currently intend to retain any earnings for use in the operations of our business. We, therefore, do not anticipate paying cash dividends on our common shares in the foreseeable future.

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 Securities and Exchange Commission, during the year ended December 31, 2021, there were no unregistered sales of equity securities by us during the year ended December 31, 2021.

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, 2021, 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, 2021 as compared to the year ended December 31, 2020. 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

Lineage Cell Therapeutics, Inc. ("Lineage," "we," "us," or "our") is a clinical-stage biotechnology company developing novel cell therapies to address unmet medical needs. Our programs are based on our proprietary cell-based technology and associated development and manufacturing capabilities. From this platform, we design, develop, and manufacture specialized human cells with anatomical and physiological functions which are similar or identical to cells found naturally in the human body. These cells which we manufacture are created by developmental differentiation protocols applied to established and well-characterized, pluripotent, and self-renewing cell lines. These functional cells are transplanted into patients to either replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury, or are administered as a means of helping the body mount a more robust and effective immune response to cancer or infectious diseases.

Our strategy is to efficiently leverage our technology platform and manufacturing capabilities to develop and advance our programs internally or in conjunction with strategic partners to further enhance their value. As one example, on December 17, 2021, we entered into a Collaboration and License Agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively, "Roche"), wherein Lineage granted to Roche exclusive worldwide rights to develop and commercialize retinal pigment epithelium cell therapies, including its proprietary cell therapy known as OpRegen®, for the treatment of ocular disorders, including advanced dry age-related macular degeneration with geographic atrophy. Roche has paid Lineage a $50.0 million upfront payment under this alliance and Lineage is eligible to receive up to an additional $620.0 million in certain developmental, regulatory, and commercialization milestone payments. Lineage also is eligible for tiered double-digit percentage royalties on net sales of OpRegen.

Currently, Lineage is working with Roche in support of the dry age-related macular degeneration (OpRegen) program and is clinically testing therapies to treat spinal cord injuries and non-small cell lung cancer, as well as conducting research and preclinical development activities intended to advance our pipeline into other therapeutic indications and target tissues or organs.

Product Candidates & Other Programs

We have several allogeneic, or "off-the-shelf," cell therapy programs in development:

- *OpRegen®*, a retinal pigment epithelium ("RPE") cell replacement therapy currently in a Phase 1/2a multicenter clinical trial for the treatment of advanced dry age-related macular degeneration ("AMD") with geographic atrophy ("GA") (also known as atrophic AMD). There are currently no therapies approved by the U.S. Food and Drug Administration ("FDA") for dry AMD. As of December 17, 2021 this program has been partnered with Roche for further clinical development and commercialization.

- *OPC1*, an oligodendrocyte progenitor cell therapy currently in long-term follow-up for a Phase 1/2a multicenter clinical trial for spinal cord injuries ("SCI"). This clinical trial has been partially funded by the California Institute for Regenerative Medicine ("CIRM").

- *VAC*, an allogeneic cancer immunotherapy of antigen-presenting dendritic cells. One of the VAC product candidates, VAC2, is currently in a Phase 1 clinical trial in non-small cell lung cancer (NSCLC). This clinical trial is being funded and conducted by Cancer Research UK, one of the world's largest independent cancer research charities. We also have another VAC-based product candidate in preclinical development with our partner, Immunomic Therapeutics, Inc. ("ITI"), for the treatment of glioblastoma multiforme ("GBM").

- *Other.* We have other product candidates in preclinical development covering a range of therapeutic areas and target tissues or organs. Generally, these candidates are based on the same pluripotent platform technology and employ a similar guided cell differentiation and transplant approach as our current clinical-stage products.

In addition to seeking to create value for shareholders by developing product candidates and other technologies through our clinical development programs, we also seek to create value from our technologies through partnering and strategic transactions. We founded two companies that later became publicly traded companies: OncoCyte Corporation ("OncoCyte") and AgeX Therapeutics, Inc. ("AgeX"). We continue to hold common stock in OncoCyte as of December 31, 2021.

During the year ended December 31, 2021, we received approximately $10.1 million in gross proceeds in connection with our sale of shares of OncoCyte. In August 2020, we also received $24.6 million from Juvenescence Limited ("Juvenescence"), representing principal and accrued interest under a promissory note we received in connection with our sale of AgeX shares to Juvenescence in August 2018.

Critical Accounting Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates and assumptions that affect the reported amounts in our consolidated financial statements and related notes. Our significant accounting policies are described in Note 2 to our consolidated financial statements included elsewhere in this Report. 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 going concern assessment of our consolidated financial statements, useful lives associated with long-lived assets, including evaluation of asset impairment, allowances for uncollectible accounts and financing receivables, valuing shares owned in nonconsolidated companies using the equity method of accounting, loss contingencies, deferred income taxes and tax reserves, including valuation allowances related to deferred income taxes, and assumptions used to value stock-based awards, debt or other equity instruments. Actual results could differ materially from those estimates. On an ongoing basis, we evaluate our estimates compared to historical experience and trends which form the basis for making judgments about the carrying value of assets and liabilities. To the extent that there are material differences between our estimates and our actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

We believe the assumptions and estimates associated with the following have the greatest potential impact on our consolidated financial statements.

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 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 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.

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 may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term. Lease expense for finance lease payments is recognized as amortization of ROU assets and related interest. Operating and finance leases are included as right-of-use assets in property and equipment, and ROU lease liabilities, current and long-term, in the consolidated balance sheets. We disclose the amortization of our ROU assets and operating lease payments as a net amount, "Amortization of ROU assets", on the consolidated statement of cash flows.

Going concern assessment – In accordance with Accounting Standards Update 2014-15, *Presentation of Financial Statements – Going Concern*, we assess going concern uncertainty in our consolidated financial statements to determine if we have sufficient cash and cash equivalents on hand and working capital to operate for a period of at least one year from the date our consolidated financial statements are issued or are available to be issued, which is referred to as the "look-forward period" as defined by ASU No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to us, we will consider various scenarios, forecasts, projections, and estimates, and we will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and our ability to delay or curtail those expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we make certain assumptions concerning our ability to curtail or delay research and development programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period in accordance with ASU 2014-15.

Revenue recognition - Lineage recognizes revenue in accordance with Financial Accounting Standards Board ("FASB") ASU 2014-09, *Revenues from Contracts with Customers (Topic 606)*, and in a manner that depicts the transfer of control of a product or a service to a customer and reflects the amount of the consideration it is entitled to receive in exchange for such product or service. In doing so, Lineage follows a five-step approach: (i) identify the contract with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations; and (v) recognize revenue when (or as) the customer obtains control of the product or service. Lineage considers the terms of a contract and all relevant facts and circumstances when applying the revenue recognition standard. Lineage applies the revenue recognition standard, including the use of any practical expedients, consistently to contracts with similar characteristics and in similar circumstances. As part of the accounting treatment for these contracts, we must develop estimates and assumptions that require judgement to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations.

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

Collaborative agreements - We review collaborative agreements to determine if the accounting treatment falls under Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), or Accounting Standards Codification *Topic 808, Collaborative Arrangements* ("ASC 808"). While these agreements may be within the scope of ASC 808, we may analogize to ASC 606 for some aspects of the agreements.

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 goals; (iii) royalties on net sales of licensed products; and (iv) reimbursement of cost-sharing of 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 arrangement, 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 judgement to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. The following items are estimated in the calculation of the stand-alone selling price: forecasted revenues and development costs, development timelines, discount rates and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if they can be satisfied at a point in time or over time, and we measure the services delivered to our collaboration partners each reporting period, which is based on the progress of the related program. If necessary, we adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis which would affect revenue and net income (loss) in the period of adjustment. In addition, variable consideration (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 condensed consolidated statements of operations.

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

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

Research and development – Research and development expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct and 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 which have an alternative future use will be capitalized as tangible assets, and 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. Royalty expenses or sublicensing fees are recorded as research and development costs, unless these costs are associated with royalties from product sales, which we classify as cost of sales on our consolidated statements of operations. We estimate preclinical, clinical, and other research related expenses based on services performed, pursuant to arrangements with contract research organizations, that conduct studies and research on our behalf. We estimate these expenses based on regular reviews with internal management personnel and external service providers as to the progress or stage of completion of services and the contracted fees to be paid for such services. Based upon the combined inputs of internal and external resources, if the actual timing of the performance of services or the level of effort varies from the original estimates, we will adjust the accrual accordingly.

Stock-based compensation – We follow accounting standards governing share-based payments, which require the measurement and recognition of compensation expense for all share-based compensation awards made to directors and employees, including employee stock options, based on estimated fair values. We utilize the Black-Scholes option pricing model. Our determination of fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, expected stock price volatility over the term of the awards, and 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. The risk-free rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities similar to the expected term of the awards. Forfeitures are accounted for as they occur.

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

In management's opinion, the existing valuation models may not provide an accurate measure of the fair value of employee stock options because the option-pricing model value may not be indicative of the fair value that would be established in a willing buyer/willing seller market transaction.

Income taxes – We account for income taxes in accordance with ASC 740, *Income Taxes*, which prescribe the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. ASC 740 guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. We file a U.S. federal income tax return as well as various state 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. We recognize 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, 2021 and 2020.

Principles of consolidation – Our consolidated financial statements include the accounts of our wholly owned and majority-owned subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation. The consolidated financial statements are presented in accordance with accounting principles generally accepted in the U.S. and with the accounting and reporting requirements of SEC Regulation S-X.

Results of Operations

Comparison of Years Ended December 31, 2021 and 2020

Revenues

The following table shows our revenues for the years ended December 31, 2021 and 2020 (amounts in thousands except percentages).

	Year Ended December 31,		$ Increase/	% Increase/
	2021	2020	(Decrease)	(Decrease)
Royalties	$ 2,776	$ 773	$ 2,003	259%
Collaboration revenues	1,120	-	1,120	100%
Grant revenues	445	1,053	(608)	(58)%
Total revenues	4,341	1,826	2,515	138%
Cost of sales	(1,426)	(385)	(1,041)	270%
Gross profit	$ 2,915	$ 1,441	$ 1,474	102%

Total revenues for the year ended December 31, 2021 were $4.3 million compared to $1.8 million for the year ended December 31, 2020. The increase of $2.5 million is primarily due to a $2.0 million increase in royalties, a $1.1 million increase in collaboration revenues from our collaboration agreements with Roche and ITI, offset by a $0.6 million decrease in grant revenues due to less grant-related activities during the year.

Our royalties are derived from product sales and license fees. For the year ended December 31, 2021 royalties were $2.0 million higher compared to the prior year, primarily due to additional royalty revenues of $1.8 million from a certain royalty customer, based on the customer's updated communication to us regarding royalties due. Consequently, Lineage also recorded 50% of these additional royalties in cost of sales during the year.

Grant revenues are generated primarily by our subsidiary Cell Cure Neurosciences Ltd ("Cell Cure") from the Israel Innovation Authority ("IIA") for the development of OpRegen and our bio retina program, and previously from a Small Business Innovation Research grant from the National Institutes of Health for our vision restoration program (the "NIH Grant"). The decreases in our grant revenues for the year ended December 31, 2021 as compared to the year ended December 31, 2020, were primarily due to less grant-related activities. Grant revenues generated by Cell Cure from the IIA for the development of OpRegen and our bio retina program amounted to $0.4 million and $0.7 million for the years ended December 31, 2021 and 2020, respectively, and grant revenues generated by the NIH Grant amounted to $0.4 million for the year ended December 31, 2020.

Operating Expenses

The following table shows our operating expenses for the years ended December 31, 2021 and 2020 (amounts in thousands, except percentages).

	Year Ended December 31,		$	%
	2021	2020	Increase	Increase
Research and development expenses	$ 33,914(1)	$ 12,317	$ 21,597	175%
General and administrative expenses	18,212	15,571	2,641	17%

(1) Includes $21.0 million of royalty and redemption fee expense to Hadasit Medical Research and Development Ltd. ("Hadasit") and the IIA, respectively, pursuant to Lineage's financial obligations related to the Roche Agreement (see Note 14), in connection with the receipt of the $50.0 million upfront payment received from Roche.

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 and 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 which have an alternative future use will be capitalized as tangible assets, and 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. Royalty expenses or sublicensing fees are recorded as research and development costs, unless these costs are associated with royalties from product sales, which we classify as cost of sales on our consolidated statements of operations.

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, (unaudited)			
	Amount		Percent of Total	
Program	**2021**	**2020**	**2021**	**2020**
OpRegen® and other ophthalmic applications	$ 25,507	$ 5,569	75%	45%
OPC1	6,145	3,958	18%	32%
VAC platform	2,178	2,472	6%	20%
All other programs	84	318	1%	3%
Total research and development expenses	$ 33,914	$ 12,317	100%	100%

Research and development expenses for the year ended December 31, 2021 were $33.9 million as compared to $12.3 million for the year ended December 31, 2020. The increase of $21.6 million is mainly attributable to the following:

- an increase of $19.9 million in OpRegen, attributable primarily to a $12.1 million redemption fee to the IIA and a royalty expense of $8.9 million to Hadasit, related to Lineage's financial obligations related to the Roche Agreement (see Note 14), in connection with receipt of the $50.0 million upfront payment received from Roche.
- an increase of $2.2 million in OPC1 related expenses, primarily related to an increase in manufacturing and development activities for this program, and a return of unspent project funds of approximately $0.8 million in the prior year from a former Asterias service provider,
- a net decrease of $0.3 million in the VAC program expenses, primarily driven by the prior year signature fee accrual of $1.6 million to Cancer Research UK related to our license agreement, substantially offset with increased manufacturing activities in the current year, as well as activities to support the ITI collaboration agreement, and
- a net decrease of $0.2 million in Renevia and related expenses due to a reduction in research activities.

General and administrative expenses

General and administrative expenses include employee and director compensation allocated to general and administrative expenses, consulting fees other than those paid for science-related consulting, facilities and equipment rent and maintenance related expenses, insurance costs allocated to general and administrative expenses, costs of patent applications, prosecution and maintenance, stock exchange-related costs, depreciation expense, marketing costs, board fees, legal and accounting costs, and other miscellaneous expenses which are allocated to general and administrative expense.

General and administrative expenses for the year ended December 31, 2021 were $18.2 million as compared to $15.6 million for the year ended December 31, 2020. The total net increase of $2.6 million was primarily attributable to a $0.9 million increase in share-based compensation expense, a $0.7 million increase in litigation and other expenses related to Lineage's merger with Asterias, a $0.6 million increase in legal and patent expenses, a $0.3 million increase in payroll and related benefits, a $0.3 million increase in investor relations expenses, a $0.2 million increase in consulting expense, partially offset with a $0.4 million reduction in rent and utilities.

Other income and expenses, net

The following table shows the amount of other income, net, during the year ended December 31, 2021 and 2020 (in thousands):

	Year Ended December 31,	
	2021	**2020**
Other income, net		
Interest income, net	$ 2	$ 1,039
Gain on sale of marketable equity securities	6,024	4,560
Gain on extinguishment of debt	523	-
Unrealized loss on marketable equity securities	(2,299)	(3,782)
Unrealized gain (loss) on warrant liability	205	(174)
Other income, net	1,486	2,880
Total other income, net	$ 5,941	$ 4,523

Interest income and expense, net - During the year ended December 31, 2020, we earned $1.0 million of interest income from our promissory note with Juvenescence.

Marketable equity securities - As of December 31, 2021, Lineage owned 1.1 million shares of OncoCyte common stock. These shares had a fair value of $2.4 million, based on the closing price of OncoCyte common stock of $2.17 per share on December 31, 2021. As of December 31, 2020, Lineage owned 3.6 million shares of OncoCyte common stock. These shares had a fair value of $8.7 million, based on the closing price of OncoCyte common stock of $2.39 per share on December 31, 2020.

For the year ended December 31, 2021, Lineage recorded a realized gain of $6.0 million due to sales of OncoCyte shares in the year. Lineage recorded a net unrealized loss on marketable equity securities of $2.2 million related to changes in fair market value of OncoCyte's common stock price during the year. For the year ended December 31, 2020, Lineage recorded a realized gain of $3.1 million due to sales of OncoCyte shares in the period. Lineage also recorded an unrealized loss on marketable equity securities of $2.5 million related to changes in fair market value of OncoCyte's common stock price during the year. All share prices are determined based on the closing price of OncoCyte common stock on the NYSE American on the applicable dates, or the last day of trading of the applicable quarter, if the last day of a quarter fell on a weekend.

We expect our other income and expenses, net, to continue to fluctuate each reporting period based on the changes in the market price of our OncoCyte shares, which could significantly impact our net income or loss reported in our condensed consolidated statements of operations for each period.

We account for the shares we hold in Hadasit Bio-Holdings Ltd ("HBL") as marketable equity securities as of December 31, 2021. These securities were carried at fair market value on our consolidated balance sheets, and the accounting transactions for the year ended December 31, 2021, were not material. For the year ended December 31, 2021, we did not hold any marketable securities related to AgeX.

For the year ended December 31, 2020, Lineage recorded realized gains of $0.8 million and $0.6 million due to sales of AgeX shares and HBL shares, respectively, in the period. For the year ended December 31, 2020, we recorded unrealized losses of $1.3 million, due to changes in fair market value of AgeX's common stock price during the period.

Gain on extinguishment of debt – For the year ended December 31, 2021, Lineage recognized a gain of $0.5 million on extinguishment of debt related to the Paycheck Protection Program ("PPP") loan from Axos Bank. Lineage applied for forgiveness on the PPP loan on September 30, 2020, and on May 13, 2021, received notice that the PPP loan was forgiven in full.

Other income, net – Other income, net, in 2021 and 2020 consist primarily of net foreign currency transaction gains recognized by Cell Cure and ESI, and changes in the fair value of the Cell Cure liability classified warrants. Foreign currency transaction gains for the periods presented are principally related to the remeasurement of the U.S. dollar denominated notes payable by Cell Cure to Lineage.

Income Taxes

The market value of the shares of OncoCyte common stock we hold creates a deferred tax liability based on the closing prices of the shares, less our tax basis in the shares. The deferred tax liability generated by the OncoCyte shares that we hold as of December 31, 2021, is a source of future taxable income to us, as prescribed by ASC 740-10-30-17, that will more likely than not result in the realization of our deferred tax assets to the extent of the deferred tax liability. This deferred tax liability is determined based on the closing prices of the OncoCyte shares as of December 31, 2021. Due to the inherent unpredictability of future prices of those shares, we cannot reliably estimate or project those deferred tax liabilities on an annual basis. Therefore, the deferred tax liability pertaining to OncoCyte shares, determined based on the actual closing prices on the last stock market trading day of the applicable accounting period, and the related impacts to the valuation allowance and deferred tax asset changes, are recorded in the accounting period in which they occur.

In connection with the Asterias Merger, a deferred tax liability of $10.8 million was recorded as part of the acquisition accounting. The deferred tax liability ("DTL") is related to fair value adjustments for the assets and liabilities acquired in the Asterias Merger, principally consisting of IPR&D. This estimate of deferred taxes was determined based on the excess of the estimated fair values of the acquired assets and liabilities over the tax basis of the assets and liabilities acquired. The statutory tax rate was applied, as appropriate, to the adjustment based on the jurisdiction in which the adjustment is expected to occur. Because the IPR&D (prior to completion or abandonment of the R&D) is considered an indefinite-lived asset for accounting purposes, the fair value of the IPR&D on the acquisition date creates a deferred income tax liability in accordance with ASC 740. This DTL is computed using the fair value of the IPR&D assets on the acquisition date multiplied by Lineage's respective federal and state income tax rates. While this DTL would reverse on impairment or sale or commencement of amortization of the related intangible assets, those events are not anticipated under ASC 740 for purposes of predicting reversal of a temporary difference to support the realization of deferred tax assets, except for certain deferred tax assets and credit carryforwards that are also indefinite in nature as of the Asterias Merger date, which may be considered for reversal under ASC 740 as further discussed below.

We have concluded that an ownership change did occur after the Asterias Merger, and the acquired net operating loss carryforwards are subject to limitation under Section 382 of the Internal Revenue Service Code; Lineage will only be able to utilize $52.8 million and $41.9 million of their federal and California net operating losses, respectively, as of December 31, 2021.

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. Lineage established a full valuation allowance as of December 31, 2018 due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets, including foreign net operating losses generated by its subsidiaries. For the year ended December 31, 2021, Lineage did not record a tax provision or deferred tax benefit.

For the year ended December 31, 2020, Lineage recorded a $1.2 million deferred tax benefit for income taxes.

We expect that deferred income tax expense or benefit we record each reporting period, if any, will vary depending on the change in the closing stock prices of OncoCyte shares from period to period and the related changes in those deferred tax liabilities and our deferred tax assets and other credits, including changes in the valuation allowance, for each period.

Liquidity and Capital Resources

At December 31, 2021, we had $58.4 million of cash, cash equivalents and marketable equity securities on hand, which includes our investments in OncoCyte and HBL. We may use our marketable equity securities for liquidity, as necessary, and as market conditions allow. The market value may not represent the amount that could be realized in a sale of investment shares due to various market and regulatory factors, including trading volume or market depth factors and volume and manner of sale restrictions under Federal securities laws, 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 equity securities may be significantly and adversely impacted by deteriorating global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

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, AgeX and OncoCyte, payments from research grants, royalties from product sales and sales of research products and services. At December 31, 2021, we had an accumulated deficit of approximately $337.1 million, working capital of $64.4 million and shareholders' equity of $90.9 million. We evaluated the projected cash flows for Lineage and our subsidiaries, and we believe that our $58.4 million in cash, cash equivalents and marketable equity securities at December 31, 2021, provide sufficient cash, cash equivalents, and liquidity to carry out our current 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 the longer-term expected future cash requirements and obligations, through our current cash and cash equivalents, milestone and other payments under our collaborative agreements, and our available capacity on the At-the-Market ("ATM") program (see Note 11). We may, in the future, sell marketable securities, including additional equity, to fund additional working capital, capital expenditures, or for other general purposes. Our cash flows are dependent on a number of factors in addition to our operational results, including our contractual obligations. We are obligated to make the following material rent payments under the terms of our operating leases at our Cell Cure facilities. We have three leases which aggregate to 1,796 rentable square meters (approximately 19,328 square feet) of office and laboratory space in Jerusalem, Israel, the leases all expire in December 2025. Total remaining rent payments due are $2.4 million, of which $0.5 million is due in 2022. See Note 14, for additional details on our contractual obligations.

In January 2022, Lineage received a $50.0 million upfront payment related to the Roche Agreement. Lineage made a subsequent payment of $12.1 million to the IIA, pursuant to Lineage's obligations under the Innovation Law. Additionally, Lineage made a subsequent payment of $8.9 million to Hadasit, pursuant to Lineage's obligations under the Second Amended and Restated License Agreement. See Note 14 for a description of the Roche Agreement and related payment obligations.

The COVID-19 pandemic previously impacted patient enrollment in our OpRegen Phase 1/2a multicenter clinical trial and is currently affecting the VAC2 Phase 1 multicenter clinical trial. In particular, we saw sites pause enrollment to focus on, and direct resources to, the COVID-19 pandemic or adhere to national or local guidelines. Additionally, currently enrolled patients may decide not to enroll or continue participating in follow-up visits as part of the ongoing clinical trials, as a result of the pandemic. At this point in time, the majority of our sites are back to normal daily operations. However, we are unable to predict with confidence if there will be future patient enrollment delays or missed study visits as the COVID-19 pandemic continues or gets worse. If patient enrollment or study follow-up is delayed for an extended period of time, our clinical trials could be delayed or otherwise adversely affected. Additionally, an inability to enroll or follow a sufficient number of patients for any of our current or future clinical trials could result in significant delays.

Our projected cash flows are subject to various risks and uncertainties, and the unavailability or inadequacy of financing to meet future capital needs could force us to modify, curtail, delay, or suspend some or all aspects of our current planned operations. Our determination as to when we will seek new financing and the amount of financing that we will need will be based on our evaluation of the progress we make in our research and development programs, any changes to the scope and focus of those programs, any changes in grant funding for certain of those programs, and projection of future costs, revenues, and rates of expenditure. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. We may be required to delay, postpone, or cancel our clinical trials or limit the number of clinical trial sites, unless we are able to obtain adequate financing. We cannot assure that adequate financing will be available on favorable terms, if at all. Sales of additional equity securities by us or our subsidiaries and affiliates could result in the dilution of the interests of our current shareholders.

Cash used in operating activities

Net cash used in operating activities of $23.6 million for the year ended December 31, 2021 primarily reflects the loss from operations of $49.2 million adjusted for the changes in assets and liabilities of $21.1 million. These items were offset primarily by non-cash expenses of $3.5 million for stock-based compensation and $0.9 million of depreciation and amortization. The unrealized loss on marketable securities, and foreign currency remeasurement are non-cash items that had no effect on cash flows.

Net cash used in operating activities of $19.8 million for the year ended December 31, 2020 primarily reflects the loss from operations of $26.4 million adjusted for the changes in assets and liabilities of $1.3 million. These items were offset primarily by non-cash expenses of $2.2 million for stock-based compensation and $2.1 million of depreciation and amortization. The unrealized loss on marketable securities, foreign currency remeasurement and deferred tax benefit are non-cash items that had no effect on cash flows.

Cash used in investing activities

Cash provided by investing activities of $9.7 million for the year ended December 31, 2021 was associated primarily with receipts of $10.1 million from sales of a portion of our OncoCyte holdings, offset with the purchase of equipment for $0.4 million.

Cash provided by investing activities of $13.0 million for the year ended December 31, 2020 was associated primarily with receipts of $10.9 million from sales of a portion of our OncoCyte holdings, $1.3 million in sales of our AgeX holdings and $0.8 million in sales of a portion of our HBL holdings.

Cash provided by financing activities

Cash provided by financing activities of $36.9 million for the year ended December 31, 2021 was associated primarily with proceeds net of financing costs of $29.8 million from the sale of common shares in at-the-market offerings under our Controlled Equity Offering^{SM} Sales Agreement with Cantor Fitzgerald & Co. and proceeds of $7.2 million from the exercise of employee stock options.

Cash provided by financing activities of $29.9 million for the year ended December 31, 2020 was associated primarily with proceeds of $24.6 million from payment of the Juvenescence promissory note, gross proceeds of $5.1 million from sales of our common shares (which excludes $0.3 million of cash in transit related to 2020 sales that settled in 2021), and proceeds of $0.5 million from a PPP loan under the Coronavirus Aid, Relief, and Economic Security Act, all offset by $0.4 million in financing costs.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

See accompanying notes to consolidated financial statements.

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Lineage Cell Therapeutics, Inc. and Subsidiaries (collectively, the "Company") as of December 31, 2021, the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity, and cash flows for the year ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021, and the results of its operations and its cash flows for the year ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

The consolidated financial statements of the Company as of and for the year ended December 31, 2020 were audited by OUM & Co. LLP, who joined WithumSmith+Brown, PC on July 15, 2021, and rendered their opinion on such statements on March 11, 2021.

Basis for Opinion

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

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

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

Critical Audit Matter

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

Accounting for revenue and collaboration agreements

Description of the Matter

The Company recorded deferred revenue and revenue from collaboration agreements of $50.4 million and $1.1 million, respectively, as of and for the year ended December 31, 2021. As described in Note 2, the terms of the Company's collaboration agreements may include 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. Amounts received under these arrangements typically include nonrefundable upfront payments and license fees, research funding, milestone and other contingent payments for the achievement of defined collaboration objectives and certain preclinical, clinical, regulatory and sales-based events, as well as royalties on sales of any commercialized products.

Auditing the Company's accounting for revenues from collaboration arrangements was complex and required significant judgments primarily in identifying which elements represent revenue producing performance obligations, determining the measurement and allocation of arrangement consideration, and evaluating estimates of the total expected inputs under the input method for revenue recognized over time.

How We Addressed the Matter in Our Audit

To test the accounting treatment for revenue from collaboration arrangements, we evaluated, among other things, whether the identified performance obligations were properly determined, and the transaction price was properly measured and allocated to the identified performance obligations. To test the measurement of efforts toward satisfying the performance obligation, our audit procedures included, among others, reviewing management's analysis for accuracy and completeness by agreeing data to the underlying contract, inspecting communications with the collaborative partner, evaluating the application of the input method for the recognition of revenue and testing the estimated total inputs and actual inputs incurred.

/s/ WithumSmith+Brown, PC

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

San Francisco, California
March 10, 2022

PCAOB ID Number 100

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the consolidated balance sheet of Lineage Cell Therapeutics, Inc. and Subsidiaries (collectively, the "Company") as of December 31, 2020, and the related consolidated statements of operations, comprehensive loss, changes in shareholders' equity, and cash flows for the year ended December 31, 2020, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020, and the results of their operations and their cash flows for the year ended December 31, 2020**,** in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

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

/s/ OUM & CO. LLP

San Francisco, California
March 11, 2021
We served as the Company's auditor since 2014.

PCAOB ID Number 252

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

	December 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 55,742	$ 32,585
Marketable equity securities	2,616	8,977
Accounts and grants receivable, net (Note 3)	50,840	4
Prepaid expenses and other current assets	2,351	2,433
Total current assets	111,549	43,999
NONCURRENT ASSETS		
Property and equipment, net (Notes 6 and 14)	4,872	5,630
Deposits and other long-term assets	630	616
Goodwill	10,672	10,672
Intangible assets, net	46,822	47,032
TOTAL ASSETS	$ 174,545	$ 107,949
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 27,969	$ 6,813
Lease liabilities, current portion (Note 14)	801	746
Financing lease, current portion (Note 14)	30	16
Deferred revenues (Note 3)	18,119	193
Liability classified warrants, current portion	197	1
Total current liabilities	47,116	7,769
LONG-TERM LIABILITIES		
Deferred tax liability	2,076	2,076
Deferred revenues, net of current portion (Note 3)	32,454	-
Lease liability, net of current portion (Note 14)	1,941	2,514
Financing lease, net of current portion	30	26
Liability classified warrants and other long-term liabilities	30	437
TOTAL LIABILITIES	83,647	12,822
Commitments and contingencies (Note 14)		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of December 31, 2021 and 2020, respectively	-	-
Common shares, no par value, authorized 250,000 shares; 169,477 and 153,096 shares issued and outstanding as of December 31, 2021 and 2020, respectively	434,529	393,944
Accumulated other comprehensive loss	(5,211)	(3,667)
Accumulated deficit	(337,097)	(294,078)
Lineage Cell Therapeutics, Inc. shareholders' equity	92,221	96,199
Noncontrolling (deficit)	(1,323)	(1,072)
Total shareholders' equity	90,898	95,127
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 174,545	$ 107,949

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,	
	2021	**2020**
REVENUES:		
Royalties	$ 2,776	$ 773
Collaboration revenues	1,120	-
Grant revenues	445	1,053
Total revenues	4,341	1,826
Cost of sales	(1,426)	(385)
Gross profit	2,915	1,441
OPERATING EXPENSES:		
Research and development	33,914	12,317
General and administrative	18,212	15,571
Total operating expenses	52,126	27,888
Loss from operations	(49,211)	(26,447)
OTHER INCOME, NET:		
Interest income, net	2	1,039
Gain on sale of marketable securities	6,024	4,560
Unrealized loss on marketable equity securities	(2,299)	(3,782)
Gain on extinguishment of debt	523	-
Unrealized gain (loss) on warrant liability	205	(174)
Other income, net	1,486	2,880
Total other income, net	5,941	4,523
LOSS BEFORE INCOME TAXES	(43,270)	(21,924)
Income tax benefit	-	1,239
NET LOSS	(43,270)	(20,685)
Net loss attributable to noncontrolling interest	251	36
NET LOSS ATTRIBUTABLE TO LINEAGE	$ (43,019)	$ (20,649)
NET LOSS PER COMMON SHARE:		
BASIC AND DILUTED	$ (0.26)	$ (0.14)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		
BASIC AND DILUTED	164,502	150,044

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,	
	2021	**2020**
NET LOSS	$ (43,270)	$ (20,685)
Other comprehensive loss, net of tax:		
Foreign currency translation adjustments, net of tax	(1,544)	(2,986)
COMPREHENSIVE LOSS	(44,814)	(23,671)
Less: comprehensive loss attributable to noncontrolling interest	251	36
COMPREHENSIVE LOSS ATTRIBUTABLE TO LINEAGE COMMON SHAREHOLDERS	$ (44,563)	$ (23,635)

See accompanying notes to the consolidated financial statements.

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

	Preferred Shares		Common Shares					
	Number of Shares	Amount	Number of Shares	Amount	Accumulated Deficit	Noncontrolling Interest/ (Deficit)	Accumulated Other Comprehensive Income/(Loss)	Total Shareholders' Equity
BALANCE AT DECEMBER 31, 2019	-	$ -	**149,804**	**$ 387,062**	**$ (273,422)**	**$ (1,712)**	**$ (681)**	**$ 111,247**
Shares issued through ATM	-	-	3,095	5,404	-	-	-	5,404
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	47	(27)	-	-	-	(27)
Shares issued for services	-	-	150	119	-	-	-	119
Stock-based compensation	-	-	-	2,227	-	-	-	2,227
Financing related fees	-	-	-	(209)	-	-	-	(209)
Dissolution of BioTime Asia	-	-	-	(676)	(7)	676	-	(7)
Hadasit non-cash warrant exercise	-	-	-	44	-	-	-	44
Foreign currency translation gain (loss)	-	-	-	-	-	-	(2,986)	(2,986)
NET LOSS	-	-	-	-	(20,649)	(36)	-	(20,685)
BALANCE AT DECEMBER 31, 2020	-	$ -	**153,096**	**$ 393,944**	**$ (294,078)**	**$ (1,072)**	**$ (3,667)**	**$ 95,127**
Shares issued through ATM	-	-	11,923	29,817	-	-	-	29,817
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	40	(54)	-	-	-	(54)
Shares issued for services	-	-	78	202	-	-	-	202
Stock-based compensation	-	-	-	3,519	-	-	-	3,519
Shares issued upon exercise of stock options	-	-	4,320	7,429	-	-	-	7,429
Financing related fees	-	-	-	(330)	-	-	-	(330)
Shares issued upon exercise of stock options	-	-	20	2	-	-	-	2
Foreign currency translation gain (loss)	-	-	-	-	-	-	(1,544)	(1,544)
NET LOSS	-	-	-	-	(43,019)	(251)	-	(43,270)
BALANCE AT DECEMBER 31, 2021	-	$ -	**169,477**	**$ 434,529**	**$ (337,097)**	**$ (1,323)**	**$ (5,211)**	**$ 90,898**

See accompanying notes to the consolidated financial statements.

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

	Year Ended December 31,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	$ (43,019)	$ (20,649)
Net loss attributable to noncontrolling interest	(251)	(36)
Adjustments to reconcile net loss attributable to Lineage to net cash used in operating activities:		
Gain on sale of marketable equity securities	(6,024)	(4,560)
Unrealized loss on marketable equity securities	2,299	3,782
Deferred tax benefit	-	(1,239)
Depreciation expense, including amortization of leasehold improvements	663	823
Amortization of right-of-use assets	14	72
Amortization of intangible assets	210	1,216
Stock-based compensation	3,519	2,227
Common stock issued for services	202	119
Change in unrealized (gain) loss on warrant liability	(205)	174
Write-off of security deposit	-	150
Amortization of deferred license fee	-	(200)
Foreign currency remeasurement and other (gain)	(1,566)	(2,957)
Loss (gain) on sale of assets	24	(20)
Realized loss on warrant exercise	-	44
Gain on extinguishment of debt	(523)	-
Changes in operating assets and liabilities:		
Accounts and grants receivable	(857)	287
Accrued interest receivable	-	(1,008)
Receivables from affiliates, net of payables	-	7
Prepaid expenses and other current assets	(72)	1,575
Accounts payable and accrued liabilities	21,645	308
Deferred revenue and other liabilities	380	132
Net cash used in operating activities	(23,561)	(19,753)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of OncoCyte common shares	10,064	10,941
Proceeds from the sale of AgeX common shares	-	1,290
Proceeds from the sale of HBL common shares	21	830
Purchase of property and equipment	(354)	(64)
Proceeds from sale of assets	14	23
Security deposit paid and other	-	18
Net cash provided by investing activities	9,745	13,038
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	7,240	-
Proceeds from payment of Juvenescence promissory note	-	24,624
Common shares received and retired for employee taxes paid	(54)	(27)
Proceeds from sale of common shares	30,865	5,127
Payments for offering costs	(1,101)	(356)
Repayment of financing lease liabilities	(20)	(26)
Proceeds from Paycheck Protection Program (“PPP”) Loan (Note 8)	-	523
Net cash provided by financing activities	36,930	29,865
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(20)	(63)
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	23,094	23,087
At beginning of year	33,183	10,096
At end of year	$ 56,277	$ 33,183
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid during year for interest	$ 13	$ 20
SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:		
Receivable from sale of common shares in at the market offering	$ 147	$ 269
Receivable from exercise of stock options	$ 189	$ -

See accompanying notes to the consolidated financial statements.

1. Organization, Basis of Presentation and Liquidity

Lineage Cell Therapeutics, Inc. ("Lineage," "we," "us," or "our") is a clinical-stage biotechnology company developing novel cell therapies to address unmet medical needs. Our programs are based on our proprietary cell-based technology and associated development and manufacturing capabilities. From this platform, we design, develop, and manufacture specialized human cells with anatomical and physiological functions which are similar or identical to cells found naturally in the human body. These cells which we manufacture are created by developmental differentiation protocols applied to established and well-characterized, pluripotent, and self-renewing cell lines. These functional cells are transplanted into patients to either replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury, or are administered as a means of helping the body mount a more robust and effective immune response to cancer or infectious diseases.

