

**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, 2019

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
(State or other jurisdiction of
incorporation or organization)

94-3127919
(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
Non-accelerated filer

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes No

As of June 28, 2019, 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 \$118.6 million.

The number of common shares outstanding as of March 5, 2020 was 149,807,709.

Documents Incorporated by Reference

Portions of the registrant's Proxy Statement for 2020 Annual Meeting of Shareholders to be filed pursuant to Regulation 14A within 120 days of the Registrant's fiscal year ended December 31, 2019 are incorporated by reference in Part III

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:

- 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 and timing to advance our product candidates into, and to successfully initiate, conduct, enroll and complete, clinical trials;
- 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 potential 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.

On August 9, 2019, BioTime, Inc. changed its corporate name to Lineage Cell Therapeutics, Inc. 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.

ITEM 1. BUSINESS

Overview

We are a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs. Our focus is to develop therapies for degenerative retinal diseases, neurological conditions associated with demyelination, and aiding the body in detecting and combating cancer. Our programs are based on our proprietary cell-based therapy platform and associated development and manufacturing capabilities. From this platform, we develop and manufacture specialized, terminally or partially differentiated human cells from established and well-characterized pluripotent cell lines. These differentiated cells are developed either to 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 an effective immune response to cancer.

Product Candidates & Other Programs

We have three allogeneic, or “off-the-shelf,” cell therapy programs in clinical 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”). There currently are no therapies approved by the U.S. Food and Drug Administration (“FDA”) for dry AMD, which accounts for approximately 85-90% of all AMD cases and is a leading cause of blindness in people over the age of 65.
- *OPC1*, an oligodendrocyte progenitor cell therapy for acute spinal cord injuries. We have completed enrollment in a 25-patient Phase 1/2a multicenter clinical trial with OPC1; this trial was partially funded by the California Institute for Regenerative Medicine (“CIRM”). There are currently no therapies approved by the FDA.
- *VAC2*, a cancer immunotherapy of antigen-presenting dendritic cells 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, the world’s largest independent cancer research charity.

Ownership in Other Companies

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”). As of March 5, 2020, we hold approximately 9.7% and 2.3% in OncoCyte and AgeX, respectively. The combined value of these holdings as of March 5, 2020, was approximately \$14.6 million, based on the closing price of their common stock on such date. We also hold a convertible promissory note from Juvenescence Limited (“Juvenescence”), in connection with our sale of AgeX stock to Juvenescence in August 2018. The value of the Juvenescence note of \$23.6 million at December 31, 2019 is based on the principal amount of \$21.6 million plus accrued interest. See “Risk Factors—Risks Related to Our Business Operations and Capital Requirements—The value of our investments in public companies fluctuates based on their respective stock prices and could be negatively affected by poor business performance,” below.

Though our principal focus is on advancing our three cell therapy programs in clinical development, we may seek to create additional value through corporate transactions, as we have in the past. Our securities holdings also may be a significant source of capital to fund our operations as an alternative to issuing additional Lineage securities.

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, and our phone number at that address is (442) 287-8990. Our website address is www.lineagecell.com. The information on, or that can be accessed through our website is not part of this Report. 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.

Recent Transactions Affecting Our Corporate Organization

Asterias Merger

On March 8, 2019, we acquired Asterias Biotherapeutics, Inc. (“Asterias”) via merger (the “Asterias Merger”). In the acquisition, each outstanding share of Asterias common stock was converted into 0.71 Lineage common shares.

Prior to May 13, 2016, Asterias was a majority-owned and consolidated subsidiary of Lineage. On May 13, 2016, Lineage’s percentage ownership decreased from 57.1% to 48.7% as a result of the sale of shares of common stock by Asterias in a public offering, resulting in Lineage’s loss of control of Asterias under generally accepted accounting principles in the U.S. (“GAAP”). Accordingly, Lineage deconsolidated Asterias effective May 13, 2016. As of March 8, 2019, Asterias became our wholly owned subsidiary, Asterias ceased to exist as a public company, and we consolidated Asterias’ operations and results with our operations and results beginning on that date. From May 13, 2016 until the consummation of the merger on March 8, 2019, Lineage accounted for its ownership of Asterias under the equity method of accounting, electing the fair value option, with the investment carried on the consolidated balance sheet at fair value and all subsequent changes in fair value included in Lineage’s consolidated statements of operations in other income and expenses, net. The deconsolidation of Asterias is sometimes referred to as the “Asterias Deconsolidation” in this Report.

Age X Deconsolidation and Distribution

On August 30, 2018, we entered into a Stock Purchase Agreement with Juvenescence and AgeX, under which we sold 14,400,000 of our shares of AgeX common stock to Juvenescence for \$3.00 per share. The transaction resulted in over \$43 million in non-dilutive financing for Lineage.

Upon completion of that transaction, our percentage ownership of AgeX’s outstanding shares of common stock decreased from 80.4% to 40.2%, and Juvenescence’s percentage ownership increased from 5.6% to 45.8%. As a result of the transaction, as of August 30, 2018, AgeX was no longer our subsidiary and effective that date, we deconsolidated AgeX’s consolidated financial statements and consolidated results of operations from Lineage’s under GAAP due to the decrease in our percentage ownership in AgeX to below 50%. Prior to that date, AgeX was our majority-owned and consolidated subsidiary. Beginning on August 30, 2018 through November 28, 2018 (the date on which AgeX began trading as a public company as discussed below), we accounted for AgeX using the equity method of accounting, electing the fair value option, recording the retained interest in AgeX at fair value on August 30, 2018 with all subsequent changes in fair value included in our consolidated statements of operations in other income and expenses, net.

On November 28, 2018, AgeX began trading as a public company on the NYSE American (under the symbol “AGE”) and, on that date, we distributed 12.7 million shares of AgeX common stock we owned to our shareholders, on a pro rata basis, in the ratio of one share of AgeX common stock for every 10 Lineage common shares they owned. This distribution was accounted for at fair value as a taxable, dividend-in-kind transaction in the aggregate amount of \$34.4 million. Immediately following the distribution, we owned 1.7 million shares of AgeX common stock. As of December 31, 2019, we own 1.0 million shares of AgeX common stock, which we hold as marketable equity securities.

As of, and for each reporting period after August 30, 2018, the fair value of our ownership interest in AgeX is determined by multiplying the fair value of a share of AgeX common stock by the number of such shares we own.

AgeX’s consolidated assets and liabilities are not included in our audited consolidated balance sheet at December 31, 2018, due to the deconsolidation. The fair value of the AgeX shares we owned is shown on our audited consolidated balance sheet as of December 31, 2019 and 2018. Our audited consolidated statements of operations for the year ended December 31, 2018 include AgeX’s consolidated results for the period through August 29, 2018, the day immediately preceding the deconsolidation. AgeX’s results are not included in our audited consolidated statements of operations for the year ended December 31, 2019.

The deconsolidation of AgeX is sometimes referred to as the “AgeX Deconsolidation” in this Report.

The distribution of AgeX common stock is sometimes referred to as the “AgeX Distribution” in this Report.

OncoCyte Deconsolidation

Effective February 17, 2017, we deconsolidated the financial statements and results of operations of OncoCyte under GAAP due to the decrease in our percentage ownership in OncoCyte to below 50% as a result of OncoCyte’s issuance of 625,000 shares of its common stock upon exercise of warrants. Prior to that date, OncoCyte was our majority-owned and consolidated subsidiary. From February 17, 2017 through September 11, 2019, we accounted for our OncoCyte common stock using the equity method of accounting. We sold 2.25 million shares of OncoCyte common stock for net proceeds of \$4.2 million in July 2019. Accordingly, our ownership in OncoCyte was reduced from 28% to 24%. Lineage sold an additional 4.0 million shares of OncoCyte common stock for net proceeds of \$6.5 million on September 11, 2019. Lineage’s ownership in OncoCyte was further reduced to 16% at this time. Effective September 11, 2019, Lineage began accounting for its shares of OncoCyte common stock as marketable equity securities. The calculation of fair value is the same under the equity method and as a marketable equity security. The fair value of our ownership interest in OncoCyte has been determined by multiplying the closing price of OncoCyte common stock as quoted on NYSE American by the number of such shares we owned. Changes in fair value were included in our consolidated statements of operations in other income and expenses, net.

The fair value of OncoCyte shares we owned is shown on our audited consolidated balance sheet as of December 31, 2019 and 2018. OncoCyte's results are not included in our audited consolidated statements of operations for the years ended December 31, 2019 and 2018.

The deconsolidation of OncoCyte is sometimes referred to as the "OncoCyte Deconsolidation" in this Report.

For further discussion see the Notes to Consolidated Financial Statements and Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this Report.

2019 and Early 2020 Highlights

We achieved numerous strategic accomplishments during 2019 and early 2020, including advancing clinical trials and product development in several key programs.

- During 2019, we successfully dosed two patients in our OpRegen Phase 1/2a clinical trial with a new thaw-and-inject formulation and a new delivery device, the 510(k)-cleared Subretinal Delivery System ("SDS") developed by Gyroscope Therapeutics ("Gyroscope"). The Gyroscope SDS is designed to precisely and consistently deliver therapeutics to the sub-retinal space via a suprachoroidal route, avoiding: (i) the need for a vitrectomy; (ii) perforation of the retina (retinotomy); and (iii) loss of cells and adverse safety events due to efflux. We have to date reported on two patients dosed with the combination of the new device and formulation. The first patient demonstrated notable improvements in vision, having gained 25 readable letters (or 5 lines) 6 months following administration, as assessed by the Early Treatment Diabetic Retinopathy Scale ("ETDRS"). This represented an improvement in visual acuity from a baseline of 20/250 to 20/100 in the treated eye. The second patient showed a small improvement in visual acuity in the treated eye at just 14 days following treatment. Both patients had rapid healing at the surgical site with no unexpected complications or any serious adverse events. Improvements for patients in the trial have typically become most evident approximately three to six months after treatment. Treatment for all patients in the trial continue to be well tolerated and all five patients in Cohort 4, who have better baseline vision and less advanced disease than patients in Cohorts 1-3, registered improvement according to the ETDRS eye chart assessment (improvements ranged from 8 to 25 additional letters correctly identified for all patients with at least 6 months of follow-up as of December 31, 2019). We expect to dose a total of six patients with the Gyroscope SDS under our current agreement with Gyroscope.
- In March 2019, we acquired Asterias. We entered into an Agreement and Plan of Merger with Asterias on November 7, 2018 and closed the acquisition on March 8, 2019. As a result of this acquisition, we acquired two additional cell therapy product candidates, OPC1 and VAC2, along with their associated expansion opportunities and other assets. As we integrated the two companies, we reduced costs by about 50% by eliminating duplicate costs and rationalizing non-key projects, including a reduction of headcount from 105 at the time of the merger to our current headcount of 53.
- In August 2019, we rebranded as Lineage Cell Therapeutics and relocated the corporate headquarters from the San Francisco Bay area to Carlsbad, California. During 2019, we also hired experienced biotech professionals to fill critical management positions including the Chief Financial Officer, General Counsel, and Vice President, Business Development.
- In November 2019, we reported a positive clinical update from our ongoing Phase 1/2a clinical trial of OPC1 for the treatment of acute spinal cord injury known as SCiStar. The overall safety profile of OPC1 has remained excellent with robust motor recovery in the arms/hands maintained through year 2 follow-ups to date. Gains in motor function for patients assessed to date have continued, representing improvements to quality of life and independence.
- During 2019, we entered into agreements with three separate companies, with each agreement relating to different parts of our intellectual property portfolio. All three companies have ongoing commercial operations, including with respect to their cell therapy-related assets. The aggregate up-front cash payment from the three transactions was greater than \$1.0 million, with additional cash and royalties due upon reaching certain development milestones or product sales.
- During 2019, we obtained patents associated with the manufacture of our unique cell types, adding additional protections to all three of our clinical programs. We also obtained patent rights describing the use of induced pluripotent stem cells, an alternate option for generating differentiated cells for transplant and treatment of diseases, further broadening the potential application of our work. Through the Asterias Merger, we also acquired a number of in-licensed and internally owned patents and pending applications.
- During 2019, we were awarded a \$2.5 million grant from the Israel Innovation Authority ("IIA") for our OpRegen program and a \$0.7 million Small Business Innovation Research grant from the National Institutes of Health ("NIH") for our Vision Restoration Program.
- During 2019, we were able to fund our operations primarily by selling some of our investments in OncoCyte and AgeX, two companies that originated at Lineage before becoming independent public companies. In part due to their success, we have elected to convert some of our ownership positions into cash for Lineage's operations which reduces the need to conduct dilutive equity issuances.
- 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. Accordingly, we are opening two new U.S. clinical sites to accelerate patient enrollment and broaden surgical experience among dry AMD experts.

Business Strategy

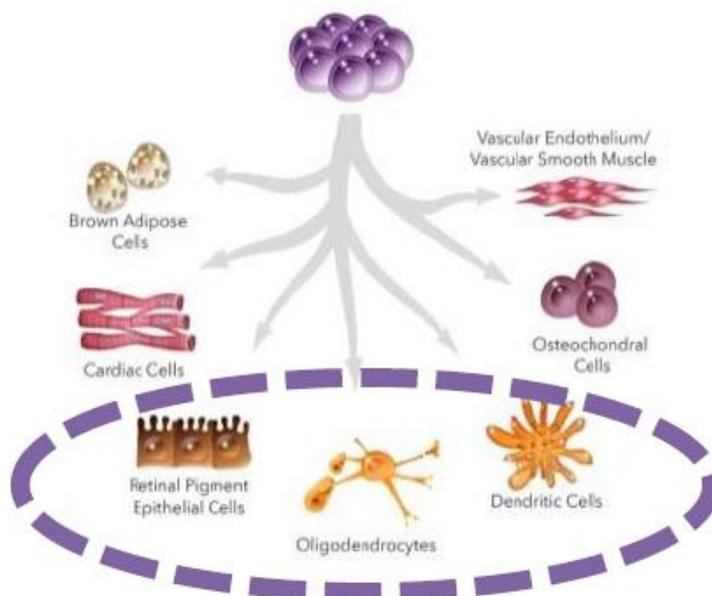
Our goal is to become a leading cell therapy company by developing allogeneic, or “off-the-shelf,” treatments that are comprised of differentiated cells derived from pluripotent cell lines, which have been directed to become specific cell types and use those cells as treatments to restore diseased or diminished functions, such as impaired vision, loss of movement and sensation, or to increase immune response to tumors. Significant near-term activities that underlie our business strategy include:

- Completing enrollment in the Phase 1/2 study of OpRegen for patients with dry AMD with GA and collecting safety and efficacy data from those patients;
- Introducing commercially enabling attributes to the OPC1 manufacturing process, such as higher scale and purity, to enable broader adoption at clinical trial sites in support of a comparative clinical trial;
- Evaluating clinical data from the VAC2 study of patients with NSCLC to assess the effect of treatment of VAC2 and evaluate the potential early exercise of our option to acquire the data from CRUK; and
- Soliciting, attracting, and assessing alliance and partnering opportunities which can accelerate the progress of our clinical programs and provide sources of non equity-dilutive capital to run our business.

Cell Therapy Technology

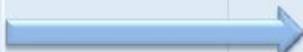
We believe we are a leader in pluripotent cell asset development based on lineage derivation protocols and whole cell manufacturing. Pluripotent cells, which are widely published as capable of becoming any human cell type, have potential applications in many areas of medicine with large unmet patient needs, including certain age-related degenerative diseases and degenerative conditions for which there presently are no cures. We currently are focused on developing pluripotent cells into three specific cell types: RPE cells, oligodendrocyte progenitor cells and dendritic cells.

Pluripotent Stem Cells

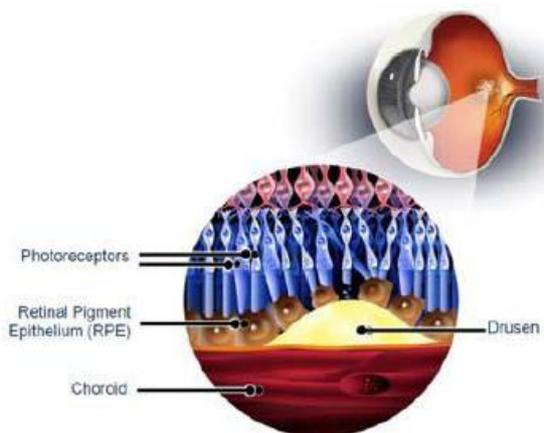


Unlike pharmaceuticals that require a narrowly defined molecular target, cellular therapies are often aimed at regenerating or replacing the entire affected cell or tissue and therefore, may have broader or more suitable applicability than many pharmaceutical products. Small molecules and biologic therapies that require systemic delivery into the body often have unexpected results, or side effects, that can limit their usefulness. When cell replacement is locally administered, systemic side effects are usually not a primary concern. The risk profile more closely resembles that of transplant medicine, focused more on whether the transplanted cells are rejected by the body and whether the cells function as expected. We currently are using our pluripotent stem cells as biological starting material from which we derive three separate and specific cell types, each of which are product candidates currently in clinical testing.

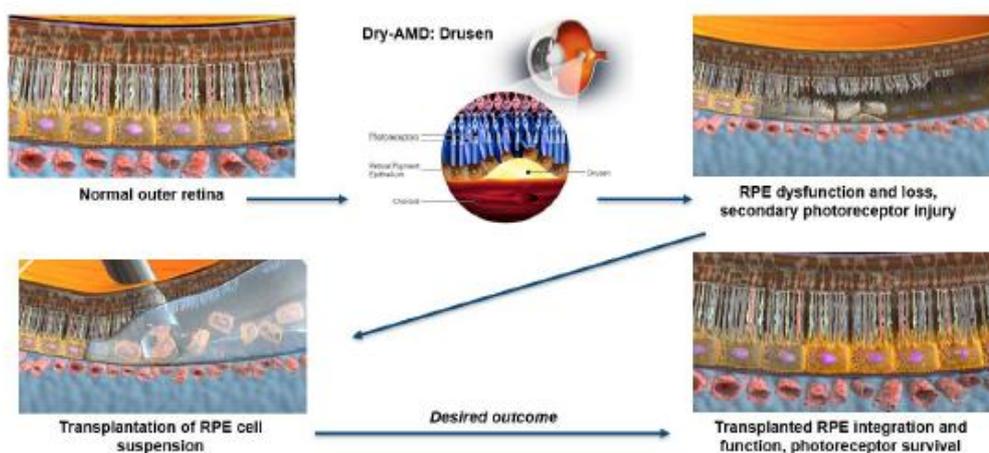
Cell Therapy Product Candidates

Programs	Phase I	Phase II	Partnerships & External Funding
OpRegen® Dry Age-Related Macular Degeneration with GA (Dry AMD)			 רשות החדשנות Israel Innovation Authority \$16M
OPC1 Spinal Cord Injury (SCI)			 >\$14M
VAC2 Non-Small Cell Lung Cancer (NSCLC)			 >\$10M in-kind

OpRegen is our lead 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 have not been 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.



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. OpRegen is a cell replacement therapy derived from our pluripotent cell technology in which our proprietary directed-differentiation methods convert pluripotent 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.



Preclinical studies in the Royal College of Surgeons (RCS) rat have shown that following a single subretinal injection, OpRegen as a suspension of cells rapidly organized into their natural monolayer structure and survived until the end of the study, which we believe is critical to the potential success of OpRegen in humans. Additionally, rats receiving OpRegen had objective evidence of improved optomotor tracking, indicating functional visual improvement compared to control animals.

OpRegen is intended to be an allogeneic, or “off-the-shelf,” product provided to retinal surgeons in an “easy-to-use” form for transplantation. Unlike other investigational treatments for dry AMD that require repeated intravitreal injections, we believe OpRegen could have a lasting benefit from a single administration, or once every several years. This approach differs from the approved agents currently marketed for wet AMD, such as Ranibizumab (Lucentis®) and Aflibercept (Eylea®), that require multiple, 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 eye in which the disease has progressed the most is treated, while their other eye serves as an internal control. 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 an additional 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 from the first 12 subjects in Cohorts 1-3 have been encouraging and suggest that OpRegen RPE cells are generally well-tolerated when administered by subretinal injection in these legally blind patients with large areas of GA that have encompassed the foveal area. The surgical procedures were generally well-tolerated, with spectral domain optical coherence tomography (SD-OCT) images showing absorption of the subretinal fluid in the bleb less than 48 hours after surgery and healing of the site of retinal penetration by the cannula within a few weeks. Initial findings using a variety of imaging modalities suggest presence of cells in the subretinal space, an observation consistent with, and supported by, the data from preclinical studies of OpRegen. Findings on clinical examination by different imaging modalities show potential improvements in retinal structure, which could precede visual functional improvements. Though it is not definitively known at this time whether these changes represent engraftment and survival of the transplanted cells, data from the preclinical animal studies suggest this is the most likely scenario.

Importantly, in this 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 mild in severity. The majority of these subjects had pre-existing epiretinal membranes at the time of trial enrollment and in most cases, experienced new or worsening epiretinal membranes following the surgical procedure, which is believed to be attributable to pars plana vitrectomy. The majority were mild to moderate in severity. These subjects are being monitored during trial follow-up. One instance of retinal detachment 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 in the trial following successful surgical repair. The independent data safety monitoring board approved moving to Cohort 4 based on the safety data from the Cohorts 1-3. Cohort 4 incorporates 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.

Many of the adverse events observed in subretinal procedures are related to the delivery technique utilized during the surgery. In January 2019, we announced an exclusive partnership with Orbit Biomedical (now Gyroscope Therapeutics) to assess its FDA-cleared Orbit Subretinal Delivery System (SDS), a single-use vitrectomy-free delivery device designed to deliver products to the subretinal space for the administration of OpRegen within the ongoing clinical trial. The device allows for access to the subretinal space via a sclerotomy and suprachoroidal approach, which means that there are no openings created into the vitreal chamber. This could eliminate the possibilities of new or worsening epiretinal membranes or generation of a cataract, both known issues with the older standard method of delivery. We believe that the use of this device could significantly decrease the number of adverse events and improve retention and dose control of OpRegen in our clinical trials.

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 or ocular adverse events. 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 Orbit SDS and our new thaw and inject formulation into our Phase 1/2a clinical trial and have treated two patients to date. We intend to dose at least six patients with the Orbit SDS. 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. Accordingly, we are opening two new clinical sites to accelerate patient enrollment and broaden surgical experience among dry AMD experts. The two new sites, Cincinnati Eye Institute and Mid Atlantic Retina, which collaborates with Wills Eye Hospital in Philadelphia, join our three other actively participating sites, Retina-Vitreous Associates in Los Angeles, Retinal Consultants Medical Group in Sacramento and West Coast Retina Medical Group in San Francisco. Our other sites in the U.S. and Israel continue to follow their patients in the long-term follow-up phase of the clinical trial.

We have established an innovative cell therapy manufacturing facility in the Jerusalem Bio Park on the campus of Hadassah University Hospital in Jerusalem, Israel. Our facility is equipped with multiple suites and is able to produce cGMP-grade OpRegen and is expected to become the manufacturing site for a range of other cell therapy products for human use in clinical trials as well as at a scale suitable for commercial introduction.

Because we believe OpRegen may provide a benefit for individuals suffering from dry AMD, we plan to administer OpRegen to additional patients this year and collect data on the safety and efficacy of their treatment, including changes or improvements to best corrected visual acuity and anatomical changes such as the continued or delayed growth of GA. In the near-term, we plan to administer OpRegen via the Orbit SDS device to at least the next four patients. Longer term, we may elect to treat additional patients with or without the Orbit SDS and/or present information on OpRegen to FDA for discussion about a subsequent, comparative clinical trial.

OPC1

OPC1 is our lead product candidate for the treatment of acute spinal cord injury (“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 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”). Clinical data to date has been collected on patients with C-4 to C-7 spinal cord injuries.

OPC1 is an oligodendrocyte progenitor cell therapy derived from our pluripotent cell technology under Current Good Manufacturing Practice (“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. Prior to their maturation, the transplanted oligodendrocyte progenitor cells 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 and demyelination disorders of the CNS.

Under a grant for clinical development, the development of OPC1 has been supported by \$14.3 million in funds from the California Institute for Regenerative Medicine (“CIRM”), from 2014 through the date of this Report. We intend to apply for additional grants from CIRM for the program’s continued development.

Prior to our acquisition, Asterias tested OPC1 in two clinical trials: a five patient Phase I safety trial and a 25 patient Phase 1/2a dose escalation trial, which we call the SCiStar trial. The SCiStar trial was an open-label, single-arm trial testing three sequential escalating doses of OPC1 administered at up to 20 million OPC1 cells in 25 patients 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 was completed in December 2017 and 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, Asterias provided top-line 12-month data from the SCiStar trial, 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 7 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 out post treatment. At 24 months, 5 of the 6 Cohort 2 patients recovered at least two motor levels on at least one side, and 1 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.

The FDA designated OPC1 as a Regenerative Medicine Advanced Therapy (“RMAT”), for the treatment of acute SCI and granted it Orphan Drug Designation, which includes the ability for increased interfacing with the FDA during clinical development, and a pathway to possible market exclusivity.

In 2019, we transferred all cGMP manufacturing processes, including the establishment of H1 cell banks and the OPC1 process development and manufacturing for clinical studies, to our cell therapy manufacturing facility in Jerusalem, Israel where OpRegen process development and production are currently ongoing.

We had a Type B meeting with the FDA to discuss the next clinical trial of OPC1. We are now analyzing the data from the SCiStar trial to inform us as to how to proceed with further discussions with the FDA. Additionally, we are leveraging our manufacturing capabilities and process development expertise learned from OpRegen to support OPC1’s development.

Because OPC1 has been shown to promote CNS repair through multiple reparative mechanisms, we believe its therapeutic benefit extends beyond SCI to other types of neurological injury and disease, particularly those that involve demyelination. Through collaborations with academic researchers, OPC1 is currently in preclinical development as a potential treatment for ischemic stroke and multiple sclerosis, two additional neurological conditions with demyelination as a key component of their pathology. In both cases, the preclinical data generated thus far has provided initial proof of concept efficacy of OPC1, which we may use to seek funding for further preclinical development.