Our strategy is to efficiently leverage our technology platform and manufacturing capabilities to develop and advance our programs internally or in conjunction with strategic partners to further enhance their value. As one example, on December 17, 2021, we entered into a Collaboration and License Agreement with F. Hoffmann-La Roche Ltd and Genentech, Inc., a member of the Roche Group (collectively, "Roche"), wherein Lineage granted to Roche exclusive worldwide rights to develop and commercialize retinal pigment epithelium cell therapies, including its proprietary cell therapy known as OpRegen®, for the treatment of ocular disorders, including advanced dry age-related macular degeneration with geographic atrophy. Roche has paid Lineage a $50.0 million upfront payment under this alliance and Lineage is eligible to receive up to an additional $620.0 million in certain developmental, regulatory, and commercialization milestone payments. Lineage also is eligible for tiered double-digit percentage royalties on net sales of OpRegen.

Currently, Lineage is working with Roche in support of the dry age-related macular degeneration (OpRegen) program and is clinically testing therapies to treat spinal cord injuries and non-small cell lung cancer, as well as conducting research and preclinical development activities intended to advance our pipeline into other therapeutic indications and target tissues or organs.

Product Candidates & Other Programs

We have several allogeneic, or "off-the-shelf," cell therapy programs in development:

- *OpRegen®*, a retinal pigment epithelium ("RPE") cell replacement therapy currently in a Phase 1/2a multicenter clinical trial for the treatment of advanced dry age-related macular degeneration ("AMD") with geographic atrophy ("GA") (also known as atrophic AMD). There are currently no therapies approved by the U.S. Food and Drug Administration ("FDA") for dry AMD. As of December 17, 2021 this program has been partnered with Roche for further clinical development and commercialization.

- *OPC1*, an oligodendrocyte progenitor cell therapy currently in long-term follow-up for a Phase 1/2a multicenter clinical trial for spinal cord injuries ("SCI"). This clinical trial has been partially funded by the California Institute for Regenerative Medicine ("CIRM").

- *VAC*, an allogeneic cancer immunotherapy of antigen-presenting dendritic cells. One of the VAC product candidates, VAC2, is currently in a Phase 1 clinical trial in non-small cell lung cancer ("NSCLC"). This clinical trial is being funded and conducted by Cancer Research UK, one of the world's largest independent cancer research charities. We also have another VAC-based product candidate in preclinical development with our partner, Immunomic Therapeutics, Inc. ("ITI"), for the treatment of glioblastoma multiforme ("GBM").

- *Other.* We have other product candidates in preclinical development covering a range of therapeutic areas and target tissues or organs. Generally, these candidates are based on the same pluripotent platform technology and employ a similar guided cell differentiation and transplant approach as our current clinical-stage products.

In addition to seeking to create value for shareholders by developing product candidates and other technologies through our clinical development programs, we also seek to create value from our technologies through partnering and strategic transactions. We founded two companies that later became publicly traded companies: OncoCyte Corporation ("OncoCyte") and AgeX Therapeutics, Inc. ("AgeX"). We continue to hold common stock in OncoCyte as of December 31, 2021.

During the year ended December 31, 2021, we received approximately $10.1 million in gross proceeds in connection with our sale of shares of OncoCyte. In August 2020, we also received $24.6 million from Juvenescence Limited ("Juvenescence"), representing principal and accrued interest under a promissory note we received in connection with our sale of AgeX shares to Juvenescence in August 2018.

Asterias Merger

On November 7, 2018, Lineage, Asterias Biotherapeutics, Inc. (“Asterias”) and Patrick Merger Sub, Inc., a wholly owned subsidiary of Lineage, entered into an Agreement and Plan of Merger (the “Merger Agreement”) whereby Lineage agreed to acquire all of the outstanding common stock of Asterias in a stock-for-stock transaction (the “Asterias Merger”).

On March 7, 2019, the shareholders of each of Lineage and Asterias approved the Merger Agreement. Prior to the Asterias Merger, Lineage owned approximately 38% of Asterias’ issued and outstanding common stock and accounted for Asterias as an equity method investment.

On March 8, 2019, the Asterias Merger closed with Asterias surviving as a wholly owned subsidiary of Lineage. The former stockholders of Asterias (other than Lineage) received 0.71 common shares of Lineage for every share of Asterias common stock they owned. Lineage issued 24,695,898 common shares, including 58,085 shares issued in respect of restricted stock units issued by Asterias that immediately vested in connection with the closing of the Asterias Merger. The aggregate dollar value of such shares, based on the closing price of Lineage common shares on March 8, 2019, was $32.4 million. The total purchase price was $52.6 million. Lineage also assumed warrants to purchase shares of Asterias common stock.

The Asterias Merger was accounted for using the acquisition method of accounting in accordance with Accounting Standards Codification (“ASC”) Topic 805, *Business Combinations*, which requires, among other things, that the assets and liabilities assumed be recognized at their fair values as of the acquisition date.

Use of estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. (“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. Significant estimates and assumptions which are subject to significant judgment include those related to going concern assessment of consolidated financial statements, useful lives associated with long-lived assets, including evaluation of asset impairment, allowances for uncollectible accounts receivables, loss contingencies, deferred income taxes and tax reserves, including valuation allowances related to deferred income taxes, and assumptions used to value stock-based awards, debt or other equity instruments. Actual results could differ materially from those estimates.

Principles of consolidation

Lineage’s consolidated financial statements include the accounts of its subsidiaries. The following table reflects Lineage’s ownership, directly or through one or more subsidiaries, of the outstanding shares of its operating subsidiaries as of December 31, 2021.

Subsidiary	Field of Business	Lineage Ownership	Country
Asterias BioTherapeutics, Inc.[1]	Cell based therapeutics to treat neurological conditions and cancer	100%	USA
Cell Cure Neurosciences Ltd (“Cell Cure”)	Manufacturing of Lineage’s cell replacement platform technology	99%[2]	Israel
ES Cell International Pte. Ltd. (“ESI”)[3]	Research and clinical grade cell lines	100%	Singapore
OrthoCyte Corporation (“OrthoCyte”)	Research in orthopedic diseases and injuries	99.8%	USA

(1) Asterias was acquired by Lineage in March 2019.

(2) Includes shares owned by Lineage and ESI.

(3) The operating activities and fields of business listed under these subsidiaries are conducted primarily by Lineage as the parent company.

All material intercompany accounts and transactions have been eliminated in consolidation. As of December 31, 2021, Lineage consolidated its direct and indirect wholly owned or majority-owned subsidiaries because Lineage has the ability to control their operating and financial decisions and policies through its ownership, and the noncontrolling interest is reflected as a separate element of shareholders’ equity on Lineage’s consolidated balance sheets.

Liquidity

Lineage has incurred significant operating losses and in recent years has funded its operations primarily through sale of common stock of AgeX and OncoCyte, both former subsidiaries, sale of common stock of Hadasit Bio-Holdings Ltd (“HBL”), receipt of research grants, royalties from product sales, license revenues, sales of research products and issuance of equity securities.

On May 1, 2020, Lineage entered into a Controlled Equity Offering^{SM} Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co., as sales agent (“Cantor Fitzgerald”), pursuant to which Lineage may offer and sell, from time to time, through Cantor Fitzgerald, common shares of Lineage (“ATM Shares”) having an aggregate offering price of up to $25.0 million. Lineage is not obligated to sell any ATM Shares. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald will use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations, and the rules of the NYSE American, to sell the ATM Shares from time to time based upon Lineage’s instructions, including any price, time or size limits specified by Lineage. Under the Sales Agreement, Cantor Fitzgerald may sell the ATM Shares by any method deemed to be an “at-the-market” offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or by any other method permitted by law, including in privately negotiated transactions. Cantor Fitzgerald’s obligations to sell the ATM Shares are subject to satisfaction of certain conditions, including the continued effectiveness of Lineage’s Registration Statement on Form S-3 (File No. 333-237975), which was filed with the Commission on May 1, 2020 and was declared effective on May 8, 2020. The Sales Agreement replaced the previous sales agreement with Cantor that had been entered into in April 2017.

On March 5, 2021, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of an additional $25.0 million of common shares under the Sales Agreement increasing the total offering to $50.0 million. As of December 21, 2021, $14.1 million remained available for sale under the Sales Agreement. On December 21, 2021, Lineage filed a prospectus supplement with the SEC in connection with the offering and sale of up to $64.1 million of common shares (the “New Sales Agreement”), with Cantor Fitzgerald as the sales agent, no additional sales will be made under the Sales Agreement. The $64.1 million under the New Sales Agreement which may be issued are registered pursuant to Lineage’s effective shelf registration on Form S-3 (File No. 333-237975), as filed with the SEC on May 1, 2020 and declared effective on May 8, 2020 (the “May 2020 Registration Statement”), and Lineage’s effective shelf registration statement on Form S-3 (File No. 333-254167), which was filed with the SEC on March 5, 2021 and declared effective on March 19, 2021. As of December 31, 2021, under the Sales Agreement, Lineage had issued 14,908,735 common shares at a weighted average price per share of $2.41 for gross proceeds of $35.9 million. As of December 31, 2021, under the New Sales Agreement, Lineage had issued 108,200 common shares at a weighted average price per share of $2.55 for gross proceeds of $0.3 million (which includes $0.2 million of cash in transit related to a 2021 transaction that settled in early 2022). As a result, as of December 31, 2021, $ 63.9 million remained available for sale under the New Sales Agreement.

As of December 31, 2021, Lineage had an accumulated deficit of approximately $337.1 million, working capital of $64.4 million and shareholders' equity of $90.9 million. Lineage has evaluated its projected cash flows and believes that its $58.4 million of cash, cash equivalents and marketable equity securities are sufficient to fund Lineage's planned operations for at least the next twelve months from the issuance date of the consolidated financial statements included herein. If Lineage needs near term working capital or liquidity to supplement its cash and cash equivalents for its operations, Lineage may sell some, or all, of its marketable equity securities, as necessary.

In January 2022, Lineage received a $50.0 million upfront payment related to the Roche Agreement. Lineage made a subsequent payment of $12.1 million to the IIA, pursuant to Lineage's obligations under the Innovation Law. Additionally, Lineage made a subsequent payment of $8.9 million to Hadasit, pursuant to Lineage's obligations under the Second Amended and Restated License Agreement. See Note 14 for a description of the Roche Agreement and related payment obligations.

Lineage's projected cash flows are subject to various risks and uncertainties, and the unavailability or inadequacy of financing to meet future capital needs could force Lineage to modify, curtail, delay, or suspend some or all aspects of its planned operations. Lineage's determination as to when it will seek new financing and the amount of financing that it will need will be based on Lineage's evaluation of the progress it makes in its research and development programs, any changes to the scope and focus of those programs, any changes in grant funding for certain of those programs, and projection of future costs, revenues, and rates of expenditure. Lineage's ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. Lineage may be required to delay, postpone, or cancel clinical trials or limit the number of clinical trial sites, unless it is able to obtain adequate financing. Lineage cannot assure that adequate financing will be available on favorable terms, if at all. Sales of additional equity securities by Lineage or its subsidiaries and affiliates could result in the dilution of the interests of current shareholders.

2. Summary of Significant Accounting Policies

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

OncoCyte shares have readily determinable fair values quoted on the NYSE American under trading symbol "OCX". The HBL shares have a readily determinable fair value quoted on the Tel Aviv Stock Exchange ("TASE") under the trading symbol "HDST" where share prices are denominated in New Israeli Shekels (NIS).

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

In applying the provisions of ASU 2014-09, Lineage has determined that government grants are out of the scope of ASU 2014-09 because the government entities do not meet the definition of a "customer," as defined by ASU 2014-09, as there is not considered to be a transfer of control of goods or services to the government entities funding the grant. In the absence of applicable guidance under U.S. GAAP, the Company's policy is to recognize grant revenue when the related costs are incurred and the right to payment is realized. Costs incurred are recorded in research and development and general and administrative expenses on the accompanying statements of operations. Deferred grant revenues represent grant funds received from the governmental funding agencies for which the allowable expenses have not yet been incurred as of the balance sheet date reported.

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

Collaborative agreements - On April 16, 2021, Lineage entered a worldwide license and collaboration agreement with ITI for the development and commercialization of the VAC platform. Under the terms of this agreement, Lineage is entitled to upfront licensing fees totaling $2.0 million paid over the first year, and up to $67.0 million in development and commercial milestones across multiple indications. Lineage will also be eligible to receive royalties up to 10% on net sales of future products. On December 17, 2021, we entered into an exclusive worldwide collaboration and license agreement with Roche, for the development and commercialization of OpRegen. Roche paid a $50.0 million upfront payment and we are eligible to receive up to $620.0 million in additional development, approval, and sales milestone payments, in addition to tiered double-digit royalties.

We review collaborative agreements to determine if the accounting treatment falls under Accounting Standards Codification, Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), or Accounting Standards Codification *Topic 808*, *Collaborative Arrangements* ("ASC 808"). While these agreements may be within the scope of ASC 808, we may analogize to ASC 606 for some aspects of the agreements.

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 goals; (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 arrangement, 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 judgement to determine the underlying stand-alone selling price for each performance obligation which determines how the transaction price is allocated among the performance obligations. The following items are estimated in the calculation of the stand-alone selling price: forecasted revenues and development costs, development timelines, discount rates and probabilities of technical and regulatory success. We evaluate each performance obligation to determine if they can be satisfied at a point in time or over time, and we measure the services delivered to our collaboration partners each reporting period, which is based on the progress of the related program. If necessary, we adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis which would affect revenue and net income (loss) in the period of adjustment. In addition, variable consideration (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.

As of December 31, 2021, we recorded $49.7 million and $0.8 million of deferred revenue on the consolidated balance sheet, related to the Roche and ITI collaboration agreements. For the year ended December 31, 2021, we recognized $0.3 million and $0.8 million of revenue on the statement of operations, related to the Roche and ITI collaboration agreements, respectively.

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 unvested restricted stock or restricted stock units, 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 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, 2021 and 2020, 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 income (loss) per common share for the periods presented because including them would have been antidilutive (in thousands):

	Years Ended December 31,	
	2021	2020
Stock options	14,883	16,215
Lineage Warrants	-	1,090
Restricted stock units [(1)]	31	93

(1) On February 11, 2022, the Board of Directors of Lineage, approved restricted stock unit awards for an aggregate of 694,424 (see Note 12).

Restricted cash - In accordance with ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, Lineage explains the change during the period in the total of cash, cash equivalents and restricted cash, and includes restricted cash with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the consolidated statements of cash flows.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheet dates that comprise the total of the same such amounts shown in the consolidated statements of cash flows for all periods presented herein (in thousands):

	December 31, 2021	December 31, 2020
Cash and cash equivalents	$ 55,742	$ 32,585
Restricted cash included in deposits and other long-term assets (see Note 14)	535	520
Restricted cash included in prepaid expenses and other current assets (see Note 14)	-	78
Total cash, cash equivalents, and restricted cash as shown in the consolidated statements of cash flows	$ 56,277	$ 33,183

Accounts and grants receivable, net – Net accounts receivables amounted to $50,640,000 and $4,000 and grants receivable amounted to $200,000 and $61,000 as of December 31, 2021 and 2020, respectively. Net trade receivables include an allowance for doubtful accounts of approximately $74,000 and $44,000 as of December 31, 2021 and 2020, respectively, for those amounts deemed uncollectible by Lineage. Lineage establishes an allowance for doubtful accounts based on the evaluation of the collectability of its receivables on a variety of factors, including the length of time receivables are past due, significant events that may impair the customer's ability to pay, such as a bankruptcy filing or deterioration in the customers operating results or financial position, and historical experience. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted.

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 condensed 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 may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Lease expense for operating lease payments is recognized on a straight-line basis over the lease term. Lease expense for finance lease payments is recognized as amortization of ROU assets and related interest. Operating and finance leases are included as ROU assets in property and equipment, and ROU lease liabilities, current and long-term, in the consolidated balance sheets.

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

Going concern assessment – Lineage assesses going concern uncertainty for its consolidated financial statements to determine if Lineage has sufficient cash and cash equivalents on hand and working capital to operate for a period of at least one year from the date the consolidated financial statements are issued or are available to be issued, which is referred to as the "look-forward period" as defined by FASB's ASU No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to Lineage, Lineage will consider various scenarios, forecasts, projections, and estimates, and Lineage will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and its ability to delay or curtail those expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, Lineage makes certain assumptions concerning its ability to curtail or delay research and development programs and expenditures within the look-forward period in accordance with ASU No. 2014-15.

Cash and cash equivalents – Lineage considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. As of December 31, 2021 and 2020, Lineage had $52.3 million and $28.8 million in money market funds, respectively, considered to be cash equivalents.

Concentrations of credit risk and significant sources of supply – Financial instruments that potentially subject Lineage to significant concentrations of credit risk consist primarily of cash and cash equivalents. 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 relies on single-source, third-party suppliers for a few key components of our product candidates. If these single-source, third-party suppliers are unable to continue providing a key component, the initiation or progress of any clinical studies of its product candidates may be impeded.

Property and equipment, net – Property and equipment is stated at cost and is being depreciated using the straight-line method over their estimated useful lives ranging from 3 to 10 years. Leasehold improvements are amortized over the shorter of the useful life or the lease term (see Note 6).

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

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

Accounting for warrants – Lineage determines the accounting classification of warrants that it or its subsidiaries issue, as either liability or equity, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, and then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480-10, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate the issuer to settle the warrants or the underlying shares by paying cash or other assets, or warrants that must or may require settlement by issuing variable number of shares. If warrants do not meet liability classification under ASC 480-10, Lineage assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. If the warrants do not require liability classification under ASC 815-40, in order to conclude equity classification, Lineage assesses whether the warrants are indexed to its common stock or its subsidiary's common stock, as applicable, and whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP. After all relevant assessments are made, Lineage concludes whether the warrants are classified as liability or equity. Liability classified warrants are required to be accounted for at fair value both on the date of issuance and on subsequent accounting period ending dates, with all changes in fair value after the issuance date recorded in the consolidated statements of operations as a gain or loss. Equity classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized subsequent to the issuance date.

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

Research and development expenses - Research and development expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct and 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 which have an alternative future use will be capitalized as tangible assets, and 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. Royalty expenses or sublicensing fees are recorded as research and development costs, unless these costs are associated with royalties from product sales, which we classify as cost of sales on our consolidated statements of operations.

General and administrative expenses - General and administrative expenses consist of compensation and related benefits, including stock-based compensation, for executive and corporate personnel; professional and consulting fees; and allocated overhead such as facilities 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, and other miscellaneous expenses which are allocated to general and administrative expense.

Foreign currency translation adjustments and other comprehensive income or loss - In countries in which Lineage operates where the functional currency is other than the U.S. dollar, assets and liabilities are translated using published exchange rates in effect at the consolidated balance sheet date. Revenues and expenses and cash flows are translated using an approximate weighted average exchange rate for the period. Resulting foreign currency translation adjustments are recorded as other comprehensive income or loss, net of tax, in the consolidated statements of comprehensive income or loss and included as a component of accumulated other comprehensive income or loss on the consolidated balance sheets. Foreign currency translation adjustments are primarily attributable to Cell Cure and ESI, Lineage's consolidated foreign subsidiaries. For the years ended December 31, 2021 and 2020, comprehensive loss includes foreign currency translation adjustments, net of tax, of $1.5 million and $3.0 million, respectively.

Foreign currency transaction gains and losses - For transactions denominated in other than the functional currency of Lineage or its subsidiaries, Lineage recognizes transaction gains and losses in the consolidated statements of operations and classifies the gain or loss based on the nature of the item that generated it. The majority of Lineage's foreign currency transaction gains and losses are generated by Cell Cure's intercompany debt due to Lineage, which are U.S. dollar-denominated, while Cell Cure's functional currency is the Israeli New Shekel ("ILS"). At each balance sheet date, Lineage remeasures the intercompany debt using the current exchange rate at that date pursuant to ASC 830, *Foreign Currency Matters.* These foreign currency remeasurement gains and losses are included in other income and expenses, net.

Income taxes - Lineage accounts for income taxes in accordance with ASC 740, *Income Taxes*, which prescribe the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more likely than not that a portion or all of the deferred tax assets will not be realized. ASC 740 guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. Lineage files a U.S. federal income tax return as well as various state and foreign income tax returns. Lineage's judgments regarding future taxable income may change over time due to changes in market conditions, changes in tax laws, tax planning strategies or other factors. If Lineage assumptions, and consequently the estimates, change in the future with respect to Lineage's own deferred tax assets and liabilities, the valuation allowance may be increased or decreased, which may have a material impact on Lineage's consolidated financial statements. Lineage recognizes accrued interest and penalties related to unrecognized tax benefits, if any, as income tax expense; however, no amounts were accrued for the payment of interest and penalties as of December 31, 2021 and 2020.

On December 22, 2017, the United States enacted major federal tax reform legislation, Public Law No. 115-97, commonly referred to as the 2017 Tax Cuts and Jobs Act ("2017 Tax Act"), which enacted a broad range of changes to the Internal Revenue Code. Beginning in 2018, the 2017 Tax Act subjects a U.S. stockholder to tax on Global Intangible Low Tax Income ("GILTI") earned by certain foreign subsidiaries. In general, GILTI is the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets. The provision further allows a deduction of 50% of GILTI, however this deduction is limited to the Company's pre-GILTI U.S. income. For the year ended December 31, 2020, our foreign subsidiaries operated at a loss, as a result there was no income inclusion. For the year ended December 31, 2021, Lineage's foreign subsidiaries generated income arising from an intercompany transaction. As a result, there was in inclusion of $15.0 million included in federal income for 2021. The income was fully offset by our federal net operating loss carryforwards

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

On January 1, 2021, Lineage adopted ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The ASU enhances and simplifies various aspects of the income tax accounting guidance in ASC 740 and removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. The Company's adoption of ASU 2019-12 did not have a material impact on the Consolidated Financial Statements.

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, including employee stock options, based on estimated fair values. Lineage utilizes 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 Lineage's stock price as well as by assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, expected stock price volatility over the term of the awards, and 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. The risk-free rate is based on the U.S. Treasury yield in effect at the time of grant for zero coupon U.S. Treasury notes with maturities similar to the expected term of the awards. Forfeitures are accounted for as they occur.

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

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which modifies certain disclosure requirements for reporting fair value measurements. ASU 2018-13 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Lineage adopted this standard on January 1, 2020 and it did not have a significant impact on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*. The ASU enhances and simplifies various aspects of the income tax accounting guidance in ASC 740 and removes certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. This ASU is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years with early adoption permitted. Lineage adopted this standard as of January 1, 2021 and it did not have a material impact on its consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, *Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, which simplifies the accounting for goodwill impairments by eliminating the requirement to compare the implied fair value of goodwill with its carrying amount as part of step two of the goodwill impairment test referenced in ASC 350, *Intangibles - Goodwill and Other*. As a result, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit's fair value. However, the impairment loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. ASU 2017-04 is effective for smaller reporting companies for annual reporting periods beginning after December 15, 2022, including any interim impairment tests within those annual periods, with early application permitted. On January 1, 2021, we elected to early adopt ASU 2017-04, and the adoption had no impact on our consolidated financial statements. We will perform goodwill impairment tests in accordance with ASU 2017-04.

Recently Issued Accounting Pronouncements Not Yet Adopted - The following accounting standards, which are not yet effective, are presently being evaluated by Lineage to determine the impact that they might have on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 is intended to provide financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. ASU 2016-13 is effective for Lineage beginning January 1, 2023. Lineage has not yet completed its assessment of the impact of the new standard on its consolidated financial statements.

3. Revenue

Our disaggregated revenues were as follows (in thousands):

	Year Ended December 31,	
	2021	2020
Royalties	$ 2,776	$ 773
Grant revenues		
Israel Innovation Authority (“IIA”)	$ 445	$ 666
National Institutes of Health (“NIH”)	-	387
Total grant revenues	445	1,053
Revenues under collaborative agreements		
Upfront license fees	452	-
Event-based development milestones	123	-
Reimbursements, cost-sharing payments	545	-
Total revenues under collaborative agreements	1,120	-
Total revenue	$ 4,341	$ 1,826

During the year ended December 31, 2021 we recognized $4.3 million in total revenue. We recognized $1.1 million in revenues from new license agreements granted in the period, which were recorded as revenues under collaboration agreements. This amount represents upfront license fees and reimbursement revenues earned in the current year, as well as $0.1 million of variable consideration where development milestones were achieved. We also recognized revenue of $0.1 million during the period for grant revenues which had been included in deferred revenues at December 31, 2020.

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

	December 31, 2021	December 31, 2020
	(unaudited)	
Accounts receivable and other receivable, net [1][2]	$ 50,640	$ 242
Deferred revenues [1][2]	50,500	-

(1) Increase in accounts receivable due to accrual of $50.0 million upfront payment related to Roche Agreement, offset to deferred revenues.

(2) Excludes government grants as Lineage has determined government grants are outside the scope of ASU 2014-09 - Revenue from Contracts with Customers (Topic 606).

As of December 31, 2021, the amounts in the transaction price of our contracts with customers, including collaboration partners, and allocated good and services not yet provided were $52.1 million, of which $0.8 million has been collected and is reported as deferred revenues, $49.7 million was accrued to deferred revenues, and $1.7 million relates to unfulfilled commitments. The unfulfilled commitments are estimated to be delivered by the end of the fourth quarter of 2022. Of the total deferred revenues of $50.5 million, approximately $18.0 million is expected to be recognized within the next 12 months.

The following table presents amounts under our collaboration agreements included in the transaction price (i.e., cumulative amounts triggered or probable) as of December 31, 2021 (in thousands):

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

(1) Upfront license fees.

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

(3) Reimbursements and costs-sharing payments.

(4) Regarding the accounting treatment for the collaborative agreement, the license and related development deliverables were determined to be highly interdependent and interrelated and have been combined as one performance obligation. Delivery is determined to be over time and revenue will be recognized utilizing an input method of costs incurred over total estimated costs in the work plan. The regulatory milestones are variable consideration that are fully constrained until the uncertainty of each milestone has been resolved. Sales-based milestones and royalties are variable consideration that will not be included in the transaction price until the related commercialization and sales have occurred. The cost reimbursements are considered variable consideration and are included in the transaction price. Revenues related to the cost reimbursements are presented gross on the consolidated statement of operations instead of a reduction to the costs being reimbursed. We currently estimate the unsatisfied performance obligations within the contract to be completed by December 31, 2022.

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

4. Marketable Equity Securities

As of December 31, 2021, Lineage owned approximately 1.1 million shares of OncoCyte common stock. These shares had a fair value of approximately $2.4 million, based on the closing price of OncoCyte of $2.17 per share on December 31, 2021. As of December 31, 2020, Lineage owned approximately 3.6 million shares of OncoCyte common stock. These shares had a fair value of approximately $8.7 million, based on the closing price of OncoCyte of $2.39 per share on December 31, 2020.

For the year ended December 31, 2021, Lineage recorded a realized gain of $6.0 million due to sales of OncoCyte shares in the period. Lineage also recorded a net unrealized loss on marketable equity securities of $2.2 million related to changes in fair market value of OncoCyte's common stock price during the period. For the year ended December 31, 2020, Lineage recorded a realized gain of $3.1 million due to sales of OncoCyte shares in the period. Lineage also recorded a net unrealized loss on marketable equity securities of $2.5 million related to changes in fair market value of OncoCyte's common stock price in the period.

All share prices are determined based on the closing price of OncoCyte common stock on the NYSE American on the applicable dates, or the last day of trading of the applicable quarter, if the last day of a quarter fell on a weekend.

We account for the shares we hold in HBL as marketable equity securities as of December 31, 2021. These securities were carried at fair market value on our consolidated balance sheets, and the accounting transactions for the year ended December 31, 2021 were not material.

For the year ended December 31, 2021, we did not hold any marketable securities related to AgeX. For the year ended December 31, 2020, Lineage recorded realized gains of $0.8 million, due to sales of AgeX shares in the period. For the year ended December 31, 2020, we recorded unrealized losses of $1.3 million, respectively, due to changes in fair market value of AgeX's common stock price during the period.

5. Sale of Significant Ownership Interest in AgeX to Juvenescence Limited

On August 30, 2018, Lineage entered into a Stock Purchase Agreement with Juvenescence and AgeX, pursuant to which Lineage sold 14.4 million shares of common stock of AgeX to Juvenescence for $3.00 per share, or an aggregate purchase price of $43.2 million (the "Purchase Price"). Juvenescence paid $10.8 million of the Purchase Price at closing, issued an unsecured convertible promissory note dated August 30, 2018 in favor of Lineage for $21.6 million (the "Promissory Note"), and paid $10.8 million on November 2, 2018. The Stock Purchase Agreement contains customary representations, warranties and indemnities from Lineage relating to the business of AgeX, including an indemnity cap of $4.3 million, which is subject to certain exceptions. In connection with the sale, Lineage also entered into a Shared Facilities Agreement with AgeX.

The Promissory Note bore interest at 7% per annum, with principal and accrued interest payable at maturity on August 30, 2020. The Promissory Note was paid in full on August 28, 2020.

6. Property and Equipment, Net

At December 31, 2021 and 2020, property and equipment, net were comprised of the following (in thousands):

	December 31,	
	2021	**2020**
Equipment, furniture and fixtures	$ 3,472	$ 3,628
Leasehold improvements	2,539	2,472
Right-of-use assets	4,163	3,845
Accumulated depreciation and amortization	(5,302)	(4,315)
Property and equipment, net	$ 4,872	$ 5,630

Property and equipment at December 31, 2021 and December 31, 2020 includes $79,000 in financing leases. In September 2020, Lineage terminated its leases in Alameda and entered into a new lease for a reduced amount of square footage. This resulted in a reduction to right-of-use assets of approximately $1.4 million. See additional information in Note 14.

Depreciation and amortization expense amounted to $663,000 and $823,000 for the years ended December 31, 2021 and 2020, respectively. During the year ended December 31, 2021, Lineage sold non-capitalized assets for a net gain of $30,000, which was included in R&D expenses on the consolidated statements of operations. During the year ended December 31, 2021, Lineage sold equipment with a net book value of $9,000 and recognized a gain of $5,000. Additionally, Lineage wrote off assets with a net book value of $29,000.

During the year ended December 31, 2020, Lineage sold equipment with a net book value of $32,000 and recognized a loss of $9,000. Lineage also wrote off assets with a net book value of $156,000, with $104,000 of this amount related to the termination of its leases in Alameda. Additionally, Lineage sold non-capitalized assets for a net gain of $72,000.

7. Goodwill and Intangible Assets, Net

At December 31, 2021 and 2020, goodwill and intangible assets, net consisted of the following: (in thousands):

	December 31,	
	2021	2020
Goodwill [1]	$ 10,672	$ 10,672
Intangible assets:		
Acquired IPR&D – OPC1 (from the Asterias Merger) [2]	$ 31,700	$ 31,700
Acquired IPR&D – VAC2 (from the Asterias Merger) [2]	14,840	14,840
Intangible assets subject to amortization:		
Acquired patents	18,953	18,953
Acquired royalty contracts [3]	650	650
Total intangible assets	66,143	66,143
Accumulated amortization [4]	(19,321)	(19,111)
Intangible assets, net	$ 46,822	$ 47,032

(1) Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in the Asterias Merger.

(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 consisted of $31.7 million pertaining to the OPC1 program and $14.8 million pertaining to the VAC2 program.

(3) Asterias had royalty cash flows under certain specific patent families that Asterias previously acquired from Geron Corporation (“Geron”). The Geron patents are expected to continue to generate revenue and are not used in the OPC1 or the VAC platform, these patents are considered to be separate long-lived intangible assets under ASC 805.

(4) As of December 31, 2021 the acquired patents were fully amortized and the acquired royalty contracts had a remaining unamortized balance of $282,000.

Lineage amortizes its intangible assets over an estimated period of 5 to 10 years on a straight-line basis. Lineage recognized $0.2 million and $1.2 million in amortization expense of intangible assets during the years ended December 31, 2021 and 2020, respectively.

Amortization of intangible assets for periods subsequent to December 31, 2021 is as follows (in thousands):

Year Ended December 31,	Amortization Expense
2022	$ 130
2023	130
2024	22
Total	$ 282

8. Accounts Payable and Accrued Liabilities

At December 31, 2021 and 2020, accounts payable and accrued liabilities consist of the following (in thousands):

	December 31,	
	2021	2020
Accounts payable	$ 3,543	$ 2,611
Accrued compensation	2,162	1,959
Accrued liabilities [(1)]	22,086	1,711
PPP loan payable	-	523
Other current liabilities	178	9
Total	$ 27,969	$ 6,813

(1) Includes $21.0 million of royalty and redemption fee expense to Hadasit and the IIA, respectively, pursuant to Lineage's financial obligations related to the Roche Agreement (see Note 14).

PPP Loan Payable

In April 2020, Lineage received a loan for $523,000 from Axos Bank under the Paycheck Protection Program ("PPP") contained within the Coronavirus Aid, Relief and Economic Security ("CARES") Act. The PPP loan had a term of two years, was unsecured, and was guaranteed by the U.S. Small Business Administration ("SBA"). The loan carried a fixed interest rate of one percent per annum, of which the first six months of interest was deferred. Under the CARES Act and Paycheck Protection Program Flexibility Act, Lineage was eligible to apply for forgiveness of all loan proceeds used to pay payroll costs, rent, utilities and other qualifying expenses during the 24-week period following receipt of the loan, provided that Lineage maintains its employment and compensation within certain parameters during such period. Not more than 40% of the forgiven amount may be for non-payroll costs. If the conditions outlined in the PPP loan program were adhered to by Lineage, all or part of such loan could be forgiven. Lineage applied for forgiveness of the PPP loan on September 30, 2020, and on May 13, 2021, received notice that the entire PPP loan principal balance and interest charges were forgiven in full, which the Company recorded as a gain on debt extinguishment in the consolidated statements of operations. The PPP loan forgiveness amount was excluded from Lineage's taxable income for federal and California purposes. However, for California income taxes, public companies cannot deduct expenses from loan proceeds which were forgiven.

9. Fair Value Measurements

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

- Level 1 – Inputs to the valuation methodology are quoted prices for identical assets or liabilities in active markets.
- Level 2 – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 – Inputs to the valuation methodology are unobservable; that reflect management's own assumptions about the assumptions market participants would make and significant to the fair value.

We measure cash, cash equivalents, marketable securities and our liability classified warrants at fair value on a recurring basis. The fair values of such assets were as follows for December 31, 2021 and 2020 (in thousands):

		Fair Value Measurements Using		
	Balance at December 31, 2021	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 55,742	$ 55,742	$ -	$ -
Marketable securities	2,616	2,616	-	-
Liabilities:				
Lineage Warrants	-	-	-	-
Cell Cure Warrants	227	-	-	227

		Fair Value Measurements Using		
	Balance at December 31, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 32,585	$ 32,585	$ -	$ -
Marketable securities	8,977	8,977	-	-
Liabilities:				
Lineage Warrants	1	-	-	1
Cell Cure Warrants	437	-	-	437

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

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

The following table sets forth the establishment of the Company's Level 3 liabilities, as well as a summary of the changes in the fair value and other adjustments:

(Dollars in thousands)	Cell Cure Warrants	Lineage Warrants	Total
Balance as of December 31, 2020	$ 437	$ 1	$ 438
Change in fair value and other adjustments	(210)	-	(210)
Expiration of warrants	-	(1)	(1)
Balance as of December 31, 2021	$ 227	$ -	$ 227

Marketable equity securities include our positions in OncoCyte, and HBL. Both of these securities have readily determinable fair values quoted on the NYSE American or TASE stock exchanges. These securities are measured at fair value and reported as current assets on the consolidated balance sheets based on the closing trading price of the security as of the date being presented.

The fair value of Lineage's assets and liabilities, which qualify as financial instruments under FASB guidance regarding disclosures about fair value of financial instruments, approximate the carrying amounts presented in the accompanying consolidated balance sheets. The carrying amounts of accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate fair values because of the short-term nature of these items.

10. Related Party Transactions

Lineage incurred costs of $5,050 per month for the use of approximately 900 square feet of office space in New York City, which was made available to Lineage on a month-by-month basis by one of its directors at an amount that approximates his cost (see Note 14). In March 2021, Lineage terminated without penalty its leasing term related to the New York City office lease.

In connection with the putative shareholder class action lawsuits filed in February 2019 and October 2019 challenging the Asterias Merger (see Note 14), Lineage has agreed to pay for the legal defense of Neal Bradsher, director, Broadwood Partners, L.P., a shareholder of Lineage, and Broadwood Capital, Inc., which manages Broadwood Partners, L.P., all of which were named in the lawsuits. Through December 31, 2021, Lineage has incurred a total of $593,782 in legal expenses on behalf of the director, shareholder and the manager of the shareholder.

As part of financing transactions in which there were multiple other purchasers, Broadwood Partners, L.P. purchased 623,090 shares of OncoCyte common stock from Lineage in January 2020.

11. Shareholders' Equity

Preferred Shares

Lineage is authorized to issue 2,000,000 shares of preferred stock. The preferred shares may be issued in one or more series as the board of directors may by resolution determine. The 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 board of directors may, by resolution, increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series of preferred shares subsequent to the issue of shares of that series. As of December 31, 2021, no shares of preferred stock were issued or outstanding.

Common Shares

At December 31, 2021, Lineage was authorized to issue 250,000,000 common shares, no par value. As of December 31, 2021 and 2020, Lineage had 169,477,347 and 153,095,883 issued and outstanding common shares, respectively.

During the years ended December 31, 2021 and 2020, Lineage issued 40,000 and 47,000 common shares, net of shares withheld and retired for employee taxes paid, respectively, for vested restricted stock units (see Note 12).

At-the-Market ("ATM") Offering

On May 1, 2020, Lineage entered into the Sales Agreement, pursuant to which Lineage may offer and sell, from time to time, through Cantor Fitzgerald, common shares of Lineage ("ATM Shares") having an aggregate offering price of up to $25.0 million. Lineage is not obligated to sell any ATM Shares. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald will use commercially reasonable efforts, consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations, and the rules of the NYSE American, to sell the ATM Shares from time to time based upon Lineage's instructions, including any price, time or size limits specified by Lineage. Under the Sales Agreement, Cantor Fitzgerald may sell the ATM Shares by any method deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended, or by any other method permitted by law, including in privately negotiated transactions. Cantor Fitzgerald's obligations to sell the ATM Shares are subject to satisfaction of certain conditions, including the continued effectiveness of Lineage's Registration Statement on Form S-3 (File No. 333-237975), which was filed with the Commission on May 1, 2020 and was declared effective on May 8, 2020. The Sales Agreement replaced the previous sales agreement with Cantor that had been entered into in April 2017.

On March 5, 2021, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of an additional $25.0 million of common shares under the Sales Agreement increasing the total offering to $50.0 million. As of December 21, 2021, $14.1 million remained available for sale under the Sales Agreement. On December 21, 2021, Lineage filed a prospectus supplement with the SEC in connection with the New Sales Agreement, with Cantor Fitzgerald as the sales agent, and no additional sales will be made under the Sales Agreement. The $64.1 million under the New Sales Agreement which may be issued are registered pursuant to the May 2020 Registration Statement, and Lineage's effective shelf registration statement on Form S-3 (File No. 333-254167), which was filed with the SEC on March 5, 2021 and declared effective on March 19, 2021. As of December 31, 2021, under the Sales Agreement, Lineage had issued 14,908,735 common shares at a weighted-average price per share of $2.41 for gross proceeds of $35.9 million. As of December 31, 2021, under the New Sales Agreement, Lineage had issued 108,200 common shares at a weighted-average price per share of $2.55 for gross proceeds of $0.3 million (which includes $0.2 million of cash in transit related to a 2021 transaction that settled in early 2022). As a result, as of December 31, 2021, $63.9 million remained available for issuance under the New Sales Agreement.

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

Warrants

Lineage (previously Asterias) Warrants – Liability Classified

In March 2019, in connection with the closing of the Asterias Merger, Lineage assumed outstanding Asterias Warrants. The total number of common shares of Lineage subject to warrants that were assumed by Lineage in connection with the Asterias Merger was 1,089,900, which were converted to Lineage Warrants 30 days after the closing of the Asterias Merger, with similar terms and conditions retained under the Lineage Warrants as per the original Warrant Agreements. The Lineage Warrants had an exercise price of $6.15 per warrant share and expired on May 13, 2021.

Cell Cure Warrants – Liability Classified

Cell Cure has two sets of issued warrants (the "Cell Cure Warrants"). Warrants to purchase 24,566 Cell Cure ordinary shares at an exercise price of $40.5359 were issued to HBL in July 2017. These warrants expire in July 2022. Warrants to purchase 13,738 Cell Cure ordinary shares at exercise prices ranging from $32.02 to $40.00 per share were issued to consultants. 11,738 of these warrants were cashless exercised in October 2020. The expense related to the cashless exercise was approximately $44,000 and it was recorded as other income/(expense), net on the statements of operations. The remaining 2,000 warrants have an exercise price of $40.00 and expire in January 2024.

ASC 815 requires freestanding financial instruments, such as warrants, with exercise prices denominated in currencies other than the functional currency of the issuer to be accounted for as liabilities at fair value, with all subsequent changes in fair value after the issuance date to be recorded as gains or losses in the consolidated statements of operations. Because the exercise price of the Cell Cure Warrants is U.S. dollar-denominated and settlement is not expected to occur in the next twelve months, Cell Cure classified the Cell Cure Warrants as a long-term liability in accordance with ASC 815.

The fair value of the Cell Cure Warrants at the time of issuance was determined by using the Black-Scholes option pricing model using the respective contractual term of the warrants. In applying this model, the fair value is determined by applying Level 3 inputs, as defined by ASC 820; these inputs are based on certain key assumptions including the fair value of the Cell Cure ordinary shares, adjusted for lack of marketability, as appropriate, and the expected stock price volatility over the term of the Cell Cure Warrants. The fair value of the Cell Cure ordinary shares is determined by Cell Cure's Board of Directors, which may engage a valuation specialist to assist it in estimating the fair value, or may use recent transactions in Cell Cure shares, if any, as a reasonable approximation of fair value, or may apply other reasonable methods to determining the fair value, including a discount for lack of marketability. In connection with the cashless exercise in October 2020, Cell Cure had an independent third-party update the fair value of the Cell Cure shares. Lineage determines the stock price volatility using historical prices of comparable public company common stock for a period equal to the remaining term of the Cell Cure Warrants. The Cell Cure Warrants are revalued each reporting period using the same methodology described above, with changes in fair value included as gains or losses in other income and expenses, net, in the consolidated statements of operations.

For the years ended December 31, 2021 and 2020, Lineage recorded a noncash gain of $0.2 million and a noncash loss of $0.2 million, respectively, for the increase/decrease in the fair value of the Cell Cure Warrants included in other income and expenses, net for each period. The decrease in the fair value of the Cell Cure Warrants was mainly attributable to the time premium amortization, due to the shorter duration of the warrants. As of December 31, 2021 and 2020, the Cell Cure Warrants, valued at $0.2 million and $0.4 million, respectively, were included in current and long-term liabilities on the consolidated balance sheets.

12. Stock-Based Awards

*Equity Incentive Plan Award*s

On September 13, 2021, the shareholders of Lineage approved the 2021 Equity Incentive Plan (the "2021 Plan"), and the plan became effective. The 2021 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units awards ("RSUs"), and other stock awards. All of our employees (including 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) 15,000,000 shares and (ii) the Prior Plan Returning Shares ("Prior Plan Returning Shares"). The Prior Plan Returning Shares are defined as an award granted under the Lineage Cell Therapeutics Inc. 2012 Equity Incentive Plan (the "2012 Plan"), which were outstanding when the 2021 Plan became effective, and are not issued because such Prior Plan Award or any option thereof expires or otherwise terminates without all of the shares covered by such Prior Plan Award having been issued. Given the approval of the 2021 Plan, no additional awards will be granted from the 2012 Plan or the Asterias 2013 Equity Incentive Award (the "Asterias Equity Plan"). As of December 31, 2021, there were no outstanding equity awards issued under the 2021 Plan. As of December 31, 2021, there were 16,382,385 shares available for grant under the 2021 Plan.

On February 11, 2022, the Board of Directors at Lineage, approved restricted stock unit awards for an aggregate amount of 694,424. The awards were issued under the 2021 Plan, which defines restricted stock units as a full value award, which reduce the Plan's common shares available for grant by 1.50 shares for each share issued.

A summary of Lineage's 2012 Plan activity and other stock option awards granted outside of the 2012 Plan related information is as follows (in thousands, except per share amounts):

	Number of Options Outstanding	Number of RSUs Outstanding	Weighted Average Exercise Price
December 31, 2019	**14,710**	**166**	**$ 2.17**
Options granted	5,256	-	0.71
Options forfeited	(4,101)	-	2.61
Restricted stock units vested	-	(73)	-
December 31, 2020	**15,865**	**93**	**$ 1.57**
Options granted	6,245	-	2.50
Options exercises	(4,321)	-	1.72
Options forfeited	(3,146)	-	1.99
Restricted units vested	-	(62)	-
December 31, 2021	**14,643**	**31**	**$ 1.84**
Options exercisable at December 31, 2021	**6,391**		**$ 1.68**

As of December 31, 2021, options outstanding and options exercisable under the 2012 Plan have a weighted-average remaining contractual term of 7.3 years and 5.3 years, respectively, and intrinsic value of $9.6 million and $5.2 million, respectively.

In connection with the vested RSUs during the year ended December 31, 2021, Lineage paid $54,000 in minimum employee withholding taxes in exchange for 21,000 vested Lineage common shares issuable to the employees and immediately retired those shares. For the year ended December 31, 2021, Lineage recorded a noncash stock-based compensation expense of $0.1 million, in connection with the vested RSUs, included in consolidated stock-based compensation expense.

In connection with the vested RSUs during the year ended December 31, 2020, Lineage paid $27,000 in minimum employee withholding taxes in exchange for 26,000 vested Lineage common shares issuable to the employees and immediately retired those shares. For the year ended December 31, 2020, Lineage recorded a noncash stock-based compensation expense of $0.1 million, in connection with the vested RSUs, included in consolidated stock-based compensation expense.

A summary of activity under the Asterias Equity Plan from the closing date of the Asterias Merger through December 31, 2021 is as follows (in thousands, except per share amounts):

	Number of Options Outstanding	Number of RSUs Outstanding	Weighted Average Exercise Price
December 31, 2019	**350**	**-**	**$ 1.57**
Options granted	-	-	-
Options forfeited	-	-	-
December 31, 2020	**350**	**-**	**$ 1.57**
Options granted	-	-	-
Options forfeited	**(109)**	**-**	**1.57**
December 31, 2021	**241**	**-**	**$ 1.57**
Options exercisable at December 31, 2021	**241**		**$ 1.57**

As of December 31, 2021, options outstanding and options exercisable under the Asterias Equity Plan both have a weighted-average remaining contractual term of 0.3 years and intrinsic value of $212,000 and $212,000, respectively.

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,	
	2021	**2020**
Expected life (in years)	6.2	6.2
Risk-free interest rates	1.0%	0.8%
Volatility	73.2%	67.7%
Dividend yield	-%	-%

The weighted-average estimated fair value of stock options granted under the 2012 Plan and other stock option awards granted outside of the 2012 Plan, during the years ended December 31, 2021 and 2020 was $1.62 and $0.43 per share, respectively.

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

	Year Ended December 31,	
	2021	**2020**
Research and development	$ 833	$ 464
General and administrative	2,686	1,763
Total stock-based compensation expense	$ 3,519	$ 2,227

As of December 31, 2021, total unrecognized compensation costs related to unvested stock options under Lineage's 2012 Plan and the Asterias Equity Plan was $8.5 million, which is expected to be recognized as expense over a weighted average period of approximately 2.5 years.

13. Income Taxes

For the year ended December 31, 2021, Lineage did not record a tax provision or deferred tax benefit. For the year ended December 31, 2020, Lineage recorded a $1.2 million deferred tax benefit for income taxes.

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

	December 31,	
	2021	2020
Domestic	$ (16,998)	(17,500)
Foreign	(26,272)	(4,424)
Loss before net income tax benefit	$ (43,270)	(21,924)

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

	Year Ended December 31,	
	2021	2020
Computed tax benefit at federal statutory rate	21%	21%
Research and development and other credits	1%	1%
Permanent differences	(1)%	-%
Change in valuation allowance	(16)%	(17)%
State tax benefit	8%	3%
GILTI inclusion	(12)%	-%
Foreign rate differential and other	(1)%	(2)%
Income tax benefit	-%	6%

The primary components of the deferred tax assets and liabilities at December 31, 2021 and 2020 were as follows (in thousands):

	December 31,	
Deferred tax assets/(liabilities):	2021	2020
Net operating loss carryforwards	$ 68,766	$ 63,941
Research and development and other credits	9,466	8,878
Patents and licenses	1,403	1,178
Stock options	1,717	2,131
Operating lease liability	134	242
Other	1,608	1,523
Total deferred tax assets	83,094	77,893
Valuation allowance	(70,967)	(64,069)
Deferred assets, net of valuation allowance	12,127	13,824
Operating lease ROU assets	(115)	(215)
Intangibles	(13,299)	(13,226)
Equity method investments and marketable securities at fair value	(789)	(2,459)
Total deferred tax liabilities	(14,203)	(15,900)
Net deferred tax liabilities	$ (2,076)	$ (2,076)

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. Lineage established a full valuation allowance as of December 31, 2018 due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets, including foreign net operating losses generated by its subsidiaries. During the year ended December 31, 2021, Lineage had taxable income and therefore did not generate any indefinite lived deferred tax assets as tax provision benefit. As new indefinite lived deferred tax assets are generated, we will continue to book provision benefits until the deferred tax liability position is exhausted, barring any new developments.

As of December 31, 2021, Lineage has gross net operating loss carryforwards of approximately $155.6 million for federal purposes. As of December 31, 2021, Lineage's foreign subsidiaries have net operating loss carryforwards of approximately $60.2 million which carryforward indefinitely.

As of December 31, 2021, Lineage has net operating losses of $151.8 million for state tax purposes.

As of December 31, 2021, Lineage has research tax credit carryforwards for federal and state tax purposes of $3.7 million and $5.8 million, respectively. These tax credits reflect the amounts for Lineage, Asterias and OrthoCyte as of December 31, 2021. For federal purposes, the credits generated each year have a carryforward period of 20 years. The federal tax credits expire in varying amounts between 2021 and 2041, while the state tax credits have no expiration period.

On August 5, 2020, Lineage began the liquidation of its foreign subsidiary BioTime Asia. At the time of the liquidation, BioTime Asia had an intercompany payable due to Lineage. For book purposes, the corresponding balances eliminate in consolidation. For federal purposes, the activities of their foreign subsidiaries are not included in the consolidated tax return. Accordingly, the payable was written off for tax purposes by Lineage, creating a $3.6 million bad debt deduction increasing its NOL carryover. For California, the activities of its foreign subsidiaries, including BioTime Asia, are included in the combined tax return. As such, the corresponding intercompany balances are eliminated.

On December 17, 2021, Lineage and its subsidiary, Cell Cure, entered into a Collaboration and License Agreement with Roche, wherein Lineage granted to Roche exclusive worldwide rights to develop and commercialize RPE cell therapies. Under the agreement Roche will pay Lineage a $50.0 million upfront payment. This payment was received in January of 2022 (see further discussion at Note 14).

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

Beginning in 2018, the 2017 Tax Act subjects a U.S. stockholder to GILTI earned by certain foreign subsidiaries. In general, GILTI is the excess of a U.S. shareholder's total net foreign income over a deemed return on tangible assets. The provision further allows a deduction of 50% of GILTI, however this deduction is limited to the company's pre-GILTI U.S. income. For the year ended December 31, 2020, our foreign subsidiaries generated losses, as a result there was no inclusion. For the year ended December 31, 2021, Lineage's combined foreign entities generated a profit arising from intercompany transactions. As a result, there was an inclusion of $24.8 million for GILTI purposes for 2021. The resulting net income for federal income tax purposes was fully offset by their federal net operating loss carryforwards.

Other Transactions and Related Impact on Income Taxes

The market value of the respective shares Lineage holds in OncoCyte and Asterias (through the merger date of March 8, 2019) creates a deferred tax liability to Lineage based on the closing price of the security, less the tax basis of the security Lineage has in such shares. The deferred tax liability generated by shares that Lineage holds as of December 31, 2021 and 2020, is a source of future taxable income to Lineage, as prescribed by ASC 740-10-30-17, that will more likely than not result in the realization of its deferred tax assets to the extent of those deferred tax liabilities. This deferred tax liability is determined based on the closing price of those securities as of December 31, 2021 and 2020.

Other Income Tax Matters

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

Lineage files a U.S. federal income tax return as well as various state and foreign income tax returns. In general, Lineage is no longer subject to tax examination by major taxing authorities for years before 2016. Although the statute is closed for purposes of assessing additional income and tax in these years, the taxing authorities may still make adjustments to the NOL and credit carryforwards used in open years. Therefore, the statute should be considered open as it relates to the NOL and credit carryforwards used in open years.

Lineage may be subject to potential examination by U.S. federal, U.S. states or foreign jurisdiction authorities in the areas of income taxes. These potential examinations may include questioning the timing and amount of deductions, the nexus of income among various tax jurisdictions and compliance with U.S. federal, U.S. state and foreign tax laws. Based on Lineage's assessment, no liabilities for uncertain tax positions should be recorded as of December 31, 2021 and 2020. Lineage's management does not expect that the total amount of unrecognized tax benefits will materially change over the next twelve months.

Lineage's practice is to recognize interest and penalties related to income tax matters in tax expense. As of December 31, 2021 and 2020, Lineage has no accrued interest and penalties.

14. Commitments and Contingencies

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 "Carlsbad Lease"). The term of the Carlsbad Lease commenced on August 1, 2019 and expires on October 31, 2022.

Base rent under the Carlsbad Lease, beginning on August 1, 2021, is $23,959 per month and increases by 3% on August 1, 2022. Base rent for the first twenty-four months of the lease was based upon a deemed rentable area of 7,000 square feet. Base rent was abated for months two through five of the lease.

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. As security for the performance of its obligations under the Carlsbad Lease, Lineage provided the landlord with a security deposit of $17,850.

Alameda Leases and Alameda Sublease

In December 2015, Lineage entered into leases of office and laboratory space located in two buildings in Alameda, California (the "Alameda Leases") comprised of 22,303 square feet (the "1010 Atlantic Premises") and 8,492 square feet (the "1020 Atlantic Premises"). Base rent under the Alameda Leases beginning on February 1, 2020 was $72,676 per month with annual increases of approximately 3%. In addition to base rent, Lineage paid 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. As security for its obligations, Lineage provided the landlord with a security deposit of approximately $424,000, which was reduced to $78,000 on January 24, 2019 in accordance with the terms of the lease. The security deposit was returned to Lineage in March 2021.

In April 2020, Lineage entered into a sublease with Industrial Microbes, Inc. (“Industrial Microbes”) for the use of 10,000 square feet in the 1010 Atlantic Premises (the “Industrial Microbes Sublease”). Base rent under the Industrial Microbes Sublease was $28,000 per month with annual increases of approximately 3%. Base rent for the first month was abated. In addition to base rent and utilities, Industrial Microbes paid a pro-rata portion of increases in operating expenses, after an abatement period of one year.

On September 11, 2020, Lineage entered into a Lease Termination Agreement with the landlord terminating the Alameda Leases effective as of August 31, 2020 for the 1020 Atlantic Premises and September 30, 2020 for the 1010 Atlantic Premises. In consideration for the termination of the leases, Lineage paid a termination fee of $130,000 and other amounts due under the terms of the Alameda Leases through the applicable effective termination dates, except that no rent was due with respect to the 1020 Atlantic Premises after July 31, 2020. Lineage’s security deposit was received in March 2021. Lineage paid a separate termination fee of $30,000 to Industrial Microbes in connection with the termination of the Industrial Microbes Sublease and returned the $56,000 security deposit paid by Industrial Microbes. For the period of sublease from mid-April 2020 through September 2020, Lineage received $119,000 in rental income from Industrial Microbes.

Lineage continues to occupy approximately 2,432 square feet of the 1010 Atlantic Premises under a new sublease agreement (the “Alameda Sublease”). The term of the Alameda Sublease is from October 1, 2020 through January 31, 2023. Base rent under the Alameda Sublease is $14,592 per month with annual increases of 3% each October 1 thereafter during the lease term. Base rent for the first month was abated. Lineage paid a security deposit of $16,000 under the Alameda Sublease; this amount is included in deposits and other long-term assets as of September 30, 2021 (see Note 2).

Based on the smaller footprint, and after taking into consideration the fees disclosed above, Lineage has reduced its contractual obligations by approximately $780,000 over the remaining life of the original leases through January 31, 2023.

New York Leased Office Space

Lineage incurred costs of $5,050 per month for the use of approximately 900 square feet of office space in New York City, which was made available to Lineage for use in conducting meetings and other business affairs, on a month-by-month basis, by one of its directors at an amount that approximates his cost. In March 2021, Lineage terminated without penalty its leasing term related to the New York City office lease. The lease was not in the scope of ASC 842 because it is a month-to-month lease.

Cell Cure Leases

Cell Cure leases 728.5 square meters (approximately 7,842 square feet) of office and laboratory space in Jerusalem, Israel under a lease that expires December 31, 2025, with an option to extend the lease for five years each (the “Original Cell Cure Lease”). Base monthly rent is NIS 39,776 (approximately $12,200 per month using the December 7, 2020 exchange rate). In addition to base rent, Cell Cure pays a pro-rata share of real property taxes and certain costs related to the operation and maintenance of the building in which the leased premises are located.

On January 28, 2018, Cell Cure entered into another lease agreement for an additional 934 square meters (approximately 10,054 square feet) of office space in the same facility in Jerusalem, Israel under a lease that expires on December 31, 2025, with two five-year extension options (the “January 2018 Lease”). The January 2018 Lease commenced on April 1, 2018 and included a leasehold improvement construction allowance of up to NIS 4,000,000 (approximately up to US $1.1 million using the December 31, 2018 exchange rate) from the landlord. The leasehold improvements were completed in December 2018 and the entire allowance was used. Beginning on January 1, 2019, combined base rent and construction allowance payments for the January 2018 Lease are NIS 93,827 per month (approximately $26,000 per month). In December 2018, Cell Cure made a $420,000 deposit required under the January 2018 Lease, which is included in deposits and other long-term assets on the consolidated balance sheet as of December 31, 2021, to be held as restricted cash during the term of the January 2018 Lease.

On November 30, 2021, Cell Cure entered into a lease agreement for an additional 133 square meters (approximately 1,432 square feet) of office space in the same facility in Jerusalem, Israel under a lease that expires on December 31, 2025, with one five year and one approximate three-year extension options (the "November 2021 Lease"). The November 2021 Lease commenced on December 1, 2021, with a twelve-month base rent of NIS 11,880 (approximately US $3,757 using the November 30, 2021 exchange rate). On November 1, 2022, the base monthly rent increases to NIS 12,494 (approximately US $3,951 using the November 30, 2021 exchange rate).

Adoption of ASC 842

The below tables provide the amounts recorded in connection with the adoption of ASC 842 as of, and for the years ended December 31, 2021 and 2020, for Lineage's operating and financing leases, as applicable.

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

	Year Ended December 31,	
	2021	**2020**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 935	$ 1,356
Operating cash flows from financing leases	13	20
Financing cash flows from financing leases	20	26
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	213	1,047
Financing leases	39	-

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

	December 31,	
	2021	**2020**
Operating leases		
Right-of-use assets, net	$ 2,372	$ 2,916
Right-of-use lease liabilities, current	$ 801	$ 746
Right-of-use lease liabilities, noncurrent	1,941	2,514
Total operating lease liabilities	$ 2,742	$ 3,260
Financing leases		
Right-of-use assets, net	$ 36	$ -
Property and equipment, gross	$ 79	$ 79
Accumulated depreciation	(79)	(65)
Property and equipment, net	$ -	$ 14
Lease liabilities, current	$ 13	$ -
Lease liabilities, noncurrent	23	-
Total finance lease liabilities	$ 36	$ -
Other current liabilities	$ 17	$ 16
Long-term liabilities	7	26
Total finance lease liabilities	$ 24	$ 42
Weighted average remaining lease term		
Operating leases	3.5 years	4.2 years
Finance leases	2.2 years	2.4 years
Weighted average discount rate		
Operating leases	7.7%	8.0%
Finance leases	5.7%	10.0%

Future minimum lease commitments are as follows (in thousands):

	Operating Leases	Finance Leases
Year Ending December 31,		
2022	$ 1,042	$ 33
2023	583	22
2024	551	10
2025	532	-
2026	447	-
Total lease payments	$ 3,155	$ 65
Less imputed interest	(413)	(5)
Total	$ 2,742	$ 60

Roche Collaboration Agreement

On December 17, 2021, Lineage and its subsidiary, Cell Cure, entered into the Roche Agreement, wherein Lineage granted to Roche exclusive worldwide rights to develop and commercialize RPE cell therapies, including its proprietary cell therapy known as OpRegen. Roche paid Lineage a $50.0 million upfront payment and Lineage is eligible to receive up to an additional $620.0 million in certain developmental, regulatory and commercialization milestone payments. Lineage is also eligible for tiered double-digit percentage royalties on net sales of OpRegen. All regulatory and commercial milestone payments, and royalty payments, are subject to the existence of certain intellectual property rights related to OpRegen once such payments become due.

The OpRegen program has been supported in part with contributions made by Hadasit, the technology transfer company of Hadassah Medical Center, and the IIA, an independent agency created to address the needs of global innovation ecosystems. A significant portion of early development on the OpRegen program occurred at Cell Cure. Cell Cure was established by the Hadassah Medical Center, where the intellectual property underlying the differentiation and manufacture of RPE cells originated. In addition, significant monetary support for the OpRegen program was provided by the IIA through a series of separate research grants, beginning in 2007. 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 which 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 the relevant formulas provided under the Innovation Law. In November 2021, an application made by Cell Cure to the research committee of the IIA, was approved granting an exclusive license and transfer of the technological know-how for OpRegen to Roche. Under the provisions for the redemption fee, Lineage is obligated to pay the IIA a portion of the upfront, milestone, and royalty payments which may be received under the Agreement. Lineage is obligated to pay approximately 24.3% of the upfront, milestone, and royalty payments it receives from Roche to the IIA, up to an aggregate cap on all payments. As of December 31, 2021, the IIA cap amount was calculated to be approximately $102.7 million.

In addition, pursuant to the Second Amended and Restated License Agreement, dated June 15, 2017, between Cell Cure and Hadasit, as amended, and a certain letter agreement entered into on December 17, 2021, by and between Cell Cure and Hadasit, Cell Cure is obligated to pay to Hadasit a sublicensing fee of 21.5% of the upfront payment (subject to certain reductions) and any milestone payments, and up to 50% of all royalty payments (subject to a maximum payment of 5% of net sales of products), Lineage receives from Roche. The letter agreement generally terminates upon the termination of the Agreement.

In January 2022, Lineage received the $50.0 million upfront payment from Roche. Lineage made a subsequent payment of $12.1 million to the IIA, pursuant to Lineage's obligations under the Innovation Law. Additionally, Lineage made a subsequent payment of $8.9 million to Hadasit, pursuant to Lineage's obligations under the Second Amended and Restated License Agreement. Lineage reduced the Hadasit payment by $1.9 million, due to a $8.6 million budgetary commitment under the Agreement. Lineage is required to pay Hadasit 21.5% of any portion of the commitment not incurred within five years after the execution of the Agreement. Both the IIA and Hadasit payments were accrued as research and development expenses incurred, upon the execution of the Agreement within the company's year-end consolidated statement of operations.

Unless earlier terminated by either party, the 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. Either party also may terminate the Agreement in its entirety upon certain insolvency events involving the other party.

ITI Collaboration Agreement

Under our collaborative agreement with ITI we agreed to perform certain research, development, manufacturing, and oversight activities related to a VAC-CMV product up to a budgeted amount of approximately $2.2 million. ITI will reimburse the Company for material costs and full-time employee costs with no markup related to the manufacturing of the VAC-CMV product.

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

On May 6, 2020, Lineage and its wholly owned subsidiary Asterias entered into a Second Amendment to Clinical Trial and Option Agreement (the "CTOA Amendment") with Cancer Research UK ("CRUK") and Cancer Research Technology Limited ("CRT"), which amends the Clinical Trial and Option Agreement entered into between Asterias, CRUK and CRT dated September 8, 2014, as amended September 8, 2014. Pursuant to the CTOA Amendment, Lineage assumed all obligations of Asterias and exercised early its option to acquire data generated in the Phase 1 clinical trial of VAC2 in non-small cell lung cancer being conducted by CRUK. CRUK will continue conducting the VAC2 study.

Lineage and CRT effectuated the option by simultaneously entering into a license agreement (the "License Agreement") pursuant to which Lineage agreed to pay the previously agreed signature fee of £1,250,000 (approximately $1.6 million). In consideration of Lineage's agreement to exercise the option prior to completion of the study, the parties agreed to defer the signature fee as follows: £500,000 in September 2020, £500,000 in February 2021 and £250,000 in April 2021. For the primary licensed product for the first indication, the License Agreement provides for milestone fees of up to £8,000,000 based upon initiation of a Phase 3 clinical trial and the filing for regulatory approval and up to £22,500,000 in sales-based milestones payments. Additional milestone fees and sales-based milestone payments would be payable for other products or indications, and mid-single-digit royalty payments are payable on sales of commercial products.

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

Research and Option Agreement

On January 5, 2019, Lineage and Orbit Biomedical Limited ("Orbit") entered into a Research and Option Agreement, which was assigned by Orbit to Gyroscope Therapeutics Limited ("Gyroscope") and amended on May 7, 2019, January 30, 2020, May 1, 2020 and September 4, 2020 (the "Gyroscope Agreement"). As amended, the Gyroscope Agreement provided Lineage access to Gyroscope's vitrectomy-free subretinal injection device (the "Orbit Device") as a means of delivering OpRegen in Lineage's ongoing Phase 1/2a clinical trial through the earlier of: (i) December 1, 2020; or (ii) or treatment of three additional patients with the Orbit Device between September 4, 2020 and December 1, 2020 (the "Access Period"). Following the Access Period, Lineage also had an exclusive right to negotiate a definitive agreement to distribute and sell the Orbit Device for the subretinal delivery of RPE cells for the treatment of dry AMD (the "Option Period"), which was initially set to expire in February 2021. Pursuant to the terms of the Gyroscope Agreement, Lineage paid access fees totaling $2.5 million: (i) $1.25 million in January 2019 upon execution of the Gyroscope Agreement; and (ii) $1.25 million in August 2019 upon completion of certain collaborative research activities using the Gyroscope technology for the OpRegen Phase 1/2a clinical trial. These access fees of $2.5 million were amortized on a straight-line basis throughout 2019 and included in research and development expenses. Lineage also agreed to reimburse Gyroscope for costs of consumables, training services, travel costs and other out of pocket expenses incurred by Gyroscope for performing services under the Gyroscope Agreement. In January 2020, Lineage agreed to pay an additional $0.5 million to extend the Access Period to July 5, 2020, $0.2 million of which was paid in February 2020 and $0.3 million of which was paid in November 2020. The Access Period was subsequently extended two additional times at no cost and ended in accordance with the terms of the Gyroscope Agreement in November 2020. In February 2021, Lineage exercised its right to extend the initial Option Period for $0.5 million. During the extended Option Period, Lineage determined not to pursue a definitive agreement to distribute and sell the Orbit Device, and the Gyroscope Agreement terminated on May 11, 2021 upon expiration of the Option Period.

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. Except as described below, we are not currently subject to any pending material litigation, other than ordinary routine litigation incidental to our business, as described above.

On October 14, 2019, a putative class action lawsuit was filed challenging the Asterias Merger. This action (captioned *Ross v. Lineage Cell Therapeutics, Inc., et al.*, C.A. No. 2019-0822) was filed in Delaware Chancery Court and names Lineage, the Asterias board of directors, one member of Lineage's board of directors, and certain stockholders of both Lineage and Asterias as defendants. The action was brought by a purported stockholder of Asterias, on behalf of a putative class of Asterias stockholders, and asserts breach of fiduciary duty and aiding and abetting claims under Delaware law. The complaint alleges, among other things, that the process leading up to the Asterias Merger was conflicted, that the Asterias Merger consideration was inadequate, and that the proxy statement filed by Asterias with the Commission omitted certain material information, which allegedly rendered the information disclosed materially misleading. The complaint seeks, among other things, that a class be certified, the recovery of monetary damages, and attorneys' fees and costs. On December 20, 2019, the defendants moved to dismiss the complaint. On February 10, 2020, the plaintiff filed an opposition. Defendants filed their replies on March 13, 2020. On June 23, 2020, a hearing on the motions to dismiss occurred. On September 21, 2020, the Chancery Court denied the motion to dismiss as to Lineage and certain members of the Asterias board of directors, and it granted the motion to dismiss as to all other defendants. On October 30, 2020, the remaining defendants filed an answer to the complaint. The parties are currently engaged in discovery. A five-day trial before the Chancery Court is currently scheduled for October 17-21, 2022.

Lineage believes the allegations in the action lack merit and intends to vigorously defend the claims asserted. It is impossible at this time to assess whether the outcome of this proceeding will have a material adverse effect on Lineage's consolidated results of operations, cash flows or financial position. Therefore, in accordance with ASC 450, *Contingencies*, Lineage has not recorded any accrual for a contingent liability associated with this legal proceeding based on its belief that a liability, while possible, is not probable nor estimable, and any range of potential contingent liability amounts cannot be reasonably estimated at this time. Lineage records legal expenses as incurred.

Employment Contracts

Lineage has entered into employment agreements with certain 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 provide indemnifications of varying scope under Lineage's agreements with other companies or consultants, typically Lineage's clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, Lineage will generally agree to indemnify, hold harmless, and reimburse the indemnified parties 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 provisions 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 will generally continue in effect after the termination or expiration of the particular research, development, services, or license agreement to which they relate. The potential future payments Lineage could be required to make under these indemnification agreements will generally not be subject to any specified maximum amount. Historically, Lineage has not been subject to any claims or demands for indemnification. Lineage also maintains various liability insurance policies that limit Lineage's financial exposure. As a result, Lineage believes the fair value of these indemnification agreements is minimal. Accordingly, Lineage has not recorded any liabilities for these agreements as of December 31, 2021 and 2020.

Royalty obligations and license fees

Lineage and its subsidiaries or affiliates are parties to certain licensing agreements with research institutions, universities and other parties for the rights to use those licenses and other intellectual property in conducting research and development activities. These licensing agreements provide for the payment of royalties by Lineage or the applicable party to the agreement on future product sales, if any. In addition, in order to maintain these licenses and other rights during the product development, Lineage or the applicable party to the contract must comply with various conditions including the payment of patent related costs and annual minimum maintenance fees. Annual minimum maintenance fees are expected to be approximately $30,000 to $60,000 per year.

As part of the Asterias Merger, Lineage acquired certain royalty revenues for cash flows that were generated under certain specific patent families that Asterias previously acquired from Geron. Asterias paid Geron a royalty for all royalty revenues received from these contracts. Lineage continues to make royalty payments to Geron for royalties generated from these patents.

15. Employee Benefit Plan

We have a defined contribution 401(k) plan for all employees. Under the terms of the plan, employees may make voluntary contributions as a percentage or defined amount of compensation. We provide a safe harbor contribution of up to 5.0% of the employee's compensation, not to exceed eligible limits, and subject to employee participation. For the years ended December 31, 2021 and 2020, we incurred approximately $164,000 and $149,000, respectively, in expenses related to the safe harbor contribution.

16. Segment Information

Lineage's executive management team, as a group, represents the entity's chief operating decision makers. Lineage's executive management team views Lineage's operations as one segment that includes the research and development of therapeutic products for retinal diseases, neurological diseases and disorders and oncology. As a result, the financial information disclosed materially represents all the financial information related to Lineage's sole operating segment.

17. Enterprise-Wide Disclosures

Geographic Area Information

The following table presents consolidated revenues, including license fees, royalties, grant income, and other revenues, disaggregated by geography, based on the billing addresses of customers, or in the case of grant revenues based on where the governmental entities that fund the grant are located (in thousands).

	Year Ended December 31,	
Geographic Area	**2021**	**2020**
United States	$ 3,895	$ 1,160
Foreign [(1)]	446	666
Total revenues	$ 4,341	$ 1,826

(1) Foreign revenues are primarily generated from grants in Israel.

The composition of Lineage's long-lived assets, consisting of plant and equipment, net, between those in the United States and in foreign countries, as of December 31, 2021 and 2020, is set forth below (in thousands):

	December 31,	
	2021	**2020**
Domestic	$ 548	$ 1,035
Foreign [(1)]	4,324	4,595
Total	$ 4,872	$ 5,630

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

Major Sources of Revenues

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

	Year Ended December 31,	
	2021	**2020**
REVENUES:		
Royalties	$ 2,776	$ 773
Collaboration revenues	1,120	-
Grant revenues	445	1,053
Total revenues	$ 4,341	$ 1,826

Prepaid expenses and other current assets at December 31, 2021 includes $0.1 million of receivables related to cash in transit for sales of ATM Shares in 2021 that settled in 2022, and $0.2 million of receivables related to cash in transit for the exercise of stock options in 2021 that settled in 2022.

The following table shows Lineage's major sources of revenues, as a percentage of total revenues, that were recognized during the years ended December 31, 2021 and 2020:

	Year Ended December 31,	
Sources of Revenues	**2021**	**2020**
Royalties	63.9%	42.3%
Collaboration revenues	25.8%	-%
Grant revenues	10.3%	57.7%

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

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

Year Ended December 31, 2021	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues, net	$ 391	512	2,270	1,168
Operating expenses	7,329	7,467	8,128	29,202
Loss from operations	(7,050)	(7,080)	(6,843)	(28,238)
Net loss attributable to Lineage	(1,416)	(4,788)	(7,823)	(28,992)
Basic net income (loss) per share	$ (0.01)	$ (0.03)	$ (0.05)	$ (0.17)
Year Ended December 31, 2020				
Revenues, net	$ 514	386	571	355
Operating expenses	7,858	6,713	7,194	6,123
Loss from operations	(7,438)	(6,402)	(6,725)	(5,882)
Net income (loss) attributable to Lineage	(8,399)	(6,522)	(7,760)	2,032
Basic net income (loss) per share	$ (0.06)	$ (0.04)	$ (0.05)	$ 0.01

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

19. Subsequent Events

Receipt of Roche Upfront Payment

In January 2022, Lineage received a $50.0 million upfront payment related to the Roche Agreement. Lineage made a subsequent payment of $12.1 million to the IIA, pursuant to Lineage's obligations under the Innovation Law. Additionally, Lineage made a subsequent payment of $8.9 million to Hadasit, pursuant to Lineage's obligations under the Hadasit License. Lineage reduced the Hadasit payment by $1.9 million, due to a $8.6 million budgetary commitment under the Roche Agreement. Lineage is required to pay Hadasit 21.5% of any portion of the commitment not incurred within five years after the execution of the Roche Agreement. The IIA and Hadasit payments were expensed on the consolidated statement of operations as of December 31, 2021, offset with an accrued liability on the consolidated balance sheet.