Continued improvements to the manufacturing process are planned during 2020 and include enhancements to the production process to ensure robust, controlled and commercially viable scale, purity, and reproducibility of OPC1. We intend to develop a thaw and inject formulation of OPC1 as well. A meeting with the FDA is planned around the middle of 2020 to discuss our manufacturing improvements and the further development of OPC1 in SCI to best set the program up for success moving forward. Concurrently, we will 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.

VAC2

VAC2 is our lead product candidate for the treatment of cancer. Cancer afflicts millions worldwide and is one the largest unmet clinical needs with current treatment options providing limited efficacy and a wide range of debilitating side effects. To provide a more effective and targeted treatment, we are developing VAC2 as an allogeneic, or non-patient specific, cancer vaccine candidate designed to stimulate patient immune responses to an antigen which is commonly expressed in cancerous cells but not in normal adult cells. VAC2, which is produced from our pluripotent cell technology using a directed differentiation method, is comprised of a population of mature dendritic cells. 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. To target cancerous cells, VAC2 is engineered to express the tumor-selective antigen telomerase, which is found in over 85% of all cancers. Because the tumor antigen is loaded exogenously into the dendritic cells prior to administration, VAC2 is a platform technology that can be modified to carry any antigen, including patient-specific tumor neo-antigens. Using pluripotent cells as the starting material for VAC2 production adds several additional advantages to this candidate therapeutic. 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, VAC2 has the potential to stimulate a more robust immune response through an adjuvant effect resulting from the partial immune mismatch between the VAC2 cells and patients receiving the therapy.

In September 2014, Asterias initiated clinical development of VAC2 by entering into a Clinical Trial and Option Agreement (the “CRUK Agreement”) with Cancer Research UK (“CRUK”) and Cancer Research Technology Limited, a wholly owned subsidiary of CRUK, under which CRUK agreed to fund Phase 1 clinical development of VAC2 in non-small cell lung cancer. CRUK is 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 four patients have completed dosing in the initial aspect of the trial.

Upon completion of the Phase 1 clinical trial, we will have an exclusive option to acquire the data generated in the trial and conduct further development of VAC2. The reacquisition fee is approximately \$1.6 million with additional milestone fees based upon initiation of a Phase 3 clinical trial and the filing for regulatory approval, as well as mid-single-digit royalty payments on sales of commercial products. If we decline this option, CRUK will then have an option to obtain a license to Lineage’s intellectual property to continue the development and commercialization of VAC2 and related products in exchange to Lineage for a revenue share of development and partnering proceeds. In connection with the CRUK Agreement, we sublicensed to CRUK for use in the clinical trials and product manufacturing process certain patents we licensed or sublicensed to third parties. We will also be obligated to pay to those licensors and sublicensors upon the achievement of various milestones and to pay royalties on sales of products if VAC2 is successfully developed and commercialized.

The allogeneic VAC2 program was preceded by the autologous VAC1 program which isolated dendritic cells from a patient’s own blood, modified those cells to stimulate immune responses to telomerase and then administered those cells back to the patient as a therapeutic modality. VAC1 was studied for the treatment of acute myeloid leukemia, the most common form of acute leukemia in adults. A Phase 2 clinical trial of VAC1 demonstrated that it successfully manufactured and released in 24 out of the 33 patients enrolled in the trial. Twenty-one patients received VAC1 in the trial, including 19 in clinical remission and two in early relapse. VAC1 was found to have a favorable safety and tolerability profile. Asterias performed follow-up data collection on the 19 patients treated while in complete remission to determine the long-term effects of the VAC1 administration on remission duration and disease-free survival.

VAC1 utilized an autologous approach where the cellular vaccine needs to be created specifically for each patient. This results in a longer time prior to administration of therapy as compared to the allogeneic approach of the VAC2 program, which is disadvantageous in advanced cancer patients given the rapidity of disease progression. The VAC1 program 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.

Cell/Drug Delivery Technology – HyStem[®]

HyStem is 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.

The patented technology underlying HyStem was developed at the University of Utah and has been exclusively licensed to us for human therapeutic uses. The HyStem technology is based on a unique thiol cross-linking chemistry to prepare hyaluronan-based hydrogels. Since the first published report in 2002, there have been over 200 academic scientific publications supporting the biocompatibility of thiol cross-linked hyaluronan-based hydrogels and their applications as medical devices and in cell culture, tissue engineering, and animal models of cell-based therapies.

Renovia[®]

Renovia, our facial aesthetics product, was developed as a potential treatment for facial lipoatrophy. Lipoatrophy is the loss of fat tissue and may be caused by several factors, including drug side effects, such as those that can occur from certain drugs used to treat patients with human immunodeficiency virus (“HIV”). Renovia consists of our HyStem hydrogel combined with the patient’s own fat or adipose progenitor cells. As a potential alternative to traditional fat transfer procedures, Renovia is designed to mimic the naturally occurring extracellular matrix in the body and to provide a 3-D scaffold that supports effective cell transplant, retention, engraftment and metabolic support. Renovia was developed with the goal of providing a natural looking and feeling, long-lasting option for facial volume restoration.

In 2017, Renevia met the primary endpoint of implanted volume retention in a clinical trial in Europe designed to assess its safety and effectiveness in restoring facial volume in patients whose subcutaneous fat, or adipose tissue, has been lost due to a side effect of certain drugs used to treat patients with HIV. In this clinical trial, Renevia treated patients retained approximately 100% of transplanted volume at six months ($p < 0.001$), based on 3-D volume measurement of the implanted area, and achieved the primary endpoint of the trial. Based on these clinical trial results, in March 2018 we filed for marketing authorization in the European Union (“EU”) for certain forms of facial lipoatrophy. In September 2019, we were granted a Conformité Européenne (“CE”) Mark. Renevia received a Class III classification with an intended use in adults as a resorbable matrix for the delivery of autologous adipose tissue preparations to restore and/or augment facial volume after subcutaneous fat volume loss for the treatment of facial lipoatrophy. The CE Mark provides us, or our authorized agent, with the authority to market and distribute Renevia throughout the EU and in other countries that recognize the CE Mark. We have engaged a life sciences advisory firm to identify an external partner for commercialization of Renevia in Europe.

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, which severely impact the quality of life for millions of people who have limited treatment options. In 2019, we received an additional grant of \$0.7 million to continue work on this program.

Demyelination

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

To develop OPC1 as a treatment for MS, initial proof-of-concept efficacy data has been demonstrated in collaboration with Yale University using a non-human primate model of MS. Results of this study showed OPC1 engraftment that was associated with substantial remyelination of the lesioned primate spinal cord up to 5 months post-treatment. These data are in preparation for submission to an appropriate scientific journal. Subsequently, we initiated a collaboration with University of California Irvine to assess OPC1 efficacy in additional mouse models of MS that better recapitulate the autoimmune components of the disease. Preliminary results indicate that in addition to OPC1’s capacity to remyelinate the lesioned spinal cord, the cells may also help stimulate proliferation of a distinct class of immune cells known as regulatory T cells that can help reduce or eliminate autoimmunity. Data obtained from the collaboration may be used to seek additional non-dilutive funding for further development of OPC1 as a treatment for MS.

For ischemic stroke, initial proof-of-concept efficacy data for OPC1 has been demonstrated in a collaborative study with the University of California Los Angeles using a mouse model of white matter ischemic stroke. Results of this study demonstrated that within the stroke injury site, OPC1 cells engrafted, reduced lesion formation and inflammation, and increased myelination, culminating in improved functional recovery. We have since initiated a second preclinical study in collaboration with the University of South Florida to test two different doses of OPC1 in a rat model of ischemic subcortical and white matter stroke. This study was completed in the second quarter of 2019. Results from this study demonstrated the ability of OPC1 to impact the restoration of motor function in a rat model of white matter stroke. Further, histological assessments showed a treatment-associated reduction in stroke lesion size, including in the white matter, as well as reduced inflammation and sustained OPC1 engraftment in the injured brain. These data are in preparation for submission to an appropriate scientific journal. We may use the results of these studies to seek additional funding and guide further preclinical development of OPC1 as a treatment for ischemic stroke.

Products for Other Indications

We also have rights to intellectual property applicable to other indications such as for producing cardiomyocytes, pancreatic islet cells, hepatocytes, chondrocytes, osteoblasts and other cell types. We may elect to pursue these or other programs at any time.

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 March 5, 2020, and the country where their principal business is located:

Investments:

<u>Company</u>	<u>Field of Business</u>	<u>Lineage Ownership</u>	<u>Country</u>
OncoCyte Corporation ⁽¹⁾	Cancer diagnostics	<10%	USA
AgeX Therapeutics, Inc. ⁽¹⁾	PureStem [®] progenitor cell lines, brown adipose fat, induced tissue regeneration (“iTR”) technology	<3%	USA
Hadasit Bio-Holdings Ltd. ⁽¹⁾	Owns a portfolio of R&D based companies	<5%	Israel

Significant subsidiaries:

<u>Company</u>	<u>Field of Business</u>	<u>Lineage Ownership</u>	<u>Country</u>
Cell Cure Neurosciences Ltd.	Development and manufacturing of Lineage’s cell replacement platform technology	99% ⁽²⁾	Israel
Asterias Biotherapeutics, Inc. ⁽³⁾	Cell based therapeutics to treat neurological conditions	100%	USA
ES Cell International Pte. Ltd. ⁽⁴⁾	Research and clinical grade cell lines	100%	Singapore
OrthoCyte Corporation ⁽⁴⁾⁽⁵⁾	Research in orthopedic diseases and injuries	99.8%	USA

(1) These are publicly traded companies. See Notes to Consolidated Financial Statements: Note 4. Equity Method of Accounting for Common Stock of OncoCyte, at Fair Value and Note 6. Deconsolidation and Distribution of AgeX, included elsewhere in this Report for additional information. Beginning August 30, 2018, Lineage deconsolidated AgeX and AgeX is no longer a subsidiary of Lineage as of that date but remains a marketable security for Lineage for the ownership interest retained. See “Recent Transactions Affecting Our Corporate Organization,” above.

(2) Includes shares owned by Lineage and ES Cell International Pte. Ltd. (“ESI”). During June and July of 2017, we increased our ownership of Cell Cure Neurosciences Ltd. (“Cell Cure”), by acquiring all of the Cell Cure ordinary shares and Cell Cure convertible promissory notes held by its second largest shareholder, Hadasit Bio-Holdings Ltd., and all of the Cell Cure ordinary shares held by its third largest shareholder, Teva Pharmaceutical Industries, Ltd. As a result of this acquisition, we now own, directly and through a wholly owned subsidiary, approximately 99% of the outstanding Cell Cure ordinary shares. In July 2018, we terminated the Cell Cure stock option plan and all Cell Cure issued and outstanding stock options were canceled in exchange for 775,000 Lineage stock options issued to the Cell Cure employees. See Notes to Consolidated Financial Statements: Note 12. Stock Based Awards.

(3) Asterias was acquired by Lineage in March 2019. See Notes to Consolidated Financial Statements: Note 3. Asterias Merger.

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

(5) OrthoCyte Corporation (“OrthoCyte”) adopted a stock option plan under which it may issue up to 4,000,000 shares of its common stock to officers, directors, employees, and consultants of OrthoCyte and Lineage employees, including officers. As of December 31, 2019, options to purchase 999,000 shares of OrthoCyte common stock were outstanding.

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 U.S. 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 through 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 2033. The pending applications if issued, will have estimated expiration dates ranging from 2028 to 2038. These U.S. and international issued patents and pending applications also include those in-licensed from Hadasit Medical Research Services and Development Ltd. (“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 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.

Cell Cure was a party to two pending opposition proceedings in the European Patent Office (“EPO”) involving EP Patent Numbers 2147094 (issued 08-Oct-2014) and 2554661 (issued 19-Nov-2014), both entitled, “Stem Cell-Derived Retinal Pigment Epithelial Cells”. The oral proceedings took place on March 16, 2017 and March 17, 2017, respectively. Both patents were upheld by the EPO and the patents issued as amended during the opposition proceedings. Both patents cover OpRegen until 2028.

Renevia

We have rights to U.S. and international issued patents and pending patent applications covering Renevia. The issued patents include those in-licensed from the University of Utah Research Foundation (“UURF”) having expiration dates ranging from 2023 to 2027, and a pending patent application in Europe having an estimated expiration date of 2024. We also solely own pending U.S. and European patent applications filed in 2018 that, if issued, will have estimated expiration dates in 2038.

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 2038. 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.

VAC1 and VAC2

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 2020 to 2029. The commercial success of VAC1 and VAC2 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.

Other Patents and Patent Applications

We also have U.S. and international issued patents and pending patent applications related to producing cardiomyocytes, pancreatic islet cells, hepatocytes, chondrocytes and osteoblasts. The expiration dates of these patents and pending patent applications range from 2020 to 2032. In addition, we have U.S. and international issued patents and pending patent applications related to suspension cultures and feeder-free cultures for culturing and proliferating pluripotent stem cells. The expiration dates for these patents and pending patent applications range from 2021 to 2026.

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, 2019, we had 55 employees, of which 20 were Lineage employees and 35 were employees of Cell Cure in Israel and of which 50 are employed on a full-time basis and five are employed on a part-time basis. Twelve full time employees hold Ph.D. degrees in one or more fields of science. None of our employees are covered by a collective bargaining agreement. In connection with our updated corporate objectives with a greater focus on clinical development, we reduced our worldwide headcount from the time of the Asterias Merger (March 8, 2019) by 50 employees through employee terminations and the closing of vacant positions during the year ended December 31, 2019.

Manufacturing

Cell Products

We established 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 OpRegen and a range of cell therapy products for human use in clinical trials as well as at a scale suitable for commercial launch. We transferred all cGMP manufacturing processes, including the establishment of H1 cell banks and the OPC1 process development and manufacturing for clinical studies, to this facility in 2019.

HyStem Hydrogel Products

We hold a California Device Manufacturing License in support of our 510(k)-cleared product, Premvia. We have ISO 13485:2003 certification for the design, development, manufacture, and distribution of hydrogels for therapeutic delivery applications. Although we hold these certifications, licenses, and registrations, all our HyStem[®] Hydrogel product manufacturing occurs at contract facilities located in Pennsylvania and California. Our contractors have the necessary registrations and certifications to perform this manufacturing.

Raw Materials

Except as described below, we believe the raw materials and supplies that we require to manufacture our products, as well as the raw materials that we require for our research and development operations relating to our product candidates and products, are widely available from numerous suppliers and are generally considered to be generic materials and supplies. Except as described below, we do not rely on a single supplier for the current production of any product in development or for our research and development operations relating to our products.

Most of the materials required in the research and development of our product candidates are off-the-shelf pharmaceutical products available from third-party suppliers; special production or special requirements are not required to order these materials. We typically submit purchase orders to our suppliers from time to time and as required. We do rely 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.

Most of the ingredients in the HyStem products are readily obtainable from multiple sources. Two critical ingredients, gelatin and sodium hyaluronate, are readily available from multiple sources but would require significant testing in order to qualify new vendors as sources of those ingredients for our products.

We are no longer producing research-grade HyStem. We sold HyStem-related assets and licensed the applicable technology to Advanced BioMatrix in late 2019. We retain the rights to develop human-grade HyStem and other orthopedic applications.

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.

HyStem Hydrogel Technology

In February 2006, we acquired an exclusive worldwide license from UURF under certain U.S. and international issued patents and pending applications for the production and sale of hydrogel products, including our HyStem products, excluding certain veterinary and animal health uses. Our licensed field of use includes all human pharmaceutical and medical device applications, all tissue engineering and regenerative medicine uses, and all research applications. The patents have expiration dates ranging from 2023 to 2027. There is one pending patent application in Europe having an estimated expiration date of 2024.

Under the license agreement, we will pay a 3% royalty on sales of products and services performed that utilize the licensed patents. We are obligated to pay: (i) minimum royalties to the extent that actual annual royalties on products sales and services utilizing the patents are less than \$30,000; (ii) 30% of any sublicense fees or royalties received under any sublicense of the licensed patents; and (iii) a \$225,000 milestone fee within six months after the first sale of a “tissue engineered product” that utilizes a licensed patent.

We agreed to pay an additional license fee for the additional rights licensed to us during August 2012, and the costs of filing, prosecuting, enforcing and maintaining the patents exclusively licensed to us, and a portion of those costs for patents that have been licensed to a third party for a different field of use.

We may, under certain circumstances, be obligated to sublicense to one or more third parties, on commercially reasonable terms to be negotiated between us and each prospective sublicensee, or re-grant to the UURF, rights to use the licensed patents for products and services outside the general industry in which we or any of our affiliates or sublicensees is then developing or commercializing, or has plans to develop or commercialize, a product using the licensed technology.

Hadasit Research and License Agreement

In June 2017, Cell Cure entered into a Second Amended and Restated License Agreement with Hadasit (the “Hadasit License Agreement”). Pursuant to the Hadasit License Agreement, Hadasit granted Cell Cure an exclusive, worldwide, royalty-bearing license (with the right to grant sublicenses) in its intellectual property portfolio of U.S. and international issued patents and pending patent applications relevant to materials and technology related to human stem cell derived photoreceptor cells and RPE cells, to use, commercialize and exploit any part thereof, in any manner whatsoever in the fields of the development and exploitation of: (i) human stem cell derived photoreceptor cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders; and (ii) human stem cell derived RPE cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders. This intellectual property licensed includes patents and pending applications having expiration dates, and estimated expiration dates, respectively, ranging from 2025 to 2028. Cell Cure and Hadasit also jointly own U.S. and international issued patents and patent applications directed to methods of selecting RPE cells, which patents and patent applications will expire in 2033.

Pursuant to the Hadasit License Agreement, Cell Cure paid a small one-time lump sum payment for reimbursement of intellectual property related expenses and will pay a royalty in the mid-single digits of net sales from sales of licensed intellectual property by any invoicing entity and a royalty of 21.5% on sublicensing receipts. In addition, Cell Cure will pay Hadasit an annual minimal non-refundable royalty, which will become due and payable the first January 1 following the completion of services to Cell Cure by a research laboratory.

Cell Cure agreed to pay Hadasit non-refundable milestone payments upon the recruitment of the first patient for the first Phase IIB clinical trial, upon the enrollment of the first patient in the first Phase 3 clinical trials, upon delivery of the report for the first Phase 3 clinical trials, upon the receipt of an NDA or marketing approval in the EU, whichever is the first to occur, and upon the first commercial sale in the United States or EU, whichever is the first to occur. Such milestones, in the aggregate, may be up to \$3.5 million. As of December 31, 2019, Cell Cure had not accrued any of these milestone payments.

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

License Agreement with University of California

We are party to an exclusive license agreement with The Regents of the University of California dated February 20, 2003 (the "UC License Agreement") for U.S. and international issued patents and pending patent applications covering a method for directing the differentiation of pluripotent cells to glial-restricted progenitor cells that generate pure populations of oligodendrocytes for remyelination and treatment of spinal cord injury. Under the UC License Agreement, we have an exclusive worldwide license under such patents, including the right to grant sublicenses, to create products for biological research, drug screening, and human therapy using the licensed patents. These issued patents and pending applications have expiration dates ranging from 2023 to 2024.

Under the UC License Agreement, we will pay the university a royalty of 1% from sales of products that are covered by the licensed patent rights, and a minimum annual royalty of \$5,000 starting in the year in which the first sale of a product covered by any licensed patent rights occurs and continuing for the life of the applicable patent right under the agreement. Under certain conditions, we will pay the university 7.5% of any proceeds, excluding debt financing and equity investments, and certain reimbursements, that we receive from sublicensees.

The UC License Agreement terminates on the expiration of the last-to-expire of the university's issued licensed patents. If no further patents covered by the UC License Agreement are issued, it will terminate in 2024. The university may terminate the UC License Agreement if we breach it, and we can terminate with 60 days' notice.

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 sublicensees 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 2032.

AgeX License Agreement

Concurrently with our contribution of assets to AgeX in August 2017, we and AgeX entered into a license agreement pursuant to which we licensed to AgeX, with rights to sublicense, certain intellectual property, including patents and patent applications and know-how for use in the development, manufacture and commercialization of products or services for the prevention, treatment, amelioration, diagnosis or monitoring of all human and non-human animal diseases and conditions except for the field of medical products, devices and services for the reserved Lineage fields of orthopedic, ophthalmic and medical aesthetic uses. In addition, we retained an option right to license, on terms to be negotiated, certain patents in research, development, manufacturing and commercialization of treatments in the reserved Lineage fields. The licensed patents and know-how relate generally to: (i) our PureStem human embryonic progenitor cell lines; and (ii) telomere length and DNA quality control analysis in pluripotent stem cells.

The Lineage patent rights licensed to AgeX are exclusive and worldwide except for existing third-party licenses, and for medical products, devices, and services related to tendon. AgeX also received an option to license certain Lineage retained patent rights outside of orthopedic indications unless a license grant would compete with a Lineage program or products in the retained Lineage field.

We also agreed to license or sublicense to AgeX certain additional patents and patent rights and know-how relating to Lineage HyStem hydrogel technology, human embryonic progenitor cell technology, and human pluripotent stem cell lines and technology for use outside the fields reserved to Lineage or in the case of certain sublicense rights in fields previously licensed to third parties.

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 Cellular, Tissue and Gene 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 investigational new drug ("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 efficacy and preliminary safety, 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, request additional information 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-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 is 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.

Renevia is regulated in the EU as a medical device by way of a certification. The CE mark shows that the device has a Certificat de Conformité. The means for achieving the requirements for the CE mark vary according to the nature of the device. Devices are classified in accordance with their perceived risks, similar to the U.S. system. The class of a product determines the conformity assessment required before the CE mark can be placed on a product. Each member state can appoint Notified Bodies within its jurisdiction. If a Notified Body of one member state has issued a Certificat de Conformité, the device can be sold throughout the EU without further conformance tests being required in other member states. The CE mark is contingent upon continued compliance with the applicable regulations and the quality system requirements of the ISO standards.

Renevia is subject to controls on product manufacturing and production methods, analytical controls to assure that the product meets its release specification, data from analytical assay and process validations, and ISO 10993 biocompatibility testing.

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. For example, our HyStem hydrogel products may be used to administer one or more pluripotent stem cell-based therapy products. 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 a pre-market notification or pre-market approval application for a medical device (“PMA”), or an amendment to an NDA, a BLA or a pre-market notification or PMA, 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 National Institutes of Health (“NIH”) adopted guidelines on the use of hES cells in federally funded research. The central focus of the guidelines is to assure that hES cells used in federally funded research are derived from human embryos that were created for reproductive purposes, are no longer needed for this purpose, and are voluntarily donated for research purposes with the informed written consent of the donors. hES cells that were not derived in compliance with the guidelines, are not eligible for use in federally funded research.

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

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

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

The Health Insurance Portability and Accountability Act (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and their respective implementing regulations impose obligations on “covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, 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 health care 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.

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 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 health care item or service reimbursable, in whole or in part, under a federal health care 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 health care 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 Health Care 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 health care 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 health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care 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 health care 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, a defined by such law, 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 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 health care 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 health care programs. Since its enactment, there have been judicial, Congressional, and executive branch challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. In addition, the 2017 Tax Act was enacted, which, among other things, removes penalties for not complying with ACA's individual mandate to carry health insurance. Since the enactment of the 2017 Tax Act, there have been additional amendments to certain provisions of the ACA. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the 2017 Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, if any, and other efforts to repeal and replace the ACA will impact the ACA.

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 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. At the federal level, the Trump administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation such as measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. While some of measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Major 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, 2019 and 2018:

Sources of Revenues	Year Ended December 31,	
	2019	2018
NIH grant income	17.5%	21.2%
IIA grant income (Cell Cure Neurosciences Ltd, Israel)	40.5%	50.4%
Royalties, licenses, subscriptions, advertising and other ⁽¹⁾	34.7%	20.5%
Sale of research products	7.3%	4.2%
Other	-	3.7%

(1) Subscription and advertising revenues were generated by LifeMap Sciences, which is a subsidiary of AgeX. The 2018 revenues shown are for the period January 1, 2018 through August 29, 2018. As a result of the AgeX Deconsolidation on August 30, 2018, Lineage does not expect to recognize subscription and advertisement revenues during subsequent accounting periods.

Geographic Area

	Year Ended December 31,	
	2019	2018
United States	\$ 2,092	\$ 1,804
Foreign ⁽¹⁾	1,423	3,184
Total revenues	<u>\$ 3,515</u>	<u>\$ 4,988</u>

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

Marketing

Therapeutic Products and Medical Devices

Because our planned therapeutic products 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 of 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. Specific efforts in the development of treatments for dry AMD include, but are not limited to, neuroprotection, reducing by-product accumulation, and suppressing inflammation. Specific approaches include small molecules, antibodies, and cell therapies. Some of these efforts have reached clinical development and at least one effort to reduce inflammation, complement inhibition, is currently in a Phase 3 clinical trial. We believe that replacing the entire cell rather than attempts to fix one aberrant pathway or signal confer a greater probability of success for individuals suffering with dry AMD.

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. Ocata Therapeutics, Inc. ("Ocata"), which was acquired by a subsidiary of Astellas Pharma Inc. for approximately \$379 million in 2016, and Retinal Patch Technologies Inc. have conducted clinical trials of a hES cell products designed to treat dry AMD. 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.

ITEM 1A. RISK FACTORS

Our business is subject to various risks, including those described below. You should consider the following risk factors, together with all of the other information included in this report, which could materially adversely affect our proposed operations, our business prospects, and financial condition, and the value of an investment in our business. There may be other factors that are not mentioned here or of which we are not presently aware that could also affect our business operations and prospects.

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, 2019 and 2018 were \$38.9 million and \$41.8 million, respectively, and we had an accumulated deficit of \$273.4 million as of December 31, 2019. 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 \$17.9 million and \$21.0 million during the fiscal years ended December 31, 2019 and 2018, 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, 2019, we had \$30.7 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. 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 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, 2019 will be sufficient to fund our planned operations for at least the next 12 months. 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 Biotherapeutics, Inc. (“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, Lineage, Neal Bradsher, Broadwood Capital, Inc. and Broadwood Partners, L.P. 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 defendants specifically deny all allegations in the litigation and intend to defend it vigorously. However, any adverse ruling in this case could result in additional payments. 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, legislation enacted in 2017, informally known as the Tax Cuts and Jobs Act (the “2017 Tax Act”), enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the 2017 Tax Act may affect us, and certain aspects of the 2017 Tax Act could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the 2017 Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the 2017 Tax Act or future 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 to offset future taxable income may be subject to limitations.

As of December 31, 2019, we had net operating loss (“NOL”) carryforwards for U.S. federal and state tax purposes of approximately \$164.0 million and \$121.1 million, respectively. A portion of the federal and state NOL carryforwards will begin to expire, if not utilized, in varying amounts between 2027 and 2039. NOLs that expire unused will be unavailable to offset future income tax liabilities. Under federal income tax law, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is uncertain if and to what extent various states 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.

As part of the merger with Asterias, we acquired various tax attribute carryforwards including federal and California NOLs of \$75.8 million each, as well as California research and development credits of \$2.3 million. As a result of the merger, Asterias incurred an ownership change under Section 382 of the Internal Revenue Service Code, which places annual limits on the amount of these NOLs that are available to offset income. Because of the annual limitation, the total amount of these NOLs are not immediately available to offset future income, and some will expire. The California research and development credit of \$2.3 million has no expiration.

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, or Transfer Pricing Regulations. 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.

Significant disruptions of information technology systems or data security breaches could adversely affect our business.

We are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store, process and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal 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 vendors who may have, or could gain, access to our confidential information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties.

Our information technology systems are large and complex and store large amounts of confidential information. The size and complexity of these systems make them potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third party vendors and/or business partners, or from cyber-attacks by malicious third parties. Attacks of this nature are increasing in frequency, persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, “hacktivists,” nation states and others. In addition to the extraction of important information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of our information. 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.

Significant disruptions of our, our third party vendors’ and/or business partners’ information technology systems or security breaches could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal information), and could result in financial, legal, business and reputational harm to us. Any such event that leads to unauthorized access, use or disclosure of personal information, including personal information regarding our patients or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. In addition, security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may further harm us. Moreover, the prevalent use of mobile devices to access confidential information increases the risk of security breaches. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business. In addition, failure to maintain effective internal accounting controls related to security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and subject us to regulatory scrutiny.

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.

We have equity investments in two publicly traded companies, OncoCyte and AgeX. As of December 31, 2019, the value of our investments in OncoCyte and AgeX was approximately \$19.0 million and \$1.7 million, respectively, based on their stock prices as of that date. If these companies 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 their common stock and the valuation of our investment could be negatively affected. If these companies were to fail and ultimately cease operations, we may lose the entire value of our investments.

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.

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, it 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 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;
- the federal Health Insurance Portability and Accountability Act of 1996 (“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 the Health Information Technology for Economic and Clinical Health Act, (“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, 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 to report annually to CMS information related to payments and other transfers of value to physicians, as defined by such law, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers 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 health care 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 health care 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, President Obama lifted certain restrictions on federal funding of research involving the use of hES cells, and in accordance with President Obama's Executive Order, the National Institutes of Health ("NIH") has adopted guidelines for determining the eligibility of hES cell lines for use in federally funded research. The central focus of the guidelines is to assure that hES cells used in federally funded research were derived from human embryos that were created for reproductive purposes, were no longer needed for this purpose, and were voluntarily donated for research purposes with the informed written consent of the donors. The hES cells that were derived from embryos created for research purposes rather than reproductive purposes, and other hES cells that were not derived in compliance with the guidelines, are not eligible for use in federally funded research. California law requires that stem cell research be conducted under the oversight of a stem cell review oversight committee ("SCRO"). 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 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 Health Care 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.

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.

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;
- 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 Centers for Medicare & Medicaid Services 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 remains judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part 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 delaying the implementation of certain ACA-mandated fees. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the 2017 Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act 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 2029 unless additional Congressional action is taken. 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, 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 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's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. In addition, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and, at the same, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

If we fail to comply with the extensive legal and regulatory requirements affecting the health care 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, advertising and promotion, product distribution, adverse event reporting and product risk management. Our interactions in the U.S. or abroad with physicians and other health care providers that may prescribe or purchase our products 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 health care companies. Health care companies are facing heightened scrutiny of their relationships with health care providers from anti-corruption enforcement officials. In addition, health care 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 health care 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 health care 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 health care availability, pricing or marketing practices, compliance with wage and hour laws and other employment practices, method of delivery, payment for health care 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 outweighs 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 Institutional Review Board (“IRB”) approval at each clinical trial site;
- failure to obtain permission from regulatory authorities to conduct a clinical trial after review of an investigational new drug (“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 trial 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, 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 particular, data presented from the Phase 1/2a open-label trial showed that both the surgical procedure and the OpRegen cells were generally well tolerated, with no treatment-related systemic serious adverse events reported to date in the first nine patients. The best corrected visual acuity of these patients remained relatively stable. In addition, the imaging of patients 8 and 9 suggested early signs of structural improvement within the retina. 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. A number of companies in the biotechnology industry have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

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 or 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 acute 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 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 health care 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 health care 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, particular 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 health care 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 health care 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 a 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. We do not currently have nor do we plan to acquire the infrastructure or capability to internally manufacture Renevia or our other HyStem products on a clinical or commercial scale. Although we have manufacturing capability through Cell Cure for OpRegen 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 current good manufacturing practices (“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 market place 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 market place 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.

We may not secure a commercialization partner for Renevia.

In September 2019, Renevia was granted a CE Mark and Class III classification with an intended use in adults as a resorbable matrix for the delivery of autologous adipose tissue preparations to restore and/or augment facial volume after subcutaneous fat volume loss for the treatment of facial lipoatrophy. The CE Mark provides us, or our authorized agent, the authority to market and distribute Renevia throughout the European Union (“EU”) and in other countries that recognize the CE Mark.

However, because we have no commercial infrastructure, we are seeking a commercialization partner in the EU. We can give no assurance that we will secure a commercialization partner for Renevia or otherwise commercialize Renevia.

The spread of COVID-19 may adversely affect our operations, including the conduct of our clinical trials.

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. If COVID-19 continues to spread in the United States and Israel, we may experience disruptions that could adversely affect our operations and clinical trials, including:

- delays or difficulties in enrolling, or 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; and
- manufacturing difficulties for us and our suppliers of raw materials caused by business closures.

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.

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, result in restrictions or imposition of taxes and duties for importing our product candidates into the EU, and may require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the EU.

On June 23, 2016, the U.K. held a referendum in which a majority of the eligible members of the electorate voted for the U.K. to leave the EU. The U.K. formally left the EU on January 31, 2020, which is commonly referred to as Brexit. The U.K. is subject to a transition period until December 31, 2020 (the “Transition Period”), during which EU rules continue to apply. Negotiations between the U.K. and the EU are expected to continue in relation to the customs and trading relationship between the U.K. and the EU following the expiry of the Transition Period.

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, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. For example, as a result of the uncertainty surrounding Brexit, the European Medicines Agency (the “EMA”) relocated to Amsterdam from London. Following the Transition Period, the U.K. will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorization from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products, including our product candidates, will be required in the U.K., the potential process for which is currently unclear. 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. or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the EU, or we may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. or the EU for our product candidates, or incur significant additional expenses 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. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the EU.

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 Israel Innovation Authority (“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 foreign 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 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 are 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. As of December 31, 2019, we received approximately \$14.5 million of such grants.

The restrictions under the Innovation Law may impair our ability to enter into agreements which involve IIA-funded products or know-how without the approval of IIA. 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 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;
- 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 Practice 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.

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 contract research organizations, 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.

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 \$14.0 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 partner. 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. The failure of our earnings to meet analysts' expectations could result in a significant rapid decline in the market price of our common shares.

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.

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 28% of our outstanding common shares as of December 31, 2019. 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.

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.

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 stockholder 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, 2019, Lineage had 149,804,284 common shares outstanding, 14,710,250 common shares reserved for issuance upon the exercise of outstanding options under our employee stock option plans, 166,087 common shares reserved for issuance upon the vesting and settlement of restricted stock units under our equity incentive plan, and 1,089,900 common shares subject to warrants.

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

Generally

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 the Notes to Consolidated Financial Statements – Note 14. Commitments and Contingencies 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 maintain offices and laboratory facilities comprised of 30,795 square feet in two buildings in Alameda, California. This space was previously shared with former affiliate companies, which have since relocated. We are seeking to sublease all or a portion the Alameda facilities as we no longer need this large of a facility.

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, 2020, with two options to extend the term for 5 years each.

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 options to extend the lease for 5 years each. 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.

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 15, 2019, a purported stockholder filed a putative class action lawsuit in Delaware Chancery Court against certain former members of Asterias' board of directors, Lineage, Neal Bradsher, Broadwood Capital, Inc. and Broadwood Partners, L.P. (*Ross v. Lineage Cell Therapeutics, Inc., et al.*, C.A. No. 2019-0822). The complaint asserts claims for breach of fiduciary duty and aiding and abetting in connection with our acquisition of Asterias Biotherapeutics, Inc. ("Asterias"). The complaint alleges, among other things, 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. On December 20, 2019, the defendants moved to dismiss the complaint. On February 10, 2020, the plaintiff filed an opposition. Defendants intend to file their replies on March 13, 2020.

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.

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 February 20, 2020, 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, 2019, there were no unregistered sales of equity securities by us during the year ended December 31, 2019.

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended. Accordingly, we are not required to provide the information required by this item in this Report.

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, 2019, 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, 2019 as compared to the year ended December 31, 2018. 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."

Overview

We are a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs. Our focus is to develop therapies for degenerative retinal diseases, neurological conditions associated with demyelination, and aiding the body in detecting and combating cancer. Our programs are based on our proprietary cell-based therapy platform and associated development and manufacturing capabilities. From this platform, we develop and manufacture specialized, terminally or partially differentiated human cells from established and well-characterized pluripotent cell lines. These differentiated cells are developed either to 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 an effective immune response to cancer.

We have three allogeneic, or "off-the-shelf," three cell therapy programs in clinical 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. There currently are no therapies approved by the U.S. Food and Drug Administration ("FDA") for dry AMD, which accounts for approximately 85-90% of all AMD cases and is a leading cause of blindness in people over the age of 65.
- *OPC1*, an oligodendrocyte progenitor cell therapy for acute spinal cord injuries. We have completed enrollment in a 25-patient Phase 1/2a multicenter clinical trial with OPC1; this trial was partially funded by the California Institute for Regenerative Medicine ("CIRM"). There are currently no therapies approved by the FDA.
- *VAC2*, a cancer immunotherapy of antigen-presenting dendritic cells currently in a Phase 1 clinical trial in non-small cell lung cancer. This clinical trial is being funded and conducted by Cancer Research UK, the world's largest independent cancer research charity.

We are also currently working to identify a commercialization partner for Renevia, our proprietary three-dimensional scaffold designed to support adipose tissue transplants that was granted a Conformité Européenne ("CE") Mark in September 2019.

Lineage completed its merger (the "Asterias Merger") with Asterias Biotherapeutics, Inc. ("Asterias") on March 8, 2019, which incorporated OPC1 and VAC2 into its cell therapy product portfolio.

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"). As of March 5, 2020, we hold approximately 9.7% and 2.3% in OncoCyte and AgeX, respectively. The combined value of these holdings as of March 5, 2020, was approximately \$14.6 million, based on the closing price of their common stock on that date. We also hold a convertible promissory note from Juvenescence Limited ("Juvenescence") in connection with our sale of AgeX stock to Juvenescence in August 2018. The value of the Juvenescence note of \$23.6 million at December 31, 2019 is based on the principal amount of \$21.6 million plus accrued interest. The values of OncoCyte and AgeX are based on the closing price of their common stock on that date. See "Risk Factors—Risks Related to Our Business Operations and Capital Requirements—The value of our investments in public companies fluctuates based on their respective stock prices and could be negatively affected by poor business performance".

Though our principal focus is on advancing our three cell therapy programs in clinical development, we may seek to create additional value through corporate transactions, as we have in the past. Our securities holdings also may be a significant source of capital to fund our operations as an alternative to issuing additional Lineage securities.

Critical Accounting Policies

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.

Business Combinations – We account for business combinations, such as the Asterias Merger, in accordance with Accounting Standards Codification (“ASC”) Topic 805, *Business Combinations*, which requires the purchase price to be measured at fair value. When the purchase consideration consists entirely of our common shares, we calculate the purchase price by determining the fair value, as of the acquisition date, of shares issued in connection with the closing of the acquisition. We recognize estimated fair values of the tangible assets and intangible assets acquired, including in-process research and development (“IPR&D”), and liabilities assumed as of the acquisition date, and we record as goodwill any amount of the fair value of the tangible and intangible assets acquired and liabilities assumed in excess of the purchase price.

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 not amortized but is tested for impairment at least annually, or more frequently if circumstances indicate potential impairment. 35 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 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.

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 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 lease ROU asset 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 lease payments is recognized on a straight-line basis over the lease term. Operating 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. Financing leases are included in property and equipment, and in financing 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 (“ASU”) 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 – During May 2014, the FASB issued ASU 2014-09 (“Topic 606”), *Revenue from Contracts with Customers* which supersedes the revenue recognition requirements in Topic 605 *Revenue Recognition* (“Topic 605”). Topic 606 describes principles an entity must apply to measure and recognize revenue and the related cash flows, using the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. Topic 606’s core principle is that it requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services.

Lineage adopted Topic 606 as of January 1, 2018 using the modified retrospective transition method applied to those contracts which were not completed as of the adoption date. Results for reporting periods beginning on January 1, 2018 and thereafter are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with Lineage’s historic revenue recognition accounting under Topic 605.

On January 1, 2018, the adoption and application of Topic 606 resulted in an immaterial cumulative effect adjustment of Lineage’s beginning consolidated accumulated deficit balance. In the applicable paragraphs below, Lineage has summarized its revenue recognition policies for its various revenue sources in accordance with Topic 606.

Royalties from product sales and license fees – Lineage’s performance obligations in agreements with certain customers is to provide a license to allow customers to make, import and sell company licensed products or methods for preclinical studies and commercial use. Customers pay a combination of a license issue fee paid up front and a sales-based royalty, if any, in some cases with yearly minimums. The transaction price is deemed to be the license issue fee stated in the contract. The license offered by Lineage is a functional license with significant standalone functionality and provides customers with the right to use Lineage’s intellectual property. This allows Lineage to recognize revenue on the license issue fee at a point in time at the beginning of the contract, which is when the customer begins to have use of the license. Variable consideration related to sales-based royalties is recognized only when (or as) the later of one or more of the following events occur: (i) a sale or usage occurs; or (ii) the performance obligation to which some, or all, of the sales-based or usage-based royalty that has been allocated and has been satisfied or partially satisfied. Due to the contract termination clauses, Lineage does not expect to receive all of the minimum royalty payments throughout the term of the agreements. Therefore, Lineage fully constrains recognition of the minimum royalty payments as revenues until its customers are obligated to pay, which is generally within 60 days prior to the beginning of each year the minimum royalty payments are due.

Research and development contracts with customers – In its agreements with customers, Lineage’s performance obligations of research and development are completed as services are performed and control passes to the customer, and accordingly revenues are recognized over time. Lineage generally receives a fee at the inception of an agreement, with variable fees, if any, tied to certain milestones, if achieved. Lineage estimates this variable consideration using a single most likely amount. Based on historical experience, there has been no variable consideration related to milestones included in the transaction price due to the significant uncertainty of achieving contract milestones and milestones not being met. If a milestone is met, subsequent changes in the single most likely amount may produce a different variable consideration, and Lineage will allocate any subsequent changes in the transaction price on the same basis as at contract inception. Amounts allocated to a satisfied performance obligation will be recognized as revenue in the period in which the transaction price changes with respect to variable consideration, which could result in a reduction of revenue. Contracts of this kind are typically for a term greater than one year.

Sale of research products and services – Revenues from the sale of research products and services are primarily derived from the sale of hydrogels and stem cell products for research use and are recognized when earned. These revenues are recognized at a point-in-time when control of the product transfers to the customer, which is typically upon shipment to the customer from the Alameda facility. Cost of sales from the sale of research products include direct and indirect overhead expenses incurred to purchase and manufacture those products, including lab supplies, personnel costs, freight, and royalties paid, if any, in accordance with the terms of applicable licensing agreements for those products.

Subscription and advertisement revenues – Lineage no longer has subscription and advertisement revenues due to the AgeX Deconsolidation. Through August 30, 2018, Lineage recorded revenues of \$691,000 from LifeMap Sciences, a direct majority-owned subsidiary of AgeX, for subscription-based products, including research databases and software tools, for biomedical, gene, disease, and stem cell research. LifeMap Sciences deferred subscription revenues primarily represent subscriptions for which cash payment has been received for the subscription term, but the subscription term has not been completed as of the balance sheet date reported.

Grant revenues – In applying the provisions of Topic 606, Lineage has determined that government grants are out of the scope of Topic 606 because the government entities do not meet the definition of a “customer”, as defined by Topic 606, as there is not considered to be a transfer of control of good or services to the government entities funding the grant. Lineage has, and will continue to, account for grants received to perform research and development services in accordance with ASC 730-20, *Research and Development Arrangements*, which requires an assessment, at the inception of the grant, of whether the grant is a liability or a contract to perform research and development services for others. If Lineage or a subsidiary receiving the grant is obligated to repay the grant funds to the grantor regardless of the outcome of the research and development activities, then Lineage is required to estimate and recognize that liability. Alternatively, if Lineage or a subsidiary receiving the grant is not required to repay, or if it is required to repay the grant funds only if the research and development activities are successful, then the grant agreement is accounted for as a contract to perform research and development services for others, in which case, grant revenue is recognized when the related research and development expenses are incurred.

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.

Arrangements with multiple performance obligations – Lineage’s contracts with customers may include multiple performance obligations. For such arrangements, Lineage allocates revenue to each performance obligation based on its relative standalone selling price. Lineage generally determines or estimates standalone selling prices based on the prices charged, or that would be charged, to customers for that product or service. As of, and for the year ended, December 31, 2019, Lineage did not have significant arrangements with multiple performance obligations.

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. We expense research and development costs 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.

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. Upon adoption of ASU 2016-09 on January 1, 2017, forfeitures are accounted for as they occur instead of based on the number of awards that were expected to vest prior to adoption of ASU 2016-09. Based on the nature and timing of our grants, straight line expense attribution of stock-based compensation for the entire award and the relatively low forfeiture rates on Lineage’s experience, the impact of adoption of ASU 2016-09 pertaining to forfeitures was not material to our consolidated financial statements. 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, derived from actual and projected employee stock option exercise behaviors. The expected term of options granted is derived from historical data on employee exercises and post-vesting employment termination behavior. The risk-free rate is based on the U.S. Treasury rates in effect during the corresponding period of grant.

Certain of our privately held formerly consolidated subsidiaries have their own share-based compensation plans. For share-based compensation awards granted by those privately held consolidated subsidiaries under their respective equity plans, which are included in our consolidated financial statements and results of operations for the years presented, we determined the expected stock price volatility using historical prices of comparable public company’s common stock for a period equal to the expected term of the options. The expected term of those privately held company options is based upon the “simplified method” provided under *Staff Accounting Bulletin, Topic 14*, or SAB Topic 14. The fair value of the shares of common stock underlying the stock options of these privately held formerly consolidated subsidiaries is determined by the Board of Directors of those subsidiaries, as applicable, which is also used to determine the exercise prices of those stock options at the time of grant.

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, 2019 and 2018.

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. Changes to taxes on corporations affected by the 2017 Tax Act include, among others, lowering the U.S. federal tax rates to a 21% flat tax rate, elimination of the corporate alternative minimum tax, imposing additional limitations on the deductibility of interest and net operating losses, allowing any net operating loss generated in tax years ending after December 31, 2017 to be carried forward indefinitely and generally repealing carrybacks, reducing the maximum deduction for NOL carryforwards arising in tax years beginning after 2017 to a percentage of the taxpayer's taxable income, and allowing for the expensing of certain capital expenditures. The 2017 Tax Act also puts into effect a number of changes impacting operations outside of the United States including, but not limited to, the imposition of a one-time tax “deemed repatriation” on accumulated offshore earnings not previously subject to U.S. tax, and shifts the U.S. taxation of multinational corporations from a worldwide system of taxation to a territorial system. ASC 740 requires the effects of changes in tax rates and laws on deferred tax balances (including the effects of the one-time transition tax) to be recognized in the period in which the legislation is enacted.

Beginning in 2018, the 2017 Tax Act subjects a U.S. shareholder 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 percent of GILTI; however, this deduction is limited by the company's pre-GILTI U.S. income. For the years ended December 31, 2018 and 2019, we incurred a net loss from foreign activity, accordingly there was no GILTI inclusion in U.S. income for 2018 and 2019. Based on current interpretations under ASC 740, 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 only. We have elected to account for GILTI as a current period expense when incurred.

On December 22, 2017, the Securities and Exchange Commission (the “SEC”) staff issued Staff Accounting Bulletin No. 118 (“SAB 118”) to provide guidance for companies that are not able to complete their accounting for the income tax effects of the 2017 Tax Act in the period of enactment. SAB 118 allows us to record provisional amounts during a measurement period not to extend beyond one year of the enactment date. We applied the guidance in SAB 118 when accounting for the enactment-date effects of the Tax Act in 2017 and throughout 2018. At December 31, 2018, we have completed our accounting for all the enactment-date income tax effects of the Tax Act. ASC 740 requires the effects of changes in tax rates and laws on deferred tax balances (including the effects of the one-time transition tax) to be recognized in the period in which the legislation is enacted (see Note 13 to our consolidated financial statements included elsewhere in this Report).

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.

As further discussed in Notes 5 and 6 to the consolidated financial statements included elsewhere in this Report, on August 30, 2018, we consummated the sale of AgeX Shares to Juvenescence (the “Juvenescence Transaction”). Prior to the Juvenescence Transaction, Juvenescence owned 5.6% of AgeX's issued and outstanding common stock. Upon completion of the Juvenescence Transaction, our ownership in AgeX decreased from 80.4% to 40.2% of AgeX's issued and outstanding shares of common stock, and Juvenescence's ownership in AgeX increased from 5.6% to 45.8% of AgeX's issued and outstanding shares of common stock. As a result of the consummation of the Juvenescence Transaction on August 30, 2018, AgeX is no longer our subsidiary and, as of that date, we experienced a “loss of control” of AgeX, as defined by GAAP. Loss of control is deemed to have occurred when, among other things, a parent company owns less than a majority of the outstanding common stock of a subsidiary, lacks a controlling financial interest in the subsidiary, and is unable to unilaterally control the subsidiary through other means such as having, or being able to obtain, the power to elect a majority of the subsidiary's Board of Directors based solely on contractual rights or ownership of shares representing a majority of the voting power of the subsidiary's voting securities. All of these loss-of-control factors were present with respect to our ownership interest in AgeX as of August 30, 2018. Accordingly, we have deconsolidated AgeX's consolidated financial statements and consolidated results from our consolidated financial statements.

As further discussed in Note 3 to our consolidated financial statements included elsewhere in this Report, effective March 8, 2019, we completed the Asterias Merger in which we acquired the approximate 62% remaining ownership interest in Asterias in a stock-for-stock acquisition. As of March 8, 2019, Asterias is our wholly owned subsidiary, Asterias ceased to exist as a public company, and we consolidated Asterias' operations and results with our operations and results beginning on that date. Prior to March 8, 2016, the fair value of the Asterias common stock we held was accounted for as an investment under the equity method.

Results of Operations

Comparison of Years Ended December 31, 2019 and 2018

Revenues

The following table shows our revenues for the years ended December 31, 2019 and 2018 (amounts in thousands).

	Year Ended December 31,		\$ Increase/ (Decrease)	% Increase/ (Decrease)
	2019	2018		
Grant revenues	\$ 2,037	\$ 3,572	\$ (1,535)	(43%)
Royalties from product sales and license fees	1,221	392	829	211%
Subscription and advertising revenues	-	691	(691)	(100%)
Sale of research products and services	257	333	(76)	(23%)
Total revenues	3,515	4,988	(1,473)	(30%)
Cost of sales	(412)	(302)	(110)	(36%)
Gross profit	\$ 3,103	\$ 4,686	\$ (1,583)	(34%)

Total revenues for the year ended December 31, 2019 were \$3.5 million compared to \$5.0 million for the year ended December 31, 2018. The decrease of \$1.5 million is primarily due to a \$1.5 million decrease in grant revenue and a \$0.7 million decrease in subscription and advertising revenues, partially offset by a \$0.8 million increase in royalties from product sales and license fees.

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 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, 2019 as compared to the year ended December 31, 2018, were primarily due to timing of grant-related activities. Grant revenues generated by Cell Cure from the IIA for the development of OpRegen amounted to \$1.4 million and \$2.5 million for the years ended December 31, 2019 and 2018, respectively, and grant revenues generated by the NIH grant amounted to \$0.6 million and \$1.1 million for the years ended December 31, 2019 and 2018, respectively.

Subscription and advertising revenues, including certain service revenues, were generated entirely by LifeMap Sciences, AgeX's majority-owned subsidiary, and are included in our consolidated revenues for periods through August 29, 2018, the date before the AgeX Deconsolidation. The decrease in those revenues is due to the AgeX Deconsolidation on August 30, 2018. Due to the AgeX Deconsolidation, we do not expect to earn subscription and advertising revenues in future accounting periods.