Restricted Stock Unit Awards

On February 11, 2022, the Board of Directors at Lineage, approved restricted stock unit awards for an aggregate amount of 694,424. The awards were issued under the 2021 Plan, which defines restricted stock units as a full value award, which reduce the Plan's common shares available for grant by 1.50 shares for each share issued. As of December 31, 2021, there were 16,382,385 shares available for grant under the 2021 Plan.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Securities Exchange Act of 1934 ("Exchange Act"). Our management, including our principal executive officer and our principal financial officer, as amended, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of the end of our fourth quarter. Following this review and evaluation, management collectively determined that our disclosure controls and procedures are effective 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 Securities and Exchange Commission rules and forms; and (ii) is accumulated and communicated to management, including our chief executive officer and our chief 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 2021 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, our principal operations 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, 2021, based on criteria established in the 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management believes that, as of that date, our internal control over financial reporting was effective.

ITEM 9B. OTHER INFORMATION

On March 9, 2022, our board of directors set June 16, 2022 as the date of our 2022 annual meeting of shareholders (the "2022 Annual Meeting"). This date is more than 30 days before the one-year anniversary of our 2021 annual meeting of shareholders, which was held on September 13, 2021. In light of the foregoing, and in accordance with our amended and restated bylaws (the "Bylaws"), in order for any business to be brought before the 2022 Annual Meeting by a shareholder and for any person to be nominated for election to our board of directors at the 2022 Annual Meeting, by a shareholder, such shareholder must notify us of such intention by notice received at our principal executive offices not later than the close of business on March 31, 2022. Shareholder proposals intended for inclusion in our proxy statement for the 2022 Annual Meeting pursuant to Rule 14a-8 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), must be received at our principal executive offices no later than the close of business on March 31, 2022, which we believe is a reasonable time before we begin to print and mail proxy materials for the 2022 Annual Meeting. In addition, all such shareholder notices and shareholder proposals must conform to the applicable requirements of the Bylaws, the rules and regulations promulgated under the Exchange Act and other applicable law. All such notices and shareholder proposals should be directed to: "2173 Salk Avenue, Suite 200, Carlsbad, CA 92008, Attention: Secretary."

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The name, age, and background of each of our directors are contained under the caption “Board of Directors” in our Proxy Statement for our 2022 Annual Meeting of Shareholders (the “2022 Proxy Statement”) and are incorporated herein by reference. Information about our executive officers, committees of the Board of Directors, and compensation of directors is reported under the captions “Executive Officers” and “Corporate Governance” in our 2022 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.

Information about our compliance with Section 16(a) of the Securities Exchange Act of 1934 is reported under the caption “Delinquent Section 16(a) Reports” in our 2022 Proxy Statement and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

Information on compensation of our executive officers is reported under the caption “Executive Compensation” in our 2022 Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT, AND RELATED STOCKHOLDER MATTERS

Information on the number of common shares of Lineage beneficially owned by: (i) each shareholder known by us to be the beneficial owner of 5% or more of our common shares; (ii) each of our directors; (iii) each of our named executive officers; and (iv) all of our current directors and executive officers as a group is contained under the caption “Principal Shareholders” in our 2022 Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information about transactions with related persons; review, and approval or ratification of transactions with related persons; and director independence is reported under the captions “Board of Directors” and “Certain Relationships and Related Transactions” in our 2022 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information about our Audit Committee’s pre-approval policy for audit services, and information on our principal accounting fees and services is reported under the caption “Ratification of the Selection of Our Independent Registered Public Accounting Firm” in our 2022 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND, FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements.

The following financial statements of Lineage are filed in this Report:

(a)(2) Financial Statement Schedules

There are no financial statement schedules provided because the information called for is either not required or is shown either in the financial statements or the notes thereto.

(a)(3) Exhibits.

		Incorporation by Reference			
Exhibit Number	**Description**	**Exhibit Number**	**Filing**	**Filing Date**	**File No.**
2.1^	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
3.1	Restated Articles of Incorporation, as amended	3.1	10-Q	May 10, 2018	001-12830
3.2	Certificate of Ownership	3.1	8-K	August 12, 2019	001-12830
3.3	Amended and Restated Bylaws	3.2	8-K	August 12, 2019	001-12830
4.1	Specimen of Common Share Certificate		S-1	December 18, 1991	033-44549
4.2	Description of Capital Stock of the Registrant	4.2	10-K	March 11, 2021	001-12830
10.1	Commercial License and Option Agreement between Registrant and Wisconsin Alumni Research Foundation ("WARF Agreement")	10.1	8-K	January 9, 2008	001-12830
10.1(a)	First Amendment of WARF Agreement dated March 11, 2009	10.38	10-K	March 23, 2009	001-12830
10.2+	Lineage Cell Therapeutics 2012 Equity Incentive Plan, as amended July 2015 ("2012 Plan")	4.1	S-8	July 15, 2015	333-205661
10.2(a)+	Amendment to 2012 Plan effective June 2017	4.2	S-8	July 7, 2017	333-219204
10.2(b)+	Amendment to 2012 Plan effective July 2019	99.3	S-8	August 8, 2019	333-233132
10.2(c)+	Amendment to 2012 Plan effective August 2019	10.1	10-Q	November 12, 2019	001-12830
10.2(d)+	2012 Plan Form of Employee Incentive Stock Option Agreement	10.7	10-Q	November 12, 2013	001-12830
10.2(e)+	2012 Plan Form of Non-employee Director Stock Option Agreement	10.8	10-Q	November 12, 2013	001-12830
10.2(f)+	2012 Plan Stock Option Grant Agreement	10.2	10-Q	November 12, 2019	000-12830
10.2(g)+	2012 Plan Form of Restricted Stock Unit	10.6	10-K	March 12, 2020	001-12830
10.3+	Inducement Stock Option Agreement between Registrant and Brian Culley	10.38	10-K	March 14, 2019	001-12830
10.4†	Second Amended and Restated License Agreement dated June 15, 2017, between Cell Cure Neurosciences, Ltd. and Hadasit Medical Research Services and Development Ltd. ("Hadasit License")	10.2	10-Q	August 9, 2017	001-12830

10.4(a)	Amendment to Hadasit License dated January 8, 2018	10.38	10-K	March 15, 2018	001-12830
10.4(b) *††	Second Amendment to Hadasit License dated December 1, 2019				
10.4(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(d) *††	Second Side Letter Agreement dated December 17, 2021 between Hadasit Medical Research Services and Development Ltd. and Cell Cure Neurosciences Ltd.				
10.5†	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
10.6†	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
10.7+	Employment Agreement effective September 17, 2018, between Registrant and Brian Culley	10.1	8-K	September 18, 2018	001-12830
10.8	Royalty Agreement dated October 1, 2013, between Asterias and Geron Corporation	10.6	Asterias S-1/A	August 13, 2013	333-187706
10.9	Exclusive Sublicense Agreement between Geron Corporation and Asterias	10.7	Asterias S-1/A	August 13, 2013	333-187706
10.10†	Non-exclusive License Agreement dated October 7, 2013, between WARF and Asterias	10.5	Asterias 10-Q	November 12, 2013	000-55046
10.11†	Clinical Trial and Option Agreement dated September 8, 2014, between Asterias and Cancer Research UK and Cancer Research Technology Limited	10.1	Asterias 10-Q/A	January 13, 2015	001-36646
10.11(a)††	Second Amendment to Clinical Trial and Option Agreement dated May 6, 2020 between Cancer Research UK, Cancer Research Technology Limited, Asterias Biotherapeutics, Inc. and Registrant	10.1	10-Q	August 6, 2020	001-12830
10.12††	Agreement dated May 6, 2020 between CRT and Registrant	10.2	10-Q	August 6, 2020	001-12830
10.13*††	Collaboration and License Agreement dated December 17, 2021 between F. Hoffmann-La Roche Ltd, Genentech, Inc., Cell Cure Neurosciences Ltd., and Registrant				
21.1*	List of Subsidiaries				
23.1*	Consent of WithumSmith+Brown, PC				
23.2*	Consent of OUM & Co. LLP				
31.1*	Certification of Chief Executive Officer and Interim Chief Financial Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002				
32.1#	Certification of Chief Executive Officer and Interim Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101*	Interactive Data File				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase				
101.DEF*	XBRL Taxonomy Extension Definition Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase				
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
† Portions of this exhibit have been omitted pursuant to a request for confidential treatment
†† Certain information in this exhibit has been omitted pursuant to Item 601 of Regulation S-K.

ITEM 16. FORM 10-K SUMMARY

None

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized on the 10th day of March 2022.

LINEAGE CELL THERAPEUTICS, INC.

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

Signature	Title	Date
/s/ Brian M. Culley BRIAN M. CULLEY	Chief Executive Officer and Director (Principal Executive)	March 10, 2022
/s/ Kevin Leon Cook KEVIN LEON COOK	Chief Financial Officer (Principal Financial and Accounting Officer)	March 10, 2022
/s/ Deborah Andrews DEBORAH ANDREWS	Director	March 10, 2022
/s/ Dipti Amin DIPTI AMIN	Director	March 10, 2022
/s/ Don M. Bailey DON M. BAILEY	Director	March 10, 2022
/s/ Neal C. Bradsher NEAL C. BRADSHER	Director	March 10, 2022
/s/ Alfred D. Kingsley ALFRED D. KINGSLEY	Director	March 10, 2022
/s/ Anula Jayasuriya ANULA JAYASURIYA	Director	March 10, 2022
/s/ Michael H. Mulroy MICHAEL H. MULROY	Director	March 10, 2022
/s/ Angus C. Russell ANGUS C. RUSSELL	Director	March 10, 2022

Exhibit 10.4

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

SECOND AMENDMENT TO SECOND AMENDED AND RESTATED LICENSE AGREEMENT

This Second Amendment (this "**Amendment**") is made on December 1, 2019 as an amendment to the Second Amended and Restated License Agreement of June 15, 2017 (the "**Agreement**") and amended by the First Amendment to the Second Amended and Restated License Agreement of November 2017, by and between **HADASIT MEDICAL RESEARCH SERVICES AND DEVELOPMENT LTD.** ("**Hadasit**") and **CELL CURE NEUROSCIENCES LTD.** (the "**Company**") (each a "**Party**" and jointly the "**Parties**"), effective as of the same date as the Agreement.

WHEREAS: The Parties have discussed the terms of the Agreement and have mutually agreed to further amend the Agreement terms as set out herein.

NOW THEREFORE THE PARTIES DO HEREBY AGREE AS FOLLOWS:

1. Capitalized terms used but not defined herein shall, unless otherwise indicated, have the meaning ascribed to such terms in the Agreement.

2. The New Research Agreement which is being executed contemporaneously with this Amendment, and which forms Annex E of the Agreement, is attached hereto and marked: Annex E — Research Agreement.

3. Annex G which lists the Development Milestones is hereby replaced, in its entirety, with the updated version attached hereto and marked "Annex G - Projected Development Milestones for Photoreceptor Fields - August 15, 2019".

4. The definition of "Hadasit IP" appearing in Section 1.2.12 of the Agreement is hereby amended by the addition of the following sentence:

   "In addition, 'Hadasit IP' shall include all 'Research Results' and all 'Hadasit Research Inventions' as defined in the New Research Agreement."

5. The definition of "Joint IP" appearing in Section 1.2.18 of the Agreement is hereby amended by the addition of the following sentence:

   "In addition, 'Joint IP' shall include all 'Joint Research Inventions' as defined in the New Research Agreement."

6. The Parties agree that, if the Company seeks IIA funding to fund the research performed by Hadasit under the New Research Agreement and the IIA demands, as a pre-condition to such funding, deviations from Hadasit's ownership rights in intellectual property developed by Hadasit under the New Research Agreement as set forth in this Agreement pursuant to the definitions of Hadasit IP and Joint IP, the Parties will negotiate in good faith and in a timely manner, possible changes to the provisions of the Agreement relating to the ownership of such intellectual property, so as to facilitate such funding.

7. Except as specifically provided in and required by this Amendment, the terms and conditions of the Agreement shall remain in full force and effect. In the event of a contradiction between the provisions of this Amendment and the provisions of the Agreement, the provisions of this Amendment shall prevail.

IN WITNESS WHEREOF, the Parties have duly executed this Amendment:

HADASIT		**CELL CURE NEUROSCIENCES LTD.**	
By:	*/s/ Dr. Tamar Raz*	By:	*/s/ Rami Skaliter*
Name:	DR. TAMAR RAZ	Name:	Rami Skaliter
Title:	CEO, Hadasit Medical Research Services & Development, Ltd.	Title:	CEO
Date:	1/12/2019	Date:	Nov 25 2019

RAMI SKALITER
CHIEF EXECUTIVE OFFICER
CELL CURE NEUROSCIENCES

Annex E
(Second Amendment to the Second Amended and Restated License Agreement)

- [***].

Annex G
(Second Amendment to the Second Amended and Restated License Agreement)

- [***].

Exhibit 10.4(c)

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

SIDE LETTER TO SECOND AMENDED AND RESTATED LICENSE AGREEMENT

This side letter ("**Side Letter**") to the Second Amended and Restated License Agreement is made and entered into, effective as of December 17, 2021 (the "**Side Letter Effective Date**"), by and among Hadasit Medical Research Services and Development Ltd. ("**Hadasit**"), Cell Cure Neurosciences Ltd. ("**CCN**") and Genentech, Inc. ("**Genentech**") and F. Hoffmann-La Roche Ltd. ("**FHLR**"; together with Genentech, "**Roche**"). Hadasit, CCN and Roche are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

Hadasit and CCN entered into that certain Second Amended and Restated License Agreement, effective as of June 15, 2017, as amended on November 30 2017 and on December 1, 2019, (the "**Agreement**"), pursuant to which Hadasit granted an exclusive license to CCN under certain of its intellectual property rights. Lineage Cell Therapeutics, Inc., parent of CCN ("**Lineage**"), and Roche, concurrently with the execution of this Side Letter, will execute a global collaboration and license agreement (the "**Roche Agreement**"; attached hereto as **Exhibit A**) related to the continued development and commercialization of products containing or comprising human stem cell-derived (such as human embryonic stem cell-derived and human induced pluripotent stem cell-derived) retinal pigment epithelial cells, and any precursors or progenitors thereof ("**RPE Cells**") (including without limitation, OpRegen®).

In relation to the Roche Agreement, the Parties desire to modify certain terms and conditions under the Agreement solely as they apply to the Roche Agreement and only with respect to the use of RPE Cells solely for use in cell therapy for the diagnosis, amelioration, prevention and/or treatment of eye disorders ("**RPE Field**"). For clarity, such modifications shall only apply with respect to the Parties' obligations under the Agreement with respect to activities under the Roche Agreement. In addition, such changes shall cease to apply if CCN or its assets relating to subject matter of the Roche Agreement is/are acquired by Roche or an Affiliate of Roche or if CCN becomes an Affiliate of Roche.

Further to the above, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS

1.1 **Capitalized Terms**. Capitalized terms used in this Side Letter shall have the meanings set forth in the Agreement, unless otherwise defined hereunder.

2. ACKNOWLEDGMENT; SCOPE; OPPORTUNITY TO CURE BREACH; DIRECT LICENSE TO ROCHE

2.1 **Acknowledgment of Roche Agreement.** Hadasit hereby acknowledges and consents to the identity of Roche as a Sublicensee of Lineage as contemplated under the Roche Agreement with Roche. Nothing in this Section 2.1 shall be deemed a confirmation by Hadasit that the Roche Agreement is consistent with the terms of the Agreement or as a consent by Hadasit to any provisions that may be inconsistent with the Agreement, except as specifically agreed to in this Side Letter.

2.2 **Scope**. This Side Letter and the terms and conditions hereunder relate to the scope of the rights and obligations granted under the Agreement for the RPE Field only.

2.3 **Ability for Roche to Cure Breach**. If, at any time during the Term (as defined in the Roche Agreement), CCN breaches the Agreement, Hadasit shall notify Roche of such breach in writing simultaneously with Hadasit's notice thereof to CCN pursuant to the Agreement. If CCN fails to cure such breach within the applicable cure period set forth in the Agreement and such breach was not caused by an act or omission of Roche, Roche shall have the right, within thirty (30) days after the last day of CCN's cure period to cure such breach on behalf of CCN, provided Roche notifies Hadasit on or before the last day of CCN's cure period under the Agreement that it intends to cure such breach. For clarity, if Roche elects not to cure such breach, such election shall not be deemed a breach of this Side Letter by Roche or of the Roche Agreement.

2.4 **Direct License to Roche**.

2.4.1 During the Term (as defined in the Roche Agreement), if the Agreement, or any license thereunder with respect to the Licensed Materials or Licensed Technology in the RPE Field, is terminated or otherwise ceases to be in effect for any reason, Hadasit and CCN shall within [***] provide written notice thereof to Roche (the "**Termination Notice**"). Whether or not such notice is provided, the agreement attached hereto in Exhibit B ("**Direct License**") will automatically and without further action required by Roche (including any obligation to pay to Hadasit any additional consideration that is not set forth in the Agreement with respect to Licensed Products in the RPE Field) go into effect, with effect from the effective date of termination of the Agreement (or, as applicable, termination of any of the license(s) thereunder with respect to the Licensed Materials or Licensed Technology. Upon effectiveness of the Direct License, CCN and Lineage hereby waive any claims against Hadasit for breach of the Agreement due to grant of the Direct License.

2.4.2 As a condition to the Direct License remaining in effect, within [***] of Roche receiving the Termination Notice, Roche shall: (a) provide written confirmation to Hadasit that (i) Roche is not in breach of the Roche Agreement at the time the Direct License becomes effective and (ii) termination of the Agreement did not result from an uncured material breach of the Roche Agreement by Roche; and (b) pay to Hadasit any outstanding amounts that are or become due under Article 3 of the Agreement (as amended by that certain side letter of even date herewith among Hadasit, CCN and Lineage) by CCN to Hadasit. For clarity, Roche shall not owe to Hadasit amounts in addition to, or in excess of, the amounts that would be owed by CCN to Hadasit pursuant to Article 3 of the Agreement with respect to the Licensed Products in the RPE Field. If Roche provides written notice to Hadasit that Roche does not wish to retain the Direct License, or if Roche does not satisfy its obligations under (a) and (b) of this Section 2.4.2, then the Direct License shall terminate upon the lapse of such [***] period.

3. AMENDMENTS TO AGREEMENT

3.1 **Amendment to Section 2.2**. Notwithstanding anything to the contrary stated in Section 2.2 of the Agreement or herein:

3.1.1 With respect to Hadasit's or its Affiliate's exercise of the retained rights to practice the Licensed Technology and to use the Licensed Materials within the Field under Section 2.2(A), Hadasit shall provide to Roche: (a) any results generated by Hadasit or its Affiliates following the date of this Side Letter using the [***] cell lines or RPE Cells derived therefrom, (b) any results received from any academic or not-for-profit research organizations using the Licensed Technology, [***] cell lines, or RPE Cells derived therefrom, transferred to such organizations pursuant to an MTA, subject to Section 3.1.2, and (c) any resulting proposed publications for Roche's review and potential reasonable delay of publication to enable related patent filings.

3.1.2 With respect to Hadasit's or its Affiliate's exercise of its retained rights to transfer the Licensed Materials (except for the Licensed Feeder Cell Line) within the Field under Section 2.2(A)(ii), the MTA governing such transfer shall be substantially in the form of Annex F, which shall be revised to include a prohibition of Third Parties from filing any patent applications within the RPE Field.

3.2 **Amendment to Section 2.5**. Notwithstanding anything to the contrary stated in Section 2.5 of the Agreement or herein:

3.2.1 Roche, as the Sublicensee, may grant further sublicenses (through multiple tiers) (each, a "**Further Sublicense**") in accordance with the Roche Agreement; provided that such Further Sublicenses comply with the terms of Section 2.5 of the Agreement, subject to the amendments set forth in this Section 3.2 and provided, further, that Roche shall remain responsible for each Further Sublicensee's compliance with the applicable provisions of the Agreement in connection with such performance. CCN and Hadasit hereby agree that each Further Sublicense shall be deemed a "Sublicense" and each entity granted a Further Sublicense shall be deemed a "Sublicensee" for purposes of the Agreement.

3.2.2 Section 2.5(i) of the Agreement shall not apply with respect to any Further Sublicensees.

3.2.3 Section 2.5(v) of the Agreement shall not apply with respect to any Further Sublicensee; provided that Roche remains responsible for such Further Sublicensee's compliance with the applicable provisions of the Roche Agreement in connection with such Further Sublicensee's performance. Notwithstanding the foregoing sentence, if Roche exclusively sublicenses its right to commercialize a Licensed Product under the Roche Agreement, Section 2.5(v) of the Agreement shall apply to such Further Sublicensee.

3.2.4 To satisfy its obligations under Section 2.5(v), Roche may, in its sole discretion, self-insure, in part or in whole, for coverage of any liability resulting from the performance of a Further Sublicensee.

3.2.5 Section 2.5(vii) of the Agreement shall not apply with respect to any agreements between Roche and Further Sublicensees; provided that, Roche shall provide to Hadasit the identity of each such Further Sublicensee and the scope of rights granted to such Further Sublicensee with respect to Licensed Materials promptly after execution of the sublicense agreement with such Further Sublicensee.

3.2.6 Section 2.5(viii)(A) of the Agreement shall not apply with respect to the performance of any activities under or in connection with the Roche Agreement; provided however that if the human embryonic stem cell line known as [***] is transferred to a Further Sublicensee, Roche shall provide to Hadasit the identity of such Further Sublicensee together with a confirmation that the Further Sublicensee has undertaken to limit its use of such line to the RPE Field.

3.2.7 Section 2.5(x) of the Agreement shall not apply with respect to the performance of any activities under or in connection with the Roche Agreement; provided that if Roche desires to transfer Licensed Materials to a Further Sublicensee, Roche shall provide to Hadasit the identity of such Further Sublicensee together with a confirmation that the Further Sublicensee has undertaken to limit its use of such line to the RPE Field.

3.2.8 Pursuant to Section 2.5(xi) of the Agreement, Roche shall provide to Hadasit any amendments to the Roche Agreement, provided however that the approval provisions of Section 2.5(xi) of the Agreement shall not apply with respect to such amendments. To the extent any provision of the Roche Agreement that is referred to in this Side Letter is amended or is impacted by any such proposed amendment, such provision shall be deemed unchanged for purposes of this Side Letter unless Hadasit consents in writing to such amended provision (such consent not to be unreasonably withheld).

3.3 **Amendment to Section 4.1**. Notwithstanding anything set forth in Section 4.1 of the Agreement, the obligations of CCN under Section 4.1 of the Agreement with respect to the development of Licensed Products in the RPE Field shall be deemed satisfied for so long as Roche satisfies its diligence obligations as set forth in Section 3.8 of the Roche Agreement with respect to a "Licensed Product" (as defined in the Roche Agreement). For the avoidance of doubt, the Parties acknowledge and agree that a "Licensed Product" as defined in the Roche Agreement qualifies as a "Licensed Product" as defined in the Agreement.

3.4 **Amendment to Article 5**. Notwithstanding anything set forth in Article 5 of the Agreement:

3.4.1 With respect to Roche's obligations as a Sublicensee under Section 5.3 and Section 5.5 of the Agreement, such obligations shall not apply to Roche with respect to the performance of activities under or in connection with the Roche Agreement for so long as Roche complies with any applicable federal, state, local, foreign, or multinational law (including, GCP, GLP, GMP, and data protection and privacy laws), ethical guidelines (such the ISSCR guidelines and the American Academy of Sciences), statute, standard, ordinance, code, rule, regulation, resolution, or promulgation, or any order, writ, judgment, injunction, decree, stipulation, ruling, determination, or award entered by or with any governmental authority, or any license, franchise, permit, or similar right granted under any of the foregoing, or any similar provision having the force or effect of law with respect to Roche's activities under the Roche Agreement or exercise of it rights.

3.4.2 Section 5.8 of the Agreement shall not apply with respect to the performance of activities pursuant to the Roche Agreement. However, in the event that Roche decides to conduct a Phase IIb and/or a Phase III clinical trial in Israel in the RPE Field, Roche shall in good faith provide Hadasit with an opportunity to make a proposal to conduct the applicable clinical trial and include Hadasit in a priority review for Roche's clinical trial feasibility assessment taking into account Hadassah Medical Organization's previous experience, staff availability, competing studies, site equipment, patient population, enrollment potential, budget, and start-up timelines. Notwithstanding the foregoing, final clinical site selection shall be in Roche's reasonable discretion.

3.5 **Amendment to Article 7**. Notwithstanding anything set forth in Article 7 of the Agreement:

3.5.1 With respect to Section 7.1 of the Agreement, with respect to activities performed under the Roche Agreement, (a) a Development Report shall be provided to Hadasit by CCN [***], and (b) such Development Report shall consist of a summary of Roche's progress in the development of Licensed Products (as defined in the Roche Agreement). For the avoidance of doubt, such Development Report shall not be required to include (i) sales forecasts or (ii) any reports with respect to testing results regarding the Licensed Materials, including safety test results and QC characterization results that will be performed on the Licensed Materials by or on behalf of Roche, or any documentation related thereto.

3.5.2 With respect to Section 7.2 of the Agreement, with respect to activities performed under the Roche Agreement, (a) the identity of the seller (as described in Section 7.2(ii) of the Agreement) shall not be required in sales report; and (b) deductions to Net Sales (as described in Section 7.2(iii) of the Agreement) shall be listed by category of deduction (not individual deductions).

3.6 **Amendment to Article 9 and Article 10**.

3.6.1 Company may grant Roche the right to act in its place under Article 9 and Article 10 of the Agreement with respect to the prosecution, maintenance, defense, and enforcement of any Licensed Patents that cover the Licensed Products (as defined in the Roche Agreement) for so long as the Roche Agreement remains in effect. If Company grants such right, references to "Company" in Article 9 and Article 10 of the Agreement shall be replaced by "Roche" as applicable.

3.7 **Amendment to Article 11**. Notwithstanding anything set forth in Article 11 of the Agreement:

3.7.1 For the avoidance of doubt, the publication rights of Hadasit, Prof. Reubinoff, and other Researchers under Section 11.7 of the Agreement shall not apply with respect to the activities performed or information generated under the Roche Agreement. Hadasit represents and warrants that, except for (i) materials produced by Hadasit or HMO for CCN and (ii) materials received or work performed under clinical trial agreements between Hadasit and its Affiliates, on the one hand, and Lineage or CCN or their respective Affiliate, on the other hand, to its knowledge, neither Hadasit nor its Affiliates has received OpRegen® or access thereto. Hadasit further represents and warrants that neither Hadasit nor its Affiliates is conducting, will conduct, or will enable any third party to conduct, any research using OpRegen®.

3.7.2 For the avoidance of doubt, Section 11.8 shall not apply to any activities performed under the Roche Agreement, provided that such studies were not in progress as of the Side Letter Effective Date.

3.8 **Amendment to Article 13**. Notwithstanding anything set forth in Article 13 of the Agreement:

3.8.1 With respect to Section 13.4.1, any continued development efforts (including non-clinical development efforts) by CCN or Roche, and any periods during which either CCN or Roche, as applicable, is awaiting feedback from regulatory authorities shall qualify as "continuing clinical development" for purposes of Section 13.4.1.

3.8.2 With respect to Section 13.4.2, in the event that CCN fails to satisfy its obligations to furnish a Development Report under Section 7.1 of the Agreement, Hadasit shall provide written notice to Roche as set forth in Section 2.3 of this Agreement, and Roche shall have the right to cure such breach in accordance with such provision.

3.8.3 Section 13.5 of the Agreement shall not apply with respect to any Company IP or any other Intellectual Property arising under or in connection with the performance of activities pursuant to the Roche Agreement.

4. MISCELLANEOUS

4.1 **Notices**. Any notice or communication required to be given by one Party to any other in connection with this Side Letter shall be made in accordance with Article 17, *mutatis mutandis*, and shall specifically refer to this Side Letter. Notices to Roche shall be sent at the addresses set forth below.

F. Hoffmann-La Roche Ltd
Attention: Legal Department
Grenzacherstrasse 124
CH-4070 Basel
Switzerland

and to

Genentech, Inc.
Attn: Corporate Secretary
1 DNA Way
South San Francisco, CA 94080

with required copies (which shall not constitute notice) to**:**

Genentech, Inc.
Attn: Head of Global Asset & Alliance Management
1 DNA Way
South San Francisco, CA 94080

4.2 **Amendments.** No amendment, modification, release, or discharge of this Side Letter shall be binding upon the Parties unless in writing and duly executed by authorized representatives of all Parties. Hadasit and CCN each covenants to Roche that it will not amend the Agreement in a manner that, directly or indirectly, would impair or have an adverse effect on any of Roche's (sub)licenses or other rights under the Agreement or the Roche Agreement, without Roche's prior written consent. Hadasit and CCN acknowledge that this Side Letter constitutes a valid amendment for purposes of Section 19.5 of the Agreement if and to the extent any terms and conditions of the Agreement, as applicable, are expressly modified or amended by this Side Letter solely as they apply to the Roche Agreement. Except as contemplated by the immediately preceding sentence, the terms and conditions of the Agreement shall remain unchanged as set forth therein.

4.3 **Assignment.** Each of Hadasit, CCN, Roche and their respective Affiliates shall have the right to assign this Side Letter only to the extent such assignment would be permitted under Article 14 of the Agreement (with respect to such agreement), including in the case of Roche, as if Roche were CCN under the Agreement. Notwithstanding the foregoing, Roche shall have the right to assign this Side Letter to any of its Affiliates together with the assignment of the Roche Agreement to such Affiliate, to the extent such assignment would be permitted under Section 15.3 of the Roche Agreement and without the advance written consent of Hadasit or CCN.

4.4 **Side Letter Controls.** This is the entire Side Letter among the Parties with respect to the subject matter hereof and supersedes all prior representations, understanding and agreements among the Parties with respect to the subject matter hereof. In the event of any conflict between the Agreement and this Side Letter as it applies to Roche's rights and obligations, the terms of this Side Letter shall control with respect to Roche's rights and obligations.

4.5 **Governing Law.** This Side Letter shall be governed by and interpreted in accordance with the laws of Israel and the Parties hereby submit to the exclusive jurisdiction of the competent courts in Jerusalem.

4.6 **Counterparts.** This Side Letter may be executed in two or more counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Side Letter by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Side Letter.

4.7 **Termination.** This Side Letter shall terminate concurrently upon the termination of the Roche Agreement only if the Roche Agreement is terminated by (a) Lineage for Roche's uncured material breach or (b) Roche in exercise of its right of elective termination. For clarity, in the event that Roche does not satisfy the conditions set forth in Section 2.4.2 of this Side Letter, or Roche notifies Hadasit that it does not wish to retain the Direct License, then this Side Letter shall terminate.

[***Remainder of the Page Intentionally Left Blank***]

Hadasit, CCN, FHLR, and Genentech have executed this Side Letter by their respective and duly authorized officers, as evidenced by their signatures below.

HADASIT MEDICAL RESEARCH SERVICES AND DEVELOPMENT LTD.

By: */s/ Carol Grumbach*

Name: Carol Grumbach

Title: CFO

Date: 12/14/21

CELL CURE NEUROSCIENCES LTD.

By: */s/ Rami Skaliter*

Name: Rami Skaliter

Title: CEO

Date: 12/13/2021

LINEAGE CELL THERAPEUTICS, INC.

By: */s/ Brian Culley*

Name: Brian Culley

Title: CEO

Date: 12/13/2021

F. HOFFMANN - LA ROCHE LTD

By: */s/ Barbara Schroeder de Castro Lopes*

Name: Barbara Schroeder de Castro Lopes

Title: Authorized Signatory

Date: 12/14/2021

By: */s/ Vikas Kabra*

Name: Vikas Kabra

Title: Head Transaction Excellence

Date: 12/14/2021

GENENTECH, INC.

By: */s/ Edward Harrington*

Name: Edward Harrington

Title: CFO, Genentech

Date: 12/14/2021

By: */s/ Andrew Le*

Name: Andrew Le

By: */s/ Jon Aumais*

Name: Jon Aumais

Exhibit 10.4(d)

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Confidential

December 17, 2021

SECOND SIDE LETTER TO SECOND AMENDED AND RESTATED LICENSE AGREEMENT

This side letter (the "**Second Side Letter**") to the Second Amended and Restated License Agreement is made and entered into, effective as of December 17, 2021 by and between Hadasit Medical Research Services and Development Ltd. ("**Hadasit**") and Cell Cure Neurosciences Ltd. ("**CCN**"). Hadasit and CCN are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**".

Hadasit and CCN entered into that certain Second Amended and Restated License Agreement, effective as of June 15, 2017 (the "**License Agreement**") as amended in November 2017 by the First Amendment to Second Amended and Restated License Agreement (the "**First Amendment**") and on December 1, 2019 by the Second Amended and Restated License Agreement (the "**Second Amendment**") (the License Agreement as amended by the First Amendment and the Second Amendment, the "**Agreement**"), pursuant to which Hadasit granted an exclusive license to CCN under certain of its intellectual property rights.

Lineage Cell Therapeutics, Inc., parent of CCN (together with CCN, "**Lineage**") and Genentech, Inc. ("**Genentech**") and F. Hoffmann-La Roche Ltd. ("**FHLR**"; together with Genentech, "**Roche**") are entering into a global collaboration and license agreement effective December 17, 2021 (the "**Roche Agreement**") related to the continued development and commercialization of products containing or comprising RPE cells (including without limitation, OpRegen®).

Lineage, Hadasit and Roche have reached an agreement to modify certain terms and conditions under the Agreement solely as they apply to the Roche Agreement, as reflected in a side letter of even date (the "**First Side Letter**").

The Parties have further agreed to modify certain terms and conditions under the Agreement solely as they apply to certain obligations of CCN vis-à-vis Hadasit in relation to the Roche Agreement.

Further to the above, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS

1.1 **Capitalized Terms**. Capitalized terms used in this Second Side Letter shall have the meanings set forth in the Agreement, unless otherwise defined hereunder.

2. REVISED FINANCIAL UNDERSTANDINGS

2.1 All references to the Roche Agreement shall be deemed references to the Roche Agreement as it exists on the effective date of this Second Side Letter. Lineage hereby undertakes not to amend the Roche Agreement in a manner that would impact the consideration to be received by Hadasit under the Agreement, as amended by this Second Side Letter, without Hadasit's prior written consent.

2.2 **Net Sales and Royalties**.

2.2.1 **Definition of Net Sales, "Sale" and "Sold".** Notwithstanding the definition of "Net Sales" as appears in Section 1.2.28 of the Agreement, for purposes of calculating Royalties due to Hadasit on Sales of Licensed Products under the Roche Agreement, "Net Sales" shall have the meaning ascribed to such term in Section 1.95 of the Roche Agreement and "Sale" and "Sold" shall have the meaning ascribed to the term "Sales" under the Roche Agreement.

2.2.2 **Royalties.** Notwithstanding any provision of the Agreement, including, without limitation, the royalty rate pursuant to Section 3.1.2 and the duration of the Royalty Period as determined pursuant to Section 1.2.2 of the Agreement, the Parties hereby agree that with respect to royalties due on Net Sales generated under the Roche Agreement:

2.2.2.1 If the amount that would be due to Hadasit under Section 3.1.2 (as may be adjusted in accordance with Section 3.3) of the Agreement on any Net Sales under the Roche Agreement exceeds fifty percent (50%) of the amount due to Lineage on account of such Net Sales, the Royalties due to Hadasit under the Agreement with respect to such Net Sales will be reduced to an amount equal to fifty percent (50%) of the amount due to Lineage under the Roche Agreement on account of such Net Sales so that Lineage shall never be obligated to pay Hadasit Royalties in respect to any Licensed Product Sold pursuant to the Roche Agreement that exceeds more than fifty percent (50%) of the underlying royalty payment received from Roche;

2.2.2.2 Lineage shall be obligated to pay Royalties to Hadasit in connection with Licensed Products Sold pursuant to the Roche Agreement only starting from and for as long as royalties are paid to Lineage in respect of such Licensed Products under the Roche Agreement;

2.2.2.3 Royalties will be due and payable in the same manner as Sublicensing Receipts, i.e. within [***] of receipt of the underlying payments from Roche. Lineage undertakes to diligently pursue the legal remedies available to it against Roche, should Lineage not receive payment with respect to any Net Sales from Roche within [***] of the end of the calendar quarter in which such Net Sales were generated; and

2.2.2.4 Royalties shall be due and payable to Hadasit in the same currency received from Roche.

2.3 **Deductions from Sublicensing Receipts.**

2.3.1 Pursuant to the Roche Agreement, Lineage and CCN have undertaken to: (i) carry out Licensed Product-related research, development and manufacturing activities for Roche, which are defined thereunder as the "**Lineage Activities**"; (ii) continue the conduct of the ongoing Phase I/IIa clinical trial entitled "Phase I/IIa Dose Escalation Safety and Efficacy Study of Human Embryonic Stem Cell-Derived Retinal Pigment Epithelium Cells Transplanted Subretinally in Patients With Advanced Dry-Form Age-Related Macular Degeneration (Geographic Atrophy)" and identified as NCT02286089, in the US and in Israel (collectively, the "**Existing Trials**") and (iii) carry out technology transfer pursuant to Section 4 of the Roche Agreement (the "**Technology Transfer**").

2.3.2 CCN hereby confirms and declares that payment for services and the reimbursement of expenses in respect of the Lineage Activities, the Existing Trials and the Technology Transfer (collectively, the "**Lineage Services**") have been taken into account in determining the Sublicensing Receipts that are payable by Roche under the Roche Agreement, although not separately itemized, due to internal considerations of Roche.

2.3.3 The budget for carrying out the Lineage Services, which includes overheads of [***] (the "**Costs**") is attached hereto as **Exhibit A** (the "**Budgeted Amount**").

2.3.4 Hadasit hereby acknowledges CCN's right to deduct the Budgeted Amount from the first Sublicensing Receipts paid by Roche pursuant to Section 6.1 of the Roche Agreement, provided, however, that the actual incurrence and/or expenditure of the Budgeted Amount shall be confirmed, on an annual basis, in the manner set forth in Section 1.2.7 of the Agreement, and any part of the Budgeted Amount not incurred or expended on the Lineage Services within [***] of the execution of the Roche Agreement shall be deemed Sublicensing Receipts as to which 21.5% will be immediately due and payable by CCN to Hadasit under the Agreement.

2.3.5 For the avoidance of doubt, CCN shall be entitled to deduct the costs of additional development activities plus an overhead of [***], not to exceed the amounts shown on the preliminary budget attached hereto as **Exhibit B** from any future Sublicensing Receipts (i.e. under provisions other than Section 6.1 of the Roche Agreement) payable under the Roche Agreement if actually incurred and/or expended in carrying out development activities in relation to OpRegen v 1.3 pursuant to the Roche Agreement, if any.

2.4 The Parties hereby agree that upon Hadasit's reasonable written request, Lineage shall cause the performance of an audit of Roche's records in accordance with Section 7.9.2 of the Roche Agreement, at Hadasit's expense. Should the auditor's report show any underpayment by Roche to Lineage, Lineage will immediately provide Hadasit with the details of any such underpayment and promptly pay to Hadasit the amount owed by Lineage to Hadasit in respect any payment received by Lineage in respect of such underpayment together with interest thereon (to the extent received by Lineage) in accordance with the Agreement. Moreover, Lineage shall reimburse Hadasit for the cost of the audit should any such underpayment by Roche result in an underpayment by CCN to Hadasit in excess of [***].

2.5 The Parties hereby agree that in the event of a termination of the Agreement and the grant of a Direct License by Hadasit to Roche as contemplated in First Side Letter, which license includes rights under Company IP, Section 13.5.2 shall not apply to amounts received by Hadasit under such Direct License.

3. ENGAGEMENT OF CONSULTANTS

3.1 Lineage hereby undertakes to engage Professor Benjamin Reubenoff and Professor Eyal Banin as scientific consultants in relation to the JAC (as defined in the Roche Agreement), provided that (a) they agree to be bound to confidentiality and invention assignment obligations as required under the Roche Agreement; and (b) Hadasit confirms its agreement to any such invention assignments.

4. MISCELLANEOUS

4.1 **Notices**. Any notice or communication required to be given by one Party to any other in connection with this Second Side Letter shall be made in accordance with Section 17 of the Agreement and shall specifically refer to this Second Side Letter. It is hereby agreed that notwithstanding the provisions of Section 17 of the Agreement, notices in relation to the Agreement in general and to this Second Side Letter in particular may be served by electronic mail, rather than by facsimile, subject to receipt of confirmation of transmission, to the addresses set forth below.

If to Lineage:

with a copy (which shall not constitute notice) to**:**

If to Hadasit:

4.2 **Amendments.** No amendment, modification, release, or discharge of this Second Side Letter shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties and by Lineage. Hadasit and CCN confirm that this Second Side Letter constitutes a valid amendment for purposes of Section 19.5 of the Agreement. Except as contemplated by the immediately preceding sentence, the terms and conditions of the Agreement shall remain unchanged as set forth therein, save as amended by the First Side Letter.

4.3 **Assignment.** Each of Hadasit and CCN and their respective Affiliates shall have the right to assign this Second Side Letter only to the extent such assignment would be permitted under Article 14 of the Agreement.

4.4 **Side Letter Controls.** This is the entire Second Side Letter between Hadasit and CCN with respect to the subject matter hereof and supersedes all prior representations, understanding and agreements between them with respect to the subject matter hereof.

4.5 **Counterparts.** This Second Side Letter may be executed in one or more counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Second Side Letter by electronic transmission shall be effective as delivery of a manually executed original counterpart of this Second Side Letter.

4.6 **Termination.** This Second Side Letter shall automatically terminate upon termination of the Roche Agreement for any reason.

[***Remainder of the Page Intentionally Left Blank***]

Hadasit and CCN have executed this Side Letter by their respective and duly authorized officers, as evidenced by their signatures below.

HADASIT MEDICAL RESEARCH SERVICES AND DEVELOPMENT LTD.

By: */s/ Carol Grumbach*

Name: Carol Grumbach

Title: CFO

Date: 12/14/2021

By: */s/ Tamar Raz*

Name: Tamar Raz

Title: CEO

Date: 12/14/2021

CELL CURE NEUROSCIENCES LTD.

By: */s/ Rami Skaliter*

Name: Rami Skaliter

Title: CEO

Date: 12/14/2021

Read and agreed:

LINEAGE CELL THERAPEUTICS

By: */s/ Brian M. Culley*

Name: Brian M. Culley

Title: CEO

Date: 12/14/2021

Exhibit 10.13

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

COLLABORATION AND LICENSE AGREEMENT

BETWEEN

LINEAGE CELL THERAPEUTICS, INC. AND CELL CURE NEUROSCIENCES LTD.

AND

GENENTECH, INC. AND F. HOFFMANN-LA ROCHE LTD

AS OF DECEMBER 17, 2021

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COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (this "**Agreement**") is made and entered into as of December 17, 2021 (the "**Effective Date**"), between Cell Cure Neurosciences Ltd., having its principal place of business at Jerusalem Bio-Park Building, Hadassah Ein Kerem Medical Center, POB 12247, Jerusalem 91121 ("**Cell Cure**") and Lineage Cell Therapeutics, Inc., having its principal place of business at 2173 Salk Avenue, Suite 200, Carlsbad, CA 92008 (together with Cell Cure, "**Lineage**"), on the one hand, and Genentech, Inc., a Delaware corporation, having its principal place of business at 1 DNA Way, South San Francisco, California 94080 ("**Genentech**") and F. Hoffmann-La Roche Ltd, having its principal place of business at Grenzacherstrasse 124, CH 4070 Basel, Switzerland (together with Genentech, "**Roche**"), on the other hand. Roche and Lineage are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

Background

WHEREAS, Lineage is a biotechnology company that has expertise in cell therapy replacement technology;

WHEREAS, Roche is a biopharmaceutical company that is engaged in the research, development, manufacture and sale of pharmaceutical products;

WHEREAS, the Parties desire to collaborate in the creation and development of cell therapy replacement products for the treatment or prevention of eye disorders; and

WHEREAS, Roche desires to obtain an exclusive license and other rights from Lineage to develop and commercialize Licensed Products (defined below) and Lineage agrees to grant Roche licenses and other rights in exchange for certain agreed upon upfront and other payments and other consideration, all as set forth herein.

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Roche and Lineage agree as follows:

Article 1
Definitions

Capitalized terms used in this Agreement, whether used in the singular or plural, shall have the meanings set forth below, unless otherwise specifically indicated herein.

1.1 "**Accounting Standards**" means the maintenance of records and books of accounts in accordance with either IFRS or US GAAP, in each case, as currently used at the applicable time by, and as consistently applied by, the applicable Party or its Affiliate or Sublicensee.

1.2 "**Acquirer**" is defined in Section 5.7.2(a).

1.3 "**Acquisition Affiliate**" is defined in Section 5.7.2.

1.4 "**Additional Technology Transfer Activities**" is defined in Section 4.3.1(f).

1.5 "**Affiliate**" means any entity that, directly or indirectly (through one (1) or more intermediaries) controls, is controlled by, or is under common control with a Party, at any point in time and for so long as such control exists. For purposes of the preceding sentence, "controls", "controlled", and "control" means (a) the direct or indirect ownership of more than fifty percent (>50%) of the voting stock or other voting interests or interest in the profits of the Party, or (b) the ability to otherwise control or direct the decisions of the board of directors or equivalent governing body thereof. Notwithstanding the foregoing, for purposes of this Agreement, Chugai Pharmaceutical Co., Ltd (for purposes of this definition, "**Chugai**") and all business entities controlled by Chugai, shall not be considered an Affiliate of Roche, unless and until Roche elects to include Chugai or such business entities as an Affiliate of Roche, by providing written notice to Lineage of such election.

1.6 "**Alliance Manager**" is defined in Section 2.4.

1.7 "**Annual Net Sales**" means, with respect to a Licensed Product, all Net Sales of such Licensed Product during a Calendar Year.

1.8 "**Applicable Law**" means any applicable federal, state, local, foreign, or multinational law (including, GCP, GLP, GMP, and data protection and privacy laws), statute, standard, ordinance, code, rule, regulation, resolution, or promulgation, or any order, writ, judgment, injunction, decree, stipulation, ruling, determination, or award entered by or with any governmental authority, or any license, franchise, permit, or similar right granted under any of the foregoing, or any similar provision having the force or effect of law. For clarity, any specific references to any Applicable Law or any portion thereof, will be deemed to include all then-current amendments thereto or any replacement or successor law, statute, standard, ordinance, code, rule, regulation, resolution, order, writ, judgment, injunction, decree, stipulation, ruling, or determination thereto.

1.9 "**Authorized Subcontractors**" means, with respect to any activity (the "**Subcontracted Activity**") within the Lineage Activities or Manufacturing activities pursuant to Section 4.2, the Lineage subcontractors (a) set forth on Exhibit A to perform such activity or (b) approved in writing by the JMC, with respect to the Manufacturing activities, and Roche, with respect to all other activities, in each case, prior to initiation of such activity.

1.10 "**Board of Directors**" is defined in Section 1.14(a).

1.11 "**Business Day**" means any day, other than a Saturday, Sunday or day on which commercial banks located in San Francisco, California (US) are authorized or required by law to be closed.

1.12 "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1 (Q1), April 1 (Q2), July 1 (Q3) or October 1 (Q4), except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.13 "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall commence on January 1 of the year in which the Term ends and end on the last day of the Term.

1.14 "**Change in Control**" with respect to Lineage, shall be deemed to have occurred if any of the following occurs after the Effective Date:

(a) any "person" or "group" (as such terms are defined below) (i) becomes the "beneficial owner" (as defined below), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of Lineage then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions ("**Voting Stock**") of Lineage representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of Lineage or (ii) acquires the power, directly or indirectly, to elect a majority of the members of Lineage's board of directors, or similar governing body ("**Board of Directors**"); or

(b) Lineage enters into a merger, consolidation or similar transaction with a Third Party (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction (i) the members of the Board of Directors of Lineage immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of Lineage or such surviving entity immediately following such transaction or (ii) the individuals or entities that beneficially owned, directly or indirectly, the shares of Voting Stock of Lineage immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of Lineage representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving entity in substantially the same proportions as their ownership of Voting Stock of Lineage immediately prior to such transaction; or

(c) Lineage sells or transfers to any Third Party, in one (1) or more related transactions, properties or assets representing all or substantially all of Lineage's assets to which this Agreement relates.

For the purpose of this Section 1.14, (x) "person" and "group" have the meanings given such terms under Section 13(d) and 14(d) of the US Securities Exchange Act of 1934 and the term "group" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act; (y) a "beneficial owner" shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (z) the terms "beneficially owned" and "beneficially own" shall have meanings correlative to that of "beneficial owner." Notwithstanding the foregoing, (A) a transaction solely to change the domicile of Lineage; (B) the consummation of an initial public offering of Lineage's securities; or (C) any merger or consolidation between a Party and one (1) or more Affiliates shall not constitute a Change in Control. For clarity, a Change in Control shall be considered an assignment under this Agreement and subject to Section 15.3.

1.15 "**Clinical Supply and Quality Agreement**" is defined in Section 4.2.3.

1.16 "**CMO**" means a Third Party contract manufacturing organization.

1.17 "**Combination**" is defined in Section 1.96.

1.18 "**Commercial Supply and Quality Agreement**" is defined in Section 4.2.3.

1.19 "**Commercialization**" means marketing, promoting, detailing, distributing, importing, exporting, offering for sale or selling a product, including medical affairs activities, regulatory activities directed to obtaining pricing and reimbursement approvals, price calculations and related reporting to governmental authorities, and interacting with Regulatory Authorities with respect to the foregoing. When used as a verb, "**Commercialize**" means to engage in Commercialization activities.

1.20 "**Commercially Reasonable Efforts**" means [***].

1.21 "**Competing Product**" means, on a country-by-country basis, [***] in such country.

1.22 "**Competing Program**" is defined in Section 5.7.2.

1.23 "**Compulsory Sublicense**" means a license or sublicense granted to a Third Party, through the order, decree or grant of a governmental authority having competent jurisdiction, authorizing such Third Party to make, use, sell, offer for sale, import or export a Licensed Product in any country.

1.24 "**Compulsory Sublicensee**" means a Third Party that was granted a Compulsory Sublicense.

1.25 "**Confidential Information**" is defined in Section 9.1.

1.26 "**Control**" or "**Controlled by**" means the rightful possession by a Party, as of the Effective Date or during the Term, of the ability to grant a license, sublicense or other right to Exploit (other than by operations of the licenses granted herein) any item or right under Patents, Know-How or other Intellectual Property rights, as provided herein, without violating the terms of any agreement with any Third Party or causing such Party to incur any payment obligations by reason of the grant of such license, sublicense or other right, unless the Party receiving such license, sublicense or other right agrees to reimburse the other Party for such payments.

1.27 "**Cover**" means, with respect to a Valid Claim and in reference to a particular Licensed Product (whether alone or in combination with one (1) or more other ingredients) that the manufacture, use, sale, offer for sale or import of such Licensed Product in a country would, but for ownership thereof or a license granted in this Agreement thereunder, infringe a Valid Claim of such Patent in such country on the date of sale. "**Covered**" and "**Covering**" have corresponding meanings.

1.28 "**CPA Firm**" is defined in Section 7.9.2.

1.29 "**Development**" means, for a given product, any activity directed to obtaining, maintaining or expanding Regulatory Approval, including all preclinical and clinical drug or biologic product development activities, including: the conduct of clinical trials, cell line development, master cell bank generation, test method development and stability testing, toxicology, formulation and delivery system development, process development, pre-clinical and clinical supply, manufacturing (including Manufacturing) scale-up, development-stage manufacturing, quality assurance/quality control procedure development and performance with respect to clinical materials, statistical analysis, report writing and clinical studies, and regulatory affairs with respect to the foregoing. "**Develop**," "**Developed**" and "**Developing**" have corresponding meanings.

1.30 "**Disclosing Party**" is defined in Section 9.1.

1.31 "**Disposition Transaction**" is defined in Section 6.7.

1.32 "**Dispute**" is defined in Section 14.1.

1.33 "**Divestiture**" is defined in Section 5.7.2(b).

1.34 "**Dollars**" or "**$**" means US dollars.

1.35 "**Effective Date**" is defined in the preamble.

1.36 "**Existing Patents**" means all Lineage Patents existing as of the Effective Date (Schedule 1.36).

1.37 "**Existing Trial**" means the ongoing Phase I/IIa clinical trial initiated by Lineage entitled "Phase I/IIa Dose Escalation Safety and Efficacy Study of Human Embryonic Stem Cell-Derived Retinal Pigment Epithelium Cells Transplanted Subretinally in Patients With Advanced Dry-Form Age-Related Macular Degeneration (Geographic Atrophy)" and identified as NCT02286089.

1.38 "**Existing Third Party Agreement Payments**" means the payments owed under the Existing Third Party In-License Agreements.

1.39 "**Existing Third Party In-License Agreements**" means the agreements set forth on Schedule 1.39.

1.40 "**Exploit**" means to make, have made, import, use, sell or offer for sale, including to research, Develop, Commercialize, register, manufacture (including Manufacture, if applicable), have manufactured (or Manufactured, if applicable), hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of. "**Exploitation**" means the act of Exploiting a compound, cell, cellular composition, product or process.

1.41 "**FDA**" means the US Food and Drug Administration, or any successor entity thereto performing similar functions.

1.42 "**Field**" means [***].

1.43 "**First Commercial Sale**" means, with respect to a particular Licensed Product in a given country, the first bona fide commercial sale to a Third Party of such Licensed Product following Marketing Authorization in such country by or under authority of Roche (or its Affiliates or Sublicensee(s) hereunder), which sale is included in the calculation of Net Sales for such Licensed Product. Sales prior to receipt of Marketing Authorization for such Licensed Product in such country, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale.

1.44 "**Force Majeure Event**" is defined in Section 15.7.

1.45 "**FTE**" means a full-time equivalent employee (i.e., one (1) fully-committed or multiple partially-committed employees aggregating to one (1) full-time employee) employed by a Party (or any of its Affiliates) and assigned to perform specific work, with such commitment of time and effort to constitute one (1) employee performing such work on a full-time basis, which for purposes hereof will be one thousand eight hundred eighty (1880) hours per year.

1.46 "**FTE Costs**" means the sum of (a) all costs and expenses for the employee providing the applicable services, including salaries, wages, bonuses, commissions, benefits, FICA costs and other similar costs, travel, meals and entertainment, training, recruiting, relocation, operating supplies, and equipment and other disposable goods to the extent required for the performance of the applicable services, and (b) a pro rata allocation of equipment maintenance costs, utilities, and facilities expenses for such employee, including allocated building operating costs and depreciation and repairs and maintenance, in any case (a) or (b), whether internal costs and expenses or amounts paid to Third Parties.

1.47 "**Geographic Atrophy**" is defined in Section 1.42.

1.48 "**German WHT Requirement**" is defined in Section 7.8.1.

1.49 "**Good Clinical Practice**" or "**GCP**" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials, including, as applicable, (a) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("**ICH**") Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), as amended, (b) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 54 (Financial Disclosure by Clinical Investigators), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application) and (c) the equivalent Applicable Law in any relevant country, each as may be amended and applicable from time to time and, in each case of (a) – (c), that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.50 "**Good Laboratory Practice**" or "**GLP**" means all applicable Good Laboratory Practice standards, including, as applicable, (a) as set forth in the Good Laboratory Practice standards promulgated or endorsed by the FDA as defined in 21 C.F.R. Part 58 for the conduct of nonclinical laboratory studies, and (b) the equivalent Applicable Law in any relevant country, each as may be amended and applicable from time to time.

1.51 "**Good Manufacturing Practice**" or "**GMP**" means all applicable current Good Manufacturing Practice including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practice regulations, 21 C.F.R. Sections 210, 211, 600, and 610, (b) the principles detailed in the ICH Q7 guidelines, and (c) the equivalent Applicable Law in any relevant country, each as may be amended and applicable from time to time.

1.52 "**Hadasit**" is defined in Section 5.4.2.

1.53 "**Hadasit Agreement**" is defined in Section 5.4.2.

1.54 "**Hadasit Side Letter**" is defined in Section 5.4.2.

1.55 "**hESC Cells**" means [***].

1.56 "**hESC Cell Technology**" means [***]. For clarity, hESC Cell Technology excludes any Know-How or Patents that are directly and primarily related to any Licensed Product (or the Manufacture of any Licensed Product).

1.57 "**hESC Know-How**" is defined in Section 8.1.5.

1.58 "**hESC Patents**" is defined in Section 8.1.5. hESC Patents existing as of the Effective Date are listed on Schedule 1.58.

1.59 "**ICH**" is defined in Section 1.49.

1.60 "**IFRS**" means International Financial Reporting Standards.

1.61 "**Improvements**" means any invention, discovery, development, derivative, or modification, whether or not patented or patentable, with respect to (a) the Lineage RPE Cells, (b) hESC Cell Technology, or (c) a Licensed Product, or relating to the Exploitation thereof, including any enhancement in the efficiency, operation, Manufacture, ingredients, preparation, presentation, formulation, means of delivery (including the development of any delivery system or enhancement thereto) or dosage of such Licensed Product, any discovery or development of any new or expanded Indications for such Licensed Product, or any discovery or development that improves the stability, safety or efficacy of such Licensed Product.

1.62 "**In-License Payments**" is defined in Section 6.6.1.

1.63 "**IND**" means an investigational new drug application filed with the FDA pursuant to 21 C.F.R. §312 before the commencement of clinical trials of a product, or any comparable filing with any relevant regulatory authority in any other jurisdiction.

1.64 "**Indemnitee**" is defined in Section 12.3.

1.65 "**Indemnitor**" is defined in Section 12.3.

1.66 "**Indication**" means a specific disease, disorder or condition that is recognized by the applicable Regulatory Authority in a given country or jurisdiction as a disease, disorder or condition. All variants of a single disease, disorder or condition (whether classified by severity or otherwise), regardless of the patient population, shall be treated as the same Indication. By way of example, (a) the treatment of a disease, disorder or condition in a particular patient population and the treatment of the same disease, disorder or condition in another population (e.g., adult population and pediatric population) shall be treated as the same Indication and (b) label expansions for a given Indication shall be treated as the same Indication.

1.67 "**Information Security Incident**" means, with respect to Confidential Information, any unauthorized use, unauthorized disclosure, corruption (including ransomware attack) or loss of such Confidential Information.

1.68 "**Infringement**" is defined in Section 8.7.1.

1.69 "**Initiation**" or "**Initiated**" means, with respect to a clinical trial or a portion thereof, the first dosing of a Licensed Product in the first human subject in such clinical trial or portion thereof.

1.70 "**Intellectual Property**" means all intellectual property and proprietary rights, including (a) all inventions (whether patentable or unpatentable and whether or not reduced to practice), all improvements thereto, and all patents, patent applications, and patent and invention disclosures, together with all provisionals, reissuances, continuations, continuations-in-part, divisions, revisions, extensions, and reexaminations thereof, (b) all trademarks, service marks, trade dress, logos, slogans, brand names, trade names, domain names, and business and product names, and all applications and registrations therefor, and all extensions and renewals thereof, and all goodwill of the business connected with the use of and symbolized by the foregoing, (c) all copyrights and copyrightable works, works of authorship (whether or not copyrightable), all mask works, industrial designs, and protectable designs, and all applications and registrations therefor, and all extensions and renewals thereof, (d) all trade secrets and confidential business information (including research and development, know-how, formulae, compositions, processes, techniques, methodologies, technical information, designs, industrial models, manufacturing, engineering and technical drawings, specifications, research records, records of inventions, test information, customer and supplier lists, customer data, pricing and cost information, and business and marketing plans and proposals), and (e) all rights to use all of the foregoing and all other rights in, to, and under the foregoing.

1.71 "**Israel CTA**" is defined in Section 3.6.2.

1.72 "**JAC**" is defined in Section 2.1.1.

1.73 "**JAC Co-Chair**" is defined in Section 2.1.1.

1.74 "**JMC**" is defined in Section 2.2.1.

1.75 "**JMC Co-Chair**" is defined in Section 2.2.1.

1.76 "**Joint Know-How**" is defined in Section 8.1.3.

1.77 "**Joint Patents**" is defined in Section 8.1.3.

1.78 "**Know-How**" means all non-public information, inventions (whether or not patentable), improvements, practices, formula, trade secrets, techniques, methods, manufacturing processes, differentiation protocols, cell expansion and maintenance protocols, procedures, knowledge, results, test data (including pharmacological, toxicological, pharmacokinetic, pre-clinical and clinical information, test data, related reports, structure-activity relationship data, and statistical analysis), analytical and quality control data, protocols, processes, models, designs, and other information regarding discovery, Development, marketing, pricing, distribution, cost, sales and manufacturing. Know-How shall not include any Patents.

1.79 "**Launch Quarter**" is defined in Section 6.6.2.

1.80 "**Licensed Product**" means [***].

1.81 "**Lineage**" is defined in the preamble.

1.82 "**Lineage Activities**" is defined in Section 3.2.2.

1.83 "**Lineage Expenses**" means the Out-of-Pocket Costs incurred by Lineage in the performance of Lineage's obligations as expressly stated under this Agreement. [***].

1.84 "**Lineage Know-How**" means [***].

1.85 "**Lineage Patents**" means [***].

1.86 "**Lineage RPE Cells**" means any RPE Cells owned or Controlled by Lineage or its Affiliates as of the Effective Date or at any time during the Term.

1.87 "**Lineage Work Plan**" is defined in Section 3.2.2.

1.88 "**Loss**" or "**Losses**" is defined in Section 12.1.

1.89 "**Major European Country**" means France, Germany, Italy, Spain or the United Kingdom.

1.90 "**Manufacture**" and "**Manufacturing**" means all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and holding of any Licensed Product, or any intermediate thereof, including the thawing, culturing, expansion and differentiation of hESC Cells to RPE Cells, formulating, freezing, storing, and delivery of the Licensed Product to a patient's treating physician or treatment center, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control.

1.91 "**Manufacturing Costs**" means, to the extent specifically identifiable or reasonably allocable to any Licensed Product, the fully burdened manufacturing cost (including as applicable, Manufacturing, indirect labor (including allocations of costs for supervisory services, occupancy and similar functions and activities customarily treated as manufacturing plant overhead in accordance with GAAP), quality testing/review, project management, distribution, logistics, and any customs costs and expenses) without any markup or premium unless otherwise agreed, incurred by Lineage or any of its Affiliates pursuant to Section 4.2.2 as determined in accordance with Accounting Standards.

1.92 "**Manufacturing Process**" means, with respect to a Licensed Product, the Manufacturing production steps and control system (e.g., analytical methods), including any Improvements or modifications thereto, for Manufacturing such Licensed Product, including the thawing, culturing, expansion and differentiation of hESC Cells to RPE Cells, formulating, freezing, storing, and delivery of the Licensed Product to a patient's treating physician or treatment center.

1.93 "**Marketing Authorization**" means with respect to a Licensed Product, final Regulatory Approval (including pricing approval, where required) required to sell such Licensed Product for an Indication in accordance with the Applicable Law of a given country. In the US, its territories and possessions, Marketing Authorization means approval of a New Drug Application, Biologics License Application or an equivalent by the FDA. In Japan, Marketing Authorization means marketing approval (*seizo hanbai shonin*) by the Ministry of Health, Labour and Welfare. In the European Union, Marketing Authorization means marketing authorization granted by the European Commission pursuant to the centralized approval procedure or by a national competent authority in the European Union pursuant to the mutual recognition or other national approval procedure.

1.94 "**Materials**" is defined in Section 4.3.1(b).

1.95 "**NDA**" is defined in Section 9.6.

1.96 "**Net Sales**" with respect to a Licensed Product means [***]:

(a) [***];

(b) [***]; and

(c) [***].

1.97 "**Ongoing Knowledge Transfer**" is defined in Section 4.3.2.

1.98 "**OpRegen Product**" means, individually or collectively, OpRegen v 1.0, OpRegen v 1.1, OpRegen v 1.2 and OpRegen v 1.3, as the case may be.

1.99 "**OpRegen Trademarks**" means the Trademarks set forth on Schedule 1.98.

1.100 "**OpRegen v 1.0**" means the Lineage RPE Cells produced from hESC Cells differentiated on feeder cells and formulated with human serum requiring a preparation process prior to clinical use at a dose preparation laboratory, delivered as a cell suspension, and as described in the Existing Trial.

1.101 "**OpRegen v 1.1**" means the Lineage RPE Cells produced from hESC Cells differentiated on feeder cells and formulated with thaw and inject cryopreservation, delivered as a cell suspension, and as described in the Existing Trial.

1.102 "**OpRegen v 1.2**" means [***].

1.103 "**OpRegen v 1.3**" is defined in Section 3.2.5(c).

1.104 "**OpRegen v 1.3 Patents**" means [***].

1.105 "**Out-of-Pocket Costs**" means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with Accounting Standards) by either Party or its Affiliates or Sublicensees in connection with activities under this Agreement without markup, excluding FTE Costs.

1.106 "**Patent(s)**" means any and all patents and patent applications and any patents issuing therefrom or claiming priority thereto, worldwide, together with any extensions (including patent term extensions and supplementary protection certificates) and renewals thereof, reissues, re-examinations, substitutions, confirmation patents, registration patents, invention certificates, patents of addition, renewals, divisionals, continuations, and continuations-in-part of any of the foregoing.

1.107 "**Permitted Activities**" means [***].

1.108 **"Pharmacovigilance Agreement"** is defined in Section 3.5.

1.109 "**Phase I Clinical Trial**" means a human clinical trial, the principal purpose of which is preliminary determination of safety and pharmacokinetics of a Licensed Product in healthy individuals or patients as described in 21 C.F.R. §312.21, or similar clinical study in a country other than the US.

1.110 "**Phase II Clinical Trial**" means a human clinical trial, for which the primary endpoints include a determination of dose ranges and a preliminary determination of efficacy of a Licensed Product in patients being studied as described in 21 C.F.R. §312.21, or similar clinical study in a country other than the US. For the avoidance of doubt, in no event will the Existing Trial be deemed a Phase II Clinical Trial.

1.111 "**Phase II Lead-In**" means, with respect to OpRegen v 1.2 or OpRegen v 1.3, Initiation of the portion of a Phase II Clinical Trial that is an open-label study to demonstrate safety and proof of activity of the applicable OpRegen Product.

1.112 "**Phase II Randomization**" means, with respect to OpRegen v 1.2 or OpRegen v 1.3 and following Phase II Lead-In for such OpRegen Product, the Initiation of the portion of a Phase II Clinical Trial designed to enable a Phase III Clinical Trial that is a controlled, randomized study to evaluate the safety and efficacy of the applicable OpRegen Product.

1.113 "**Phase III Clinical Trial**" means a human clinical trial, the principal purpose of which is to demonstrate clinically and statistically the efficacy and safety of a Licensed Product for one (1) or more Indications in order to obtain Marketing Authorization of such Licensed Product for such Indication(s), as further defined in 21 C.F.R. §312.21 or a similar clinical study in a country other than the US.

1.114 [***].

1.115 "**Primary Patent**" means [***].

1.116 "**Product Improvement Know-How**" is defined in Section 8.1.4.

1.117 "**Product Improvement Patents**" is defined in Section 8.1.4.

1.118 "**Product Infringement**" is defined in Section 8.7.2(b).

1.119 "**Product Labeling**" means, with respect to a Licensed Product in a country, (a) the Regulatory Authority-approved prescribing information for such Licensed Product for such country, including any required patient information, and (b) all labels and other written, printed, or graphic matter upon a container, wrapper, or any package insert utilized with or for such Licensed Product in such country.

1.120 "**Product Trademarks**" means the Trademarks to be used for the commercialization of Licensed Products in the Territory and any registrations thereof or any pending applications relating thereto in the Territory, including, if applicable, the OpRegen Trademarks (but excluding, in any event, any Trademarks, service marks, names or logos that include any corporate name or logo of the Parties or their Affiliates or Sublicensees).

1.121 "**Prosecution and Maintenance**" or "**Prosecute and Maintain**," with respect to a given Patent, means all activities associated with the preparation, filing, prosecution, and maintenance of such Patent, as well as supplemental examinations, re-examinations, reissues, applications for patent term extensions, calculation and applications for patent term adjustments, supplementary protection certificates, and the like with respect to such Patent. For clarity, Prosecute and Maintain shall not include any such actions with respect to a Patent brought by a Third Party, including any reexaminations, inter partes reviews, and post grant reviews, as well as interferences and derivation proceedings, oppositions and other similar proceedings brought by a Third Party with respect to such Patent.

1.122 "**Receiving Party**" is defined in Section 9.1.

1.123 "**Regulatory Approval**" means, with respect to a Licensed Product in a country or jurisdiction, any and all approvals (including INDs and Biologics License Applications and any supplements thereto), licenses, registrations, or authorizations of any Regulatory Authority necessary to Manufacture, use, store, import, transport, commercially distribute, sell, or market such Licensed Product in such country, including, where applicable, (a) pricing or reimbursement approval in such country, (b) post-approval marketing authorizations (including any prerequisite Manufacturing approval or authorization related thereto), and (c) labeling approval.

1.124 "**Regulatory Authority**" means any federal, national, multinational, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the Development, Manufacturing, Commercialization or other use or Exploitation (including the granting of Regulatory Approvals) of the pharmaceutical or biological products in any jurisdiction, including the FDA.

1.125 "**Regulatory Documentation**" means all (a) applications (including all INDs and other regulatory filings), registrations, licenses, authorizations, and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files, and complaint files; and (c) data, including all information that is made, collected, or otherwise generated pursuant to a clinical trial, contained or relied upon in any of the foregoing (including data related to the Manufacturing Process), in each case of (a), (b), and (c), relating to a Licensed Product.

1.126 "**Release**" is defined in Section 10.2.

1.127 "**Residuals**" is defined in Section 9.7.

1.128 "**Reversion Product**" is defined in Section 13.5.2.

1.129 "**Roche**" is defined in the preamble.

1.130 "**Roche Know-How**" means [***].

1.131 "**Roche Patents**" means [***].

1.132 "**Royalty Term**" is defined in Section 6.5.1.

1.133 "**RPE Cells**" means a human stem cell-derived (such as human embryonic stem cell-derived and human induced pluripotent stem cell-derived) retinal pigment epithelial cells, and any precursors or progenitors thereof.

1.134 "**Rules**" is defined in Section 14.2.1.

1.135 "**SAC**" is defined in Section 2.4.1.

1.136 "**SAC Co-Chair**" is defined in Section 2.4.1.

(a) "**Sales**" means for a Licensed Product in a particular period, [***].

1.137 "**Secondary Patent**" means [***].

1.138 "**Subcontracted Activity**" is defined in Section 1.9.

1.139 "**Sublicensee**" means any Third Party, other than a Compulsory Sublicensee, to which Roche or any of its Affiliates grants a sublicense under the Lineage Patents and Lineage Know-How to Commercialize a Licensed Product.

1.140 "**Technology Transfer**" is defined in Section 4.3.1(d).

1.141 "**Technology Transfer Plan**" is defined in Section 4.3.1(d).

1.142 "**Term**" is defined in Section 13.1.

1.143 "**Territory**" means all the countries of the world.

1.144 "**Third Party**" means any entity other than a Party or any of its Affiliates.

1.145 "**Third Party Claims**" is defined in Section 12.1.

1.146 "**Third Party Infringement Claim**" is defined in Section 8.9.1.

1.147 "**Title 11**" is defined in Section 13.3.

1.148 "**Trademark**" means any word, name, symbol, color, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, logo or business symbol, whether or not registered.

1.149 "**Transition Agreement**" is defined in Section 13.5.2.

1.150 "**Transition Negotiation Period**" is defined in Section 13.5.2.

1.151 "**US**" means the United States of America and its territories and possessions.

1.152 "**US GAAP**" means US Generally Accepted Accounting Principles.

1.153 "**Valid Claim**" means, [***].

1.154 "**Voting Stock**" is defined in Section 1.14(a).

Article 2
Governance

2.1 **Joint Advisory Committee.**

2.1.1 **Formation and Composition**. Within thirty (30) days after the Effective Date, the Parties shall establish a joint advisory committee (the "**JAC**") to oversee the Lineage Activities and the Development activities for Licensed Products. The JAC shall be composed of up to three (3) representatives designated by each of Lineage and Roche (though the Parties need not have the same number of representatives on the JAC). Each Party shall designate one (1) of its representatives as its primary contact for JAC matters (such Party's "**JAC Co-Chair**"). Representatives must be appropriate for the tasks then being undertaken and the stage of Development, in terms of their seniority, function in their respective organizations, training and experience. Subject to the foregoing sentence, a Party may replace any or all of its JAC representatives (or JAC Co-Chair) at any time by informing the other Party in advance in writing (which may be by email). Once established, the JAC shall meet at least once each Calendar Quarter (unless otherwise agreed by the Parties) until the last patient has completed the dosing regimen for the Existing Trial, and then subsequently at least twice each Calendar Year (unless otherwise agreed by the Parties) and shall meet at such other times as deemed appropriate by the JAC. Either Party may invite a reasonable number of other employees, consultants, clinical contractors, or scientific advisors to attend a JAC meeting with prior written notice to the other Party; *provided* that such invitees are bound by appropriate confidentiality and invention assignment obligations consistent with the terms of this Agreement. The JAC shall meet and operate until the last patient has completed the dosing regimen for Phase II Randomization for OpRegen v 1.2 or OpRegen v 1.3, as applicable, or such longer period as Roche determines is reasonably necessary or useful. Thereafter, the JAC shall cease operations and perform no further functions under this Agreement.

2.1.2 **Responsibilities of the JAC**. The JAC shall be responsible for performing the following functions:

(a) serving as a forum for discussion and consultation with respect to Development activities under this Agreement; and

(b) performing such other functions as agreed to by the Parties or as specified in this Agreement.

2.1.3 **Decisions**. The JAC shall be a consultative body and shall not have any independent decision-making authority.