Royalties from product sales and license fees are generated from non-exclusive license agreements with multiple third parties. A majority of our royalties from product sales and license fees for the year ended December 31, 2019 are related to technologies that were acquired in the Asterias Merger. The increase of \$0.8 million for the year ended December 31, 2019 compared to the year ended December 31, 2018 was primarily related to a \$0.6 million upfront, non-refundable payment for a new license agreement with a third party for the use of certain patents related to the culture of undifferentiated pluripotent stem cells in suspension.

Operating Expenses

The following table shows our operating expenses for the years ended December 31, 2019 and 2018 (in thousands).

	Year Ended December 31,		\$	%
	2019	2018		
Research and development expenses	\$ 17,948	\$ 21,755 ⁽²⁾	\$ (3,807)	(17.5%)
General and administrative expenses	24,031 ⁽¹⁾	24,726 ⁽³⁾	(695)	(2.8%)

(1) Includes \$5.1 million of acquisition related costs for the Asterias Merger.

(2) Includes \$4.6 million of AgeX research and development expenses incurred before the AgeX Deconsolidation.

(3) Includes \$3.1 million of AgeX general and administrative expenses incurred before the AgeX Deconsolidation.

Research and development expenses

Research and development expenses for the year ended December 31, 2019 were approximately \$17.9 million as compared to \$21.8 million for the year ended December 31, 2018. The decrease of \$3.9 million was primarily attributable to: decreases of \$4.6 million related to the AgeX Deconsolidation and the absence of AgeX R&D expenses incurred after August 30, 2018, \$3.8 million in Renevia and HyStem expenses and \$0.2 million in OpRegen expenses, offset by a net increase of \$4.8 million in OPC1 and VAC2 expenses (these programs were acquired in the Asterias Merger).

The following table shows the amounts and percentages of our total research and development expenses of \$17.9 million and \$21.8 million allocated to our primary research and development programs during the years ended December 31, 2019 and 2018, respectively (amounts in thousands).

Company	Program	Year Ended December 31,			
		Amount ⁽¹⁾		Percent of Total	
		2019	2018	2019	2018
Lineage and subsidiaries ⁽²⁾	OpRegen [®] , vision restoration and other ophthalmic research	\$ 12,069	\$ 12,265	66.4%	56.4%
Lineage and subsidiaries ⁽²⁾	OPC1	4,488	-	25.9%	-
Lineage and subsidiaries ⁽²⁾	VAC2	322	-	1.8%	-
Lineage and subsidiaries ⁽²⁾	Renevia [®] and other HyStem [®] products	1,069	4,893	5.9%	22.4%
AgeX including ReCyte ⁽³⁾	PureStem [®] progenitor cell lines, brown adipose fat, iTR technology, and preclinical cardiovascular therapy research and development	-	2,779	-	12.8%
AgeX ⁽⁴⁾	Acquired in-process research and development	-	800	-	3.7%
LifeMap Sciences ⁽⁵⁾	Biomedical, gene, and disease databases and tools	-	1,018	-	4.7%
Total research and development expenses		<u>\$ 17,948</u>	<u>\$ 21,755</u>	<u>100.0%</u>	<u>100.0%</u>

(1) Amount includes research and development expenses incurred directly by the named subsidiary and certain general research and development expenses, such as lab supplies, lab expenses, rent, and insurance allocated to research and development expenses, incurred directly by Lineage on behalf of the subsidiary and allocated to the subsidiary.

(2) "Lineage and subsidiaries" includes Cell Cure, ES Cell International Pte. Ltd. ("ESI"), and OrthoCyte Corporation ("OrthoCyte").

(3) Research and development expenses shown for 2018 are through August 29, 2018, the date prior to the AgeX Deconsolidation.

(4) On March 23, 2018, AgeX purchased certain in-process research and development assets, primarily related to stem cell derived cardiomyocytes (heart muscle cells) to be developed by AgeX, for a total cash consideration of \$800,000. The transaction was considered an asset acquisition rather than a business combination. Accordingly, the \$800,000 was expensed on the acquisition date as acquired in-process research and development as those assets have no alternative future use.

(5) LifeMap Sciences is a subsidiary of AgeX. Research and development expenses shown for the periods presented in 2018 are through August 29, 2018, the date prior to the AgeX Deconsolidation.

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.

The following table shows the amount and percentages of our total general and administrative expenses of \$24.0 million and \$24.7 million incurred and allocated to Lineage and our subsidiaries during the years ended December 31, 2019 and 2018, respectively (amounts in thousands).

Company	Year Ended December 31,			
	Amount ⁽¹⁾		Percent	
	2019	2018	2019	2018
Lineage and subsidiaries other than AgeX ⁽²⁾	\$ 24,031	\$ 21,596	100.0%	87.3%
AgeX including ReCyte ⁽³⁾	-	2,584	-%	10.5%
LifeMap Sciences ⁽⁴⁾	-	546	-%	2.2%
Total general and administrative expenses	\$ 24,031	\$ 24,726	100.0%	100.0%

(1) Amount includes general and administrative expenses incurred directly by the named subsidiary and allocations from Lineage for certain general overhead expenses to the subsidiary.

(2) Lineage and subsidiaries includes Cell Cure, ESI, and OrthoCyte.

(3) General and administrative expenses shown for the periods presented in 2018 are through August 29, 2018, the date prior to the AgeX Deconsolidation.

(4) LifeMap Sciences is a subsidiary of AgeX. General and administrative expenses shown for the periods presented in 2018 are through August 29, 2018, the date prior to the AgeX Deconsolidation.

General and administrative expenses for the year ended December 31, 2019 were \$24.0 million as compared to \$24.7 million for the year ended December 31, 2018. The decrease of \$0.7 million is primarily attributable to: a \$3.1 million decrease in AgeX related general and administrative expenses, a \$1.4 million decrease in salaries, benefits and severance costs due to reductions in headcount, a \$1.1 million reduction in legal and patent expenses and a \$0.7 million reduction in consulting fees, offset by a \$5.6 million increase in severance, legal, accounting and other expenses related to the Asterias Merger.

Other income and expenses, net

The following table shows the amount of other income and expenses, net, during the year ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,	
	2019	2018
Other income/(expenses), net		
Interest income (expense), net	\$ 1,685	\$ 711
Gain on sale of equity method investment in Ascendance	-	3,215
Gain (loss) on equity method investment in OncoCyte at fair value	8,001	(47,985)
Gain (loss) on equity method investment in Asterias at fair value	6,744	(35,449)
Gain on deconsolidation of AgeX	-	78,511
Loss on equity method investment in AgeX at fair value	-	(4,181)
Unrealized (loss) gain on marketable equity securities	(2,898)	1,158
Gain on sale of marketable securities	2,421	-
Gain on sale of equity method investment in OncoCyte	546	-
Unrealized gain on warrant liability	611	-
Other income (expenses), net	2,532	(1,315)
Total other income (expenses), net	\$ 19,642	\$ (5,335)

Interest income and expense, net – During 2019, we earned \$1.7 million of interest income; \$1.5 million earned from our Juvenescence promissory note and \$0.2 million earned from our money market funds. During 2018, we earned \$0.9 million of interest income principally from our Juvenescence promissory note and our money market funds, which was offset by \$0.2 million of interest expense.

Gain on sale of equity method investment in Ascendance – On March 23, 2018, Ascendance Biotechnology, Inc. (“Ascendance”), a company in which AgeX owned a minority stake, was acquired by a third party in a merger through which AgeX received approximately \$3.2 million in cash for its shares of Ascendance common stock. AgeX recognized a \$3.2 million gain as a sale of its equity method investment in Ascendance, which is included in other income and expenses, net, for the year ended December 31, 2018.

Gain (loss) on investment in OncoCyte – Lineage elected to account for its shares of OncoCyte common stock at fair value using the equity method of accounting beginning on February 17, 2017, the date of the OncoCyte Deconsolidation, through September 11, 2019. Lineage sold 2.25 million shares of OncoCyte common stock for net proceeds of \$4.2 million in July 2019. Accordingly, Lineage’s ownership in OncoCyte was reduced from 28% to 24%. Lineage sold an additional 4.0 million shares of OncoCyte common stock for net proceeds of \$6.5 million on September 11, 2019. Lineage’s ownership in OncoCyte was further reduced to 16% at this time. Effective September 11, 2019, Lineage began accounting for its shares of OncoCyte common stock as marketable equity securities.

As of December 31, 2019, Lineage had 8.4 million shares of OncoCyte common stock. These shares had a fair value of \$19.0 million, based on the closing price of OncoCyte of \$2.25 per share on December 31, 2019. As of December 31, 2018, Lineage had 14.7 million shares of OncoCyte common stock. These shares had a fair value of \$20.3 million, based on the closing price of OncoCyte of \$1.38 per share on December 31, 2018. For the year ended December 31, 2019, Lineage recorded a realized gain of \$0.5 million due to sales of OncoCyte shares in the period. Lineage also recorded an unrealized gain of \$8.8 million due to the increase in OncoCyte’s stock price from \$1.38 per share at December 31, 2018 to \$2.25 per share at December 31, 2019; \$8.0 million of the unrealized gain was recorded as an unrealized gain on an equity method investment as it was prior to September 11, 2019; and \$0.8 million was recorded as an unrealized gain on marketable equity securities.

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 consolidated statements of operations for each period.

Gain (loss) on equity method investment in Asterias shares – Prior to the closing of the Asterias Merger on March 8, 2019, where we acquired 100% of its outstanding shares, we owned 21.7 million shares of common stock of Asterias. We elected to account for our shares in Asterias at fair value using the equity method of accounting beginning on May 13, 2016, the date of the Asterias Deconsolidation. The fair value of our Asterias shares was approximately \$20.2 million as of March 8, 2019, the closing date of the Asterias Merger, based on \$0.93 per share, which was calculated by multiplying (a) \$1.31, the closing price of our common shares on such date by (b) the merger exchange ratio of 0.71. The fair value of our Asterias shares was approximately \$13.5 million as of December 31, 2018, based on the closing price of Asterias common stock of \$0.62 per share on such date. Accordingly, we recorded an unrealized gain of \$6.7 million for the year ended December 31, 2019, representing the change in fair value of Asterias common stock from December 31, 2018 to March 8, 2019.

Our Asterias shares had a fair value of \$13.5 million and \$48.9 million as of December 31, 2018, and December 31, 2017, respectively, based on the closing price of Asterias common stock on the NYSE American of \$0.62 per share, and \$2.25 per share, respectively, on those dates or the last trading day of the quarter. Accordingly, we recorded an unrealized loss of \$35.4 million for the year ended December 31, 2018.

Marketable equity securities – We also account for the shares we hold in Hadasit Bio-Holdings (“HBL”) and AgeX as marketable equity securities, carried at fair market value on our consolidated balance sheets. Beginning on January 1, 2018, in accordance with our adoption of ASU 2016-01, all gains and losses we generate each period due to changes in fair market value, including changes in foreign currency exchange rates, from these securities are included in other income and expenses, net, in our consolidated statements of operations. For the year ended December 31, 2019, Lineage recorded a realized gain of \$2.4 million due to sales of HBL and AgeX shares in the period. For the year ended December 31, 2019, we recorded an unrealized loss of \$3.7 million due to changes in fair market value of these marketable equity securities from December 31, 2018 to December 31, 2019.

For the year ended December 31, 2018, we recorded an unrealized gain of \$0.7 million due to the increase in fair market value of the HBL marketable equity securities from January 1, 2018 to December 31, 2018. For the year ended December 31, 2018, we recorded an unrealized gain of \$0.5 million due to the increase in fair market value of the AgeX marketable equity securities from November 28, 2018 to December 31, 2018.

Gain on deconsolidation of AgeX – On August 30, 2018, we sold 14.4 million shares of our AgeX common stock to Juvenescence Limited for \$3.00 per share, or aggregate consideration of \$43.2 million. Upon completion of the sale, our percentage ownership in AgeX decreased from 80.4% to 40.2% and Juvenescence’s percentage ownership in AgeX increased from 5.6% to 45.8%. As a result, on August 30, 2018, we experienced a loss of control of AgeX in accordance with GAAP and deconsolidated AgeX’s consolidated financial statements and consolidated results from ours. In connection with this transaction, we recorded a gain on deconsolidation of \$78.5 million, which includes a gain on the sale of the AgeX shares of \$39.2 million, during the year ended December 31, 2018, included in other income and expenses, net.

Other income and expenses, net – Other income and expenses, net, in 2019 and 2018 consist primarily of net foreign currency transaction gains and losses recognized by Cell Cure and ESI, and changes in the fair value of the Cell Cure liability classified warrants. Foreign currency transaction gains and losses 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 deconsolidation of Asterias and OncoCyte financial statements from Lineage were not taxable transactions and did not create a current income tax payment obligation. The market values of the Asterias and OncoCyte shares we hold create a deferred tax liability to us based on the closing market prices of the shares, less our tax basis in the shares. The deferred tax liability generated by the Asterias and OncoCyte shares that we hold is a source of taxable income to us that will more likely than not result in the realization of our deferred tax assets to the extent of those deferred tax liabilities. Because the deferred tax liabilities are determined based on the closing prices of those shares and, 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 liabilities pertaining to Asterias and OncoCyte shares, measured as of the period end being reported, and the related impact to the valuation allowance and deferred tax assets, are recorded in the period in which they occur. The income tax consequences of the AgeX Deconsolidation are discussed below.

On March 23, 2018, Ascendance was acquired by a third party in a merger through which AgeX received approximately \$3.2 million in cash for its shares of Ascendance common stock. For financial reporting purposes, AgeX recognized a \$3.2 million gain as a sale of its equity method investment in Ascendance. The sale was a taxable transaction to AgeX generating a taxable gain of approximately \$2.2 million. We have sufficient net operating losses to offset the entire gain resulting in no income taxes due.

The Juvenescence Transaction was a taxable event for us that resulted in a gross taxable gain of approximately \$29.4 million, which we expect to be fully offset with available net operating losses (“NOL”) and NOL carryforwards, resulting in no net income taxes due. Although the AgeX Deconsolidation on August 30, 2018 was not a taxable transaction to us and did not result in a current tax payment obligation, the financial reporting gain on the AgeX Deconsolidation generated a deferred tax liability, primarily representing the difference between book and tax basis of AgeX common stock on the AgeX Deconsolidation date. We expect this deferred tax liability to be fully offset by a corresponding release of our valuation allowance on deferred tax assets, resulting in no income tax provision or benefit from the AgeX Deconsolidation. The deferred tax liabilities on our investments in OncoCyte and Asterias, combined with the deferred tax liability generated by the fair value of our retained marketable securities in AgeX, are considered to be sources of taxable income that will more likely than not result in the realization of its deferred tax assets to the extent of those deferred tax liabilities, thereby reducing the need for a valuation allowance.

The distribution of AgeX shares of common stock to Lineage shareholders on November 28, 2018 was a taxable event for us that resulted in a gross taxable gain of approximately \$26.4 million, which we expect to be fully offset with available net operating losses, resulting in no income taxes due.

As a result of the Asterias Merger, Lineage wrote off the equity method investment in Asterias, as well as any mark to market adjustments that had been recorded since inception for tax purposes. This write off was fully offset by a corresponding increase to the existing valuation allowance, therefore there was no net impact to tax expense or benefit.

In connection with the Asterias Merger, IPR&D was acquired with an indefinite life. Pursuant to ASC 360-10-45, “naked credits” are deferred tax liabilities that have an indefinite reversal pattern, such as a deferred tax liability that relates to an asset with an indefinite useful life (e.g., land, goodwill, indefinite-lived intangible asset). Naked credits would not ordinarily serve as a source of income for the realization of deferred tax assets with a finite loss carryforward period. In situations when another source of taxable income is not available, a valuation allowance on deferred tax assets is necessary even though an entity may be in an overall net deferred tax liability position. If we can determine the expected timing of the reversal of the temporary difference, it may be appropriate to consider a deferred tax liability as a source of income for the realization of deferred tax assets. The recording of the IPR&D related to the Asterias Merger generated a deferred tax liability with a corresponding entry to goodwill in the amount of \$10.8 million.

A portion of the valuation allowance was released as it relates to Lineage’s indefinite lived assets that can be used against the indefinite lived liabilities. During the year ended December 31, 2019, we released \$7.4 million of the valuation allowance and recorded a tax provision benefit. As new indefinite lived deferred tax assets are generated, we will continue to book a provision benefit until the deferred tax liability position is exhausted, barring any new developments.

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. For federal and state income tax purposes, as a result of the deconsolidation of AgeX, Asterias and OncoCyte and the deferred tax liabilities generated from the fair values of AgeX, Asterias and OncoCyte shares from the respective deconsolidation dates, including the changes to those deferred tax liabilities due to changes in the AgeX, Asterias and OncoCyte stock prices, our deferred tax assets exceeded our deferred tax liabilities as of December 31, 2018. As a result, we established a full valuation allowance as of December 31, 2018 due to the uncertainty of realizing future tax benefits from our net operating loss carryforwards and other deferred tax assets.

For the year ended December 31, 2018, because we experienced a loss from continuing operations but generated other comprehensive income attributable to foreign currency translation adjustments, we allocated income tax expense against the component of foreign currency translation adjustment in 2018 using a 21% tax rate. Income tax benefit related to continuing operations for the year ended December 31, 2018 includes a tax benefit of \$0.3 million due to the required intraperiod tax allocation. Conversely, other comprehensive income attributable to foreign currency translation adjustments for the year ended December 31, 2018 is net of an income tax expense of \$0.3 million.

For state income tax purposes, we established a full valuation allowance on our state deferred tax assets for all periods presented and, accordingly, no state tax provision or benefit was recorded for any period presented.

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, including any changes in the fair value of our AgeX 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.

See Note 3 to our consolidated financial statements included elsewhere in this Report for the Asterias Merger that was completed on March 8, 2019. We have concluded that an ownership change did occur after the Asterias Merger, and the acquired operating loss carryforwards are subject to limitation under Section 382 of the Internal Revenue Service Code; Lineage will only be able to utilize \$52.9 million of these operating loss carryforwards.

Liquidity and Capital Resources

At December 31, 2019, we had \$30.7 million of cash, cash equivalents and marketable equity securities on hand, which includes our investments in HBL, AgeX and OncoCyte. 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.

Since inception, we have incurred significant net losses and have funded our operations primarily through the issuance of equity securities, sale of common stock of a former subsidiary, receipt of research grants, royalties from product sales, license revenues and sales of research products. At December 31, 2019, we had an accumulated deficit of approximately \$273.4 million, working capital of \$51.0 million and shareholders' equity of \$111.2 million. We evaluated the projected cash flows for Lineage and our subsidiaries, and we believe that our \$30.7 million in cash, cash equivalents and marketable equity securities at December 31, 2019, 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. If we need near term working capital or liquidity to supplement our cash and cash equivalents for our operations, we may sell some, or all, of our investments, as necessary.

On March 8, 2019, the Asterias Merger closed and Asterias became our wholly owned subsidiary. We began consolidating Asterias' operations and results with our operations and results beginning on March 8, 2019. As we integrate Asterias' operations into our own, we have made extensive reductions in headcount and reduced non-clinical related spend, in each case, as compared to Asterias' operations before the merger. We have implemented significant cost savings initiatives and anticipate reduced operational spend in 2020 compared to prior periods.

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. 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. In addition, we have incurred and expect to continue incurring significant costs in connection with the acquisition of Asterias and with integrating its operations. We may incur additional costs to maintain employee morale and to retain key employees. 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 \$31.9 million for the year ended December 31, 2019 primarily reflects the loss from operations of \$38.9 million adjusted for the changes in assets and liabilities of \$2.1 million. These items were offset primarily by non-cash expenses of \$3.6 million for stock-based compensation and \$3.1 million of depreciation and amortization. The unrealized gains on equity method investments and marketable securities and deferred tax benefit are non-cash items that had no effect on cash flows.

Net cash used in operating activities of \$30.9 million for the year ended December 31, 2018 primarily reflects the loss from operations of \$41.8 million adjusted for the changes in assets and liabilities of \$0.6 million. These items were offset primarily by non-cash expenses of \$5.4 million for stock-based compensation and \$3.3 million of depreciation and amortization. The unrealized gains on equity method investments and marketable securities and deferred tax benefit are non-cash items that had no effect on cash flows. The unrealized gains and losses on equity method investments and marketable securities and gain on AgeX Deconsolidation are non-cash items that had no effect on cash flows.

Cash used in investing activities

Cash provided by investing activities of \$17.0 million for the year ended December 31, 2019 was associated primarily with receipts of \$10.7 million from sales of a portion of our OncoCyte holdings, \$1.7 million in sales of a portion of our AgeX holdings and \$1.7 million in sales of a portion of our HBL holdings as well as the receipt of \$3.1 million of cash that Asterias had on the closing date of the Asterias Merger, offset by \$0.4 million in purchases of equipment and other assets.

Cash provided by investing activities of \$11.8 million for the year ended December 31, 2018 was associated primarily with proceeds of \$21.6 million related to the sale of our AgeX shares to Juvenescence and \$3.2 million related to the sale of the equity method investment in Ascendance, offset by a \$9.7 million deconsolidation of AgeX's cash and cash equivalents as part of the AgeX Deconsolidation, \$1.9 million for the purchase of in-process research and development and \$1.4 million in purchases of equipment and other assets.

Cash provided by financing activities

Cash provided by financing activities of \$0.6 million for the year ended December 31, 2019 was associated primarily with \$0.8 million in landlord reimbursements for tenant improvements, offset by \$0.1 million in common shares received and retired for employee taxes paid.

Cash provided by financing activities of \$5.8 million for the year ended December 31, 2018 was associated primarily with \$5.0 million in proceeds from the sale of subsidiary stock and \$1.0 million in proceeds from the sale of subsidiary warrants, offset by \$0.2 million for repayment of lease liabilities.

Off-Balance Sheet Arrangements

As of December 31, 2019, we did not have any off-balance sheet arrangements, as defined under the rules of the SEC.

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

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See accompanying notes to consolidated financial statements.

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 sheets of Lineage Cell Therapeutics, Inc. and Subsidiaries (collectively, the “Company”) as of December 31, 2019 and 2018, and the related consolidated statements of operations, comprehensive income (loss), changes in shareholders’ equity, and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) and our report dated March 12, 2020 expressed an unqualified opinion thereon.

Change in Accounting Principle

As discussed in Note 2 to the accompanying financial statements, the Company has changed their method of accounting for revenue in 2018 due to the adoption of Financial Accounting Standards Board (United States) Accounting Standard Codification Topic No. 606, *Revenue from Contracts with Customers*.

Basis for Opinion

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

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

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

/s/ OUM & CO. LLP

San Francisco, California
March 12, 2020

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

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on Internal Control over Financial Reporting

We have audited Lineage Cell Therapeutics, Inc. and Subsidiaries' (the "Company's") internal control over financial reporting as of December 31, 2019, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the "COSO criteria"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive income (loss), changes in shareholders' equity, and cash flows for each of the two years in the period ended December 31, 2019, and the related notes and our report dated March 12, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, *Management's Report on Internal Control over Financial Reporting*. Our responsibility is to express an opinion on the Company's internal control over financial reporting 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 U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit of internal control over financial reporting in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's 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. Also, 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.

/s/ OUM & CO. LLP

San Francisco, California
March 12, 2020

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

	December 31, 2019 (Notes 1 and 3)	December 31, 2018 (Notes 1 and 6)
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 9,497	\$ 23,587
Marketable equity securities	21,219	7,154
Promissory note from Juvenescence (Note 5)	23,616	-
Trade accounts and grants receivable, net	317	767
Landlord receivable	-	840
Receivables from affiliates, net	7	2,112
Prepaid expenses and other current assets	2,863	1,898
Total current assets	57,519	36,358
NONCURRENT ASSETS		
Property and equipment, net (Notes 7 and 14)	8,175	5,835
Deposits and other long-term assets	864	505
Promissory note from Juvenescence (Note 5)	-	22,104
Equity method investment in OncoCyte, at fair value (Note 4)	-	20,250
Equity method investment in Asterias, at fair value (Note 3)	-	13,483
Goodwill	10,672	-
Intangible assets, net	48,248	3,125
TOTAL ASSETS	\$ 125,478	\$ 101,660
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	\$ 5,226	\$ 6,463
Financing lease and right-of-use liabilities, current portion (Note 14)	1,223	237
Promissory notes, current portion	-	70
Deferred grant revenue	45	42
Total current liabilities	6,494	6,812
LONG-TERM LIABILITIES		
Deferred tax liability	3,315	-
Deferred rent liabilities, net of current portion	-	244
Deferred revenues	200	-
Right-of-use lease liability, net of current portion (Note 14)	3,868	1,854
Financing lease, net of current portion	77	104
Liability classified warrants and other long-term liabilities	277	400
TOTAL LIABILITIES	14,231	9,414
Commitments and contingencies (Note 14)		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, authorized 2,000 shares; none issued and outstanding as of December 31, 2019 and 2018, respectively	-	-
Common shares, no par value, authorized 250,000 shares; 149,804 and 127,136 shares issued and outstanding as of December 31, 2019 and 2018, respectively	387,062	354,270
Accumulated other comprehensive income (loss)	(681)	1,426
Accumulated deficit	(273,422)	(261,856)
Lineage Cell Therapeutics, Inc. shareholders' equity	112,959	93,840
Noncontrolling interest (deficit)	(1,712)	(1,594)
Total shareholders' equity	111,247	92,246
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 125,478	\$ 101,660

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,	
	2019	2018
REVENUES:		
Grant revenue	\$ 2,037	\$ 3,572
Royalties from product sales and license fees	1,221	392
Subscription and advertisement revenues	-	691
Sale of research products and services	257	333
Total revenues	<u>3,515</u>	<u>4,988</u>
Cost of sales	<u>(412)</u>	<u>(302)</u>
Gross profit	<u>3,103</u>	<u>4,686</u>
OPERATING EXPENSES:		
Research and development	17,948	20,955
Acquired in-process research and development	-	800
General and administrative	24,031	24,726
Total operating expenses	<u>41,979</u>	<u>46,481</u>
Loss from operations	<u>(38,876)</u>	<u>(41,795)</u>
OTHER INCOME/(EXPENSES):		
Interest income (expense), net	1,685	711
Gain on sale of marketable securities	2,421	-
Gain on sale of equity method investment in OncoCyte	546	-
Gain on sale of equity method investment in Ascendance	-	3,215
Gain on sale of AgeX shares and deconsolidation of AgeX	-	78,511
Unrealized (loss) gain on marketable equity securities	(2,898)	1,158
Unrealized gain (loss) on equity method investment in OncoCyte at fair value	8,001	(47,985)
Unrealized gain (loss) on equity method investment in Asterias at fair value	6,744	(35,449)
Loss on equity method investment in AgeX at fair value	-	(4,181)
Unrealized gain on warrant liability	611	384
Other income/(expense), net	2,532	(1,699)
Total other income (expenses), net	<u>19,642</u>	<u>(5,335)</u>
LOSS BEFORE INCOME TAXES	<u>(19,234)</u>	<u>(47,130)</u>
Income tax benefit	7,407	346
NET LOSS	<u>(11,827)</u>	<u>(46,784)</u>
Net loss attributable to noncontrolling interest	<u>118</u>	<u>794</u>
NET LOSS ATTRIBUTABLE TO LINEAGE	<u>\$ (11,709)</u>	<u>\$ (45,990)</u>
NET LOSS PER COMMON SHARE:		
BASIC AND DILUTED	<u>\$ (0.08)</u>	<u>\$ (0.36)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:		
BASIC AND DILUTED	<u>145,533</u>	<u>126,903</u>

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,	
	2019	2018
NET LOSS	\$ (11,827)	\$ (46,784)
Other comprehensive income (loss), net of tax:		
Foreign currency translation adjustments, net of tax	(2,107)	1,303
COMPREHENSIVE LOSS	(13,934)	(45,481)
Less: comprehensive loss attributable to noncontrolling interest	118	794
COMPREHENSIVE LOSS ATTRIBUTABLE TO LINEAGE COMMON SHAREHOLDERS	\$ (13,816)	\$ (44,687)

See accompanying notes to the consolidated financial statements.