2.2 **Joint Manufacturing Committee.**

2.2.1 **Formation and Composition**. No later than thirty (30) days following the Effective Date, the Parties shall establish a joint manufacturing committee (the "**JMC**") to oversee the Technology Transfer, Ongoing Knowledge Transfer, and development, improvement, validation and performance of the Manufacturing Process for each Licensed Product. The JMC shall be composed of up to three (3) representatives designated by each of Lineage and Roche (though the Parties need not have the same number of representatives on the JMC). Each Party shall designate one (1) of its representatives as its primary contact for JMC matters (such Party's "**JMC Co-Chair**"). Representatives must be appropriate for the tasks then being undertaken and the stage of Manufacturing Process development, in terms of their seniority, availability, function in their respective organizations, training and experience, *provided* that at least one (1) representative from each Party shall have relevant decision-making authority within their respective functions. Subject to the foregoing sentence, a Party may replace any or all of its JMC representatives (or JMC Co-Chair) at any time by informing the other Party in advance in writing (which may be by email). Once established, the JMC shall meet at least once each Calendar Quarter (unless otherwise agreed by the Parties) and shall meet at such other times as deemed appropriate by the JMC. Either Party may invite a reasonable number of other employees, consultants, manufacturing contractors, or scientific advisors to attend a JMC meeting in a non-voting capacity with prior written notice to the other Party; *provided* that such invitees are bound by appropriate confidentiality and invention assignment obligations consistent with the terms of this Agreement. The JMC shall meet and operate during the period commencing upon its formation until the later of (a) the completion of Technology Transfer or (b) the Initiation of the first Phase III Clinical Trial or such longer period as may reasonably be requested by Roche. Thereafter, the JMC shall cease operations and perform no further functions under this Agreement.

2.2.2 **Responsibilities of the JMC**. The JMC shall be responsible for performing the following functions:

(a) reviewing and updating the Technology Transfer Plan;

(b) coordinating the Technology Transfer (and subsequent cooperation set forth in Section 4.3.1(f)), Ongoing Knowledge Transfer set forth in Section 4.3.2, and transfer of Materials set forth in Section 4.3.1(b);

(c) coordinating and proposing Manufacturing Process Improvements, including as set forth in Section 4.2.5, for each Licensed Product;

(d) coordinating the provision of Know-How and Regulatory Documentation set forth in Section 5.6;

(e) discussing any Improvements as set forth in Section 5.6.3;

(f) reviewing and updating the Lineage Work Plan and coordinating the conduct of Lineage Activities;

(g) advising on any manufacturing issues regarding OpRegen v 1.2 or OpRegen v 1.3;

(h) establishing, dissolving and overseeing other joint committees or teams, as appropriate, to carry out its functions;

(i) discussing and attempting to resolve any potential or evolving disagreement between the Parties related to the Manufacturing Process development, any Development of OpRegen v 1.3, Technology Transfer, or Ongoing Knowledge Transfer; and

(j) performing such other functions as advised by the JAC or as reasonably contemplated under this Agreement.

2.2.3 **Decisions**. [***].

2.3 **Committee and Team Meetings; Minutes**. Under Section 2.1 or Section 2.2, in order to hold a committee meeting or to make a committee decision, at least one (1) member of such committee from each Party must participate in the meeting or vote; *provided* that either Party may defer a meeting or a vote if such Party desires to postpone until the applicable committee members are able to attend, so long as such postponement does not cause material or undue delays to any Lineage Activities or Lineage's obligations under Section 4.3. Committees may meet in person or via teleconference, video conference or the like, *provided* that at least one (1) meeting per Calendar Year shall be held in person, if reasonably practicable, unless otherwise agreed by the Parties. Each Party shall bear the expense of its respective representatives' participation in committee meetings. Each committee shall keep minutes of its meetings that record in writing all decisions made, action items assigned or completed and other appropriate matters. The Parties shall alternate the responsibility for keeping such meeting minutes for a particular committee. Meeting minutes shall be sent to both Parties promptly after a meeting for review, comment and approval. A decision that is made at a committee meeting shall be recorded in minutes and decisions that are made by the committee outside of a meeting shall be documented in writing (which may be by email).

2.4 **Alliance Managers**. Promptly following the Effective Date, each Party shall designate an individual to act as the primary business contact for such Party for matters related to this Agreement (such Party's "**Alliance Manager**"), unless another contact is expressly specified in the Agreement or designated by the Parties for a particular purpose. The Alliance Managers shall facilitate communication and collaboration between the Parties and assist in the resolution of potential and pending issues and potential non-technical Disputes in a timely manner to enable the Parties to reach consensus and avert escalation of such issues or potential Disputes. The Alliance Managers may attend all meetings of the committees contemplated herein as non-voting participants and will be responsible for assisting such committees and teams in performing their informational and review responsibilities. Either Party may replace its Alliance Manager at any time by notifying the other Party's Alliance Manager in writing (which may be by email).

Article 3
Development; Regulatory Affairs; Commercialization

3.1 **Generally**. Except with respect to the Lineage Activities, Lineage's Manufacturing responsibilities set forth in ARTICLE 4, the Permitted Activities and any other activities allocated to Lineage, as between the Parties, Roche shall be responsible for all aspects of Development and Commercialization of Licensed Products in the Field, which it shall conduct in its sole discretion and control, at its sole cost and expense.

3.2 **Development.**

3.2.1 **General**. Except for Lineage's responsibilities with respect to the Lineage Activities, Roche shall (a) have sole responsibility for, and bear all costs for, Developing Licensed Products; and (b) have the sole right and authority to control all decisions related to the Development of any Licensed Products.

3.2.2 **Lineage Work Plan.** The research, Development, Manufacturing and other activities to be conducted by or on behalf of Lineage or its Affiliates with respect to the OpRegen Product shall be set forth in a written work plan, which may be updated and amended in writing from time to time by the JMC (the "**Lineage Work Plan**" and the activities set forth therein, the "**Lineage Activities**"). The initial Lineage Work Plan is attached hereto as Exhibit B. Lineage shall perform all such Lineage Activities at its sole cost and expense [***].

3.2.3 **Existing Trial.** Lineage shall conduct the Existing Trial at its sole cost and expense and in accordance with all Applicable Law, any applicable protocols, and this Agreement, including, as more specifically set forth in the Lineage Work Plan, managing safety reporting, drafting the final clinical study report(s), preparing and compiling the final tables, listings and figures, drafting such other plans or documents as Roche requires or as requested by a Regulatory Authority, and contracting with any necessary contract research organizations. Lineage shall provide Roche regular updates on the progress of the Existing Trial at the JAC or as otherwise reasonably requested by Roche and shall, at the conclusion of the Existing Trial, provide copies of all reports and data. Neither Party may amend the clinical trial protocol of the Existing Trial without the prior written consent of the other Party, except that if any amendment or additional data is required or requested by a Regulatory Authority, the Parties shall confer in good faith and reasonably cooperate with each other to satisfactorily respond to such requirement or request by such Regulatory Authority.

3.2.4 **Additional OpRegen Development Prior to Phase II Lead-In.** From time to time prior to commencement by Roche of Phase II Lead-In for the OpRegen Product, if a Regulatory Authority requires Roche to conduct, or if Roche otherwise determines that it is reasonably necessary or desirable to conduct, additional Development activities with respect to the OpRegen Product that are not included in the Lineage Work Plan, then upon Roche's request, the JMC shall update the Lineage Work Plan to include such additional Development activities. Lineage shall use Commercially Reasonable Efforts to conduct any such additional Development activities in accordance with such updated plan. Each Party shall be responsible for its own FTE Costs and Out-of-Pocket Costs incurred in connection with performing such additional Development activities, [***].

3.2.5 **Assessment and Further Development.**

(a) **Assessment**. Prior to Initiation of Phase II Randomization for OpRegen v 1.2, Roche, in its sole discretion, shall assess whether to continue further Development of OpRegen v 1.2. Lineage shall provide Roche all Know-How and other information reasonably requested by Roche to make such assessment.

(b) **Modified Plan for OpRegen v 1.2**. If Roche determines that OpRegen v 1.2 is not suitable for continued Development, but that additional Development activities may enable continued Development, then at Roche's request, the JMC shall amend the Lineage Work Plan to describe such additional Development activities. The Parties shall agree, through the JMC, with respect to any such amendment to the Lineage Work Plan taking into account the capabilities of the Parties and a reasonable allocation of responsibilities based thereon, and the Parties shall use Commercially Reasonable Efforts to conduct such additional Development activities at each Party's sole cost and expense [***].

(c) **Development Activities for OpRegen v 1.3**. Whether or not the Parties implement a modified plan according to Section 3.2.5(b), if, in Roche's sole discretion, a new version of the OpRegen Product, comprised of Lineage RPE Cells differentiated from hESC Cells and delivered as a cell suspension, with defining features specified in Schedule 3.2.5 ("**OpRegen v 1.3**") is required or desirable in order to support further Development of the OpRegen Product, then at Roche's request, the JMC shall amend the Lineage Work Plan to include such Development activities for OpRegen v 1.3. The Parties shall agree, through the JMC, with respect to any such amendment to the Lineage Work Plan taking into account the capabilities of the Parties and a reasonable allocation of responsibilities based thereon, and the Parties shall use Commercially Reasonable Efforts to conduct such additional Development activities at each Party's sole cost and expense [***]. Prior to Initiation of Phase II Randomization for OpRegen v 1.3, Roche, in its sole discretion, shall assess whether to continue further Development of OpRegen v 1.3. Lineage shall provide Roche all Know-How and other information reasonably requested by Roche to make such assessment.

3.2.6 **Conduct of Lineage Activities.** Except as otherwise expressly provided in this Agreement [***], Lineage shall be responsible for its own FTE Costs and Out-of-Pocket Costs incurred in connection with performing the Lineage Activities. In its sole discretion, Roche shall have the right to assume and complete some or all of such Lineage Activities by providing written notice to Lineage. If Roche exercises such right, Lineage shall (a) without limitation of Section 5.6, transfer any Know-How or assign any Regulatory Documentation relating to such Lineage Activities and (b) use Commercially Reasonable Efforts to ensure that Roche obtains the benefits of any or all Third Party agreements relating to such Lineage Activities.

3.2.7 **Supporting Activities**. Without limiting Lineage's obligations hereunder, including the Lineage Activities and as set forth in ARTICLE 4, Lineage agrees to provide further consultations with Roche as may be reasonably necessary regarding the Development, Manufacture and Commercialization of Licensed Products at Roche's reasonable request.

3.2.8 **Progress Reports; Notices**.

(a) **Lineage Work Plan**. Lineage will furnish to the JAC, at least [***] prior to each JAC meeting, to the extent applicable, an update on Lineage's progress under the Lineage Work Plan (including any work with respect to the Existing Trial) during the relevant Calendar Quarter, including a summary of any material results and data generated by Lineage under the Lineage Work Plan.

(b) **Roche Reports**. Within [***] after each Calendar Year of the Term, Roche shall provide to Lineage an annual written report summarizing Roche's progress in the Development of Licensed Products. Roche's obligations under this Section 3.2.8(b) shall end upon the first Marketing Authorization of a Licensed Product.

(c) **Permitted Activities; [***]**. Lineage will furnish to the JAC, at least [***] prior to each JAC meeting, to the extent applicable, an update on Lineage's progress under any Permitted Activities during the relevant Calendar Quarter, including detailed material results and data generated for such Permitted Activities (including [***], and any new intellectual property created by Lineage). Additionally, Lineage shall provide to the JAC within [***] of receipt by Lineage of the following items [***].

3.3 **Compliance**. Each Party shall perform or cause to be performed, any and all of its Development activities in good scientific manner and in compliance with all Applicable Law and Regulatory Authority requirements.

3.4 **Records**. Each Party shall, and shall ensure that any Third Parties contracted pursuant to Section 3.9, maintain records in sufficient detail and in good scientific manner appropriate for Patent and regulatory purposes, and in compliance with Applicable Law, which shall be complete and accurate and shall properly reflect all work done and results achieved in the performance of its Development activities set forth in Section 3.2, which shall record only such activities and shall not include or be commingled with records of activities other than Development activities for the Licensed Products. All laboratory notebooks shall be maintained for no less than the term of any Patent issuing therefrom. All other records shall be maintained by the applicable Party through the end of the Term and for three (3) years thereafter, or for such longer period as may be required by Applicable Law.

3.5 **Pharmacovigilance; Safety Databases**. Within sixty (60) days of the Effective Date: (a) the Parties shall enter into a pharmacovigilance agreement with respect to the Existing Trial to enable monitoring of the safety of applicable products and to meet reporting requirements with any applicable Regulatory Authority ("**Pharmacovigilance Agreement**"), and (b) Lineage shall transfer to Roche all safety databases related to the Existing Trial. The Parties acknowledge that such Pharmacovigilance Agreement and transfer of safety databases are pre-conditions that must be satisfied before transfer of Regulatory Documentation (including any INDs) under Section 3.6.2. Any unreasonable delay by Lineage beyond such sixty (60)-day period shall constitute a material breach under Section 13.2. Until such safety database has been successfully transferred and such Pharmacovigilance Agreement has been successfully executed, Lineage shall notify Roche of any serious adverse event within twenty-four (24) hours of such occurrence and shall otherwise promptly notify Roche of any and all adverse events or other safety observations.

3.6 **Regulatory Affairs.**

3.6.1 **Regulatory Interactions.** As between the Parties, subject to Section 3.6.4 with respect to the Lineage Activities conducted in connection with the Israel CTA, Roche shall have the sole right to prepare, obtain and maintain applications for Regulatory Approval (including the setting of the overall regulatory strategy therefor) and other submissions and to conduct communications with the Regulatory Authorities, for Licensed Products in the Territory (which shall include filings of or with respect to INDs and other filings or communications with the Regulatory Authorities with respect to Development activities). Without limiting Lineage's obligations under the Lineage Work Plan, Lineage shall support Roche, as may be reasonably necessary, in obtaining Regulatory Approvals for the Licensed Products and in the activities in support thereof, including providing all documents or other materials in the possession or control of Lineage or any of its Affiliates as may be necessary or useful for Roche or any of its Affiliates or its or their Sublicensees to obtain Regulatory Approvals for the Licensed Products. For clarity, if a Regulatory Authority requests or requires the submission of any Lineage Confidential Information (including trade secret information) with respect to cell line development, a master cell bank or a working cell bank, or any other information that Lineage has not already provided to Roche, then Lineage will promptly provide such information either to Roche or directly to such Regulatory Authority, *provided*, *however*, that if Lineage opts to provide such information directly to such Regulatory Authority, Lineage shall first confer with Roche and provide a redacted version of the proposed submission for Roche's approval. If Lineage is required under Applicable Law to engage with any Regulatory Authority with respect to any Licensed Product (e.g., in connection with the Existing Trial), Lineage shall ensure that Roche is promptly notified and include Roche in its interactions, and shall ensure that all responses or interactions are done with Roche's knowledge and approval.

3.6.2 **Regulatory Documentation.** Except to the extent prohibited by Applicable Law, all Regulatory Documentation (including all Regulatory Approvals) relating to the OpRegen Product (excluding the clinical trial application for the Existing Trial being conducted in Israel (the "**Israel CTA**")) or other Licensed Products, developed or granted after the Effective Date shall be owned by and shall be the sole property and held in the name of, Roche or its designated Affiliate, Sublicensee or designee. Lineage hereby assigns to Roche all of its right, title, and interest in and to all such Regulatory Documentation (including such Regulatory Approvals, but excluding the Israel CTA). Lineage shall transfer to Roche, within [***] of satisfying the pre-conditions set forth in Section 3.5, all such Regulatory Documentation (including, for clarity, transfer of the IND associated with the Existing Trial). Lineage shall perform all acts and assure execution of all documents necessary to confer unto Roche its rights under this Section 3.6.2, including, if applicable, appropriate rights of reference. Lineage shall also perform additional actions as Roche may reasonably request in connection with securing Roche's rights under this Section 3.6.2.

3.6.3 **Regulatory Correspondence Related to Manufacturing**. Lineage shall immediately (but in any event within [***]) notify Roche in writing of, and provide Roche with copies of, any correspondence and other documentation received or prepared by Lineage in connection with receipt of a regulatory letter, warning letter, Form 483 (Inspectional Observations) or similar item, from the FDA or any other Regulatory Authority.

3.6.4 **Israel CTA Lineage Activities.**

(a) **Interactions with Regulatory Authorities**. Lineage shall, at its cost and expense, be responsible for liaising and managing interactions with Regulatory Authorities in Israel (including acting as a clinical trial sponsor) with respect to the Israel CTA. Lineage shall provide Roche with prior written notice of any substantive meeting, conference, or discussion (including any advisory committee meeting) with a Regulatory Authority in Israel relating to any Licensed Product, within [***] after Lineage first receives notice of the scheduling of such meeting (or within such shorter period as may be necessary in order to give Roche a reasonable opportunity to have at least two (2) representatives attend such meeting). Roche shall have the right to attend and participate in all such meetings, to the extent permitted by Applicable Law. In addition, Roche shall have the right to participate in any substantive preparatory pre-meetings held prior to such a Regulatory Authority meeting.

(b) **Regulatory Correspondence**. Lineage shall promptly provide to Roche copies of any material documents, information or other correspondence received from a Regulatory Authority pertaining to the Existing Trial, including, but not limited to, the Israel CTA and amendments thereto, Regulatory Authority meeting requests, and Regulatory Authority advice (including scientific advisory packages). Lineage shall provide Roche access to a draft of all materials pertaining to the Existing Trial in Israel to be submitted by Lineage to a Regulatory Authority, sufficiently in advance of the intended submission dates, but in any event no later than [***] prior to the intended submission date, to enable Roche to review and provide comments to Lineage concerning the content thereof. Lineage shall incorporate all reasonable comments of Roche.

(c) **Adverse Event Reports**. Lineage shall comply with (or assist Roche with) the collection, review, assessment, tracking and filing of information related to any adverse events in accordance with Applicable Law, and the Pharmacovigilance Agreement. Until such Pharmacovigilance Agreement is successfully executed, Lineage shall notify Roche of any serious adverse event within [***] of occurrence and shall otherwise promptly notify Roche of any and all adverse events or other safety observations.

3.7 **Commercialization.** Roche, at its own expense, shall have sole responsibility and decision-making authority for the Commercialization of Licensed Products in accordance with Applicable Law.

3.8 **Diligence**. [***].

3.9 **Subcontracting.**

3.9.1 **Roche.** Roche shall have the right to subcontract any of its activities under this Agreement to a Third Party. If practicable, Roche shall notify Lineage of its intent to subcontract any Manufacturing of the Licensed Products to a Third Party to allow Lineage the opportunity to provide feedback regarding the selection of any such Third Party with respect to such subcontractor's cell therapy manufacturing capabilities.

3.9.2 **Lineage.** Lineage shall not subcontract any material Lineage Activities or Manufacturing activities to a Third Party, other than to the applicable Authorized Subcontractors solely to perform the relevant Subcontracted Activities. Such activities performed by an Authorized Subcontractor on behalf of Lineage shall be pursuant to a written subcontract specifying the work to be subcontracted, and containing provisions consistent with the terms and conditions of this Agreement, including with respect to confidentiality and Intellectual Property. Lineage shall provide Roche the opportunity to review and approve any such subcontract prior to its execution.

3.9.3 **Performance.** Each Party shall be responsible (and liable) to the other Party for the performance of such Party's activities pursuant to this Agreement by its subcontractors and for any failure by its subcontractors to comply with the restrictions, limitations and obligations set forth in this Agreement as if such performance or failure of such subcontractors were the performance or failure of such Party under this Agreement.

Article 4
Manufacturing; Technology Transfer

4.1 **Manufacture by Roche.** Subject to Lineage's obligation to Manufacture and supply described in Section 4.2 and except as otherwise may be agreed by the Parties in writing, following the successful completion of Technology Transfer, Roche shall be solely responsible for clinical and commercial supply and Manufacture of all Licensed Products in the Territory.

4.2 **Manufacture by Lineage**.

4.2.1 **Certain Clinical Trial Material.** Until the completion of Phase II Randomization or as otherwise agreed to by the Parties, Lineage shall Manufacture and supply to Roche, at Lineage's sole cost and expense all RPE Cells and Licensed Products sufficient for all Development activities with respect to Licensed Products, including the Lineage Activities, or as mutually agreed upon by the Parties.

4.2.2 **Phase II Clinical Trial Quality Agreement**. The Parties shall enter into a quality agreement as it relates to Lineage's Manufacture and supply for Roche's Phase II Clinical Trial. Such quality agreement shall be executed within sixty (60) days of the Effective Date, unless Roche in its sole discretion elects to extend such time period.

4.2.3 **Phase III Clinical Trial Material and Commercial Supply.** Notwithstanding Section 4.2.1, at Roche's request, the Parties shall discuss and negotiate in good faith whether Lineage shall continue to Manufacture and supply Licensed Product to Roche for Roche's Phase III Clinical Trials for OpRegen v 1.2 or OpRegen v 1.3, as applicable (a "**Clinical Supply and Quality Agreement**"), and/or for commercial quantities of Licensed Products under a supply agreement and a quality agreement for Manufacture of Licensed Products by Lineage ("**Commercial Supply and Quality Agreement**"), in either case, consistent with the terms and conditions of this ARTICLE 4. Lineage shall not be obligated to Manufacture and supply to Roche, and Roche shall not be obligated to purchase or otherwise procure from Lineage, any quantities of Licensed Product following completion of the Phase II Clinical Trial for OpRegen v 1.2 or OpRegen v 1.3, as applicable, unless and until the Parties have entered into a Clinical Supply and Quality Agreement, in the case of any additional clinical supply, or a Commercial Supply and Quality Agreement, in the case of any commercial supply. If Lineage agrees to negotiate a Clinical Supply and Quality Agreement or a Commercial Supply and Quality Agreement (each a "**Supply Agreement**"), the Parties will use diligent, good faith efforts to execute such Supply Agreement within [***] days.

4.2.4 **Supply Agreement**. It is the intention of the Parties that any Supply Agreement will (a) be entered into with a lead time that would take into account [***]. Roche shall have the right, at its own cost under the Commercial Supply and Quality Agreement, to conduct audits of any relevant facility and of all suppliers, including any relevant books and records.

4.2.5 **Process Improvements**. In the course of conducting Manufacturing pursuant to this Section 4.2, Lineage will, in consultation with the JMC, use Commercially Reasonable Efforts to (a) reduce Manufacturing Costs for the applicable Manufacturing Process, (b) develop methods to facilitate practical use of a more centralized network of Manufacturing facilities and improve turn-around time, and (c) otherwise implement the JMC's requests with respect to the Manufacturing Process (and modifications thereto). In the event Lineage reasonably believes that it will not be able to implement any of the foregoing, it will promptly notify the JMC.

4.2.6 **Compliance**. Lineage shall conduct all its respective Manufacturing and supply activities hereunder in compliance with all Applicable Law, rules and regulations, including current Good Manufacturing Practices (with respect to clinical supply). Lineage shall be responsible for establishing and maintaining proper quality assurance and quality control policies and procedures in connection with such Manufacturing activities.

4.2.7 **Audit Rights**. Roche shall have the right, at its own cost, to conduct (a) one (1) initial audit prior to execution of a Supply Agreement at a reasonable time during normal business hours and upon reasonable prior notice to Lineage and (b) subsequent audits, of any facility at which the Manufacture of Licensed Products under such agreement will be performed and of all suppliers of materials therefor, including any relevant books and records, *provided* that any such subsequent audits will take place (i) at reasonable times during normal business hours, (ii) upon at least [***] prior written notice to Lineage and (iii) no more than [***] per Calendar Year. For clarity, an audit requested by a Regulatory Authority shall not be subject to the limitations of subsections (a) and (b) of this Section 4.2.7. Lineage shall use Commercially Reasonable Efforts to comply with, or support Roche's compliance with, any deadlines pursuant to such audit request by a Regulatory Authority.

4.3 **Technical and Knowledge Transfer.**

4.3.1 **Technology Transfer.**

(a) **Documents Transfer**. Lineage shall, at its sole cost and expense, in accordance with the timeframes set forth on Exhibit D or Exhibit E, as applicable, effect a full transfer to Roche or its designee of (i) the documents set forth in Exhibit D and Exhibit E and (ii) any additional documents that are within the scope of the licenses granted to Roche pursuant to Section 5.1 or reasonably necessary or desirable for Exploiting the OpRegen Product. Such transfer shall include the provision of copies of the clinical data, research data, records, lab reports, technical documentation, materials lists and equipment lists (including the identity of source vendors, suppliers, etc., as applicable), specifications, procedures as well as any documents related to the Manufacture, Manufacturing Process and/or testing of the OpRegen Product.

(b) **Materials Transfer**. Lineage shall, at its sole cost and expense, within [***] after Roche's request, assign and transfer to Roche or its designee and deliver to Roche or its designee, at a location to be specified by Roche, all (as and to the extent requested by Roche) inventory of the Licensed Product or any other materials (including cell banks or intermediate materials) in Lineage's possession set forth in Table 1 of Exhibit E (collectively, "**Materials**"). Thereafter, Roche or its CMO shall maintain the master cell bank for each working cell bank delivered to Roche and, if any such working cell bank is contaminated (or becomes contaminated) or is no longer usable to Manufacture the Licensed Products, then, upon Roche's reasonable request, Lineage shall make a new master cell bank and working cell bank and shall perform the necessary testing and assays required or requested by Roche or the Regulatory Authorities, sufficient to resume Exploitation of the Licensed Products. Further, if Roche for any other reason requests a new master cell bank, Lineage shall use Commercially Reasonable Efforts to make such cell bank and perform the necessary testing and assays requested by Roche, at Roche's sole expense.

(c) **Know-How Transfer; Manufacturing**. Lineage shall, at its sole cost and expense, at a timeline determined by the JMC, effect a full transfer to Roche or its designee of the Know-How (including Lineage Know-How) that is within the scope of the licenses granted to Roche pursuant to Section 5.1 or reasonably necessary or desirable for Exploiting the OpRegen Product, as set forth in Exhibit C. Such transfer shall include (i) technical training to enable Roche to use the Manufacturing Know-How provided in this Section 4.3.1 to make Licensed Products, including reasonable access to Lineage's employees and facilities and, if practicable, Third Party service providers with relevant subject matter expertise, to answer questions and assist Roche in understanding and implementing such Manufacturing Know-How and (ii) support for Roche's qualification and Manufacture of OpRegen v 1.2 or OpRegen v 1.3, as applicable, including performing certain studies and Manufacturing batches of the applicable OpRegen Product required to support Roche's clinical activities to the extent necessary or desirable for qualification and comparability testing of OpRegen v 1.2 or OpRegen v 1.3, as applicable. Such access and assistance shall occur through the JMC, on-site visits at Lineage's or Roche's facilities (or facilities of its Affiliates or designated CMO, as applicable), or telephonic, videoconference or other meetings with personnel of Lineage and Authorized Subcontractors. Lineage shall, and shall cause its Affiliates to, take such steps as are reasonably necessary or useful to assist Roche (or its Affiliate or designated CMO, as applicable) in obtaining any necessary licenses, permits or approvals from Regulatory Authorities with respect to the Manufacture of the OpRegen Product at the applicable facilities.

(d) **Definitions**. The Parties shall cooperate to document transfer of the documents, Materials, and Know-How described in subclauses (a), (b), and (c) of this Section 4.3.1 (such transfer obligations, the "**Technology Transfer**"). The plan that lists documents and materials to be transferred from Lineage to Roche during the Technology Transfer (including the descriptions of the activities to be conducted to effect the Technology Transfer, an estimated timeline and allocation of responsibility with respect to such Technology Transfer, and the success criteria that must be achieved for the Technology Transfer to be deemed complete) that are related to Lineage Know-How, Joint Know-How or Know-How within the Lineage Patents or Joint Patents existing as of the date of Roche's request pursuant to subclauses (a), (b), and (c) of this Section 4.3.1 is attached hereto as Exhibit C, Exhibit D, and Exhibit E (collectively, the "**Technology Transfer Plan**"); *provided*, *however*, that the Technology Transfer Plan is not intended to limit, and shall not be construed as limiting, Lineage's obligation to effect the Technology Transfer pursuant to subclauses (a), (b), and (c) of this Section 4.3.1. The Technology Transfer Plan will be reviewed by the JMC at least every Calendar Quarter and may be updated and amended from time to time, as the JMC determines, as may be desirable or required to achieve the Technology Transfer success criteria.

(e) **Completion of Technology Transfer**. The Technology Transfer shall be considered complete only after the success criteria set forth in Exhibit C of the Technology Transfer Plan has been achieved [***].

(f) **Additional Technology Transfer Activities**. Following completion of the Technology Transfer, Roche shall have the right, at any time and from time to time through Marketing Authorization of the first Licensed Product, to require Lineage, at its sole expense [***], to provide Roche with reasonable access to its employees and facilities, to answer questions that may arise in maintenance of the Manufacturing Process and Know-How provided as part of the Technology Transfer ("**Additional Technology Transfer Activities**"). Following Marketing Authorization of the first Licensed Product, Lineage shall reasonably assist Roche in responding to requests from a Regulatory Authority.

4.3.2 **Ongoing Transfer of Technical Information**. On an ongoing basis throughout the Term, at least once each Calendar Quarter (or such other frequency as mutually agreed by the Parties through the JMC), Lineage shall provide to the JMC, any and all Lineage Know-How that is within the scope of the licenses granted to Roche pursuant to Section 5.1 and Project Know-How ("**Ongoing Knowledge Transfer**"). Lineage will respond to Roche's reasonable requests for such Know-How and make appropriate personnel available to Roche at reasonable times and places and upon reasonable prior notice for the purpose of assisting Roche to understand and use such Lineage Know-How and Project Know-How in connection with the research, Manufacturing, Development or Commercialization of Licensed Products.

Article 5
Licenses

5.1 **License Grant to Roche**. Lineage hereby grants Roche and its Affiliates:

5.1.1 an exclusive (even as to Lineage and its Affiliates), worldwide license, including the right to sublicense through multiple tiers, under the Lineage Patents, the Lineage Know-How, and Lineage's interest in the Joint Patents and Joint Know-How, to research, Develop, make, have made, Manufacture, use, register, offer for sale, sell, import, modify, Commercialize and otherwise fully Exploit Licensed Products and any Improvement with respect thereto in the Field in the Territory [***]; and

5.1.2 an exclusive (even as to Lineage and its Affiliates), worldwide license, including the right to sublicense through multiple tiers, under the OpRegen Trademarks, to Manufacture, use, register, offer for sale, sell, import, modify, distribute, Commercialize and otherwise fully Exploit Licensed Products and any Improvement with respect thereto in the Territory.

5.2 **License Grant to Lineage**. Roche hereby grants to Lineage:

5.2.1 a non-exclusive, worldwide, royalty-free, non-transferable, non-sublicensable license and right of reference under the Roche Know-How, the Roche Patents and any relevant Regulatory Documentation solely to perform Lineage's obligations under this Agreement; and

5.2.2 a non-exclusive, worldwide, royalty-free, non-transferable, non-sublicensable sublicense under the licenses granted to Roche in Section 5.1.1 and Section 5.1.2, solely to perform Lineage's obligations under this Agreement.

5.3 **Sublicenses**. Roche and its Affiliates shall have the right to sublicense the rights granted under Section 5.1.1 and Section 5.1.2 to Third Parties; *provided* that such sublicense is subject to and consistent with the terms and conditions of this Agreement, and *provided*, *further*, that Roche or its Affiliate shall remain responsible for the Sublicensee's compliance with the applicable provisions of this Agreement in connection with such performance. Roche hereby expressly waives any requirement that Lineage exhaust any right, power, or remedy, or proceed against a Sublicensee, for any obligation or performance hereunder prior to proceeding directly against Roche.

5.4 **Existing Third Party In-License Agreements.**

5.4.1 [***]. For avoidance of doubt, as between the Parties, Lineage shall have the sole obligation to make all payments owed under written agreements entered into by Lineage with Third Parties as of the Effective Date that relate to any Licensed Product, including the Existing Third Party Agreement Payments.

5.4.2 The Parties acknowledge that, on December 17, 2021, the Parties entered into a side letter agreement to that certain Second Amended and Restated License Agreement by and between Hadasit Medical Research Services and Development Ltd. ("**Hadasit**") and Cell Cure, dated as of June 15, 2017, as amended on November 30, 2017, December 1, 2019, and December 17, 2021 (the "**Hadasit Agreement**"), which side letter agreement modifies certain terms of the Hadasit Agreement (the "**Hadasit Side Letter**").

5.5 **No Additional Licenses**. Except as expressly provided in this Agreement, nothing in this Agreement shall grant either Party any right, title or interest in and to the Know-How, Patents or other Intellectual Property rights of the other Party (either expressly or by implication or estoppel).

5.6 **Disclosure of Know-How and Regulatory Documentation; Improvements.**

5.6.1 Lineage shall and shall cause its Affiliates to, without additional compensation, disclose and make available to Roche, in whatever form Roche may reasonably request (including by providing copies thereof), Regulatory Documentation, Lineage Know-How, Joint Know-How and any other Know-How claimed or Covered by any Lineage Patent or otherwise relating, directly or indirectly, to any Licensed Product or the Exploitation thereof, (a) that is in existence as of the Effective Date, promptly after the Effective Date and (b) that comes into existence after the Effective Date, promptly after the earlier of the development, making, conception or reduction to practice of such Regulatory Documentation, Lineage Know-How, Joint Know-How or other Know-How. Without limiting the foregoing, Lineage shall, within [***] of the Effective Date, transfer to Roche, in such form and format (including translated into English, as appropriate) as Roche may reasonably request, (i) the IND(s) of all OpRegen Products, (ii) all clinical and non-clinical data, research, analyses and other Know-How relating to the Licensed Products, (iii) copies of all correspondence, as of the Effective Date, to and from any Regulatory Authority that relates to the Licensed Products, and (iv) copies of all relevant Regulatory Documentation.

5.6.2 Lineage, at its sole cost and expense, shall provide Roche with all reasonable assistance required in order to transfer to Roche the Regulatory Documentation, Lineage Know-How, Joint Know-How and any other Know-How required to be produced pursuant to Section 5.6.1, in each case, in a timely manner, and shall assist Roche with respect to the exploitation of the Licensed Products. Without limiting the foregoing, Lineage shall make available to Roche, including at Roche's facilities (or at facilities of its Affiliates or its designated CMO), those of Lineage's representatives as Roche may reasonably request for purposes of transferring the Regulatory Documentation, Lineage Know-How, Joint Know-How or other Know-How to Roche or for purposes of Roche acquiring expertise on the practical application of such Know-How or assisting on issues arising during such Exploitation.

5.6.3 Without limiting the foregoing, Lineage shall without delay disclose to Roche any Improvements made or otherwise Controlled by Lineage or its Affiliates during the Term and provide Roche with all relevant Know-How and materials with respect to such Improvements. [***].

5.7 **Exclusivity; Change in Control.**

5.7.1 **Exclusivity**. Lineage shall not, and shall cause its Affiliates not to, directly or indirectly (except with respect to the Permitted Activities, Lineage Activities and as agreed with respect to Manufacturing and Technology Transfer), research, Develop, use, manufacture, modify, Commercialize or otherwise Exploit, or license, authorize, appoint, or otherwise assist or enable any Third Party to directly or indirectly do any of the foregoing, in each case, anywhere in the Territory during the period [***].

5.7.2 **Exceptions**. Subject to Section 15.3, if a Third Party becomes an Affiliate of Lineage or its Affiliate after the Effective Date through a Change in Control (each, an "**Acquisition Affiliate**"), and as of the closing date of such transaction, such Third Party is engaged in activities that, if conducted by Lineage, would cause Lineage to be in breach of its exclusivity obligations set forth in this Section 5.7 (such Third Party program, a "**Competing Program**"), then:

(a) if Lineage or its Affiliate is acquired, then such new Acquisition Affiliate (the "**Acquirer**") may continue such Competing Program after such Change in Control and such continuation shall not constitute a breach of Lineage's exclusivity obligations set forth in this Section 5.7; *provided* that the Acquirer conducts such Competing Program independently of the activities of this Agreement (including ensuring that (i) no personnel involved in the Competing Program have access to non-public plans or information relating to the Development or Commercialization of Licensed Products or Confidential Information of Roche, (ii) and segregating all personnel conducting activities related to the Licensed Product from all personnel conducting the Competing Program) and does not incorporate or reference the Lineage Patents or Joint Patents (or any Confidential Information or inventions disclosed in the foregoing) or the Lineage Know-How or Joint Know-How, or other Confidential Information of Roche in the conduct of such Competing Program; and

(b) if Lineage or its Affiliate acquires a Third Party, then Lineage or its Affiliate and its new Acquisition Affiliate will have [***] from the closing date of such transaction to wind down or complete the Divestiture of such Competing Program and shall cease all activities with respect to such Competing Program if it has not completed such Divestiture within such period (it being understood that Lineage or its Affiliate and its new Acquisition Affiliate may thereafter continue its efforts to complete Divestiture), and its new Acquisition Affiliate's conduct of such Competing Program during such [***] period shall not be deemed a breach of the exclusivity obligations set forth in this Section 5.7; *provided* that such new Acquisition Affiliate conducts such Competing Program during such [***] period independently of the activities of this Agreement (including ensuring that (i) no personnel involved in the Competing Program have access to non-public plans or information relating to the Development or Commercialization of Licensed Products or Confidential Information of Roche, and (ii) segregating all personnel conducting activities related to the Licensed Product from all personnel conducting the Competing Program) and does not incorporate or reference the Lineage Patents or Joint Patents (or any Confidential Information or inventions disclosed in the foregoing) or the Lineage Know-How or Joint Know-How or other Confidential Information of Roche in the conduct of such Competing Program. "**Divestiture**", as used in this Section 5.7.2(b), means the sale or transfer (including via exclusive license) of all rights to the Competing Program, as applicable, to a Third Party.

5.8 **Product Trademarks.**

5.8.1 Roche shall have the sole right to determine the Product Trademarks to be used with respect to the Exploitation of the Licensed Products on a worldwide basis, including whether to use any OpRegen Trademark. Lineage shall not, and shall not permit its Affiliates to, (a) use in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Product Trademarks, or (b) do any act which endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to the Product Trademarks. Lineage shall not, and shall not permit its Affiliates to, attack, dispute, or contest the validity of or ownership of such Product Trademark anywhere in the Territory or any registrations issued or issuing with respect thereto.

5.8.2 Roche acknowledges the standards and reputation for quality symbolized by the OpRegen Trademarks as of the Effective Date, and Roche shall use the OpRegen Trademarks in a manner consistent with such quality standards and reputation. Lineage shall have the right to request representative samples of any product bearing the OpRegen Trademarks solely for purposes of exercising quality control over Roche's use of the OpRegen Trademarks on or in connection with the Licensed Products to the extent reasonably necessary under Applicable Law to maintain the validity of the OpRegen Trademarks and protect the goodwill associated therewith.

Article 6
Financial Terms

6.1 **Upfront Payment**. In consideration for the rights and licenses set forth herein, no later than thirty (30) days after the Effective Date and Roche's receipt of an invoice therefor, Roche shall pay Lineage a one-time upfront payment in the amount of fifty million Dollars ($50,000,000).

6.2 **Development Milestones**. Subject to Section 6.6, Roche shall pay Lineage each milestone payment set forth in the following table only once, in accordance with Section 7.1, following the first achievement of the corresponding milestone event:

	Milestone Event	**Milestone Payment**		
		[***]	**[***]**	**[***]**
1.	[***]	[***]	[***]	[***]
2.	[***]	[***]	[***]	[***]
3.	[***]	[***]	[***]	[***]
4.	[***]	[***]	[***]	[***]
5.	[***]	[***]	[***]	[***]
6.	[***]	[***]	[***]	[***]
7.	[***]	[***]	[***]	[***]

* For clarity, Lineage shall only be entitled to receive Milestone 3 once, for either (a) or (b).
** For clarity, Lineage shall only be entitled to receive Milestone 4 once, for either (a) or (b).

Each milestone payment specified in this Section 6.2 is payable one-time only. For the avoidance of doubt, Roche's cumulative obligation under this Section 6.2 shall in no event exceed [***].

6.3 **Annual Net Sales Milestones**. Subject to Section 6.6, Roche shall pay Lineage each milestone payment set forth in the following table, in accordance with ARTICLE 7, following the first achievement of the corresponding milestone event by the first Licensed Product [***]:

	Milestone Event	**Milestone Payment**
1.	[***]	[***]
2.	[***]	[***]
3.	[***]	[***]
4.	[***]	[***]

Each milestone payment specified in this Section 6.3 is payable one-time only. For the avoidance of doubt, Roche's cumulative obligation under this Section 6.3 shall in no event exceed [***].

6.4 **Royalties**. During the applicable Royalty Term, Roche shall pay Lineage, on a Licensed Product-by-Licensed Product and country-by-country basis, and subject to Section 6.5 and Section 6.6, a royalty on worldwide Annual Net Sales of such Licensed Product in accordance with ARTICLE 7, as follows:

6.4.1 [***]:

Worldwide Annual Net Sales	**Royalty Rate**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

6.4.2 [***]:

Worldwide Annual Net Sales	**Royalty Rate**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

6.4.3 [***]:

Worldwide Annual Net Sales	**Royalty Rate**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

6.4.4 [***]:

Worldwide Annual Net Sales	**Royalty Rate**
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

[***].

[***].

6.5 **Royalty Payments.**

6.5.1 **Royalty Term.** [***].

6.5.2 **Rights Following Expiration of Royalty Term**. Upon expiration of the Royalty Term with respect to a Licensed Product in a country, the licenses granted to Roche under Section 5.1 shall be fully paid-up, perpetual, and irrevocable in respect of that Licensed Product in that country.

6.5.3 **Single Royalty**. No more than one (1) stream of royalty payments shall be due under this ARTICLE 6 with respect to sales of any one (1) particular Licensed Product. For the avoidance of doubt, multiple royalties shall not be payable because the sale of a particular Licensed Product is Covered by more than one (1) Valid Claim of a Primary Patent or a Secondary Patent in the country in which such Licensed Product is sold.

6.6 **Payment Offsets and Reductions.**

6.6.1 **[***].**

(a) [***].

(b) [***].

(c) [***].

6.6.2 **[***]**:

(a) [***];

(b) [***].

6.6.3 **[***]**.

6.6.4 **[***]**.

6.7 **Royalty Disposition Transaction**. If Lineage wishes to enter into any transaction with a Third Party for the sale, assignment, transfer or other disposition (other than a security interest granted in the course of a financing) by Lineage of any rights to the payments due or payable by Roche to Lineage pursuant to this Agreement (a "**Disposition Transaction**"), Lineage shall notify Roche in writing and Roche will have the opportunity to negotiate in good faith with Lineage with respect to any such Disposition Transaction. For the avoidance of doubt, Lineage shall be free to negotiate and enter into the Disposition Transaction with either Roche or any Third Party at Lineage's sole discretion.

6.8 **[***]**.

6.8.1 [***].

6.8.2 [***].

6.8.3 [***].

6.8.4 [***].

Article 7
Payment Terms; Reports; Audits

7.1 **Notice of Milestone Achievement; Timing of Payment**. With respect to each of the milestone events set forth in Section 6.2, Roche shall inform Lineage within [***] following the achievement of such event. With respect to each of the milestone events set forth in Section 6.3, Roche shall inform Lineage within [***] following the end of the Calendar Quarter for which such achievement of such event occurred. Roche shall pay Lineage the respective payable milestone payment within [***] of receipt of an invoice from Lineage with respect thereto.

7.2 **Timing of Royalty Payment**. All royalty payments shall be made within [***] of the end of each Calendar Quarter in which the sale was made.

7.3 **Royalty Report**. [***]:

(a) [***]; and

(b) [***]; and

(c) [***].

If Roche is reporting Net Sales for more than one (1) Licensed Product, the foregoing information shall be reported on a Licensed Product-by-Licensed Product basis.

7.4 **Invoicing**. Lineage shall send invoices under this Agreement to Roche via email to the Alliance Manager (to be provided by the Alliance Manager) and as follows:

Alliance Manager, Pharma Partnering
Genentech, Inc.
One DNA Way, Mail Stop 53
South San Francisco, CA 94080

Or to such other address as Roche may designate from time to time. Roche shall send invoices under this Agreement to Lineage at its address set forth in Section 15.2, or to such other address as Lineage may designate from time to time.

7.5 **Mode of Payment**. All payments hereunder shall (unless otherwise specifically designated) be non-creditable and non-refundable; and all payments to Lineage hereunder shall be made in immediately available funds to the account listed below (or such other account as Lineage shall designate before such payment is due):

Bank: Wells Fargo Bank, NA
Bank Address: 420 Montgomery Street, San Francisco, CA 94104

Account #: [***]
ABA Routing Number: [***]
SWIFT Code: [***]

7.6 **Currency of Payments**. All amounts set forth herein (including all payments) are in Dollars, unless otherwise expressly provided in this Agreement. Net Sales outside of the US shall be first determined in the currency in which they are earned and shall then be converted into an amount in Dollars as follows: (a) with respect to Sales by or on behalf of Roche or an Affiliate, using Roche's or such Affiliate's customary and usual conversion procedures (e.g., using, as of the Effective Date, year-to-date average rates, as reported by Reuters), consistently applied and (b) with respect to Sales by or on behalf of a given Sublicensee, using the conversion procedures applicable to payments by such Sublicensee to Roche for such sales.

7.7 **Blocked Currency**. If, at any time, legal restrictions prevent Roche (or an Affiliate or Sublicensee) from remitting part or all of payments when due with respect to any country in the Territory where Licensed Products are sold, Roche shall continue to provide the reports set forth in Section 7.3 for such payments, and such payments shall continue to accrue in such country, but Roche shall not be obligated to make such payments, and, for clarity, Section 7.9.5 shall not apply to such payments, until such time as payment may be made through reasonable, lawful means or methods that may be available, as Roche shall determine.

7.8 **Taxes**. Each Party shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made under this Agreement. Lineage shall pay all sales, turnover, income, revenue, value added, and other taxes levied on account of any payments accruing or made to Lineage under this Agreement. Roche shall be entitled to deduct from payments made to Lineage under this Agreement, or be promptly reimbursed by Lineage if no further payments are due to Lineage, the amount of any withholding taxes required to be withheld, including under Section 7.8.1 (German Withholding Tax Requirement), to the extent paid to the appropriate governmental authority on behalf of Lineage (and not refunded or reimbursed). Roche shall deliver to Lineage, upon request and when available, proof of payment of all such withholding taxes. Each Party agrees to reasonably assist the other Party in claiming exemption from such deductions or withholdings under double taxation or similar agreement or treaty from time to time in force and in minimizing the amount required to be so withheld or deducted.

7.8.1 **German Withholding Tax**. The Parties acknowledge that payments to Lineage with respect to the rights in Germany granted to Roche under this Agreement are subject to (i) German income tax pursuant to sec. 49 para. 1 German Income Tax Act and (ii) withholding tax pursuant to sec. 50a para. 1 German Income Tax Act (the "**German WHT Requirement**"). Without limiting anything in this ARTICLE 7, the following shall apply:

(a) Lineage shall provide Roche with all information relevant to assess the applicability of and the tax assessment basis for the German WHT Requirement;

(b) Reasonably taking into account any comments and information received from Lineage, Roche shall use reasonable best efforts to determine (i) whether the German WHT Requirement is applicable on the licenses granted to Roche under this Agreement and (ii) the amount to be withheld and remitted to the competent German tax authority (including the allocation to and calculation of the assessment basis for the withholding);

(c) Based on the determination made pursuant to Section 7.8.1(b), Roche shall remit the withheld amount to the competent German tax authority in due course. With regards to Roche's payment obligations under this Agreement, any amount paid to the German tax authority pursuant to the preceding sentence shall be deemed as payment to Lineage;

(d) As soon as Roche has received a valid exemption certificate (*Freistellungsbescheinigung*) issued by a competent German tax authority (upon the application of Lineage) confirming that Lineage is not required to make a withholding pursuant to the German WHT Requirement, Roche shall not be allowed to make any deductions from any payments pursuant to this Section 7.8.1 for the time period specified in the exemption certificate; and

(e) If Roche receives a request by a competent German tax authority to make a payment based on or in connection with the German WHT Requirement, Lineage shall indemnify Roche from such payment obligation without undue delay. Roche shall be allowed to offset its indemnification claim pursuant to the preceding sentence against payments due under this Agreement to Lineage.

7.9 **Records; Inspection.**

7.9.1 **Records**. Roche agrees to keep, for [***] from the year of creation, records of all sales of Licensed Products for each reporting period in which royalty payments or Net Profits and Net Losses payments are due, showing sales of Licensed Products for Roche and applicable deductions in sufficient detail to enable the reports provided under Section 7.3 to be verified.

7.9.2 **Audits**. Either Party may request verification of the relevant financial records of the other Party by an independent, certified and internationally recognized public accounting firm selected by the auditing Party and reasonably acceptable to the audited Party (a "**CPA Firm**") according to the procedures below:

(a) Lineage shall have the right to request that reports provided under Section 7.3 be verified by a CPA Firm. Such right to request a verified report shall (i) be limited to the [***] during which Roche is required to maintain the same, (ii) not be exercised more than [***], and (iii) not more frequently than once with respect to records covering any specific period of time. Subject to Section 7.9.3, Roche shall, upon reasonable advance notice and at a mutually agreeable time during its regular business hours, make its records available for inspection by such CPA Firm at such place or places where such records are customarily kept, solely to verify the accuracy of such applicable reports and related payments due under this Agreement. The CPA Firm shall only state factual findings in the audit reports. The CPA Firm shall share all draft audit reports with Roche before the draft audit report is shared with Lineage and before the final document is issued. The final audit report shall be shared with Roche at the same time that it is shared with Lineage.

(b) Roche shall have the right to request a report summarizing all Lineage Expenses accrued under Section 6.8, and such report shall be subject to verification by a CPA Firm. Such right to request a verified report shall (i) not be exercised more than [***], and (ii) not more frequently than once with respect to records covering any specific period of time. Subject to Section 7.9.3, Lineage shall, upon reasonable advance notice and at a mutually agreeable time during its regular business hours, make its records available for inspection by such CPA Firm at such place or places where such records are customarily kept, solely to verify the accuracy of such applicable reports and related expenses under this Agreement. The CPA Firm shall only state factual findings in the audit reports. The CPA Firm shall share all draft audit reports with Lineage before the draft audit report is shared with Roche and before the final document is issued. The final audit report shall be shared with Lineage at the same time that it is shared with Roche.

7.9.3 **Confidentiality**. Prior to any audit under Section 7.9.2, the CPA Firm shall enter into a written confidentiality agreement with the audited Party that (a) limits the CPA Firm's use of the audited Party's records to the verification purpose described in Section 7.9.2; (b) limits the information that the CPA Firm may disclose to the auditing Party to the numerical summary of payments due and paid or the expenses made, as applicable; and (c) prohibits the disclosure of any information contained in such records to any Third Party for any purpose. The Parties agree that all information subject to review under Section 7.9.2 or provided by the CPA Firm to the auditing Party is the audited Party's Confidential Information, and the auditing Party shall not use any such information for any purpose that is not germane to Section 7.9.2.

7.9.4 **Underpayment; Overpayment**.

(a) For an audit pursuant to Section 7.9.2(a), after reviewing the CPA Firm's audit report, Roche shall promptly pay any uncontested, understated amounts due to Lineage. Any overpayment made by Roche shall, at Roche's election, be (i) fully credited against amounts accrued and payable in the immediately subsequent payment period or (ii) fully refunded if no amounts are payable in the immediately subsequent payment period. Any audit under Section 7.9.2(a) shall be at Lineage's expense; *provided*, *however*, Roche shall reimburse reasonable audit fees for a given audit if the results of such audit reveal that Roche underpaid Lineage with respect to royalty payments by [***] or more for the audited period.

(b) For an audit pursuant to Section 7.9.2(b), if the CPA Firm's audit discovers an error in Lineage's expense report, such records shall be corrected by Lineage, and Roche shall promptly pay any uncontested, understated amounts due to Lineage. To the extent that any error results in an overpayment made by Roche, such overpayment shall be (i) fully credited against amounts accrued and payable in the immediately subsequent payment period or (ii) fully refunded if no amounts are payable in the immediately subsequent payment period. Any audit under Section 7.9.2(b) shall be at Roche's expense; *provided*, *however*, Lineage shall reimburse reasonable audit fees for a given audit if the results of such audit reveal that Roche overpaid Lineage by [***] or more for any reimbursed Lineage Expenses within the audited period.

7.9.5 **Late Payments**. If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of [***], such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

Article 8
Intellectual Property

8.1 **Ownership.**

8.1.1 **Background Intellectual Property.** Subject to any licenses granted to the other Party under this Agreement, each Party shall retain ownership and control of any Know-How, Patents, and other Intellectual Property (a) Controlled by it or its Affiliates prior to the Effective Date or (b) first conceived, developed, or created by or on behalf of it or its Affiliates after the Effective Date outside of this Agreement without the use of the other Party's Confidential Information or such other Party's materials provided to the other Party under this Agreement.

8.1.2 **Project Intellectual Property.** [***].

8.1.3 **Joint Intellectual Property.** [***].

8.1.4 **Licensed Product Improvements.** [***].

8.1.5 **hESC Intellectual Property**. [***].

8.1.6 **US Law.** The determination of whether Know-How, Improvements and inventions are conceived, discovered, developed or otherwise made by a Party for the purpose of allocating proprietary rights (including Intellectual Property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the US irrespective of where such conception, discovery, development or making occurs. In the event that US law does not apply to the conception, discovery, development or making of any Know-How, Improvements or other inventions hereunder, each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their employees, licensees, sublicensees, independent contractors and agents to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Know-How, Improvements and other inventions as well as any Intellectual Property rights with respect thereto, as is necessary to fully effect, as applicable, (a) the sole ownership provided for in Section 8.1.2, Section 8.1.4 and Section 8.1.5, and (b) the joint ownership provided for in Section 8.1.3.

8.2 **Assignment and Cooperation**. The assignments necessary to accomplish the ownership provisions set forth in Section 8.1 are hereby made, and each Party shall execute such further documentation as may be necessary or appropriate, and provide reasonable assistance and cooperation to implement the provisions of Section 8.1. Without limiting the foregoing, each Party agrees to execute such documents, render such assistance, and take such other action as the other Party may reasonably request, to apply for, register, perfect, confirm, and protect the other Party's rights in such Know-How and Intellectual Property rights (including Patents) therein to effect the intent of Section 8.1. Each Party shall require, to the extent legally possible under relevant national or local laws, all of its employees, Affiliates and Authorized Subcontractors to assign (or otherwise convey rights) to such Party its right, title and interests in any Patents and Know-How discovered, conceived or reduced to practice by such employee, Affiliate or Authorized Subcontractor, and to cooperate with such Party in connection with obtaining Patent protection therefor.

8.3 **Prosecution and Maintenance.**

8.3.1 **Prosecution and Maintenance of hESC Patents.** [***].

8.3.2 **Prosecution and Maintenance of Other Lineage Patents and Joint Patents.** [***].

8.3.3 **Prosecution and Maintenance of Roche Patents.** [***].

8.3.4 **Cooperation**. The non-prosecuting Party shall, and shall cause its Affiliates to, assist and cooperate with the prosecuting Party, as the prosecuting Party may reasonably request from time-to-time, in the Prosecution and Maintenance of the Lineage Patents, Roche Patents and Joint Patents in the Territory under this Agreement, including that the non-prosecuting Party shall, and shall ensure that its Affiliates, provide access to relevant documents, including any data, reports, notebooks and other evidence, and make its relevant representatives, including any scientific personnel, reasonably available at reasonable business hours; *provided*, *further,* that the prosecuting Party shall reimburse the non-prosecuting Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith.

8.3.5 **Further Acts**. At the requesting Party's expense, each Party will reasonably cooperate with and assist each other in the Prosecution and Maintenance of the Lineage Patents, Roche Patents and Joint Patents, including making scientists and scientific records reasonably available and using its reasonable efforts to have documents signed as necessary in connection with such Prosecution and Maintenance.

8.4 **CREATE Act**. It is the intention of the Parties that this Agreement is a "joint research agreement" as that that term is defined in 35 USC § 100(h), and as it applies to inventions as set forth in 35 USC § 102(c) (AIA) or 35 USC § 103(c) (pre-AIA), and may be used for the purpose of overcoming a rejection of a claimed invention within the Joint Patents pursuant to the provisions of 35 USC § 102(c) or 35 USC § 103(c). In the event that either Party intends to overcome a rejection of any other claimed invention outside the Joint Patents pursuant to the provisions of 35 USC § 102(c) or 35 USC § 103(c), such Party shall first obtain the prior written consent of the other Party.

8.5 **Patent Term Extension**. [***].

8.6 **Patent Listings**. [***].

8.7 **Enforcement and Defense of IP; Defense of Third Party Infringement Claims.**

8.7.1 **Notice**. With respect to Intellectual Property that is within the scope of the licenses granted under this Agreement, each Party shall promptly notify the other Party upon learning of any (a) actual or suspected infringement or misappropriation by a Third Party of any Lineage Patent, Roche Patent or Joint Patent with respect to a Licensed Product; or (b) claim by a Third Party of invalidity, unpatentability (including any reexaminations, inter partes reviews, and post grant reviews, as well as interferences and derivation proceedings, oppositions and other similar proceedings brought by a Third Party), unenforceability or non-infringement (or non-misappropriation) of a Patent claiming a Licensed Product (or a component thereof) or its use or method of manufacture within the Lineage Patents, Roche Patents or Joint Patent (each, an "**Infringement**").

8.7.2 **Enforcement of IP.**

(a) **[***].**

(b) **[***]**.

(c) **Enforcement of Roche Patents**. [***].

(d) **Settlement**. [***].

(e) **Damages**. Any recovery realized as a result of any action described in Section 8.7.2 (whether by way of settlement or otherwise) shall be first, allocated to reimburse the Parties for their costs and expenses in making such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be allocated (i) with respect to actions under Section 8.7.2(a), [***], and (ii) with respect to actions under Section 8.7.2(b), [***].

8.8 **Defense of Patents**. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity, unenforceability or non-infringement of any of the Lineage Patents, Roche Patents or Joint Patents by a Third Party of which such Party becomes aware. [***].

8.9 **Defense of Third Party Infringement Claims.**

8.9.1 **Notice**. In the event that a Third Party makes any claim, gives notice, or brings any suit against Roche or Lineage (or any of their respective Affiliates, sublicensees or customers) for infringement or misappropriation of any Intellectual Property rights as a result of the research, development, making, using, selling, offering for sale, import or export of any Licensed Product in any country (each, a "**Third Party Infringement Claim**"), in each case, the Party receiving notice of a Third Party Infringement Claim shall notify the other Party within [***] and provide all evidence in its possession pertaining to the claim or suit that it can disclose without breach of a pre-existing obligation to a Third Party or waiver of a privilege.

8.9.2 **Defense.** The Parties shall consult, pursuant to a common joint defense agreement, as to potential strategies to defend against any Third Party Infringement Claim, consistent with the overall goals of this Agreement, including by being joined as a party. The Parties shall cooperate with each other in all reasonable respects in the defense of any Third Party Infringement Claim or raising of any counterclaim related thereto. [***].

8.9.3 **Settlement.** [***].

8.9.4 **Costs and Expenses.** [***].

8.10 **Product Trademarks.**

8.10.1 **Notice.** Each Party shall provide to the other Party prompt written notice of any actual or threatened infringement of the Product Trademarks in the Territory and of any actual or threatened claim that the use of the Product Trademarks in the Territory violates the rights of any Third Party, in each case, of which such Party becomes aware.

8.10.2 **Prosecution of Product Trademarks.** [***].

8.10.3 **Enforcement of Product Trademarks.** [***].

8.10.4 **Third Party Claims**. [***].

8.10.5 **Cooperation**. [***].

Article 9
Confidentiality

9.1 **Definition**. "**Confidential Information**" of a Party means the confidential or proprietary information (of whatever kind and in whatever form or medium, including copies thereof) disclosed in any form (written, oral, electronic, photographic or otherwise) by or on behalf of such Party (the "**Disclosing Party**") to, or otherwise accessed by, the other Party (the "**Receiving Party**") in connection with this Agreement, whether prior to or during the Term, including Know-How or other information (whether or not patentable) regarding such Party's research, development plans, clinical trial designs, preclinical and clinical data, technology, products, business information or objectives, reports and audits under this Agreement and other information of the type that is customarily considered to be confidential or proprietary information by entities engaged in activities that are substantially similar to the activities being engaged in by the Parties pursuant to this Agreement, including all proprietary materials as well as data and information associated therewith. Notwithstanding the foregoing, (a) Joint Know-How and the terms and conditions of this Agreement are the Confidential Information of both Parties; and (b) all other Know-How generated under this Agreement is the Confidential Information of the Party that owns such Know-How pursuant to Section 8.1. Confidential Information may also include any Know-How or information of a Third Party that is disclosed to the Receiving Party by the Disclosing Party or such Third Party at the Disclosing Party's direction.

9.2 **Exclusions Regarding Confidential Information**. Notwithstanding anything in this ARTICLE 9 to the contrary, Confidential Information of the Disclosing Party shall not include information that the Receiving Party can demonstrate by competent written evidence:

9.2.1 was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of receipt by the Receiving Party as shown by the Receiving Party's files and records immediately prior to the time of disclosure; *provided* that the foregoing exception shall not apply with respect to Confidential Information described in the sentence of Section 9.1;

9.2.2 was generally available to the public or otherwise part of the public domain at the time of its receipt by the Receiving Party;

9.2.3 became generally available to the public or otherwise part of the public domain after its receipt by the Receiving Party other than through any act or omission of the Receiving Party in breach of this Agreement;

9.2.4 was received by the Receiving Party without an obligation of confidentiality and non-use from a Third Party having no obligation of confidentiality and non-use regarding such information;

9.2.5 was independently developed by or for the Receiving Party without use of or reference to the Confidential Information of the Disclosing Party as shown by the Receiving Party's files and records prior to the time of disclosure; *provided* that the foregoing exception shall not apply with respect to Confidential Information described in the sentence of Section 9.1; or

9.2.6 was released from the restrictions set forth in this Agreement by express prior written consent of the Disclosing Party.

9.3 **Non-Use and Non-Disclosure of Confidential Information**. During the Term, and for a period of [***] thereafter, a Party shall (a) except to the extent expressly permitted by this Agreement or otherwise agreed to in writing, keep confidential and not disclose to any Third Party or use for any purpose any Confidential Information of the other Party; and (b) take reasonable precautions to protect the Confidential Information of the other Party from unauthorized use or disclosure (including all precautions a Party employs with respect to its own confidential information of a similar nature and taking reasonable precautions to assure that no unauthorized use or disclosure is made by others to whom access to the Confidential Information of the Party is granted); *provided*, that any Confidential Information that constitutes a trade secret shall continue to be subject to the obligations of non-use and non-disclosure until such Confidential Information is no longer a trade secret.

9.4 **Authorized Disclosures of Confidential Information**. Receiving Party may use and disclose the Confidential Information of the Disclosing Party as follows:

9.4.1 if required by law, rule or governmental regulation, *provided* that the Receiving Party (a) use all reasonable efforts to inform the Disclosing Party prior to making any such disclosures and cooperate with the Disclosing Party in seeking a protective order or other appropriate remedy (including redaction) and (b) whenever possible, request confidential treatment of such information;

9.4.2 as reasonably necessary to exercise its rights or fulfil its obligations under this Agreement;

9.4.3 to the extent such use and disclosure is reasonably required in the Prosecution and Maintenance of a Patent in accordance with this Agreement;

9.4.4 as reasonably necessary to obtain or maintain any Regulatory Approval, including to conduct preclinical studies and clinical trials and for pricing approvals, for any Licensed Products, *provided*, that, the Receiving Party shall take all reasonable steps to limit disclosure of the Confidential Information outside such Regulatory Authority and to otherwise maintain the confidentiality of the Confidential Information;

9.4.5 to the extent necessary, to permitted Sublicensees, collaborators, vendors, consultants, agents, contractors and clinicians under written agreements of confidentiality (or in the case of attorneys, pursuant to professional duties of responsibility) at least as restrictive as those set forth in this Agreement, who have a need to know such information in connection with the Receiving Party performing its obligations or exercising its rights under this Agreement. Further, the Receiving Party may disclose Confidential Information to existing or bona fide potential acquirers, merger partners, permitted collaborators, Sublicensees and sources of financing or to professional advisors (e.g., attorneys, accountants and prospective investment bankers) involved in such activities, for the limited purpose of evaluating such transaction, collaboration or sublicense and under appropriate conditions of confidentiality, *provided* that such disclosures are limited to only such information that is strictly necessary for such purpose and made under a written agreement by those permitted individuals to maintain such Confidential Information in strict confidence. Each Receiving Party shall remain liable for the breach of this Agreement by the permitted recipients in this Section 9.4.5 as if such breach were by the Receiving Party itself.

9.5 **Information Security Incident.**

9.5.1 **Notification**. A Party shall provide to the other Party written notice within [***] of such Party's confirmation of an Information Security Incident with respect to the other Party's Confidential Information. Such notice shall describe in reasonable detail the Information Security Incident, including the other Party's Confidential Information impacted, the extent of such impact and any corrective action taken or to be taken by such Party. In addition, if a Party reasonably suspects (even if it has not confirmed) that an actual or attempted Information Security Incident has occurred with respect to the other Party's Confidential Information, then the Party shall promptly notify the other Party of such suspected actual or suspected Information Security Incident.

9.5.2 **Non-Disclosure**. Except to the extent required by Applicable Law, neither Party shall disclose any information related to an actual or suspected Information Security Incident of the other Party's Confidential Information to any Third Party without the other Party's prior written consent.

9.6 **Termination of Prior Agreements**. As of the Effective Date, as between the Parties, this Agreement supersedes the Non-Disclosure Agreement between Lineage and Genentech, dated February 11, 2021 (the "**NDA**") and the Parties agree that disclosures made prior to the Effective Date pursuant to such agreement shall be subject to the provisions of this ARTICLE 9.

9.7 **Residuals**. Notwithstanding anything to the contrary herein, Roche and its Affiliates may use Residuals for any and all purposes and permit others to do so on Roche's or its Affiliate's behalf. For the purpose of this Section 9.7, "**Residuals**" means Know-How or other Confidential Information of Lineage that is retained in the unaided memory of a Party or its Affiliates, employees, consultants, or agents.

9.8 **No License**. Subject to the last sentence of Section 9.1, as between the Parties, Confidential Information disclosed hereunder shall remain the property of the disclosing Party. Disclosure of Confidential Information to the other Party shall not constitute any grant, option or license to the other Party, beyond those licenses expressly granted under ARTICLE 5 and the rights granted under Section 9.7, under any patent, trade secret or other rights now or hereinafter held by the disclosing Party.

9.9 **Attorney-Client Privilege; Common Interest**. Neither Party is waiving, nor shall be deemed to have waived or diminished, any of its attorney work product protections, attorney-client privileges or similar protections and privileges or the like as a result of disclosing information pursuant to this Agreement or any of its Confidential Information (including Confidential Information related to pending or threatened litigation) to the Receiving Party, regardless of whether the Disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties (a) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections; (b) may become joint defendants in proceedings to which the information covered by such protections and privileges relates; (c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the Disclosing Party's Confidential Information covered by such protections and privileges relates; and (d) intend that after the Effective Date both the Receiving Party and the Disclosing Party shall have the right to assert such protections and privileges.

Article 10
Publicity; Publications; Use of Name

10.1 **Publicity**. Following the Effective Date, Lineage may issue a press release concerning the execution of this Agreement in the form attached hereto as Exhibit F.

10.2 **Subsequent Releases**. Subject to Section 10.4, (a) Lineage may not issue any other press releases or other public statements or announcement concerning this Agreement, the subject matter hereof, or the research, Development or commercial results of products hereunder (a "**Release**") without Roche's prior written consent; and (b) Roche may not issue a Release without Lineage's prior written consent if it includes reference to Lineage by name, in each case of (a) and (b), such consent to not be unreasonably withheld, conditioned, or delayed. Each Party shall provide such consent (or explain why it is withholding consent) within [***] of receipt of a proposed Release from the other Party. Except as otherwise permitted, a Release shall not include any financial terms of this transaction.

10.3 **Approved Releases**. If a Release requires consent pursuant to Section 10.2, once consent has been given; or in the event that the applicable information or statement has otherwise been previously disclosed or is in the public domain, either Party may make subsequent public disclosure of such information or statement (or the press release issued pursuant to Section 10.1) without the further approval of the Party whose consent was required; *provided* that such information remains accurate as of such time and is not presented with any new data or information or conclusions and/or in a form or manner that materially alters the subject matter therein. Notwithstanding the foregoing, any press release by or on behalf of a Party that constitutes a Release shall be subject to the terms of Section 10.2 whether or not such Release includes the content of a previously approved Release.

10.4 **Releases Required by Law or Regulation**. Each Party may issue any Release it is required to issue by Applicable Law (including rules of any applicable securities exchange); *provided* that if the issuing Party seeks to disclose any of the other Party's Confidential Information in such Release it (a) uses all reasonable efforts to inform the other Party prior to making any such Release to permit such other Party the opportunity to seek to obtain a protective order or other confidential treatment preventing or limiting the required disclosure, and (b) discloses only such Confidential Information of the other Party that it is advised by counsel is legally required to be disclosed in such Release. To the extent such other Party seeks to obtain a protective order or other confidential treatment to prevent or limit the required disclosure, the issuing Party shall reasonably assist such other Party, but shall not be required to delay such Release beyond the requirements of the Applicable Law.

10.5 **Publications**. Notwithstanding Sections 10.1 through 10.4, both Parties recognize that the publication or disclosure of papers, abstracts, or written or oral presentations ("**Publications**") regarding activities under this Agreement may be beneficial to Roche, its Affiliates, and its and their Sublicensees. Accordingly, Roche, its Affiliates, and its and their Sublicensees are free, without Lineage's review or consent, to publish and disclose Publications regarding activities under this Agreement, except with respect to any Publication that includes Lineage's Confidential Information (but excluding any Confidential Information that is Joint Know-How), for which Lineage shall have the following right to review and approve such proposed disclosure:

10.5.1 For any proposed Publication by Roche, its Affiliates, or its or their Sublicensees that contains Lineage's Confidential Information, Roche shall submit to Lineage the proposed Publication at least [***] prior to the date of submission for publication or the date of presentation, whichever is earlier. Lineage shall review the Lineage Confidential Information in such submitted materials and respond to Roche as soon as reasonably possible, but in any case within [***] of receipt thereof. As requested by Lineage, Roche shall (a) delete from such proposed Publication any Lineage Confidential Information or (b) delay the date of such submission [***].

10.5.2 Once a Publication of Lineage Confidential Information has been approved by Lineage (or deemed approved by Lineage due to Lineage's failure to timely review or respond), Roche may make subsequent public disclosure of the contents of such Publication without the further review or approval of Lineage.

Except as expressly permitted by this Agreement, Lineage and its Affiliates shall not make any Publication or other public disclosures regarding any Licensed Product, RPE Cells, or any other Roche Confidential Information without Roche's prior written consent, such consent not to be unreasonably withheld, conditioned, or delayed.

10.6 **No Right to Use Names**. Except as expressly provided herein and to the extent that such use is not inconsistent with prior public disclosures or presentations, no right, express or implied, is granted by the Agreement to use in any manner the name of "Lineage", "Genentech", or "Roche", as applicable, or any other trade name, symbol, logo or Trademark of the other Party in connection with the performance of this Agreement, except to the extent required by Applicable Law. Lineage may not use the name and/or corporate logo of Roche in connection with descriptions of this Agreement in investor presentations or on Lineage's corporate website without Roche's prior written consent, such consent not to be unreasonably withheld, conditioned, or delayed. Roche shall provide such consent (or explain why it is withholding consent) within [***] of receipt of a proposed use of its name and/or corporate logo.

Article 11
Representations, Warranties and Covenants

11.1 **Mutual Representations and Warranties**. Each Party represents and warrants to the other Party that as of the Effective Date:

11.1.1 it is validly organized under the laws of its jurisdiction of incorporation;

11.1.2 it has obtained all necessary consents, approvals and authorizations of all governmental authorities and other persons or entities required to be obtained by it in connection with this Agreement;

11.1.3 the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on its part;

11.1.4 it has the legal right and power to enter into this Agreement and to fully perform its obligations hereunder;

11.1.5 the performance of its obligations will not conflict with such Party's charter documents or any agreement, contract or other arrangement to which such Party is a party; and

11.1.6 it follows reasonable commercial practices common in the industry to protect its proprietary and confidential information, including requiring its employees, consultants and agents to be bound in writing by obligations of confidentiality and non-disclosure, and requiring its employees, consultants and agents to assign to it any and all inventions and discoveries discovered by such employees, consultants or agents made within the scope of and during their employment or in the course of providing services for such Party, subject only to the Intellectual Property policies of universities or academic institutions to the contrary to which any academic consultants of Lineage are bound, and only disclosing proprietary and confidential information to Third Parties pursuant to written confidentiality and non-disclosure agreements.

11.2 **Lineage Additional Representations, Warranties, and Covenants**. Lineage also represents, warrants, and covenants to Roche that:

11.2.1 as of the Effective Date, [***];

11.2.2 it will not grant during the Term, any right, license or interest in or to the OpRegen Trademarks, Lineage Know-How or Lineage Patents, or any portion thereof, inconsistent with the rights granted to Roche herein;

11.2.3 as of the Effective Date, subject to the terms and conditions of the Existing Third Party In-License Agreements, it [***], or otherwise has the rights therein sufficient to perform its obligations under this Agreement;

11.2.4 during the Term, Lineage will take reasonable steps to safeguard and protect the confidentiality of Know-How within the Manufacturing Process for the Licensed Products;

11.2.5 all Existing Patents are listed on Schedule 1.36, and [***] have been provided to Roche prior to the Effective Date;

11.2.6 as of the Effective Date, [***];

11.2.7 as of the Effective Date, except as set forth on [***];

11.2.8 Lineage shall maintain all agreements with Third Parties that are material to [***];

11.2.9 Lineage has obtained from its Affiliates the [***];

11.2.10 [***];

11.2.11 the human embryonic stem cell line from which the OpRegen Product is derived complies with Applicable Law;

11.2.12 each of Lineage and its Affiliates hereby covenants that it shall not transfer, to Hadasit or its Affiliates, directly or indirectly, any RPE Cells (including an OpRegen Product) or any proprietary technology or information (including differentiation protocols) relating thereto (excepting as under the clinical trial agreement between Hadasit and Lineage);

11.2.13 [***];

11.2.14 [***];

11.2.15 Lineage has obtained (or will timely obtain) all informed consents, permissions and approvals that are necessary for Lineage to conduct the Existing Trial, provide the data (including all clinical trial data) to Roche and permit Roche to use such data for all purposes contemplated herein, including to research, Develop and Commercialize Licensed Products;

11.2.16 [***];

11.2.17 [***];

11.2.18 neither Lineage nor any of its Affiliates has been debarred or is subject to debarment and neither Lineage nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any individual or entity that has been debarred pursuant to Section 306 of the FFDCA, or who is the subject of a conviction described in such section. Lineage agrees to inform Roche in writing immediately if it or any individual or entity that is performing activities by or on behalf of Lineage hereunder is debarred or is the subject of a conviction described in Section 306, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the knowledge of Lineage and its Affiliates, is threatened, relating to the debarment or conviction of Lineage or any individual or entity that is performing activities by or on behalf of Lineage hereunder;

11.2.19 true, complete and correct copies of all material information with respect to the safety and efficacy of the Licensed Products known to Lineage have been provided to Roche prior to the Effective Date. Neither Lineage nor any of its Affiliates has any knowledge of any scientific or technical facts or circumstances that would adversely affect the scientific, therapeutic, or commercial potential of the Licensed Products. Neither Lineage nor any of its Affiliates is aware of anything that could adversely affect the acceptance or the subsequent approval, by any Regulatory Authority of any filing, application or request for Regulatory Approval; and

11.2.20 with respect to any Licensed Product Manufactured and supplied by or on behalf of Lineage and any quantities of OpRegen Product transferred to Roche pursuant to Sections 4.3.1(b) and 4.3.1(c), (a) all such Licensed Product shall be in conformity with the applicable specifications for such Licensed Product, (b) such Licensed Product shall have been Manufactured in conformance with current Good Manufacturing Practice, all other Applicable Law, this Agreement, the Clinical Supply and Quality Agreement and the Commercial Supply and Quality Agreement, as applicable, and (c) such Licensed Product shall have been Manufactured in facilities that are in compliance with Applicable Law at the time of such Manufacture (including applicable inspection requirements of FDA and other Regulatory Authorities).