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

	<u>Preferred Shares</u>		<u>Common Shares</u>		<u>Treasury Shares</u>		<u>Accumulated</u>	<u>Noncontrolling</u>	<u>Accumulated</u>	<u>Other</u>	<u>Total</u>
	<u>Number</u>	<u>Amount</u>	<u>Number</u>	<u>Amount</u>	<u>Number</u>	<u>Amount</u>					
	<u>of</u>		<u>of</u>		<u>of</u>				<u>Income/(Loss)</u>	<u>Equity</u>	
	<u>Shares</u>		<u>Shares</u>		<u>Shares</u>						
BALANCE AT											
DECEMBER 31, 2017	-	\$ -	126,866	\$ 378,487	-	\$ -	\$ (216,297)	\$ 1,622	\$ 451	\$ 164,263	
Cumulative-effect adjustment for adoption of ASU 2016-01 on January 1, 2018	-	-	-	-	-	-	328	-	(328)	-	
Cumulative-effect adjustment for adoption of Accounting Standard Codification, Topic 606, on January 1, 2018	-	-	-	-	-	-	103	-	-	103	
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	270	(203)	-	-	-	-	-	(203)	
Stock-based compensation	-	-	-	4,912	-	-	-	-	-	4,912	
Stock-based compensation in subsidiaries	-	-	-	-	-	-	-	490	-	490	
Sale of subsidiary shares in AgeX	-	-	-	-	-	-	-	5,239	-	5,239	
Sale of subsidiary warrants in AgeX	-	-	-	-	-	-	-	1,000	-	1,000	
Deconsolidation of AgeX	-	-	-	(163)	-	-	-	(3,467)	-	(3,630)	
Distribution of AgeX shares to Lineage shareholders, on a pro rata basis, at fair value as a dividend-in-kind	-	-	-	(34,409)	-	-	-	-	-	(34,409)	
Subsidiary financing transactions with noncontrolling interests – AgeX	-	-	-	3,790	-	-	-	(3,790)	-	-	
Foreign currency translation adjustments	-	-	-	-	-	-	-	-	1,303	1,303	
Subsidiary financing and other transactions with noncontrolling interests – Cell Cure	-	-	-	1,894	-	-	-	(1,894)	-	-	
Purchase of noncontrolling interests in Cell Cure	-	-	-	(38)	-	-	-	-	-	(38)	
NET LOSS	-	-	-	-	-	-	(45,990)	(794)	-	(46,784)	
BALANCE AT											
DECEMBER 31, 2018	-	\$ -	127,136	\$ 354,270	-	\$ -	\$ (261,856)	\$ (1,594)	\$ 1,426	\$ 92,246	
Shares issued in connection with the Asterias Merger	-	-	24,696	32,352	-	-	-	-	-	32,352	
Shares retired in connection with the Asterias Merger	-	-	(2,622)	(3,435)	-	-	-	-	-	(3,435)	
Shares issued for settlement of Lineage Warrants	-	-	252	302	-	-	-	-	-	302	
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	189	(110)	-	-	-	-	-	(110)	
Stock-based compensation	-	-	-	3,501	-	-	-	-	-	3,501	
Stock-based compensation for shares issued upon vesting of Asterias restricted stock units attributable to post combination services	-	-	60	79	-	-	-	-	-	79	
Shares issued through ATM	-	-	93	103	-	-	-	-	-	103	

Adjustment upon adoption of leasing standard	-	-	-	-	-	-	143	-	-	143
Foreign currency translation loss	-	-	-	-	-	-	-	-	(2,107)	(2,107)
NET LOSS	-	-	-	-	-	-	(11,709)	(118)	-	(11,827)
BALANCE AT DECEMBER 31, 2019	-	\$ -	149,804	\$ 387,062	-	\$ -	\$ (273,422)	\$ (1,712)	\$ (681)	\$ 111,247

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,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage	\$ (11,709)	\$ (45,990)
Net loss attributable to noncontrolling interest	(118)	(794)
Adjustments to reconcile net loss attributable to Lineage to net cash used in operating activities:		
Unrealized (gain) loss on equity method investment in OncoCyte at fair value	(8,001)	47,985
Unrealized (gain) loss on equity method investment in Asterias at fair value	(6,744)	35,449
Gain on sale of investments in OncoCyte, AgeX and Hadasit	(2,967)	-
Gain on sale of AgeX shares and deconsolidation of AgeX	-	(78,511)
Gain on sale of equity method investment in Ascendance	-	(3,215)
Acquired in-process research and development	-	800
Unrealized loss on equity method investment in AgeX at fair value	-	4,181
Unrealized (gain) loss on marketable equity securities	2,898	(1,158)
Income tax benefit	(7,407)	(346)
Depreciation expense, including amortization of leasehold improvements	1,002	1,081
Amortization of right-of-use assets	129	-
Amortization of intangible assets	1,998	2,192
Stock-based compensation	3,580	5,402
Change in unrealized gain on warrant liability	(611)	(384)
Foreign currency remeasurement and other (gain) loss	(2,367)	1,683
(Gain) loss on sale of assets	273	105
Dividend received	182	-
Changes in operating assets and liabilities:		
Accounts and grants receivable, net	467	46
Accrued interest receivable	(1,512)	(504)
Receivables from affiliates, net of payables	2,105	559
Prepaid expenses and other current assets	(260)	(437)
Other long-term assets and liabilities	-	17
Accounts payable and accrued liabilities	(2,885)	1,100
Deferred revenue and other liabilities	-	(143)
Net cash used in operating activities	<u>(31,947)</u>	<u>(30,882)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of OncoCyte common shares	10,738	-
Proceeds from the sale of AgeX common shares	1,734	-
Proceeds from the sale of Hadasit common shares	1,743	-
Cash and cash equivalents acquired in the Asterias Merger	3,117	-
Purchase of property and equipment	(440)	(556)
Proceeds from sale of assets	82	-
Deconsolidation of cash and cash equivalents of AgeX	-	(9,704)
Proceeds from the sale of AgeX common stock to Juvenescence	-	21,600
Proceeds from the sale of equity method investment in Ascendance	-	3,215
Purchase of in-process research and development by AgeX	-	(1,872)
Payments on construction in progress	-	(859)
Security deposit paid and other	(17)	(8)
Net cash provided by investing activities	<u>16,957</u>	<u>11,816</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Common shares received and retired for employee taxes paid	(110)	(203)
Proceeds from sale of subsidiary common shares	-	5,000
Proceeds from sale of subsidiary warrants	(40)	1,000
Net proceeds from sale of common shares	103	-
Repayment of financing lease liabilities	(30)	(248)
Reimbursement from landlord on tenant improvements	764	364
Repayment of principal portion of promissory notes	(70)	(101)
Payment to repurchase subsidiary shares	-	(38)
Net cash provided by financing activities	<u>617</u>	<u>5,774</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	<u>70</u>	<u>6</u>
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(14,303)	(13,286)
At beginning of year	24,399	37,685
At end of year	<u>\$ 10,096</u>	<u>\$ 24,399</u>
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid during year for interest	\$ 28	\$ 155

SUPPLEMENTAL SCHEDULE OF NON-CASH FINANCING AND INVESTING ACTIVITIES:

Issuance of common shares for the Asterias Merger (Note 3)	\$	32,353	\$	-
Assumption of liabilities in the Asterias Merger		982		-
Assumption of warrants in the Asterias Merger		867		-
Issuance of common shares for settlement of Lineage Warrants		332		-
Sale of AgeX common stock in exchange for a promissory note from Juvenescence		-		21,600
Distribution of AgeX common stock to Lineage shareholders, on a pro rata basis, as a dividend-in-kind, at fair value		-		34,409
Landlord receivable and lease liability		-		840
Construction in progress in accounts payable and accrued expenses		-		455

See accompanying notes to the consolidated financial statements.

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

1. Organization, Basis of Presentation and Liquidity

General – Lineage Cell Therapeutics, Inc. (“Lineage”) is a clinical-stage biotechnology company developing novel cell therapies for unmet medical needs. Lineage’s focus is to develop therapies for degenerative retinal diseases, neurological conditions associated with demyelination, and aiding the body in detecting and combating cancer. Lineage’s programs are based on its proprietary cell-based therapy platform and associated development and manufacturing capabilities. From this platform Lineage develops and manufactures specialized, terminally differentiated human cells from its pluripotent and progenitor cell starting materials. These differentiated cells are developed either to 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 an effective immune response to cancer.

Lineage has three allogeneic, or “off-the-shelf,” cell therapy programs in clinical development:

- *OpRegen*[®], a retinal pigment epithelium 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. There currently are no therapies approved by the U.S. Food and Drug Administration for dry AMD, which accounts for approximately 85-90% of all AMD cases and is the leading cause of blindness in people over the age of 60.
- *OPC1*, an oligodendrocyte progenitor cell therapy currently in a Phase 1/2a multicenter clinical trial for acute spinal cord injuries (“SCI”). This clinical trial has been partially funded by the California Institute for Regenerative Medicine (“CIRM”).
- *VAC2*, a cancer immunotherapy of antigen-presenting dendritic cells currently in a Phase 1 clinical trial in non-small cell lung cancer. This clinical trial is being funded and conducted by Cancer Research UK (“CRUK”), the world’s largest independent cancer research charity.

Lineage is also currently working to identify a commercialization partner for *Renevia*[®], its proprietary three-dimensional scaffold designed to support adipose tissue transplants that was granted a Conformité Européenne (“CE”) Mark in September 2019.

Asterias Merger

On November 7, 2018, Lineage, 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. Lineage also assumed warrants to purchase shares of Asterias common stock.

The Asterias Merger has been 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.

See Note 3 for a full discussion of the Asterias Merger.

Investment in OncoCyte

Lineage has significant equity holdings in OncoCyte Corporation (“OncoCyte”), a publicly traded company, which Lineage founded and, in the past, was a majority-owned consolidated subsidiary until February 17, 2017, when Lineage deconsolidated OncoCyte’s financial statements (the “OncoCyte Deconsolidation”). OncoCyte (NYSE American: OCX) is developing confirmatory diagnostic tests for lung cancer utilizing novel liquid biopsy technology. As of December 31, 2019, Lineage owned 8.4 million shares of OncoCyte common stock, or 16% of its outstanding shares (see Note 4). In January 2020, Lineage sold 2,383,090 shares of OncoCyte common stock for net proceeds of \$5.0 million and subsequently owns less than 10% of its outstanding shares (see Note 18).

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, 2019.

Subsidiary	Field of Business	Lineage Ownership	Country
Cell Cure Neurosciences Ltd (“Cell Cure”)	Development and manufacturing of Lineage’s cell replacement platform technology	99% ⁽¹⁾	Israel
ES Cell International Pte. Ltd. (“ESI”)	Stem cell products for research, including clinical grade cell lines produced under cGMP	100%	Singapore
OrthoCyte Corporation (“OrthoCyte”)	Developing bone grafting products for orthopedic diseases and injuries	99.8%	USA

(1) Includes shares owned by Lineage and ESI

All material intercompany accounts and transactions have been eliminated in consolidation. As of December 31, 2019, 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

Since inception, Lineage has incurred significant operating losses and 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 (“HBL”), receipt of research grants, royalties from product sales, license revenues, sales of research products and issuance of equity securities. At December 31, 2019, Lineage had an accumulated deficit of approximately \$273.4 million, working capital of \$51.0 million and shareholders’ equity of \$111.2 million. Lineage has evaluated its projected cash flows and believes that its \$30.7 million of cash, cash equivalents and marketable equity securities, including its positions in OncoCyte, AgeX and HBL, at December 31, 2019, provide sufficient cash, cash equivalents, and liquidity to carry out Lineage’s current planned operations through at least 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.

If the promissory note issued by Juvenescence in favor of Lineage discussed in Note 5 is converted into equity securities of Juvenescence prior to its maturity date, the Juvenescence equity securities may be marketable securities that Lineage may use to supplement its liquidity, as needed. If such promissory note is not converted, it is payable in cash, plus accrued interest, at maturity on August 30, 2020.

On March 8, 2019, with the consummation of the Asterias Merger, Asterias became Lineage’s wholly owned subsidiary. Lineage began consolidating Asterias’ operations and results with its operations and results beginning on March 8, 2019 (see Note 3). As Lineage integrates Asterias’ operations into its own, Lineage has made extensive reductions in headcount and reduced non-clinical related spend, in each case, as compared to Asterias’ operations before the Asterias Merger.

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 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. In addition, Lineage has incurred and expects to continue incurring significant costs in connection with the acquisition of Asterias and with integrating its operations. Lineage may incur additional costs to maintain employee morale and to retain key employees. 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

Business Combinations – Lineage accounts for business combinations, such as the Asterias Merger completed in March 2019, in accordance with Accounting Standards Codification (“ASC”) Topic 805, *Business Combinations*, which requires the purchase price to be measured at fair value. When the purchase consideration consists entirely of our common shares, Lineage calculates the purchase price by determining the fair value, as of the acquisition date, of shares issued in connection with the closing of the acquisition. Lineage recognizes estimated fair values of the tangible assets and intangible assets acquired, including in-process research and development (“IPR&D”), and liabilities assumed as of the acquisition date, and records as goodwill any amount of the fair value of the tangible and intangible assets acquired and liabilities assumed in excess of the purchase price.

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 not amortized but is tested for impairment at least annually, or more frequently if circumstances indicate potential impairment. 35 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 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 Lineage becomes aware of an event or a change in circumstances that would indicate the asset may be impaired.

Leases – Lineage accounts for leases in accordance with ASC 842, *Leases*. Lineage determines 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, Lineage accounts for the lease and non-lease components as a single lease component. Lineage recognizes right-of-use (“ROU”) assets and lease liabilities for leases with terms greater than twelve months in the consolidated balance sheet. ROU assets represent the right to use an underlying asset during the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most leases do not provide an implicit rate, Lineage uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. Lineage uses the implicit rate when readily determinable. The operating lease ROU asset also includes any lease payments made and excludes lease incentives. 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 lease payments is recognized on a straight-line basis over the lease term. Operating 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. Financing leases are included in property and equipment, and in financing 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.

In connection with the adoption on ASC 842 on January 1, 2019, Lineage derecognized net book value of leasehold improvements and corresponding lease liabilities of \$1.9 million and \$2.0 million, respectively, which was the carrying value of certain operating leases as of December 31, 2018, included in property and equipment and lease liabilities, respectively, recorded pursuant to build to suit lease accounting under the previous ASC 840 lease standard. The derecognition of these amounts from the superseded ASC 840 lease standard was offset by a cumulative effect adjustment of \$0.1 million as a reduction of Lineage's accumulated deficit on January 1, 2019. These build to suit leases were primarily related to the Alameda and the Cell Cure Leases described in Note 14. ASC 842 requires build to suit leases recognized on Lineage's consolidated balance sheets as of December 31, 2018 to be derecognized upon the adoption of the new lease standard and be recognized in accordance with the new standard on January 1, 2019.

The adoption of ASC 842 had a material impact in Lineage's consolidated balance sheets, with the most significant impact resulting from the recognition of ROU assets and lease liabilities for operating leases with remaining terms greater than twelve months on the adoption date (see Note 14). Lineage's accounting for financing leases (previously referred to as “capital leases”) remained substantially unchanged.

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, 2019 and 2018, Lineage had \$6.6 million and \$20.4 million in money market funds, respectively, considered to be cash equivalents.

Restricted cash – Lineage has several certificates of deposit as required under our facility leases and credit card program. Lineage is restricted from using this cash for working capital purposes. At December 31, 2019, Lineage maintains \$421,000 pursuant to the Cell Cure Leases, \$100,000 pursuant to its credit card program and \$78,000 pursuant to the Alameda Lease in deposits and other long-term assets.

Trade accounts and grants receivable, net – Net trade receivables amounted to \$44,000 and \$51,000 and grants receivable amounted to \$273,000 and \$716,000 as of December 31, 2019 and 2018, respectively. Net trade receivables include an allowance for doubtful accounts of approximately \$119,000 and \$100,000 as of December 31, 2019 and 2018, 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 customer’s operating results or financial position, and historical experience. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted.

Financing receivable from Juvenescence – Lineage accounts for the Promissory Note from Juvenescence as a financing receivable under ASC 310-10, *Receivables*, since it both represents a contractual right to receive cash on a fixed date at maturity and is recognized as an asset on Lineage’s consolidated balance sheet. Under ASC 310-10, the Promissory Note was issued at fair value on the Juvenescence Transaction date and subsequently carried at amortized cost with accrued interest, subject to impairment testing under ASC 310. Interest is accrued monthly under the provisions of the Promissory Note and all accrued interest, along with the principal of the Promissory Note, is payable at maturity two years after the closing of the Juvenescence Transaction (August 30, 2020), unless converted prior to that date (see Note 5). Lineage considers the need for an allowance for doubtful accounts based on the evaluation of the collectability of the Promissory Note and accrued interest on a variety of factors, as applicable, including significant events that may impair Juvenescence’s ability to pay, such as a bankruptcy filing or deterioration in Juvenescence’s operating results or financial position, the length of time receivable is past due and historical experience. Lineage has the right to review Juvenescence’s financial statements twice per year.

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.

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 (unadjusted) for identical assets or liabilities in active markets.
- Level 2 – Inputs to the valuation methodology include quoted prices for similar assets or liabilities in active markets, and inputs that are observable for the assets or liability, either directly or indirectly, for substantially the full term of the financial instruments.
- 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.

In determining fair value, Lineage utilizes valuation techniques that maximize 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. For the periods presented, Lineage has no financial assets or liabilities recorded at fair value on a recurring basis, except for cash and cash equivalents consisting of money market funds and the marketable equity securities in OncoCyte, AgeX and HBL, which are carried at fair value based on the applicable period-end quoted market prices as a Level 1 input. Lineage also has certain liability classified warrants issued by Cell Cure and assumed from the Asterias Merger, which are carried at fair value based on Level 3 inputs (see Note 11).

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.

Marketable equity securities – Lineage accounts for the shares it holds in OncoCyte, AgeX 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. The OncoCyte and AgeX shares have readily determinable fair values quoted on the NYSE American under trading symbols “OCX” and “AGE”. The HBL shares have a readily determinable fair value quoted on the Tel Aviv Stock Exchange (“TASE”) under trading symbol “HDST” where share prices are denominated in New Israeli Shekels (NIS). 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.

Prior to September 11, 2019, Lineage accounted for its OncoCyte shares held at fair value, using the equity method of accounting. On September 11, 2019, Lineage’s ownership percentage decreased from 24% to 16% when it sold 4.0 million shares of OncoCyte common stock. Accordingly, as the ownership percentage is less than 20%, Lineage is no longer considered to exercise significant influence over OncoCyte and is now accounting for its OncoCyte holdings as marketable equity securities. Prior to the Asterias Merger completed on March 8, 2019 discussed in Note 3, Lineage accounted for its Asterias shares held at fair value, using the equity method of accounting.

Property and equipment, net and construction in progress – 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. Construction in progress is not depreciated until the underlying asset is placed into service (see Note 7).

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, 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. In 2017, Cell Cure issued certain liability classified warrants (see Note 11) and in 2019, Lineage assumed certain warrants in connection with the closing of the Asterias Merger (see Note 3).

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 – 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 are 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.

General and administrative – 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, 2019 and 2018, comprehensive income (loss) includes foreign currency translation adjustments, net of tax, of (\$2.1) million and \$1.3 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 (see Notes 10 and 11), which are U.S. dollar-denominated, while Cell Cure’s functional currency is the Israeli New Shekel (“NIS”). 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, 2019 and 2018.

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. Changes to taxes on corporations affected by the 2017 Tax Act include, among others, lowering the U.S. federal tax rates to a 21% flat tax rate, elimination of the corporate alternative minimum tax, imposing additional limitations on the deductibility of interest and net operating losses, allowing any net operating loss generated in tax years ending after December 31, 2017 to be carried forward indefinitely and generally repealing carrybacks, reducing the maximum deduction for NOL carryforwards arising in tax years beginning after 2017 to a percentage of the taxpayer’s taxable income, and allowing for the expensing of certain capital expenditures. The 2017 Tax Act also puts into effect a number of changes impacting operations outside of the United States including, but not limited to, the imposition of a one-time tax “deemed repatriation” on accumulated offshore earnings not previously subject to U.S. tax, and shifts the U.S. taxation of multinational corporations from a worldwide system of taxation to a territorial system. ASC 740 requires the effects of changes in tax rates and laws on deferred tax balances (including the effects of the one-time transition tax) to be recognized in the period in which the legislation is enacted (see Note 13).

Beginning in 2018, the 2017 Tax Act subjects a U.S. shareholder 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 by the Company's pre-GILTI U.S. income. For the years ended December 31, 2018 and 2019, Lineage incurred a net loss from foreign activity, accordingly there was no GILTI inclusion in U.S. income for 2018 and 2019. Based on current interpretations under ASC 740, 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 only. Lineage has elected to account for GILTI as a current period expense when incurred.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to provide guidance for companies that are not able to complete their accounting for the income tax effects of the 2017 Tax Act in the period of enactment. SAB 118 allows Lineage to record provisional amounts during a measurement period not to extend beyond one year of the enactment date (see Note 13). Lineage applied the guidance in SAB 118 when accounting for the enactment-date effects of the 2017 Tax Act during the years ended December 31, 2018 and 2017. As of December 31, 2018, Lineage completed its accounting for all the enactment-date income tax effects of the 2017 Tax Act.

Income tax benefit or expense for each year is allocated to continuing operations, other comprehensive income and the cumulative effects of accounting changes, if any, recorded directly to shareholders' equity. ASC 740-20-45 *Income Taxes, Intraproduct Tax Allocation, Other Presentation Matters* includes an exception to the general principle of intraperiod tax allocations. The codification source states that the tax effect of pretax income or loss from continuing operations generally should be determined by a computation that considers only the tax effects of items that are included in continuing operations. The exception to that incremental approach is that all items, including items of other comprehensive income, be considered in determining the amount of tax benefit that results from a loss from continuing operations, and that benefit should be allocated to continuing operations. That is, when a company has a current period loss from continuing operations, management must consider income recorded in other categories in determining the tax benefit that is allocated to continuing operations. This includes situations in which a company has recorded a full valuation allowance at the beginning and end of the period, and the overall tax provision for the year is zero. The intraperiod tax allocation is performed once the overall tax provision has been computed and allocates that provision to continuing operations and other comprehensive income and balance sheet captions. While the intraperiod tax allocation does not change the overall tax provision, it results in a gross-up of the individual components. Additionally, different tax jurisdictions must be considered separately. For the year ended December 31, 2019, Lineage's other comprehensive income is comprised entirely of foreign currency translation adjustments primarily attributable to its majority-owned and consolidated Israeli subsidiary, Cell Cure. For the year ended December 31, 2018, Lineage's other comprehensive income or loss items were comprised of foreign currency translation adjustments and available-for-sale securities (see discussion under section *Marketable equity securities* for adoption of ASU 2016-01 on January 1, 2018) (see Note 13).

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. Upon adoption of ASU 2016-09 on January 1, 2017, forfeitures are accounted for as they occur instead of based on the number of awards that were expected to vest prior to adoption of ASU 2016-09. Based on the nature and timing of grants, straight line expense attribution of stock-based compensation for the entire award and the relatively low forfeiture rates on Lineage's experience, the impact of adoption of ASU 2016-09 pertaining to forfeitures was not material to the consolidated financial statements. 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, Lineage's expected stock price volatility over the term of the awards; the expected term of options granted, derived from historical data on employee exercises and post-vesting employment termination behavior; and a risk-free interest rate based on the U.S. Treasury rates in effect during the corresponding period of grant.

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.

Basic and diluted net income (loss) per share attributable to common shareholders – Basic earnings (loss) 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, 2019 and 2018, because Lineage reported a net loss attributable to common shareholders, all potentially dilutive common shares are antidilutive.