11.3 **Roche Additional Representations and Warranties**. Roche also represents and warrants to Lineage that as of the Effective Date:

11.3.1 Roche has the legal right and power to grant the licenses, rights, and interests granted to Lineage hereunder; and

11.3.2 [***].

11.4 **Disclaimers**. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, EACH PARTY EXPRESSLY DISCLAIMS ANY AND ALL REPRESENTATIONS OR WARRANTIES OF ANY KIND WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Article 12
Indemnification

12.1 **Indemnification by Lineage**. Subject to Section 12.3, Lineage shall indemnify, defend and hold each of Roche, its Affiliates and their respective directors, officers, and employees, and the successors and assigns of any of the foregoing, harmless from and against any and all liabilities, damages, settlements, penalties, fines, costs or expenses (including reasonable attorneys' fees and other expenses of litigation) (collectively, "**Loss**" or "**Losses**") as a result of any Third Party claims, suits, actions, demands or judgments ("**Third Party Claims**") arising out of [***], except, in each case, for those Losses for which Roche has an obligation to indemnify Lineage pursuant to Section 12.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

12.2 **Indemnification by Roche**. Subject to Section 12.3, Roche shall indemnify, defend and hold each of Lineage, its Affiliates and their respective directors, officers, and employees, and the successors and assigns of any of the foregoing, harmless from and against any and all Losses as a result of any Third Party Claims arising out of [***], except, in each case, for those Losses for which Lineage has an obligation to indemnify Roche pursuant to Section 12.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

12.3 **Procedure**. If a Party intends to claim indemnification under this Agreement (the "**Indemnitee**"), it shall promptly notify the other Party (the "**Indemnitor**") in writing of such alleged Loss. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, to the extent prejudicial to its ability to defend such action, shall relieve the Indemnitor of any obligation to the Indemnitee under this Section 12.3 with regard to such action, but the omission to deliver notice to the Indemnitor shall not otherwise relieve the Indemnitor of any liability that it may have to any Indemnitee otherwise under this ARTICLE 12. Only Roche and Lineage may claim indemnity under this Agreement (on its own behalf or on behalf of its Indemnitees), and other Indemnitees may not directly claim indemnity hereunder. The Indemnitor shall have the right to control the defense thereof with counsel of its choice and reasonably acceptable to Indemnitee. Any Indemnitee shall have the right to retain its own counsel at its own expense for any reason, *provided*, *however*, that if the Indemnitee shall have reasonably concluded, based upon reasonable advice from outside legal counsel, that there is a conflict of interest between the Indemnitor and the Indemnitee in the defense of such action, the Indemnitor shall pay the fees and expenses of one (1) law firm serving as counsel for the Indemnitee as part of Losses. The Indemnitee, its employees and agents, shall reasonably cooperate with the Indemnitor and its legal representatives in the investigation of any Third Party Claims covered by this Agreement. The obligations of this ARTICLE 12 shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Indemnitor, which consent shall not be unreasonably withheld, conditioned, or delayed. The Indemnitor shall not, without the written consent of the Indemnitee, effect any settlement of any Third Party Claims, unless such settlement is solely for monetary damages and includes an unconditional release of the Indemnitee from all liability on claims that are the subject matter of such proceeding.

12.4 **Insurance**. During the Term of this Agreement and for three (3) years thereafter, each Party shall maintain commercial general liability insurance (a) combined single limit for bodily injury and property damage liability, in the minimum amount per occurrence of [***], (b) workers' compensation insurance, according to Applicable Law and (c) employers' liability insurance, in the minimum amount of [***], all commencing as of the Effective Date; *provided*, *however*, Roche has the right, in its sole discretion, to self-insure, in part or in whole, for any such coverage. The insurance policies for such coverage shall be an occurrence form, but if only a claims made form is available to a Party, such Party shall maintain such coverage for at least [***] after the later of (i) termination or expiration of this Agreement or (ii) such Party has no further obligations under this Agreement. Insurance coverage shall be maintained with an insurance company or companies having an A.M. Best's rating (or its equivalent) of A-VII or better. On written request, Lineage shall provide to Roche certificates of insurance evidencing the insurance coverage required under this Section 12.4. Lineage shall provide to Roche at least [***] notice of any cancellation, nonrenewal or material adverse change in any of the required insurance coverages. Each Party agrees to waive its right of subrogation with respect to workers' compensation claims. The limits of a Party's insurance or self-insurance coverage shall not limit the Party's liability, including under the indemnification provisions of this Agreement.

12.5 **Limitation of Damages**. IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE, TREBLE OR CONSEQUENTIAL DAMAGES OR LOST PROFITS, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES, WHETHER BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY, EXCEPT IN RESPECT OF (A) THE INDEMNIFICATION OBLIGATION OF SUCH PARTY IN RESPECT OF THIRD PARTY CLAIMS UNDER THE PROVISIONS OF THIS ARTICLE 12, (B) DAMAGES AVAILABLE FOR BREACH OF ARTICLE 8 OR ARTICLE 9, (C) LIABILITY IN THE CASE OF FRAUD OR WILLFUL MISCONDUCT BY A PARTY.

Article 13
Term; Termination

13.1 **Term**. The term of this Agreement (the "**Term**") shall commence on the Effective Date and, unless sooner terminated as provided in this ARTICLE 13, shall continue in full force and effect, on a country-by-country, Licensed Product-by-Licensed Product basis until expiration of the Royalty Term with respect to a Licensed Product in a country, at which time this Agreement shall expire with respect to such Licensed Product in such country. The Term shall expire on the date this Agreement has expired in its entirety with respect to all Licensed Products in all countries in the Territory.

13.2 **Termination by Either Party for Material Breach**. Either Party may terminate this Agreement by written notice to the other Party for any material breach of this Agreement by the other Party if, in the case of remediable breach, such material breach is not cured within [***] after the breaching Party receives written notice of such breach from the non-breaching Party; *provided*, that if such breach is not capable of being cured within such [***] period, the cure period shall be extended for such amount of time that is reasonably necessary to cure such breach, so long as the breaching Party is making diligent efforts to do so; *provided*, *further*, that in the case of a material breach by Roche of its obligations under Section 5.8.2 with respect to the OpRegen Trademarks, Lineage shall not have the right to terminate this Agreement in its entirety but may only terminate the license granted in Section 5.1.2. Notwithstanding anything to the contrary herein, if the allegedly breaching Party in good faith either disputes (a) whether a breach is material or has occurred or (b) the alleged failure to cure or remedy such material breach, and provides written notice of that dispute to the other Party within the cure period, then the matter will be addressed under the dispute resolution provisions in ARTICLE 14, and the Party alleging breach may not so terminate this Agreement (in whole or in part) until it has been determined under ARTICLE 14 that the allegedly breaching Party is in material breach of this Agreement, and such breaching Party further fails to cure such breach within [***] (or such longer period as determined by the arbiter of such dispute resolution) after the conclusion of that dispute resolution procedure. It is understood that termination pursuant to this Section 13.2 shall be a remedy of last resort and may be invoked only in the case where the breach cannot be reasonably remedied by the payment of money damages.

13.3 **Termination by Either Party for Insolvency or Bankruptcy**. Either Party may terminate this Agreement effective on written notice to the other Party upon the liquidation, dissolution, winding-up, (income statement) insolvency, bankruptcy, or filing of any petition therefor, appointment of a receiver, custodian or trustee, or any other similar proceeding, by or of the other Party where such petition, appointment or similar proceeding is not dismissed or vacated within [***] calendar days. All rights and licenses granted pursuant to this Agreement are, for purposes of Section 365(n) of Title 11 of the US Code or any foreign equivalents thereof (as used in this Section 13.3, "**Title 11**"), licenses of rights to "intellectual property" as defined in Title 11. Each Party in its capacity as a licensor hereunder agrees that, in the event of the commencement of bankruptcy proceedings by or against such bankrupt Party under Title 11, (a) the other Party, in its capacity as a licensee of rights under this Agreement, shall retain and may fully exercise all of such licensed rights under this Agreement (including as provided in this Section 13.3) and all of its rights and elections under Title 11 and (b) the other Party shall be entitled to a complete duplicate of all embodiments of such intellectual property, and such embodiments, if not already in its possession, shall be promptly delivered to the other Party (i) upon any such commencement of a bankruptcy proceeding, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under (i), immediately upon the rejection of this Agreement by or on behalf of the bankrupt Party.

13.4 **Elective Termination**. On a Licensed Product-by-Licensed Product and country-by-country basis, Roche shall have the right to terminate this Agreement in part or in its entirety in its sole discretion, at any time by providing written notice to Lineage; such termination to be effective [***] after such notice.

13.5 **Effects of Termination by Lineage under Sections 13.2 or 13.3 or by Roche under Section 13.4**. Upon termination of this Agreement by Lineage under Section 13.2 or Section 13.3 or by Roche under Section 13.4, the following shall apply (in addition to any other rights and obligations under this Agreement with respect to such termination).

13.5.1 **[***]**.

13.5.2 **[***]**.

13.5.3 **[***]**.

13.6 **Effects of Termination by Roche under Section 13.2 or Section 13.3.** Upon termination of this Agreement by Roche under Section 13.2 or Section 13.3 the following shall apply:

13.6.1 [***];

13.6.2 [***];

13.6.3 [***];

13.6.4 [***]; and

13.6.5 [***].

13.7 **Accrued Rights and Obligations**. Expiration or termination of this Agreement for any reason shall not release either Party from any liability which, as of the effective date of such expiration or termination, had already accrued to the other Party or which is attributable to a period prior to such termination, nor preclude either Party from pursuing any rights and remedies it may have hereunder or at law or in equity which accrued or are based upon any event occurring prior to the effective date of such expiration or termination.

13.8 **Survival**. In addition to any provisions specified in this Agreement as surviving under the applicable circumstances, ARTICLES 1, 7, 9, 11, 12, 14, 15, Sections 3.4, 5.5, 5.8, 6.2 through 6.7 (in the event of termination under Section 13.6), 6.8.4, 8.1, 8.2, 8.3.2 (solely with respect to Joint Patents) 8.4, 8.7 (solely with respect to Joint Patents), 8.8 (solely with respect to Joint Patents), 8.10, 13.5, 13.6, 13.7 and this Section 13.8 shall survive any termination or expiration of this Agreement (for the applicable period if so specified therein).

Article 14
Dispute Resolution

14.1 **Disputes**. Lineage and Roche recognize that a dispute, controversy or claim of any nature whatsoever arising out of or relating to this Agreement, or the breach, termination or invalidity thereof (each, a "**Dispute**"), may from time to time arise during the Term. Unless otherwise specifically recited in this Agreement, such Disputes between Lineage and Roche will be resolved as recited in this ARTICLE 14. A Dispute shall first be referred to the Alliance Managers for both Parties for attempted resolution. If the Alliance Managers are unable to resolve the Dispute within [***] days following the date of such referral (as evidenced in a writing identifying the subject matter of the Dispute and referencing this Section 14.1), either Lineage or Roche may, by written notice to the other, have such Dispute referred to a Vice President of Roche and a Vice President of Lineage (or their designees who have been duly authorized to resolve such Dispute) for attempted resolution through good faith discussions. In the event the designated officers, or their respective designees, are not able to resolve such dispute within [***] days of such other Party's receipt of such written notice, either Party may initiate the dispute resolution procedures set forth in Section 14.2.

14.2 **Arbitration.**

14.2.1 **Rules**. Except as otherwise expressly provided in this Agreement (including under Section 14.3), the Parties agree that any Dispute not resolved internally by the Parties pursuant to Section 14.1 shall be resolved through binding arbitration conducted by JAMS in accordance with the then prevailing Commercial Arbitration Rules & Procedures of JAMS (for purposes of this ARTICLE 14, the "**Rules**"), except as modified in this Agreement, applying the substantive law specified in Section 14.3 and Section 15.1.

14.2.2 **Arbitrators; Location**. Each Party shall select one (1) arbitrator, and the two (2) arbitrators so selected shall choose a third arbitrator within [***] days of their election. All three (3) arbitrators shall serve as neutrals and have at least [***] of (a) dispute resolution experience (including judicial experience) or (b) legal or business experience in the biotech or pharmaceutical industry. In any event, at least one (1) arbitrator shall satisfy the foregoing experience requirement under clause (b). If a Party fails to nominate its arbitrator, or if the Parties' arbitrators cannot agree on the third, the necessary appointments shall be made in accordance with the Rules. Once appointed by a Party, such Party shall have no ex parte communication with its appointed arbitrator. The arbitration proceedings shall be conducted in San Francisco, California.

14.2.3 **Procedures; Awards**. Unless agreed otherwise by the Parties, the Parties shall have [***] days from the appointment of the last to be appointed of the three (3) arbitrators to submit their positions to the arbitrators, and the Parties shall have a hearing before the arbitrators within [***] of such submission. The arbitrators shall be instructed and required to render a written, binding, non-appealable resolution and award on each issue that clearly states the basis upon which such resolution and award is made. The written resolution and award shall be delivered to the Parties as expeditiously as possible, but in no event more than [***] after conclusion of the hearing, unless otherwise agreed by the Parties. Judgment upon such award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order for enforcement. Each Party agrees that, notwithstanding any provision of Applicable Law or of this Agreement, it will not request, and the arbitrators shall have no authority to award, damages against any Party that are prohibited under Section 12.1.

14.2.4 **Costs**. The prevailing Party, as determined by the arbitrators, shall be entitled to (a) its share of fees and expenses of the arbitrators and (b) its attorneys' fees and associated costs and expenses. In determining which Party "prevailed," the arbitrators shall consider (i) the significance, including the financial impact, of the claims prevailed upon and (ii) the scope of claims prevailed upon, in comparison to the total scope of the claims at issue. If the arbitrators determine that, given the scope of the arbitration, neither Party "prevailed," the arbitrators shall order that the Parties (A) share equally the fees and expenses of the arbitrators and (B) bear their own attorneys' fees and associated costs and expenses.

14.2.5 **Interim Equitable Relief**. Notwithstanding anything to the contrary in this Section 14.2, in the event that a Party reasonably requires relief on a more expedited basis than would be possible pursuant to the procedure set forth in this ARTICLE 14, such Party may seek a temporary injunction or other interim equitable relief in a court of competent jurisdiction pending the ability of the arbitrators to review the decision under this Section 14.2. Such court shall have no jurisdiction or ability to resolve Disputes beyond the specific issue of temporary injunction or other interim equitable relief.

14.2.6 **Protective Orders; Arbitrability**. The Parties shall maintain the confidentiality of the arbitration proceedings under this Section 14.2.6, including the hearing, except as may be required by law or judicial decision, and all such arbitration proceedings and decisions of the expert(s) or arbitrators shall be deemed Confidential Information of both Parties under ARTICLE 9. At the request of either Party, the arbitrators shall enter an appropriate protective order to maintain the confidentiality of information produced or exchanged in the course of the arbitration proceedings. The arbitrators shall have the power to decide all questions of arbitrability.

14.3 **Subject Matter Exclusions**. Notwithstanding the provisions of Section 14.2, any Dispute not resolved internally by the Parties pursuant to Section 14.1 that involves the validity or infringement of a Patent (a) that is issued in the US shall be subject to actions before the US Patent and Trademark Office or submitted exclusively to the federal court located in the jurisdiction of the district where any of the defendants resides; and (b) that is issued in any other country shall be brought before an appropriate regulatory or administrative body or court in that country, and the Parties hereby consent to the jurisdiction and venue of such courts and bodies.

14.4 **Continued Performance**. *Provided* that this Agreement has not terminated or expired, the Parties agree to continue performing under this Agreement in accordance with its provisions, pending the final resolution of any Dispute.

Article 15
Miscellaneous

15.1 **Choice of Law**. This Agreement (including the arbitration provisions of Section 14.2) shall be governed by and interpreted in accordance with the laws of the State of California, without reference to the principles of conflicts of laws. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by this Agreement.

15.2 **Notices**. Except as otherwise expressly provided in the Agreement, any notice required under this Agreement shall be in writing and shall specifically refer to this Agreement. Notices shall be sent via one (1) of the following means and shall be effective (a) on the date of delivery, if delivered in person; (b) two (2) days after the date mailed if mailed by first class certified mail return receipt requested, postage prepaid to a destination within the same jurisdiction; (c) seven (7) days after the date mailed if mailed by registered or certified mail return receipt requested, postage prepaid to a destination outside the jurisdiction of the Party sending the notice; or (d) on the date of receipt, if sent by private express courier. Notices shall be sent to the other Party at the addresses set forth below. Either Party may change its addresses for purposes of this Section 15.2 by sending written notice to the other Party.

If to Roche:

Genentech, Inc.
Attn: Corporate Secretary
1 DNA Way
South San Francisco, CA 94080

and to

F. Hoffmann-La Roche Ltd
Attention: Legal Department
Grenzacherstrasse 124
CH-4070 Basel
Switzerland

with required copies (which shall not constitute notice) to:

Genentech, Inc.
Attn: Head of Global Asset & Alliance Management
1 DNA Way
South San Francisco, CA 94080

Email address: to be provided by Alliance Manager

If to Lineage:

Lineage Cell Therapeutics
Attn: Chief Executive Officer
2173 Salk Avenue, Suite 200
Carlsbad, CA 92008

with required copies (which shall not constitute notice) to:

Lineage Cell Therapeutics
Attn: General Counsel
2173 Salk Avenue, Suite 200
Carlsbad, CA 92008

Cooley LLP
Attn: Steve Przesmicki
4401 Eastgate Mall
San Diego, CA 92121

15.3 **Assignment**. Neither Party may assign or otherwise transfer, in whole or in part, this Agreement without the prior written consent of the non-assigning Party, such approval not to be unreasonably withheld or delayed. Notwithstanding the foregoing, (a) Lineage may assign or otherwise transfer its rights to receive payments (and associated reports) pursuant to Section 6.7 without the prior written consent of Roche; and (b) either Party may assign this Agreement, without the prior written consent of the other Party, to (i) an Affiliate or (ii) subject to Section 5.7.2, to any purchaser of all or substantially all of the assets of such Party, or of all of its capital stock, or to any successor corporation or entity resulting from any merger or consolidation of such Party with or into such corporation or entity, *provided* that the party to which this Agreement is assigned expressly agrees in writing to assume and be bound by all obligations of the assigning Party under this Agreement. A copy of such written agreement by such assignee shall be provided to the non-assigning Party within [***] of execution of such assignment. Subject to the foregoing, this Agreement will benefit and bind the Parties' successors and assigns. Any attempted assignment not in accordance with this Section 15.3 shall be null and void.

15.4 **Change in Control**. Notwithstanding any other provision of this Agreement, in the event of the Change in Control, no intellectual property, products, biological substances (and any constituents, progeny, mutants, derivatives, or replications thereof or therefrom), or other tangible materials that are Controlled by an Acquirer (or its Affiliates in existence prior to such transaction) or developed or acquired by such Acquirer after such Change in Control, shall be considered as "Controlled" by Lineage, (a) so long as such intellectual property, compounds, products and other subject matter were developed independently of this Agreement and without use of intellectual property rights or Confidential Information of the other Party, subject to any segregation and firewall requirements in connection with a Competing Product as set forth in Section 5.7.2, and (b) unless, after the consummation of such Change in Control, Lineage or any of its Affiliates uses any such intellectual property, compounds, products and other subject matter in the performance of its obligations or exercise of its rights under this Agreement, in which case, such intellectual property, compounds, products and other subject matter will be considered "Controlled" by Lineage.

15.5 **Independent Contractors**. The Parties hereto are independent contractors and nothing contained in this Agreement shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

15.6 **Actions of Affiliates**. Roche may exercise its rights or perform its obligations under this Agreement personally or through one (1) or more Affiliates, *provided* that Roche shall nonetheless be primarily liable for the performance of its Affiliates and for any failure by its Affiliates to comply with the restrictions, limitations and obligations set forth in this Agreement.

15.7 **Force Majeure**. Neither Party shall be deemed to have breached this Agreement for failure to perform its obligations under this Agreement to the extent such failure results from causes beyond the reasonable control of the affected Party, such causes including acts of God, earthquakes, fires, floods, embargoes, wars, acts of terrorism, insurrections, riots, civil commotions, epidemics, pandemics (specifically including the Coronavirus Disease 2019 (COVID-19) outbreak that commenced in 2019), omissions or delays in action by any governmental authority, acts of a government or agency thereof and judicial orders or decrees (each, a "**Force Majeure Event**"), and any deadline or time period affected by such a Force Majeure Event or a Party's failure to perform resulting therefrom shall be extended automatically by the number of days equal to the number of days that such Force Majeure Event or failure persisted. If such a Force Majeure Event occurs, the Party unable to perform shall promptly notify the other Party of the occurrence of such event, and the Parties shall meet (in person or telephonically) promptly thereafter to discuss the circumstances relating thereto. The Party unable to perform shall (a) provide reasonable status updates to the other Party from time to time; (b) use Commercially Reasonable Efforts to mitigate any adverse consequences arising out of its failure to perform; and (c) resume performance as promptly as possible. Further, in the event the end of any time period set forth herein falls (or any deadline herein otherwise expires) during the period beginning on December 25 of any Calendar Year in the Term and ending on January 1 of the following year, such time period (or deadline) shall be extended by six (6) Business Days, unless otherwise agreed in writing by the Parties.

15.8 **Integration**. Except to the extent expressly provided herein, this Agreement, including the Schedules and Exhibits hereto, constitutes the entire agreement between the Parties relating to the subject matter of this Agreement and supersedes all previous oral and written communications between the Parties with respect to the subject matter of this Agreement, including the NDA as set forth in Section 9.6. In the event of any conflict or inconsistency between the body of this Agreement and a Schedule or Exhibit, the terms and conditions of the body of this Agreement shall prevail.

15.9 **Amendment; Waiver**. Except as otherwise expressly provided herein, no alteration of or modification to this Agreement shall be effective unless made in writing and executed by an authorized representative of both Parties. No course of dealing or failing of either Party to strictly enforce any term, right or condition of this Agreement in any instance shall be construed as a general waiver or relinquishment of such term, right or condition. The observance of any provision of this Agreement may be waived (either generally or any given instance and either retroactively or prospectively) only with the written consent of the Party granting such waiver.

15.10 **Further Assurances**. Each Party shall and shall use all reasonable endeavors to procure that any necessary Third Party shall promptly execute and deliver such further documents and do such further acts as may be required for the purpose of giving full effect to this Agreement.

15.11 **Severability**. The Parties do not intend to violate any public policy or statutory or common law. However, if any sentence, paragraph, clause or combination or part thereof of this Agreement is in violation of any law or is found to be otherwise unenforceable, such sentence, paragraph, clause or combination or part of the same shall be deleted and the remainder of this Agreement shall remain binding, *provided* that such deletion does not alter the basic purpose and structure of this Agreement.

15.12 **No Third Party Rights**. The Parties do not intend that any term of this Agreement should be enforceable by any person who is not a Party.

15.13 **Construction**. The Parties mutually acknowledge that they and their attorneys have participated in the negotiation and preparation of this Agreement. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have drafted this Agreement or authorized the ambiguous provision.

15.14 **Interpretation**. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words "include" or "including" shall be construed as incorporating "but not limited to" or "without limitation"; (b) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement, including the Schedules and Exhibits; (c) all references herein to Sections, Schedules or Exhibits shall be construed to refer to Sections, Schedules or Exhibits of this Agreement; (d) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein); (e) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (f) provisions that require that a Party, the Parties or any committee hereunder "agree", "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding instant messaging); (g) references to any specific law, rule or regulation, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof; (h) all references to the word "will", where the context requires, are interchangeable with the word "shall" and shall be understood to be imperative or mandatory in nature; (i) all references to "Sublicensees" shall include all Sublicensees of Sublicensees through multiple tiers of sublicensing; (j) the singular shall include the plural and vice versa; (k) the word "or" has the inclusive meaning represented by the phrase "and/or"; and (l) all references to days, months, quarters or years are references to calendar days, calendar months, Calendar Quarters, or Calendar Years.

15.15 **Counterparts**. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. For purposes hereof, a .pdf copy of this Agreement, including the signature pages hereto, will be deemed to be an original. Notwithstanding the foregoing, the Parties shall deliver original execution copies of this Agreement to one another as soon as practicable following execution thereof.

[Signature page follows – the rest of this page intentionally left blank.]

IN WITNESS WHEREOF, Lineage and Roche have executed this Agreement by their respective officers hereunto duly authorized.

LINEAGE CELL THERAPEUTICS

By: */s/ Brian Culley*

Name: Brian Culley

Title: CEO

CELL CURE NEUROSCIENCES LTD.

By: */s/ Rami Skaliter*

Name: Rami Skaliter

Title: CEO

GENENTECH, INC.

By: */s/ Edward Harrington*

Name: Edward Harrington

Title: CFO, Genentech

By: */s/ Andrew Le*

Name: Andrew Le

By: */s/ Jon Aumais*

Name: Jon Aumais

F. HOFFMANN-LA ROCHE LTD

By: */s/ Barbara Schroeder de Castro Lopes*

Name: Barbara Schroeder de Castro Lopes

Title: Authorized Signatory

By: */s/ Vikas Kabra*

Name: Vikas Kabra

Title: Head Transaction Excellence

SCHEDULE 1.36 – Existing Patents

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SCHEDULE 1.39 – Existing Third Party In-License Agreements

- The Hadasit Agreement and the Hadasit Side Letter.

SCHEDULE 1.58 – hESC Patents

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SCHEDULE 1.98 – OpRegen Trademarks

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SCHEDULE 3.2.5 – OpRegen v 1.3

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SCHEDULE 11.2.7 – Pending or Threatened Actions, Lawsuits, Claims, or Arbitration Proceedings

[***].

SCHEDULE 11.2.10 – [***]

[***].

EXHIBIT A – Authorized Subcontractors

[***].

EXHIBIT B – Lineage Work Plan

[***].

EXHIBIT C – Know-How and Materials (Process Manufacture Transfer and Analytical Transfer)

[***].

EXHIBIT D – Know-How and Materials (Non-Clinical, Clinical, and Regulatory Immediate Development Transfer)

[***].

EXHIBIT E – Know-How and Materials (CMC Immediate Development Transfer)

[***].

EXHIBIT F - Press Release Concerning the Execution of this Agreement

LINEAGE ESTABLISHES EXCLUSIVE WORLDWIDE COLLABORATION WITH GENENTECH FOR THE DEVELOPMENT AND COMMERCIALIZATION OF OPREGEN® RPE CELL THERAPY FOR THE TREATMENT OF OCULAR DISORDERS

- **Genentech Will Pay Lineage $50 Million Upfront**
- **Eligible to Receive a Total of $670 Million in Upfront and Milestone Payments**
- **Conference Call to Discuss Collaboration Planned for 8 a.m. ET**

CARLSBAD, CA– December 20, 2021 - Lineage Cell Therapeutics, Inc. (NYSE American and TASE: LCTX), today announced that Lineage and its subsidiary, Cell Cure Neurosciences Ltd., have entered into an exclusive worldwide collaboration and license agreement with Roche and Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), for the development and commercialization of a retinal pigment epithelium (RPE) cell therapy for the treatment of ocular disorders, including advanced dry age-related macular degeneration (dry AMD) with geographic atrophy (GA).

Genentech will assume responsibility for further clinical development and commercialization of Lineage's OpRegen program, which currently is being evaluated in a Phase 1/2a open-label, dose escalation clinical safety and efficacy study in patients with advanced dry AMD with GA. Under the terms of the collaboration agreement, Lineage will complete activities related to the ongoing clinical study, for which enrollment is complete, and perform certain manufacturing activities. Genentech will pay Lineage a $50 million upfront payment and Lineage is eligible to receive up to $620 million in additional development, approval and sales milestone payments and tiered double- digit royalties.
"Genentech is a clear global leader in ophthalmology and has demonstrated a longstanding commitment to patients, innovative research and successful product development," said Brian M. Culley, Lineage's CEO. "Their desire to combine our cell therapy technology with their ophthalmology expertise and capabilities will help advance the OpRegen program more rapidly and we believe successfully to patients with serious ocular disorders, such as dry age-related macular degeneration. Lineage's objective is to pioneer a new branch of regenerative medicine, based on transplanting whole cells into the body to restore activity lost to aging, injury or disease. We believe the results we have demonstrated to date with OpRegen represent a paradigm change many did not believe possible with cell therapy, by restoring retinal tissue and potentially halting or reversing the expansion of geographic atrophy. I am incredibly proud of what the Lineage team has accomplished with the OpRegen program and look forward to joining forces with the Genentech team as they work to take this program to the next level and potentially to patients in need of treatment."

Mr. Culley continued, "Looking ahead, Lineage will remain focused on advancing our spinal cord injury and oncology programs as well as announcing new disease settings where we plan to deploy our technology, either on our own or through strategic alliances. All of us at Lineage are immensely proud to have the opportunity and responsibility to advance a new and exciting branch of medicine, and our aim is to make a profound impact on the patients who serve as our inspiration."

“Genentech has a longstanding commitment to discovering and developing novel drugs for the treatment of serious eye disorders such as with advanced dry AMD with GA, which is one of our focus areas within ophthalmology,” said James Sabry, M.D., Ph.D., global head of Pharma Partnering, Roche. “We are excited to partner with Lineage Cell Therapeutics to advance potential new therapies in an area of high unmet medical need.”

Conference Call Information

Lineage will host a live conference call and webcast today beginning at 8 a.m. ET to discuss the collaboration with the Roche Group and Genentech. Interested parties may access the conference call by dialing (866) 888-8633 from the U.S. and Canada and (636) 812-6629 from elsewhere outside the U.S. and Canada and should request the “Lineage Cell Therapeutics Call”. A live webcast of the conference call will be available online in the Investors section of Lineage’s website. A replay of the webcast will be available on Lineage’s website for 30 days and a telephone replay will be available through December 27, 2021, by dialing (855) 859-2056 from the U.S. and Canada and (404) 537-3406 from elsewhere outside the U.S. and Canada and entering conference ID number 5174206.

About OpRegen

OpRegen has been developed in part through contributions and financial grants made by Hadasit Medical Research Services and Development Ltd. (“Hadasit”) and the Israeli Innovation Authority (the “IIA”). Lineage is obligated to pay a portion of upfront, milestone and royalty payments it receives to Hadasit and the IIA. OpRegen is currently being evaluated in a Phase 1/2a open-label, dose escalation safety and efficacy study of a single injection of human retinal pigment epithelium cells derived from an established pluripotent cell line and transplanted subretinally in patients with advanced dry AMD with GA. The study enrolled 24 patients into 4 cohorts. The first 3 cohorts enrolled only legally blind patients with a best corrected visual acuity (BCVA) of 20/200 or worse. The fourth cohort enrolled 12 better vision patients (BCVA from 20/65 to 20/250 with smaller mean areas of GA). Cohort 4 also included patients treated with a new “thaw-and-inject” formulation of OpRegen, which can be shipped directly to sites and used immediately upon thawing, removing the complications and logistics of having to use a dose preparation facility. The primary objective of the study was to evaluate the safety and tolerability of OpRegen as assessed by the incidence and frequency of treatment emergent adverse events. Secondary objectives are to evaluate the preliminary efficacy of OpRegen treatment by assessing the changes in ophthalmological parameters measured by various methods of primary clinical relevance. OpRegen has been well tolerated to date and there have been no new, unexpected ocular or systemic adverse events or serious adverse events related to OpRegen or study procedures that have not been previously reported.

About Lineage Cell Therapeutics, Inc.

Lineage Cell Therapeutics is a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs. Lineage’s programs are based on its robust proprietary cell-based therapy platform and associated in-house development and manufacturing capabilities. With this platform Lineage develops and manufactures specialized, terminally differentiated human cells from its pluripotent and progenitor cell starting materials. These differentiated cells are developed to either replace or support cells that are dysfunctional or absent due to degenerative disease or traumatic injury or administered as a means of helping the body mount an effective immune response to cancer. Lineage’s clinical programs are in markets with billion dollar opportunities and include three allogeneic (“off-the-shelf”) product candidates: (i) OpRegen®, a retinal pigment epithelium transplant therapy in Phase 1/2a development for the treatment of dry age-related macular degeneration, a leading cause of blindness in the developed world; (ii) OPC1, an oligodendrocyte progenitor cell therapy in Phase 1/2a development for the treatment of acute spinal cord injuries; and (iii) VAC2, an allogeneic dendritic cell therapy produced from Lineage’s VAC technology platform for immuno-oncology and infectious disease, currently in Phase 1 clinical development for the treatment of non-small cell lung cancer. For more information, please visit www.lineagecell.com or follow the Company on Twitter @LineageCell.

Forward-Looking Statements

Lineage cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as “believe,” “aim,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “intend,” “expect,” “could,” “can,” “plan,” “potential,” “predict,” “seek,” “should,” “would,” “contemplate,” “project,” “target,” “tend to,” or the negative version of these words and similar expressions. Such statements include, but are not limited to, statements relating to the collaboration and license agreement with Roche and Genentech and activities expected to occur under the collaboration and license agreement, the upfront, milestone and royalty consideration payable to Lineage, the potential benefits of treatment with OpRegen, and Lineage’s plans to advance its spinal cord injury and oncology programs and announce new disease settings where it plans to deploy its technology. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Lineage’s actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by the forward-looking statements in this press release, including the risk that competing alternative therapies may adversely impact the commercial potential of OpRegen, which could materially adversely affect the milestone and royalty payments payable to Lineage under the collaboration and license agreement, the risk that Roche and Genentech may not be successful in completing further clinical trials for OpRegen and/or obtaining regulatory approval for OpRegen in any particular jurisdiction, and risks and uncertainties inherent in Lineage’s business and other risks in Lineage’s filings with the Securities and Exchange Commission (SEC). Lineage’s forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. Further information regarding these and other risks is included under the heading “Risk Factors” in Lineage’s periodic reports with the SEC, including Lineage’s most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q filed with the SEC and its other reports, which are available from the SEC’s website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Lineage undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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Nic Johnson or David Schull
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David.schull@russopartnersllc.com
(212) 845-4242

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Exhibit 21.1

Lineage Cell Therapeutics, Inc.

The following is a list of subsidiaries of Lineage Cell Therapeutics, Inc. as of December 31, 2021, omitting some subsidiaries which, considered in the aggregate, would not constitute a significant subsidiary.

Subsidiary	State or Jurisdiction of Incorporation or Organization
Asterias Biotherapeutics, Inc.	Delaware
Cell Cure Neurosciences Ltd	Israel
ES Cell International Pte. Ltd	Singapore
OrthoCyte Corporation	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Registration Nos. 333-166862, 333-167822, 333-174282, 333-182964, 333-183557, 333-187710, 333-188066, 333-201824, 333-209000, 333-217182, 333-218807, 333-237975, 333-254167, and 333-254155), and Form S-8 (Registration Nos. 333-101651, 333-122844, 333-163396, 333-192531, 333-205661, 333-219204, 333-233132, 333-254158, and 333-259853) of Lineage Cell Therapeutics, Inc. of our report dated March 10, 2022, relating to the consolidated financial statements of Lineage Cell Therapeutics, Inc. and Subsidiaries for the year ended December 31, 2021, which appears in this Annual Report on Form 10-K.

/s/ WithumSmith+Brown, PC

San Francisco, California
March 10, 2022

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Registration Nos. 333-166862, 333-167822, 333-174282, 333-182964, 333-183557, 333-187710, 333-188066, 333-201824, 333-209000, 333-217182, 333-218807, and 333-237975), and Form S-8 (Registration Nos. 333-101651, 333-122844, 333-163396, 333-192531, 333-205661, 333-219204, and 333-233132) and related prospectuses of Lineage Cell Therapeutics, Inc. of our report dated March 11, 2021, with respect to the consolidated financial statements of Lineage Cell Therapeutics, Inc. and Subsidiaries, which appears in this Annual Report on Form 10-K for the year ended December 31, 2021.

/s/ OUM & CO. LLP

San Francisco, California
March 10, 2022

Exhibit 31.1

CERTIFICATIONS

I, Brian M. Culley, certify that:

1. I have reviewed this annual report on Form 10-K of Lineage Cell Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this periodic report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2022

/s/ Brian M. Culley

Brian M. Culley
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Kevin Leon Cook, certify that:

1. I have reviewed this annual report on Form 10-K of Lineage Cell Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this periodic report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 10, 2022

/s/ Kevin Leon Cook

Kevin Leon Cook
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Lineage Cell Therapeutics, Inc. (the "Company") for the year ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian M. Culley, Chief Executive Officer and Kevin Cook, Chief Financial Officer of the Company, certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 10, 2022

/s/ Brian M. Culley
Brian M. Culley
Chief Executive Officer
(Principal Executive Officer)

/s/ Kevin Leon Cook
Kevin Leon Cook
Chief Financial Officer
(Principal Financial and Accounting Officer)