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):

	Year Ended December 31,	
	2019	2018
Stock options	15,112	13,867
Warrants	1,001	-
Restricted stock units	250	402

Cash Flows – On January 1, 2018, Lineage adopted Financial Accounting Standards Board (“FASB”) ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, which requires that the statement of cash flows explain the change during the period in the total of cash, cash equivalents and restricted cash, and that restricted cash be included 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 adoption of ASU 2016-18 did not have a material effect on Lineage’s consolidated financial statements. However, prior period restricted cash balances included in prepaid expenses and other current assets, and in deposits and other long-term assets, on the consolidated balance sheets was added to the beginning-of-period and end-of-period total consolidated cash and cash equivalents in the consolidated statements of cash flows to conform to the current presentation shown below.

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 and effected by the adoption of ASU 2016-18 (in thousands):

	December 31,	
	2019	2018
Cash and cash equivalents	\$ 9,497	\$ 23,587
Restricted cash included in prepaid expenses and other current assets (see Note 14)	-	346
Restricted cash included in deposits and other long-term assets (see Note 14)	599	466
Total cash, cash equivalents, and restricted cash as shown in the consolidated statements of cash flows	<u>\$ 10,096</u>	<u>\$ 24,399</u>

On January 1, 2019, Lineage also adopted ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, which addresses eight specific cash flow issues with the objective of reducing diversity in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The adoption of ASU 2016-15 did not have a material effect on Lineage’s consolidated financial statements.

Revenue Recognition – During May 2014, the FASB issued ASU 2014-09 (“Topic 606”), *Revenue from Contracts with Customers* which supersedes the revenue recognition requirements in Topic 605, *Revenue Recognition* (“Topic 605”). Topic 606 describes principles an entity must apply to measure and recognize revenue and the related cash flows, using the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligation(s) in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. Topic 606 core principle is that it requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled to in exchange for those goods or services.

Lineage adopted Topic 606 as of January 1, 2018 using the modified retrospective transition method applied to those contracts which were not completed as of the adoption date. Results for reporting periods beginning on January 1, 2018 and thereafter are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with Lineage’s historic revenue recognition accounting under Topic 605.

On January 1, 2018, the adoption and application of Topic 606 resulted in an immaterial cumulative effect adjustment of Lineage’s beginning consolidated accumulated deficit balance. In the applicable paragraphs below, Lineage has summarized its revenue recognition policies for its various revenue sources in accordance with Topic 606.

Royalties from product sales and license fees – Lineage’s performance obligations in agreements with certain customers is to provide a license to allow customers to make, import and sell company licensed products or methods for preclinical studies and commercial use. Customers pay a combination of a license issue fee paid up front and a sales-based royalty, if any, in some cases with yearly minimums. The transaction price is deemed to be the license issue fee stated in the contract. The license offered by Lineage is a functional license with significant standalone functionality and provides customers with the right to use Lineage’s intellectual property. This allows Lineage to recognize revenue on the license issue fee at a point in time at the beginning of the contract, which is when the customer begins to have use of the license. Variable consideration related to sales-based royalties is recognized only when (or as) the later of one or more of the following events occur: (a) a sale or usage occurs, or (b) the performance obligation to which some, or all, of the sales-based or usage-based royalty that has been allocated and has been satisfied or partially satisfied. Due to the contract termination clauses, Lineage does not expect to receive all of the minimum royalty payments throughout the term of the agreements. Therefore, Lineage fully constrains recognition of the minimum royalty payments as revenues until its customers are obligated to pay, which is generally within 60 days prior to the beginning of each year the minimum royalty payments are due.

Research and development contracts with customers – In its agreements with customers, Lineage’s performance obligations of research and development are completed as services are performed and control passes to the customer, and accordingly revenues are recognized over time. Lineage generally receives a fee at the inception of an agreement, with variable fees, if any, tied to certain milestones, if achieved. Lineage estimates this variable consideration using a single most likely amount. Based on historical experience, there has been no variable consideration related to milestones included in the transaction price due to the significant uncertainty of achieving contract milestones and milestones not being met. If a milestone is met, subsequent changes in the single most likely amount may produce a different variable consideration, and Lineage will allocate any subsequent changes in the transaction price on the same basis as at contract inception. Amounts allocated to a satisfied performance obligation will be recognized as revenue in the period in which the transaction price changes with respect to variable consideration, which could result in a reduction of revenue. Contracts of this kind are typically for a term greater than one year.

Sale of research products and services – Revenues from the sale of research products and services are primarily derived from the sale of hydrogels and stem cell products for research use and are recognized when earned. These revenues are recognized at a point-in-time when control of the product transfers to the customer, which is typically upon shipment to the customer from the Alameda facility. Cost of sales from the sale of research products include direct and indirect overhead expenses incurred to purchase and manufacture those products, including lab supplies, personnel costs, freight, and royalties paid, if any, in accordance with the terms of applicable licensing agreements for those products.

Subscription and advertisement revenues – Beginning August 30, 2018, Lineage no longer has subscription and advertisement revenues due to the AgeX Deconsolidation (as defined in Note 6). Lineage recorded revenues of \$691,000 from LifeMap Sciences, a direct majority-owned subsidiary of AgeX, for subscription-based products, including research databases and software tools, for biomedical, gene, disease, and stem cell research.

Grant revenues – In applying the provisions of Topic 606, Lineage has determined that government grants are out of the scope of Topic 606 because the government entities do not meet the definition of a “customer”, as defined by Topic 606, as there is not considered to be a transfer of control of good or services to the government entities funding the grant. Lineage has, and will continue to, account for grants received to perform research and development services in accordance with ASC 730-20, *Research and Development Arrangements*, which requires an assessment, at the inception of the grant, of whether the grant is a liability or a contract to perform research and development services for others. If Lineage or a subsidiary receiving the grant is obligated to repay the grant funds to the grantor regardless of the outcome of the research and development activities, then Lineage is required to estimate and recognize that liability. Alternatively, if Lineage or a subsidiary receiving the grant is not required to repay, or if it is required to repay the grant funds only if the research and development activities are successful, then the grant agreement is accounted for as a contract to perform research and development services for others, in which case, grant revenue is recognized when the related research and development expenses are incurred.

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.

Revenue Recognition by Source and Geography – Revenues are recognized when control of the promised goods or services is transferred to customers, or in the case of governmental entities funding a grant, when allowable expenses are incurred, in an amount that reflects the consideration Lineage or a subsidiary, depending on which company has the customer or the grant, expects to be entitled to in exchange for those goods or services.

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

	Year Ended December 31,	
	2019	2018 ⁽¹⁾
REVENUES:		
Grant revenue	\$ 2,037	\$ 3,572
Royalties from product sales and license fees	1,221	392
Subscription and advertisement revenues ⁽²⁾	-	691
Sale of research products and services	257	333
Total revenues	<u>\$ 3,515</u>	<u>\$ 4,988</u>

(1) Amounts recognized prior to adoption of Topic 606 have not been adjusted under the Topic 606 modified retrospective transition method.

(2) These revenues were generated by LifeMap Sciences, which is a subsidiary of AgeX, are included in Lineage consolidated revenues for the period from January 1, 2018 through August 29, 2018, the date immediately preceding the AgeX Deconsolidation. As a result of the AgeX Deconsolidation on August 30, 2018, Lineage does not expect to recognize subscription and advertisement revenues during subsequent accounting periods.

The following table presents consolidated 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,	
	2019	2018
REVENUES:		
United States	\$ 2,092	\$ 1,804
Foreign ⁽¹⁾	1,423	3,184
Total revenues	<u>\$ 3,515</u>	<u>\$ 4,988</u>

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

Recently Adopted Accounting Pronouncements

Adoption of ASU 2018-07, Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting – In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies the accounting for non-employee share-based payment transactions. The new standard expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. ASU 2018-07 is effective for fiscal years beginning after December 15, 2018 (including interim periods within that fiscal year). Lineage adopted ASU 2018-07 on January 1, 2019. As Lineage does not have a significant number of nonemployee share based awards, the application of the new standard did not have a material impact on its consolidated financial statements.

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 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 is currently evaluating the impact the adoption of this guidance may have on its consolidated financial statements.

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. Early adoption is permitted. Lineage will adopt this standard on January 1, 2020 and does not believe adoption of the guidance will have a significant impact 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. This standard is currently effective for interim and annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years, with early adoption permitted for annual periods beginning after December 15, 2018. In October 2019, the FASB affirmed a proposed ASU deferring the effective date of ASU 2016-13 for all entities except public companies that are not smaller reporting companies to fiscal years beginning after December 15, 2022, including interim periods within those years. This proposed ASU has not been finalized as of the date of this report. When finalized, Lineage plans to adopt ASU 2016-13 effective January 1, 2023. Lineage has not yet completed its assessment of the impact of the new standard on its consolidated financial statements.

3. Asterias Merger

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 (the "Merger Consideration") for every share of Asterias common stock they owned (the "Merger Exchange Ratio"). 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 fair value of such shares, based on the closing price of Lineage common shares on March 8, 2019, was \$32.4 million.

In connection with the closing of the Asterias Merger, Lineage assumed outstanding warrants to purchase shares of Asterias common stock, as further discussed below and in Note 11, and assumed sponsorship of the Asterias 2013 Equity Incentive Plan (see Note 12). All stock options to purchase shares of Asterias common stock outstanding immediately prior to the closing of the Asterias Merger were canceled at the closing for no consideration.

As of December 31, 2019, the assets and liabilities of Asterias have been included in the consolidated balance sheet of Lineage. The results of operations of Asterias from March 8, 2019 through December 31, 2019 have been included in the consolidated statement of operations of Lineage for the year ended December 31, 2019.

Calculation of the purchase price

The calculation of the purchase price for the Asterias Merger and the Merger Consideration transferred on March 8, 2019 was as follows (in thousands, except for share and per share amounts):

	Lineage (38% ownership interest)	Shareholders other than Lineage (approximate 62% ownership interest)	Total
Outstanding Asterias common stock as of March 8, 2019	21,747,569	34,783,333 ⁽¹⁾	56,530,902 ⁽¹⁾
Exchange ratio	0.710	0.710	0.710
Lineage common shares issuable	15,440,774 ⁽²⁾	24,695,898 ⁽³⁾	40,136,672
Per share price of Lineage common shares as of March 8, 2019	\$ 1.31	\$ 1.31	\$ 1.31
Purchase price (in \$000s)	\$ 20,227 ⁽²⁾	\$ 32,353	\$ 52,580

(1) Includes 81,810 shares of Asterias restricted stock unit awards that immediately vested on March 8, 2019 and converted into the right to receive common shares of Lineage based on the Merger Exchange Ratio, resulting in 58,085 common shares of Lineage issued on March 8, 2019 as part of the Merger Consideration. These restricted stock units were principally attributable to pre-combination services and included as part of the purchase price in accordance with ASC 805. See Note 12 for Asterias restricted stock units that vested on the closing of the Asterias Merger attributable to post-combination services that were recorded outside of the purchase price as an immediate charge to stock-based compensation expense.

(2) Estimated fair value for Lineage's previously held 38% ownership interest in Asterias common stock is part of the total purchase price of Asterias for purposes of the purchase price allocation under ASC 805 and for Lineage's adjustment of its 38% interest to fair value at the effective date of the Asterias Merger and immediately preceding the consolidation of Asterias' results with Lineage. No actual common shares of Lineage were issued to Lineage in connection with the Asterias Merger.

(3) Net of a *de minimis* number of fractional shares which were paid in cash.

Purchase price allocation

Lineage allocated the acquisition consideration to tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values as of the acquisition date. The fair value of the acquired tangible and identifiable intangible assets were determined based on inputs that are unobservable and significant to the overall fair value measurement. It is also based on estimates and assumptions made by management at the time of the acquisition. As such, this was classified as Level 3 fair value hierarchy measurements and disclosures.

The allocation of the purchase price in the table below is based on our estimates of the fair values of tangible and intangible assets acquired, including IPR&D, and liabilities assumed as of the acquisition date, with the excess recorded as goodwill (in thousands). As of December 31, 2019, Lineage had finalized its purchase price allocation.

Assets acquired:	
Cash and cash equivalents	\$ 3,117
Prepaid expenses and other assets, current and noncurrent	660
Machinery and equipment	308
Long-lived intangible assets - royalty contracts	650
Acquired in-process research and development (“IPR&D”)	46,540
	<u>51,275</u>
Total assets acquired	<u>51,275</u>
Liabilities assumed:	
Accrued liabilities and accounts payable	982
Liability classified warrants	867
Deferred license revenue	200
Long-term deferred income tax liability	10,753
	<u>12,802</u>
Total liabilities assumed	<u>12,802</u>
Net assets acquired, excluding goodwill (a)	<u>38,473</u>
Fair value of Lineage common shares held by Asterias (b)	<u>3,435</u>
Total purchase price (c)	<u>52,580</u>
Estimated goodwill (c-a-b)	<u>\$ 10,672</u>

The valuation of identifiable intangible assets and their estimated useful lives are as follows (in thousands, except for useful life):

	Preliminary Estimated Asset Fair Value	Useful Life (Years)
	(in thousands, except for useful life)	
In process research and development (“IPR&D”)	\$ 46,540	n/a
Royalty contracts	650	5
	<u>\$ 47,190</u>	

The following is a discussion of the valuation methods used to determine the fair value of Asterias’ significant assets and liabilities in connection with the Asterias Merger:

Acquired In-Process Research and Development (“IPR&D”) and Deferred Income Tax Liability - The fair value of identifiable acquired in-process research and development intangible assets consisting of \$31.7 million pertaining to the OPC1 program that is currently in a Phase 1/2a clinical trial for SCI, which has been partially funded by CIRM, and \$14.8 million pertaining to the VAC2 program, which is a non-patient-specific (“off-the-shelf”) cancer immunotherapy derived from pluripotent stem cells for which a clinical trial in non-small cell lung cancer is being funded and sponsored by Cancer Research UK. The identification of these intangible assets are based on consideration of historical experience and a market participant’s view further discussed below; collectively, OPC1 and the VAC2 are referred to as the “AST-Clinical Programs”. These intangible assets are valued primarily through the use of a probability weighted discounted cash flow method under the income approach further discussed below. Lineage considered the VAC1 program, an autologous product candidate, manufactured from cells that come from the patient, and due to significant risks, substantial costs and limited opportunities in its current state associated with the VAC1 program, Lineage management considered this program to have de minimis value.

Lineage determined that the estimated aggregate fair value of the AST-Clinical programs was \$46.5 million as of the acquisition date using a probability weighted discounted cash flow method for each respective program. This approach estimates the probability of the AST-Clinical Programs achieving successful completion of remaining clinical trials and related approvals into the valuation technique.

To calculate fair value of the AST-Clinical programs under the discounted cash flow method, Lineage used probability-weighted, projected cash flows discounted at a rate considered appropriate given the significant inherent risks associated with cell therapy development by clinical-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to each respective program. Cash flows were assumed to extend through a seven-year market exclusivity period for the OPC1 program from the date of market launch. Revenues from commercialization of the AST-Clinical Programs were based on estimated market potential for the indication of each program. The resultant cash flows were then discounted to present value using a weighted-average cost of capital for companies with profiles substantially similar to that of Lineage, which Lineage believes represents the rate that market participants would use to value the assets. Lineage compensated for the phase of development of the program by applying a probability factor to its estimation of the expected future cash flows. The projected cash flows were based on significant assumptions, including the indications in which Lineage will pursue development of the AST-Clinical programs, the time and resources needed to complete the development and regulatory approval, estimates of revenue and operating profit related to the program considering its stage of development, the life of the potential commercialized product, market penetration and competition, and risks associated with achieving commercialization, including delay or failure to obtain regulatory approvals to conduct clinical studies, failure of clinical studies, delay or failure to obtain required market clearances, and intellectual property litigation.

These 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 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 Lineage becomes aware of an event or a change in circumstances that would indicate the asset may be impaired.

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 (“DTL”) in accordance with ASC 740, *Income Taxes* (see Note 13). This DTL is computed using the fair value of the IPR&D assets less any available indefinite life tax attributes on the acquisition date multiplied by Lineage’s 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 closing of the Asterias Merger, which may be considered for reversal under ASC 740 as further discussed in Note 13.

Royalty contracts – Asterias has certain royalty revenues for “research only use” culture media for preclinical research applications under certain, specific patent families under contracts which preclude the customers to sell for commercial use or for clinical trials. These royalty cash flows are generated under certain specific patent families which Asterias previously acquired from Geron Corporation (“Geron”). Asterias pays Geron a royalty for all royalty revenues received from these contracts. Because these patents are a subset of the clinical programs discussed above, are expected to continue to generate revenues for Asterias and are not to be used in the OPC1 or the VAC2 programs, these patents are considered to be separate long-lived intangible assets under ASC 805. These intangible assets are also valued primarily through the use of the discounted cash flow method under the income approach, and will be amortized over their useful life, estimated to be 5 years. The discounted cash flow method estimated the amount of net royalty income that can be expected under the contracts in future years. The amounts were based on observed historical trends in the growth of these revenue streams, and were estimated to terminate in approximately five years, when the key patents under these contracts will begin to expire. The resulting cash flows were discounted to the valuation date based on a rate of return that recognizes a lower level of risk associated with these assets as compared to the AST-Clinical programs discussed above.

Deferred license revenue – In September 2018, Asterias and Novo Nordisk A/S (“Novo Nordisk”) entered into an option for Novo Nordisk or its designated U.S. affiliate to license, on a non-exclusive basis, certain intellectual property related to culturing pluripotent stem cells, such as hES cells, in suspension. Under the terms of the option, Asterias received a one-time upfront payment of \$1.0 million, in exchange for a 24-month period option to negotiate a non-exclusive license during which time Asterias has agreed to not grant any exclusive licenses inconsistent with the Novo Nordisk option. This option is considered a performance obligation as it provides Novo Nordisk with a material right that it would not receive without entering into the contract.

For business combination purposes under ASC 805, the fair value of this performance obligation to Lineage, from a market participant perspective, is the estimated costs Lineage may incur, plus a normal profit margin for the level of effort required to perform under the contract after the acquisition date, assuming Novo Nordisk exercised its option, including, but not limited to, negotiation costs, legal fees, arbitration, if any, and other related costs. Management has estimated those costs, plus a normal profit margin, to be approximately \$200,000 in the estimated purchase price allocation.

Liability classified warrants – On May 13, 2016, in connection with a common stock offering, Asterias issued warrants to purchase 2,959,559 shares of Asterias common stock (the “Asterias Warrants”) with an exercise price of \$4.37 per share that expire in five years from the issuance date, or May 13, 2021. As of the closing of the Asterias Merger, there were 2,813,159 Asterias Warrants outstanding. The Asterias Warrants contain certain provisions in the event of a Fundamental Transaction, as defined in the warrant agreement governing the Asterias Warrants (“Warrant Agreement”), that Asterias or any successor entity will be required to purchase, at a holder’s option, exercisable at any time concurrently with or within thirty days after the consummation of the fundamental transaction, the Asterias Warrants for cash in an amount equal to the calculated value of the unexercised portion of such holder’s warrants, determined in accordance with the Black-Scholes option pricing model with significant inputs as specified in the Warrant Agreement. The Asterias Merger was a Fundamental Transaction for purposes of the Asterias Warrants.

The fair value of the Asterias Warrants was determined by using Black-Scholes option pricing models which take into consideration the probability of the Fundamental Transaction, which for purposes of the above valuation was assumed to be at 100% and net cash settlement occurring, using the contractual remaining term of the warrants. In applying these models, these inputs included key assumptions including the per share closing price of Lineage common shares on March 8, 2019, volatility computed in accordance with the provisions of the Warrant Agreement and, to a large extent, assumptions based on discussions with a majority of the holders of the Asterias Warrants since the closing of the Asterias Merger to settle the Asterias Warrants in cash or in common shares of Lineage. Based on such discussions, Lineage believes the fair value of the Asterias Warrants as of the closing of the Asterias Merger is not subject to change significantly, however, to the extent any Asterias Warrants that were not settled in cash or in Lineage common shares discussed below, were automatically converted to Lineage warrants 30 days after the closing of the Asterias Merger. In April 2019, Asterias Warrants representing approximately \$372,000 in fair value were settled: \$332,000 in fair value was settled in exchange for 251,835 common shares of Lineage, and \$40,000 in fair value was settled in exchange for cash. The Asterias Warrants settled in exchange for common shares of Lineage were held by Broadwood Partners, L.P., an Asterias and Lineage shareholder. The Asterias Warrants settled in exchange for cash were held by other parties. The remaining Asterias Warrants (representing approximately \$495,000 in fair value as of March 31, 2019) were converted into warrants to purchase common shares of Lineage using the Merger Exchange Ratio (the “Lineage Warrants”).

As of December 31, 2019, 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, with similar terms and conditions retained under the Lineage Warrants as per the original Warrant Agreements. The Lineage Warrants have an exercise price of \$6.15 per warrant share and expire on May 13, 2021. Lineage is accounting for the outstanding Lineage Warrants as a liability at fair value, with subsequent changes to the fair value of the Lineage Warrants at each reporting period thereafter included in the consolidated statement of operations (see Note 11).

Fair value of Lineage common shares held by Asterias – As of March 8, 2019, Asterias held 2,621,811 common shares of Lineage as marketable securities on its standalone financial statements. The fair value of those shares acquired by Lineage from Asterias is determined based on the \$1.31 per share closing price of Lineage common shares on March 8, 2019. Although treasury shares are not considered an asset and were retired upon Lineage’s acquisition of Asterias, the fair value of those shares is a part of the purchase price allocation shown in the tables above. These Lineage shares were retired at the completion of the Asterias Merger.

Goodwill – 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 not amortized but is tested for impairment at least annually, or more frequently if circumstances indicate potential impairment.

Depending on the structure of a particular acquisition, goodwill and identifiable intangible assets may not be deductible for tax purposes. Goodwill recorded in the Asterias Merger is not expected to be deductible for tax purposes (see Note 13).

During the year ended December 31, 2019, Lineage incurred \$5.1 million in acquisition related costs which were recorded in general and administrative expenses in the accompanying consolidated statements of operations.

Prior to the Asterias Merger being consummated in March 2019, Lineage elected to account for its 21.7 million shares of Asterias common stock at fair value using the equity method of accounting. The fair value of the Asterias shares was approximately \$20.2 million as of March 8, 2019, the closing date of the Asterias Merger, based on \$0.93 per share, which was calculated by multiplying (a) \$1.31, the closing price of Lineage common shares on such date by (b) the Merger Exchange Ratio. The fair value of the Asterias shares was approximately \$13.5 million as of December 31, 2018, based on the closing price of Asterias common stock of \$0.62 per share on such date. Accordingly, Lineage recorded an unrealized gain of \$6.7 million for the year ended December 31, 2019, representing the change in fair value of Asterias common stock from December 31, 2018 to March 8, 2019. For the year ended December 31, 2018, Lineage recorded an unrealized loss of \$35.4 million on the Asterias shares due to the decrease in Asterias’ stock price from December 31, 2017 to December 31, 2018 from \$2.25 per share to \$0.62 per share. All share prices were determined based on the closing price of Lineage or Asterias common stock on the NYSE American on the applicable dates.

4. Accounting for Common Stock of OncoCyte, at Fair Value

Lineage elected to account for its shares of OncoCyte common stock at fair value using the equity method of accounting beginning on February 17, 2017, the date of the OncoCyte Deconsolidation, through September 11, 2019. Lineage sold 2.25 million shares of OncoCyte common stock for net proceeds of \$4.2 million in July 2019. Accordingly, Lineage's ownership in OncoCyte was reduced from 28% to 24%. Lineage sold an additional 4.0 million shares of OncoCyte common stock for net proceeds of \$6.5 million on September 11, 2019. Lineage's ownership in OncoCyte was further reduced to 16% at this time. Effective September 11, 2019, Lineage began accounting for its shares of OncoCyte common stock as marketable equity securities. The calculation of fair value is the same under the equity method and as a marketable equity security.

As of December 31, 2019, Lineage owned 8.4 million shares of OncoCyte common stock. These shares had a fair value of \$19.0 million, based on the closing price of OncoCyte of \$2.25 per share on December 31, 2019. As of December 31, 2018, Lineage had 14.7 million shares of OncoCyte common stock. These shares had a fair value of \$20.3 million, based on the closing price of OncoCyte of \$1.38 per share on December 31, 2018.

For the year ended December 31, 2019, Lineage recorded a realized gain of \$0.5 million due to sales of OncoCyte shares in the period. Lineage also recorded an unrealized gain of \$8.8 million due to the increase in OncoCyte's stock price from \$1.38 per share at December 31, 2018 to \$2.25 per share at December 31, 2019; \$8.0 million of the unrealized gain was recorded as an unrealized gain on an equity method investment as it was prior to September 11, 2019; and \$0.8 million was recorded as an unrealized gain on marketable equity securities.

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.

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

On August 30, 2018, Lineage entered into a Stock Purchase Agreement with Juvenescence Limited and AgeX Therapeutics, Inc., pursuant to which Lineage sold 14.4 million shares of the common stock of AgeX to Juvenescence for \$3.00 per share, or an aggregate purchase price of \$43.2 million. 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.

The Promissory Note bears interest at 7% per annum, with principal and accrued interest payable at maturity two years after the closing of the Juvenescence Transaction (August 30, 2020). The Promissory Note cannot be prepaid prior to maturity or conversion. On the maturity date, if a "Qualified Financing" (as defined below) has not occurred, Lineage will have the right, but not the obligation, to convert the principal balance of the Promissory Note and accrued interest then due into a number of Series A Preferred Shares of Juvenescence at a conversion price of \$15.60 per share. Upon the occurrence of a Qualified Financing on or before the maturity date, the principal balance of the Promissory Note and accrued interest will automatically convert into a number of shares of the class of equity securities of Juvenescence sold in the Qualified Financing, at the price per share at which the Juvenescence securities are sold in the Qualified Financing; and, if AgeX common stock is listed on a national securities exchange in the U.S., the number of shares of the class of equity securities issuable upon conversion may be increased depending on the market price of AgeX common stock. A Qualified Financing is generally defined as an underwritten initial public offering of Juvenescence equity securities in which gross proceeds are not less than \$50.0 million. The Promissory Note is not transferable, except in connection with a change of control of Lineage.

For the year ended December 31, 2019, Lineage recognized \$1.5 million in interest income on the Promissory Note. As of December 31, 2019, the Promissory Note principal and accrued interest balance was \$23.6 million.

Shareholder Agreement

Lineage and Juvenescence entered into a Shareholder Agreement, dated August 30, 2018, setting forth the governance, approval and voting rights of the parties with respect to their holdings of AgeX common stock, including rights of representation on AgeX's board of directors, approval rights, preemptive rights, rights of first refusal and co-sale and drag-along and tag-along rights for so long as either Lineage or Juvenescence continue to own at least 15% of the outstanding shares of AgeX common stock. Under the Shareholder Agreement, Juvenescence and Lineage each had the right to designate two persons to a six-member AgeX board of directors, with the remaining two individuals to be independent of Juvenescence and Lineage. Following Juvenescence's payment of \$10.8 million on November 2, 2018 under the Stock Purchase Agreement, Juvenescence had the right to designate an additional member of the AgeX board of directors. As of February 28, 2020, Juvenescence has not exercised such right. Immediately following the AgeX Distribution on November 28, 2018 (see Note 6), Lineage owned 1.7 million shares of AgeX common stock, representing 4.8% of AgeX's then issued and outstanding shares of common stock. Accordingly, in accordance with the Shareholder Agreement, as of November 28, 2018, Lineage had no right to designate any member to the AgeX board of directors.

In connection with the Juvenescence Transaction, the termination provision of the Shared Facilities Agreement (see Note 10) entitling AgeX or Lineage to terminate the agreement upon six months advance written notice was amended. Pursuant to the amendment, following the AgeX Deconsolidation on August 30, 2018 (see Note 6), each party retained the right to terminate the Shared Facilities Agreement at any time by giving the other party six months advance written notice, provided that Lineage could not do so prior to September 1, 2020.

Shared services with AgeX were terminated on July 31, 2019 with respect to the use of Lineage's office and laboratory facilities and September 30, 2019 with respect to all other remaining shared services.

6. Deconsolidation and Distribution of AgeX

Deconsolidation of AgeX

On August 30, 2018, Lineage sold 14.4 million shares of the common stock of AgeX to Juvenescence (see Note 5). Immediately before that sale, Lineage and Juvenescence owned 80.4% and 5.6%, respectively, of AgeX's outstanding common stock. Immediately following that sale, Lineage and Juvenescence owned 40.2% and 45.8%, respectively, of AgeX's outstanding common stock. As a result, on August 30, 2018, AgeX was no longer a subsidiary of Lineage and, as of that date, Lineage experienced a "loss of control" of AgeX, as defined by GAAP. Loss of control is deemed to have occurred when, among other things, a parent company owns less than a majority of the outstanding common stock of a subsidiary, lacks a controlling financial interest in the subsidiary, and is unable to unilaterally control the subsidiary through other means such as having, or being able to obtain, the power to elect a majority of the subsidiary's Board of Directors based solely on contractual rights or ownership of shares representing a majority of the voting power of the subsidiary's voting securities. All of these loss-of-control factors were present with respect to Lineage's ownership interest in AgeX as of August 30, 2018. Accordingly, Lineage has deconsolidated AgeX's consolidated financial statements and consolidated results from Lineage's consolidated financial statements and consolidated results effective on August 30, 2018, in accordance with ASC, 810-10-40-4(c) (the "AgeX Deconsolidation").

In connection with the Juvenescence Transaction discussed in Note 5 and the AgeX Deconsolidation on August 30, 2018, in accordance with ASC 810-10-40-5, Lineage recorded a gain on deconsolidation of \$78.5 million, which includes a financial reporting gain on the sale of the AgeX shares of \$39.2 million, during the year ended December 31, 2018, included in other income and expenses, net, in the consolidated statements of operations.

Distribution of AgeX Shares

On November 28, 2018, Lineage distributed 12.7 million shares of AgeX common stock owned by Lineage to holders of Lineage common shares, on a pro rata basis, in the ratio of one share of AgeX common stock for every 10 Lineage common shares owned. The AgeX Distribution was accounted for at fair value as a dividend-in-kind in the aggregate amount of \$34.4 million. This amount was determined by valuing the 12.7 million shares of AgeX common stock distributed to Lineage shareholders at the \$2.71 per share closing price of AgeX common stock, as quoted on the NYSE American, on November 29, 2018, the first trading day of AgeX common stock.

Because Lineage has an accumulated deficit in its consolidated shareholders' equity, the entire fair value of the AgeX Distribution was charged against common stock equity included in the consolidated statements of changes in shareholders' equity for the year ended December 31, 2018.

Immediately following the distribution, Lineage owned 1.7 million shares of AgeX common stock. During the year ended December 31, 2019, Lineage sold a total of 765,889 shares of AgeX common stock for net proceeds of \$1.8 million. As of December 31, 2019, Lineage owns 1.0 million shares of common stock, which represents approximately 2.5% of AgeX's outstanding common stock as of December 31, 2019 and which shares Lineage holds as marketable equity securities.

7. Property and Equipment, Net

At December 31, 2019 and 2018, property and equipment, net and construction in progress were comprised of the following (in thousands):

	December 31,	
	2019	2018
Equipment, furniture and fixtures	\$ 4,148	\$ 3,842
Leasehold improvements	2,862	3,910
Right-of-use assets ⁽¹⁾	5,756	-
Accumulated depreciation and amortization	(4,591)	(3,185)
Property and equipment, net	8,175	4,567
Construction in progress	-	1,268
Property and equipment, net and construction in progress	<u>\$ 8,175</u>	<u>\$ 5,835</u>

(1) Lineage adopted ASC 842 on January 1, 2019. For additional information on this standard and right-of-use assets and liabilities see Notes 2 and 14.

Property and equipment at December 31, 2019 and 2018 includes \$96,000 and \$146,000 financed by capital leases, respectively. Depreciation and amortization expense amounted to \$1.1 million for both years ended December 31, 2019 and 2018, respectively. During the year ended December 31, 2019, Lineage sold equipment with a net book value of \$209,000 and recognized a loss of \$109,000, which is included in research and development expenses on the statement of operations. Primarily in connection with the close out of the Asterias facility, Lineage also sold non-capitalized assets for a net gain of \$337,000 which is included in research and development expenses on the statement of operations.

Construction in progress

Construction in progress of \$1.3 million as of December 31, 2018 entirely relates to the leasehold improvements made at Cell Cure's lease facilities in Jerusalem, Israel, primarily financed by the landlord (see Note 14). The leasehold improvements were substantially completed in December 2018 and the assets placed in service in January 2019.

8. Goodwill and Intangible Assets, Net

At December 31, 2019 and 2018, goodwill and intangible assets, net consisted of the following: (in thousands):

	December 31,	
	2019	2018
Goodwill ⁽¹⁾	\$ 10,672	\$ -
Intangible assets:		
Acquired IPR&D – OPC1 (from the Asterias Merger) ⁽²⁾	\$ 31,700	\$ -
Acquired IPR&D – VAC2 (from the Asterias Merger) ⁽²⁾	14,840	
Intangible assets subject to amortization:		
Acquired patents	18,953	19,010
Acquired royalty contracts (2)	650	-
Other	-	10
Total intangible assets	66,143	19,020
Accumulated amortization	(17,895)	(15,895)
Intangible assets, net	<u>\$ 48,248</u>	<u>\$ 3,125</u>

(1) Goodwill represents the excess of the purchase price over the fair value of the net tangible and identifiable intangible assets acquired and liabilities assumed in the Asterias Merger (see Note 3).

(2) See Note 3 for information on the Asterias Merger which was consummated on March 8, 2019.

Lineage amortizes its intangible assets over an estimated period of 5 to 10 years on a straight-line basis. Lineage recognized \$2.0 million and \$2.2 million in amortization expense of intangible assets during the years ended December 31, 2019 and 2018, respectively.

Amortization of intangible assets for periods subsequent to December 31, 2019 is as follows (in thousands):

<u>Year Ended December 31,</u>	<u>Amortization Expense</u>
2020	\$ 1,216
2021	210
2022	130
2023	130
2024	22
Total	<u>\$ 1,708</u>

9. Accounts Payable and Accrued Liabilities

At December 31, 2019 and 2018, accounts payable and accrued liabilities consist of the following (in thousands):

	<u>December 31,</u>	
	<u>2019</u>	<u>2018</u>
Accounts payable	\$ 2,427	\$ 2,359
Accrued liabilities	1,246	1,639
Accrued compensation	1,549	2,456
Other current liabilities	4	9
Total	<u>\$ 5,226</u>	<u>\$ 6,463</u>

In connection with the Asterias Merger, several Asterias employees were terminated as of the Asterias Merger date. Three of these employees had employment agreements with Asterias which entitled them to change in control and separation payments in the aggregate of \$2.0 million, which such conditions were met on the Asterias Merger date. Accordingly, \$2.0 million was accrued and recorded in general and administrative expenses on the merger date and paid in April 2019.

Additionally, Lineage entered into a plan of termination with substantially all other previous employees of Asterias with potential separation payments in the aggregate of \$0.5 million. Termination dates for these individuals ranged from May 31, 2019 to June 28, 2019. These employees were required to provide services related to the transition and be an employee of the combined company as of their date of termination in order to receive separation benefits. Since the employees were required to render future services after the merger date, Lineage recorded the aggregate liability ratably over their respective service periods from the Asterias Merger date through the above termination dates, in accordance with ASC 420, *Exit or Disposal Cost Obligations*. All payments were completed by July 31, 2019.

In connection with the relocation of Lineage's corporate headquarters to Carlsbad, California, discussed in Note 14, Lineage entered into a plan of termination with certain Lineage employees with potential separation payments in the aggregate of \$0.7 million. Termination dates for these individuals range from August 9, 2019 to September 30, 2019. These employees had to provide services related to the transition of services and activities in connection with the relocation and be an employee of Lineage as of their date of termination in order to receive separation benefits. Lineage recorded the aggregate liability ratably over their respective service periods from June through the above termination dates, in accordance with ASC 420. As of December 31, 2019, all separation payments had been made.

10. Related Party Transactions

Shared Facilities and Service Agreements with Affiliates

The receivables from affiliates shown on the consolidated balance sheet as of December 31, 2018, primarily represent amounts owed to Lineage by OncoCyte and AgeX under separate Shared Facilities and Service Agreements (each a "Shared Facilities Agreement"), with amounts owed by OncoCyte comprising most of that amount. These outstanding amounts were paid in full in the first quarter of 2019. Under the terms of the Shared Facilities Agreements, Lineage allowed OncoCyte and AgeX to use Lineage's premises and equipment located at Lineage's headquarters in Alameda, California for the purpose of conducting business. Lineage also provided accounting, billing, bookkeeping, payroll, treasury, payment of accounts payable, and other similar administrative services to OncoCyte and AgeX. The Shared Facilities Agreements also allowed Lineage to provide the services of attorneys, accountants, and other professionals who may provide professional services to Lineage. Lineage also provided OncoCyte and AgeX with the services of laboratory and research personnel, including Lineage employees and contractors, for the performance of research and development work for OncoCyte and AgeX at the premises. Shared services with AgeX were terminated on July 31, 2019 with respect to the use of Lineage's office and laboratory facilities and September 30, 2019 with respect to all other remaining shared services. Shared services with OncoCyte were terminated on September 30, 2019, and December 31, 2019 with respect to all other remaining shared services.

Lineage charged OncoCyte and AgeX a “Use Fee” for services provided and for use of Lineage facilities, equipment, and supplies. For each billing period, Lineage prorated and allocated to OncoCyte and AgeX costs incurred, including costs for services of Lineage employees and use of equipment, insurance, leased space, professional services, software licenses, supplies and utilities. The allocation of costs depended on key cost drivers, including actual documented use, square footage of facilities used, time spent, costs incurred by Lineage for OncoCyte and AgeX, or upon proportionate usage by Lineage, OncoCyte and AgeX, as reasonably estimated by Lineage. Lineage, at its discretion, had the right to charge OncoCyte and AgeX a 5% markup on such allocated costs. The allocated cost of Lineage employees and contractors who provided services was based upon the number of hours or estimated percentage of efforts of such personnel devoted to the performance of services.

The Use Fee was determined and invoiced to OncoCyte and AgeX on a regular basis, generally monthly or quarterly. Each invoice was payable in full within 30 days after receipt. Any invoice, or portion thereof, not paid in full when due bore interest at the rate of 15% per annum until paid, unless the failure to make a payment was due to any inaction or delay in making a payment by Lineage. Through December 31, 2019, Lineage did not charge OncoCyte or AgeX any interest. In addition to the Use Fee, OncoCyte and AgeX reimbursed Lineage for any out of pocket costs incurred by Lineage for the purchase of office supplies, laboratory supplies, and other goods and materials and services for the account or use of OncoCyte or AgeX. Lineage was not obligated to purchase or acquire any office supplies or other goods and materials or any services for OncoCyte or AgeX, and if any such supplies, goods, materials or services were obtained, Lineage could arrange for the suppliers to invoice OncoCyte or AgeX directly.

In the aggregate, Lineage charged Use Fees to OncoCyte and AgeX as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Research and development	\$ 1,286	\$ 1,378
General and administrative	890	790
Total use fees	\$ 2,176	\$ 2,168

The Use Fees charged to OncoCyte and AgeX shown above are not reflected in revenues, but instead Lineage’s general and administrative expenses and research and development expenses are shown net of those charges in the consolidated statements of operations. As of December 31, 2019, Lineage has an immaterial amount receivable from OncoCyte and AgeX included in receivable from affiliates, net. As of December 31, 2018, Lineage had a \$2.1 million receivable from OncoCyte included in receivable from affiliates, net.

Lineage accounts for receivables from affiliates, net of payables to affiliates, if any, for similar shared services and other transactions Lineage’s consolidated subsidiaries may enter into with nonconsolidated affiliates. Lineage and the affiliates record those receivables and payables on a net basis since Lineage and the affiliates intend to exercise a right of offset of the receivable and the payable and to settle the balances net by having the party that owes the other party pay the net balance owed.

Other related party transactions

In February 2018, Alfred D. Kingsley, the Chairman of our board of directors and a former officer and director of AgeX, purchased AgeX stock purchase warrants entitling him to purchase 248,600 shares of AgeX common stock at an exercise price of \$2.50 per share. AgeX received \$124,300, or \$0.50 per warrant, from Mr. Kingsley. The warrants were sold to Mr. Kingsley on the same terms as other warrants were sold by AgeX to other unaffiliated investors.

Lineage currently pays \$5,050 per month for the use of approximately 900 square feet of office space in New York City, which is 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 April 2019, Lineage issued 251,835 common shares of Lineage to Broadwood Partners, L.P., an Asterias and Lineage shareholder, in exchange for the settlement of Asterias Warrants in connection with the Asterias Merger (see Note 3).

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, and 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, 2019, Lineage has incurred a total of \$221,000 in legal expenses on behalf of the director, shareholder and the manager of the shareholder.

As part of financing transactions, Broadwood Partners, L.P. purchased 1,000,000 shares, 2,000,000 shares and 623,090 shares of OncoCyte common stock from Lineage in July 2019, September 2019 and January 2020, respectively.

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, 2019, no shares of preferred stock were issued or outstanding.

Common Shares

At December 31, 2019, Lineage was authorized to issue 250,000,000 common shares, no par value. As of December 31, 2019 and 2018, Lineage had 149,804,284 and 127,135,774 issued and outstanding common shares, respectively.

During the years ended December 31, 2019 and 2018, Lineage issued 189,000 and 270,000 common shares, net of shares withheld and retired for employee taxes paid, respectively, for vested restricted stock units (see Note 12).

In April 2017, Lineage entered into a Controlled Equity OfferingSM 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, Lineage common shares having an aggregate offering price of up to \$25,000,000. Lineage is not obligated to sell any shares under the Sales Agreement. 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 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 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 shares under the Sales Agreement are subject to satisfaction of certain conditions, including the continued effectiveness of Lineage's Registration Statement on Form S-3 which became effective on May 5, 2017. As of December 31, 2019, \$24.1 million remained available for sale through the Sales Agreement under the Registration Statement.

Lineage will 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.

Transactions with Noncontrolling Interests of Cell Cure

On July 10, 2017, Lineage purchased all of the outstanding Cell Cure Convertible Notes and Cell Cure ordinary shares held by HBL, a former Cell Cure shareholder that owned 21.2% of the issued and outstanding Cell Cure ordinary shares and substantially all of the Cell Cure Convertible Notes issued by Cell Cure shareholders other than Lineage. On the same date, Lineage also purchased all of the Cell Cure ordinary shares owned by Teva Pharmaceutical Industries, Ltd. ("Teva"), a former Cell Cure shareholder that owned 16.1% of the issued and outstanding Cell Cure ordinary shares. Teva did not have any Cell Cure Convertible Notes. To acquire the Cell Cure ordinary shares from HBL and Teva, Lineage issued 1,220,207 and 927,673 common shares, valued at \$3.8 million and \$2.8 million, to HBL and Teva, respectively, based on the closing price of Lineage common shares on the NYSE American. Prior to the consummation of the transactions with HBL and Teva, Lineage held 62.5% of the issued and outstanding Cell Cure ordinary shares and upon the consummation of the transactions Lineage held 99.8%. Accordingly, Lineage recorded a corresponding charge to equity of \$10.1 million and a proportional transfer of carrying value of \$3.5 million for purchase of noncontrolling interests in Cell Cure, included in the consolidated statement of shareholders' equity for the year ended December 31, 2017, in accordance with ASC 810-10-45-23.

In October 2017, an unaffiliated third party exercised stock options to purchase 4,400 Cell Cure ordinary shares, reducing Lineage's ownership from 99.8% to 98.8% of outstanding Cell Cure ordinary shares.

In May 2018, Lineage purchased 937 shares of Cell Cure ordinary shares for \$40.5359 per share, the same Cell Cure price per ordinary share paid by Lineage to each of HBL and Teva discussed above, resulting in an increase in Lineage's ownership from 98.8% to 99.0%. Accordingly, Lineage recorded a \$1.9 million net proportional equity transfer, at carrying value, from noncontrolling interests in Cell Cure to Lineage included in consolidated shareholders' equity for the year ended December 31, 2018, in accordance with ASC 810-10-45-23.

Warrants

Lineage (previously Asterias) Warrants – Liability Classified

In March 2019, in connection with the closing of the Asterias Merger, Lineage assumed outstanding Asterias Warrants. As of December 31, 2019, 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 have an exercise price of \$6.15 per warrant share and expire on May 13, 2021. Lineage is accounting for the outstanding Lineage Warrants as a liability at fair value, with subsequent changes to the fair value of the Lineage Warrants at each reporting period thereafter included in the consolidated statement of operations (see Note 3).

For the year ended December 31, 2019, Lineage recorded an unrealized gain of \$476,000 due to the decline in the fair value of the Lineage Warrants from the Asterias Merger date through December 31, 2019. The decrease in the fair value of the Lineage Warrants was mainly attributable to the short remaining life of the warrants, the low probability of a fundamental transaction occurring in that short timeframe and an exercise price considerably higher than market price of Lineage common shares. As of December 31, 2019, the fair value of the Lineage Warrants was \$20,000 included in long-term liabilities on the consolidated balance sheets.

Cell Cure Warrants – Liability Classified

In July 2017, as an inducement to HBL to sell their Cell Cure ordinary shares to Lineage, Cell Cure issued warrants to HBL (the “HBL Warrants”) to purchase up to 24,566 Cell Cure ordinary shares at an exercise price of \$40.5359 per share, payable in U.S. dollars, the same Cell Cure price per ordinary share paid by Lineage to each of HBL and Teva for the purchase of their Cell Cure ordinary shares discussed above. No warrants were issued to Teva. The HBL Warrants are immediately exercisable and expire on the earliest of the lapse of 5 years from the issuance date or immediately prior to the closing of a Corporate Transaction or an initial public offering, as defined in the HBL Warrant Agreement.

Cell Cure also has issued warrants to purchase up to 13,738 Cell Cure ordinary shares at exercise prices ranging from \$32.02 to \$40.00 per share, payable in U.S. dollars, to consultants (the “Consultant Warrants”), expiring in October 2020 and January 2024. The HBL Warrants and the Consultant Warrants are collectively referred to as the “Cell Cure Warrants”.

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. 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. Changes in any of the key assumptions used to value the Cell Cure Warrants could materially impact the fair value of the Cell Cure Warrants and Lineage’s consolidated financial statements.

For the years ended December 31, 2019 and 2018, Lineage recorded a noncash gain of \$0.1 million and \$0.4 million, respectively, for the 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 reduced remaining life of the warrants from the prior period, and management’s assumption on the lack of marketability discount adjustment on the fair value of Cell Cure ordinary shares. As of December 31, 2019 and 2018, the Cell Cure Warrants, valued at \$0.3 million and \$0.4 million, respectively, were included in long-term liabilities on the consolidated balance sheets.

12. Stock-Based Awards

Equity Incentive Plan Awards

Effective November 8, 2019, Lineage adopted an amendment changing the name of the BioTime, Inc. 2012 Equity Incentive 2012 Plan to the Lineage Cell Therapeutics, Inc. 2012 Equity Incentive Plan (the “2012 Plan”). The 2012 Plan provides for the grant of stock options, restricted stock, restricted stock units (“RSUs”) and stock appreciation rights. As of December 31, 2019, a maximum of 24,000,000 common shares were available for grant under the 2012 Plan. Recipients of stock options are eligible to purchase common shares at an exercise price equal to the fair market value of such shares on the date of grant. The maximum term of options granted under the 2012 Plan is 10 years. Stock options generally vest over a four-year period based on continuous service; however, the 2012 Plan allows for other vesting periods. Upon the expiration of the restrictions applicable to an RSU, Lineage will either issue to the recipient, without charge, one common share per RSU or cash in an amount equal to the fair market value of one common share. RSUs granted from the 2012 Plan reduce the shares available for grant by two shares for each RSU granted.

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):

	Shares Available for Grant	Number of Options Outstanding	Number of RSUs Outstanding	Weighted Average Exercise Price
December 31, 2017	2,485	8,043	62	\$ 3.38
Board mandated restriction restored ⁽¹⁾	5,000	-	-	
Exchange of options with Cell Cure ⁽²⁾	(866)	866	-	2.16
Restricted stock units granted ⁽³⁾	(1,586)	-	793	-
Inducement option grant ⁽⁴⁾	-	1,500	-	2.31
Options granted	(1,559)	1,559	-	2.84
Options forfeited	731	(750)	-	3.33
Adjustment due to the AgeX Distribution ⁽⁵⁾	(2,294)	2,294	-	-
Adjustment to inducement options due to the AgeX Distribution ⁽⁵⁾	-	355	-	-
Adjustment to restricted stock units due to the AgeX Distribution ⁽⁵⁾	(272)	-	136	-
Restricted stock units vested	-	-	(466)	-
Restricted stock units expired unvested	246	-	(123)	-
December 31, 2018	1,885	13,867	402	\$ 2.44
Adjustment due to the AgeX Distribution ⁽⁵⁾	117	(2)	3	-
Increase to the 2012 Plan	8,000	-	-	-
Options granted	(3,581)	3,581	-	1.06
Options forfeited	2,736	(2,736)	-	2.13
Restricted stock units vested	-	-	(239)	-
December 31, 2019	9,157	14,710	166	\$ 2.17
Options exercisable at December 31, 2019		9,555		\$ 2.54

The disclosures below regarding share-based awards that were granted on or before November 28, 2018 are before the applicable adjustments made to such awards to maintain intrinsic value before and after the AgeX Distribution, as discussed above.

- On October 13, 2017, Lineage's Board of Directors determined to temporarily set a 5.0 million total share limit on shares available for the grant of share-based awards pursuant to the 2012 Plan. As of December 31, 2017, the total 2.5 million shares available for grant was net of this 5.0 million share restriction. On May 4, 2018, Lineage's Board of Directors removed this restriction, thereby increasing shares available for the grant of share-based awards pursuant to the 2012 Plan.
- On July 9, 2018, Lineage's Board of Directors terminated the Cell Cure Equity Incentive Plan (the "Cell Cure Plan"), under which Cell Cure employees and certain consultants ("Cell Cure Option Holders") held outstanding options to purchase shares of common stock in Cell Cure, and Lineage granted the Cell Cure Option Holders Lineage options of equivalent value under the 2012 Plan in exchange for their Cell Cure options (the "Lineage Exchange"). The Lineage Exchange resulted in 866,000 grants of Lineage stock options under the 2012 Plan, all issued with an exercise price of \$2.16 per share to the Cell Cure Option Holders, based on Lineage's closing stock price on July 9, 2018. Of the total options granted under the Lineage Exchange, 275,000 are subject to continued service-based vesting from the original terms under the Cell Cure Plan, and 591,000 were immediately vested on the exchange date to reflect the fact that the Cell Cure Options Holders held prior to the exchange were already vested. Equivalent value of the Lineage Exchange was determined using the Black-Scholes option pricing model. The Lineage Exchange was accounted for as a modification under ASC 718, and Lineage recorded a noncash stock-based compensation expense of \$298,000 for the year ended December 31, 2018 included in consolidated stock-based compensation expense.
- On May 24, 2018 and August 10, 2018, Lineage granted 485,000 and 8,000 RSUs, respectively, to employees. The RSUs vest in increments upon the attainment of specified performance conditions, as determined by Lineage's Board of Directors, including the completion of the AgeX Distribution and certain clinical milestones in the development of OpRegen and Renevia. Stock-based compensation expense for these performance-based RSUs is recognized when it is probable that the respective milestone will be achieved, as determined by Lineage's Board of Directors. On October 4, 2018, Lineage's Board of Directors determined that Lineage had achieved the AgeX Distribution performance condition and as a result 25%, or 123,250, of the RSUs granted in May and August 2018 vested. On December 18, 2018, Lineage's Board of Directors determined that Lineage had achieved other milestones related to the RSUs and as a result an additional 50%, or 246,500, of the RSUs granted in May and August 2018 vested. The remaining 25%, or 123,250 RSUs, expired unvested on December 31, 2018.

On September 17, 2018, Lineage granted Lineage’s new President and Chief Executive Officer, Brian M. Culley, two RSU awards under the 2012 Plan: (1) an award of 200,000 restricted stock units (“RSU Award No. 1”) and (2) an award of 100,000 restricted stock units (“RSU Award No. 2” and together with RSU Award No. 1, the “RSU Awards”). Subject to Mr. Culley’s continued service with Lineage, 25% of the shares subject to RSU Award No. 1 will vest on the first anniversary of the date of grant, and the balance of the shares subject to RSU Award No. 1 will vest in 12 equal quarterly installments at the end of each quarter thereafter. RSU Award No. 2 vested in full on January 1, 2019.

- (4) On September 17, 2018 (the “Start Date”), Brian M. Culley became President and Chief Executive Officer of Lineage. In connection with Mr. Culley’s employment, Lineage granted Mr. Culley an inducement option to purchase 1,500,000 of Lineage’s common shares (the “Culley Option”). The exercise price of the Culley Option is \$2.31 per share, which was the closing stock price on September 17, 2018. This grant was made outside of the 2012 Plan and was approved by the independent members of the Board of Directors. Subject to Mr. Culley’s continued service with Lineage on the applicable vesting date, the Culley Option will vest and become exercisable with respect to 25% of the shares on the first anniversary of the Start Date, and the balance of the Culley Option will vest and become exercisable in 36 equal monthly installments thereafter.
- (5) Reflects the equitable adjustment to the exercise prices and number of outstanding stock options, and to restricted stock units, necessary to maintain the intrinsic value of those awards immediately prior to and following the AgeX Distribution.

As of December 31, 2019, options outstanding and options exercisable under the 2012 Plan have a weighted-average remaining contractual term of 6.1 years and 4.7 years, respectively, and intrinsic value of \$23,000 and zero, respectively.

In connection with the vested RSUs during the year ended December 31, 2019, Lineage paid \$0.1 million in minimum employee withholding taxes in exchange for 109,000 vested Lineage common shares issuable to the employees and immediately retired those shares. For the year ended December 31, 2019, Lineage recorded a noncash stock-based compensation expense of \$0.3 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, 2018, Lineage paid \$0.2 million in minimum employee withholding taxes in exchange for 134,000 vested Lineage common shares issuable to the employees and immediately retired those shares. For the year ended December 31, 2018, Lineage recorded a noncash stock-based compensation expense of \$1.2 million, which includes \$1.0 million related to the performance-based awards discussed above, in connection with the vested RSUs, included in consolidated stock-based compensation expense.

At the effective time of the Asterias Merger, Lineage assumed sponsorship of the Asterias 2013 Equity Incentive Plan (the “Asterias Equity Plan”), with references to Asterias and Asterias common stock therein to be deemed references to Lineage and Lineage common shares. There were 7,309,184 shares available under the Asterias Equity Plan immediately before the closing of the Asterias Merger, which became 5,189,520 shares immediately following the Asterias Merger. The shares available under the Asterias Equity Plan will be for awards granted to those former Asterias employees who continued as Lineage employees upon consummation of the Asterias Merger. A summary of activity under the Asterias Equity Plan from the closing date of the Asterias Merger through December 31, 2019 is as follows (in thousands, except per share amounts):

	Shares Available for Grant	Number of Options Outstanding	Number of RSUs Outstanding	Weighted Average Exercise Price
March 8, 2019	5,190	-	-	\$ -
Options granted	(490)	490	-	1.59
Options forfeited	140	(140)	-	1.63
December 31, 2019	4,840	350	-	\$ 1.57
Options exercisable at December 31, 2019		-		-

As of December 31, 2019, options outstanding under the Asterias Equity Plan have a weighted-average remaining contractual term of 9.2 years and intrinsic value of zero.

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,	
	2019	2018
Expected life (in years)	6.0	5.6
Risk-free interest rates	2.2%	2.8%
Volatility	63.1%	56.1%
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, 2019 and 2018 was \$0.68 and \$1.24 per share, respectively. Operating expenses include stock-based compensation expense as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Research and development	\$ 516	\$ 785
General and administrative	3,064	4,617
Total stock-based compensation expense	\$ 3,580	\$ 5,402

The expense related to 84,940 shares of Asterias restricted stock unit awards that immediately vested on the closing of the Asterias Merger and converted into the right to receive common shares of Lineage based on the Merger Exchange Ratio, resulting in 60,304 common shares of Lineage issued on March 8, 2019, was included in stock-based compensation expense for the year ended December 31, 2019. The expense was not included as part of the purchase price of the Asterias Merger because these awards were principally attributable to post-combination services.

As of December 31, 2019, total unrecognized compensation costs related to unvested stock options under Lineage's 2002 Plan and 2012 Plan was \$4.1 million, which is expected to be recognized as expense over a weighted average period of approximately 2.5 years.

Options and RSU Adjustment

In connection with the AgeX Distribution discussed in Note 6 and in accordance with the provisions of the 2012 Plan and awards granted outside of the 2012 Plan, Lineage awards issued and outstanding as of November 28, 2018 were adjusted to maintain the intrinsic value of those awards immediately prior to and following the AgeX Distribution shown below. The adjustments to the number of shares subject to each RSU, stock option and the option exercise prices were based on the relative market capitalization of Lineage and AgeX as of the AgeX Distribution date. Since the adjustments were done to maintain intrinsic value of the Lineage options and RSUs in accordance with the 2012 Plan and awards issued outside of the 2012 Plan, there was no modification in accordance with ASC 718.

13. Income Taxes

Lineage recorded a federal and state deferred income tax benefit of \$3.6 million and \$3.8 million, respectively, for the year ended December 31, 2019 due to the indefinite lived assets generated in the period and the release of the valuation allowance. The Company recorded a current foreign income tax expense of \$31,000 for the year ended December 31, 2019. Accordingly, the net impact for the year ended December 31, 2019 was a net income tax benefit of \$7.4 million.

For the year ended December 31, 2018, Lineage recorded a federal current income tax benefit of \$0.3 million due to the intraperiod allocation discussed in Note 2. No income tax expense or benefit was recorded for state or foreign purposes for the period ended December 31, 2018.

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

	December 31,	
	2019	2018
Domestic	\$ (7,303)	(36,675)
Foreign	(11,931)	(10,455)
Loss before net income tax benefit	\$ (19,234)	(47,130)

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,	
	2019	2018
Computed tax benefit at federal statutory rate	21%	21%
Research and development and other credits	3%	1%
Removal of DTL for equity investment in Asterias due to merger	22%	-
Permanent differences	(1%)	(3%)
Change in valuation allowance	(106%)	4%
Establish DTL for deferred assets from Asterias Merger	42%	-
Establish DTL for AgeX/OncoCyte shares at deconsolidation	-	8%
Deconsolidation of AgeX and subsidiaries net deferred tax assets	3%	(28%)
State tax benefit, net of effect on federal income taxes	54%	-
Foreign rate differential	1%	(2%)
Income tax benefit	39%	1%

The primary components of the deferred tax assets and liabilities at December 31, 2019 and 2018 were as follows (in thousands):

Deferred tax assets/(liabilities):	2019	2018
Net operating loss carryforwards	\$ 62,060	\$ 37,761
Research and development and other credits	8,619	5,288
Patents and licenses	1,220	1,080
Stock options	2,708	2,062
Operating lease liability	832	-
Operating lease ROU assets	(775)	-
Equity method investments and marketable securities at fair value	(19,367)	(7,848)
Other, net	984	174
Total	56,281	38,517
Valuation allowance	(59,596)	(38,517)
Net deferred tax liabilities	\$ (3,315)	\$ -

A valuation allowance is provided when it is more likely than not that all or 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. At December 31, 2019, a portion of the valuation allowance was released as it relates to Lineage's indefinite lived assets that can be used against the indefinite lived liabilities. The amount of the valuation allowance released was \$7.4 million year to date; 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, 2019, Lineage has gross net operating loss carryforwards of approximately \$164.0 million for federal purposes. As of December 31, 2019, Lineage's foreign subsidiaries have net operating loss carryforwards of approximately \$84.8 million which carryforward indefinitely.

As of December 31, 2019, Lineage has net operating losses of \$121.1 million for state tax purposes.

Federal net operating losses generated on or prior to December 31, 2017, expire in varying amounts between 2027 and 2037, while federal net operating losses generated after December 31, 2017, carryforward indefinitely. The state net operating losses expire in varying amounts between 2030 and 2039.

As of December 31, 2019, Lineage has research tax credit carryforwards for federal and state tax purposes of \$3.1 million and \$5.5 million, respectively. These tax credits reflect the amounts for Lineage, Asterias and OrthoCyte as of December 31, 2019. For federal purposes, the credits generated each year have a carryforward period of 20 years. The federal tax credits expire in varying amounts between 2020 and 2039, while the state tax credits have no expiration period.

U.S. Federal Income Tax Reform

On December 22, 2017, in response to the enactment of the 2017 Tax Act (see Note 2), the SEC staff issued SAB 118 that allows companies to record provisional amounts during a measurement period not to extend beyond one year from the enactment date. The repatriation tax is based primarily on LifeMap Sciences Ltd, an Israeli subsidiary of LifeMap Sciences, accumulated foreign earnings and profits that Lineage previously excluded from U.S. income taxes. As a result, LifeMap Sciences included \$227,000 in foreign earnings in federal income for the year ended December 31, 2017. The federal taxable income was offset by the LifeMap Sciences' net operating loss carryforwards resulting in no federal income tax due.

In addition, for the year ended December 31, 2017, Lineage remeasured certain deferred tax assets and liabilities based on the enacted tax rate at which they are expected to reverse in the future. The estimated tax effected amount related to the remeasurement of these balances was a reduction of Lineage's net deferred tax assets by \$8.9 million with a corresponding decrease in the valuation allowance by the same amount, recognized as of December 31, 2017, discussed below. Lineage applied the guidance in SAB 118 when accounting for the enactment-date effects of the 2017 Tax Act for the years ended December 31, 2019 and 2018. As of December 31, 2018, Lineage completed its accounting for all the enactment-date income tax effects of the 2017 Tax Act.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. As of December 31, 2017, the federal portion of the deferred tax assets and liabilities for 2017 were re-rated from 34% to 21% pursuant to the 2017 Tax Act.

Other Transactions and Related Impact on Income Taxes

On March 23, 2018, Ascendance Biotechnology, Inc. (“Ascendance”), a company in which AgeX owned a minority stake, was acquired by a third party in a merger through which AgeX received approximately \$3.2 million in cash for its shares of Ascendance common stock. For financial reporting purposes, AgeX recognized a \$3.2 million gain as a sale of its equity method investment in Ascendance. The sale was a taxable transaction to AgeX generating a taxable gain of approximately \$2.2 million. Lineage has sufficient net operating losses to offset the entire gain resulting in no income taxes due.

The Juvenescence Transaction discussed in Note 5 was a taxable event for Lineage that resulted in a gross taxable gain of approximately \$29.4 million, which Lineage expects to be fully offset with available current year net operating losses (“NOL”) and NOL carryforwards, resulting in no net income taxes due. Although the AgeX Deconsolidation on August 30, 2018 was not a taxable transaction to Lineage and did not result in a current tax payment obligation, the unrealized financial reporting gain (see Note 6) on the AgeX Deconsolidation generated a deferred tax liability in accordance with ASC 740, *Income Taxes*, primarily representing Lineage’s difference between book and tax basis of AgeX common stock on the AgeX Deconsolidation date. Lineage expects this deferred tax liability to be fully offset by a corresponding release of Lineage’s valuation allowance on deferred tax assets, resulting in no income tax provision or benefit from the AgeX Deconsolidation. The deferred tax liabilities on Lineage’s investments in OncoCyte, Asterias and AgeX are considered to be sources of taxable income 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, thereby reducing the need for a valuation allowance.

The distribution of AgeX shares of common stock to Lineage shareholders (see Note 6) on November 28, 2018 was a taxable event for Lineage that resulted in a gross taxable gain of approximately \$26.4 million, which Lineage fully offset with available net operating losses, resulting in no income taxes due.

Although the OncoCyte Deconsolidation on February 17, 2017 was not a taxable transaction to Lineage and did not result in a tax payment obligation, the \$71.7 million unrealized gain on the OncoCyte Deconsolidation generated a deferred tax liability that was fully offset by Lineage’s net operating losses. Subsequent to the OncoCyte Deconsolidation, an unrealized loss of \$2.9 million was recorded on the OncoCyte shares during the year ended December 31, 2017, which was fully offset by a corresponding increase in Lineage’s valuation allowance. An unrealized loss of \$48.0 million was recorded on the OncoCyte shares during the year ended December 31, 2018, which was fully offset by a corresponding increase in Lineage’s valuation allowance.

The market value of the respective shares Lineage holds in OncoCyte, AgeX 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, 2019 and 2018, 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, 2019 and 2018.

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 2015. 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. 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, 2019 and 2018, 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, 2019 is \$17,850 per month and will increase by 3% annually on every August 1 thereafter during the lease term. Base rent for the first twenty-four months of the lease is based upon a deemed rentable area of 7,000 square feet. Base rent is abated for months two through five of the lease.

In addition to base rent, Lineage will pay 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 Lease

In December 2015, Lineage entered into a lease for approximately 30,795 square feet of rentable space in two buildings located in an office park in Alameda, California (the “Alameda Lease”). The term of the Alameda Lease is seven years and Lineage has an option to renew the term for an additional five years. The term of the Alameda Lease commenced effective February 1, 2016 and expires on January 31, 2023, unless the renewal option is exercised.

Base rent under the Alameda Lease beginning on February 1, 2019 is \$70,521 per month and will increase by approximately 3% annually on every February 1 thereafter during the lease term.

Prior to the adoption of ASC 842 on January 1, 2019 (see Note 2), the lease payments allocated to the lease liability for leasehold improvements reimbursed by the landlord were amortized as debt service on that liability using the effective interest method over the lease term.

See Note 2 for discussion of the impact of adoption of ASC 842 on January 1, 2019, and below for the ROU assets and liabilities recorded in connection with the adoption of ASC 842 as of, and during the year ended December 31, 2019 for the Alameda Lease. In addition to base rent, Lineage will pay 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 Alameda Lease, 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 amount is considered restricted cash (see Note 2) and \$78,000 is included in deposits and other long-term assets as of December 31, 2019 (see Note 2).

New York Leased Office Space

Lineage currently pays \$5,050 per month for the use of approximately 900 square feet of office space in New York City, which is 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. This lease was not in the scope of ASC 842 because it is a month to month lease (see Note 2).

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, 2020, with two options to extend the lease for 5 years each (the “Original Cell Cure Lease”). Base monthly rent is NIS 37,882 (approximately US \$11,000 per month using the December 31, 2018 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 options to extend the lease for 5 years each (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 \$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).

Prior to the adoption of ASC 842 on January 1, 2019, Cell Cure was considered the owner of the tenant improvements under construction under ASC 840-40-55 as Cell Cure, among other things, had the primary obligation to pay for construction costs and Cell Cure retains exclusive use of the leased facilities for its office, research and cGMP manufacturing facility requirements after construction was completed (“build to suit” lease). In accordance with the ASC 840 guidance, amounts expended by Cell Cure for construction was reported as construction in progress, and the proceeds received from the landlord, if any, are reported as a lease liability. As of December 31, 2018, approximately \$1.1 million under the January 2018 Lease was incurred and recorded as leasehold improvement construction in progress (see Note 7), with a corresponding amount included in long term lease liability representing the full amount utilized from the landlord’s leasehold improvement construction allowance. By March 2019, the landlord paid the complete leasehold improvement construction allowance and the property was placed in service.

See Note 2 for discussion of the impact of adoption of ASC 842 on January 1, 2019, and below for the ROU assets and liabilities recorded in connection with the adoption of ASC 842 as of, and during the year ended December 31, 2019 for the Original Cell Cure Lease and January 2018 Lease (the “Cell Cure Leases”).

In December 2018, Cell Cure made a \$388,000 deposit required under the January 2018 Lease, which amount is included in deposits and other long-term assets on the consolidated balance sheet as of December 31, 2018, to be held as restricted cash during the term of the January 2018 Lease.

Adoption of ASC 842

The below tables provide the amounts recorded in connection with the adoption of ASC 842 as of, and during the year ended December 31, 2019, 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, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	\$ 1,364
Operating cash flows from financing leases	28
Financing cash flows from financing leases	30
Right-of-use assets obtained in exchange for lease obligations:	
Operating leases	738
Financing leases	-

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

	December 31, 2019
Operating leases	
Right-of-use assets, net	\$ 4,666
Right-of-use lease liabilities, current	\$ 1,190
Right-of-use lease liabilities, noncurrent	3,868
Total operating lease liabilities	\$ 5,058
Financing leases	
Property and equipment, gross	\$ 96
Accumulated depreciation	(48)
Property and equipment, net	\$ 48
Current liabilities	\$ 33
Long-term liabilities	77
Total finance lease liabilities	\$ 110
Weighted average remaining lease term	
Operating leases	4.1 years
Finance leases	3.4 years
Weighted average discount rate	
Operating leases	9.1%
Finance leases	10.0%

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

Year Ending December 31,	Operating Leases	Finance Leases
2020	\$ 1,590	\$ 43
2021	1,528	36
2022	1,508	36
2023	397	15
2024	308	-
Thereafter	811	-
Total lease payments	\$ 6,142	\$ 130
Less imputed interest	(1,084)	(20)
Total	\$ 5,058	\$ 110

Research and Option Agreement

On January 5, 2019, Lineage and Orbit Biomedical Limited (“Orbit”) entered into a Research and Option Agreement (the “Orbit Agreement”) for an exclusive partnership to assess Orbit’s vitrectomy-free subretinal injection device as a means of delivering OpRegen in Lineage’s ongoing Phase 1/2a clinical trial. The term of the Orbit Agreement is for one year unless certain research activities and related data specified in the Orbit Agreement is obtained sooner. The access fees payable by Lineage to Orbit for its technology and the injection device are \$2.5 million in the aggregate, of which \$1.25 million was paid in January 2019 upon execution of the Orbit Agreement and the remaining \$1.25 million payment which was due on the earlier of (i) six months from the Orbit Agreement date or, (ii) upon completion of certain collaborative research activities using the Orbit technology for the OpRegen Phase 1/2a clinical trial, as specified in the Orbit Agreement. In addition to the access fees, Lineage reimburses Orbit for costs of consumables, training services, travel costs and other out of pocket expenses incurred by Orbit for performing services under the Orbit Agreement. Lineage has exclusive rights to the Orbit technology and its injection device for the treatment of dry-AMD during the term of the Orbit Agreement and may extend the term for an additional three months by paying Orbit a cash fee of \$500,000. In July 2019, Lineage completed the collaborative research activities referred to above and the second \$1.25 million payment was made in August 2019. The Orbit fees of \$2.5 million were amortized on a straight-line basis throughout 2019 and included in research and development expenses.

Litigation – General

Lineage is subject to various claims and contingencies in the ordinary course of its business, including those related to litigation, business transactions, employee-related matters, and others. When Lineage is aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. If it is probable that a loss will result and the amount of the loss can be reasonably estimated, Lineage will record a liability for the loss. If the loss is not probable or the amount of the loss cannot be reasonably estimated, Lineage discloses the claim if the likelihood of a potential loss is reasonably possible and the amount involved could be material. Lineage is not aware of any claims likely to have a material adverse effect on its financial condition or results of operations.

On February 19, 2019, a putative shareholder class action lawsuit was filed (captioned *Lampe v. Asterias Biotherapeutics, Inc. et al.*, Case No. RG19007391) in the Superior Court of the State of California, County of Alameda challenging the Asterias Merger. On March 1, 2019, Asterias made certain amendments and supplements to its public disclosures regarding the Asterias Merger (the “Supplemental Disclosures”). On May 3, 2019, an amended class action complaint (the “Amended Complaint”) was filed. The Amended Complaint named Lineage, Patrick Merger Sub, Inc., the Asterias board of directors, one member of Lineage’s board of directors, and certain stockholders of both Lineage and Asterias. The action was brought by two purported stockholders of Asterias, on behalf of a putative class of Asterias stockholders, and asserted breach of fiduciary duty and aiding and abetting claims under Delaware law. The Amended Complaint alleged, among other things, that the process leading up to the Asterias Merger was conflicted and 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 Amended Complaint sought, among other things, that a class be certified, the recovery of monetary damages, and attorneys’ fees and costs.

On June 3, 2019, defendants filed demurrers to the Amended Complaint. On August 13, 2019, the parties submitted a stipulation to the court seeking dismissal of the action with prejudice as to the named Plaintiffs and without prejudice as to the unnamed putative class members, and disclosing to the court the parties’ agreement to resolve, for \$200,000, Plaintiffs’ claim for an award of attorneys’ fees and expenses in connection with the purported benefit conferred on Asterias stockholders by the Supplemental Disclosures. The court granted the stipulation and dismissed the action August 14, 2019. Lineage continues to believe that the claims and allegations in the action lack merit, but believed that it was in Lineage’s shareholders’ best interest for the action to be dismissed and to resolve the fee claim in a timely manner without additional costly litigation expenses.

On October 14, 2019, another 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.

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, 2019 and 2018.

Second Amended and Restated License Agreement

On June 15, 2017, Cell Cure entered into a Second Amended and Restated License Agreement (the “License Agreement”) with Hadasit Medical Research Services and Development Ltd. (“Hadasit”), the commercial arm and a wholly owned subsidiary of Hadassah Medical Organization. Pursuant to the License Agreement, Hadasit granted Cell Cure an exclusive, worldwide, royalty bearing license (with the right to grant sublicenses) in its intellectual property portfolio of materials and technology related to human stem cell derived photoreceptor cells and retinal pigment epithelial cells (the “Licensed IP”), to use, commercialize and exploit any part thereof, in any manner whatsoever in the fields of the development and exploitation of (i) human stem cell derived photoreceptor cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders, and (ii) human stem cell derived retinal pigment epithelial cells, solely for use in cell therapy for the diagnosis, amelioration, prevention and treatment of eye disorders.

As consideration for the Licensed IP, Cell Cure will pay a small one-time lump sum payment, a royalty in the mid-single digits of net sales from sales of Licensed IP by any invoicing entity, and a royalty of 21.5% of sublicensing receipts. In addition, Cell Cure will pay Hadasit an annual minimal non-refundable royalty, which will become due and payable the first January 1 following the completion of services to Cell Cure by a research laboratory.

Cell Cure will pay Hadasit non-refundable milestone payments upon the recruitment of the first patient for the first Phase 2b clinical trial, upon the enrollment of the first patient in the first Phase 3 clinical trials, upon delivery of the report for the first Phase 3 clinical trials, upon the receipt of an NDA or marketing approval in the European Union, whichever is the first to occur, and upon the first commercial sale in the United States or European Union, whichever is the first to occur. Such milestones, in the aggregate, may be up to \$3.5 million. As of December 31, 2019, Cell Cure had not accrued any milestone payments under the License Agreement.

The License Agreement terminates upon the expiration of Cell Cure's obligation to pay royalties for all licensed products, unless earlier terminated. In addition to customary termination rights of both parties, Hadasit may terminate the License Agreement if Cell Cure fails to continue the clinical development of the Licensed IP or fails to take actions to commercialize or sell the Licensed IP over any consecutive 12 month period. The License Agreement also contains mutual confidentiality obligations of Cell Cure and Hadasit, and indemnification obligations of Cell Cure.

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. Prior to the AgeX Distribution, annual minimum maintenance fees were approximately \$135,000 to \$150,000 per year. For 2019 and future years, we now expect annual minimum maintenance fees to be approximately \$30,000 to \$60,000 per year. License fees and related expenses under these agreements were \$47,000 and \$133,000 for the years ended December 31, 2019 and 2018, respectively.

Grants

Under the terms of the grant agreement between Cell Cure and Israel Innovation Authority ("IIA") (formerly the Office of the Chief Scientist of Israel) of the Ministry of Economy and Industry, for the development of OpRegen[®], Cell Cure will be required to pay royalties on future product sales, if any, up to the amounts received from the IIA, plus interest indexed to LIBOR. Cell Cure's research and product development activities under the grant are subject to substantial risks and uncertainties and performed on a best efforts basis. As a result, Cell Cure is not required to make any payments under the grant agreement unless it successfully commercializes OpRegen[®]. Accordingly, pursuant to ASC 730-20, the Cell Cure grant is considered a contract to perform research and development services for others and grant revenue is recognized as the related research and development expenses are incurred (see Note 2).

Israeli law pertaining to such government grants contain various conditions, including substantial penalties and restrictions on the transfer of intellectual property, or the manufacture, or both, of products developed under the grant outside of Israel, as defined by the IIA.

15. 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, orthopedics, oncology, and neurological diseases and disorders, blood and vascular system diseases and disorders, blood plasma volume expansion, diagnostic products for the early detection of cancer, and hydrogel products that may be used in surgery, and products for pluripotent cell technologies. As a result, the financial information disclosed materially represents all of the financial information related to Lineage's sole operating segment.

16. 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).

Geographic Area	Year Ended December 31,	
	2019	2018 ⁽¹⁾
United States	\$ 2,092	\$ 1,804
Foreign ⁽²⁾	1,423	3,184
Total revenues	<u>\$ 3,515</u>	<u>\$ 4,988</u>

(1) Amounts recognized prior to adoption of Topic 606 have not been adjusted under the Topic 606 modified retrospective transition method.

(2) 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, 2019 and 2018, is set forth below (in thousands):

	December 31,	
	2019	2018
Domestic	\$ 3,654	\$ 2,038
Foreign ⁽¹⁾	4,521	3,797
Total	<u>\$ 8,175</u>	<u>\$ 5,835</u>

(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).

REVENUES:	Year Ended December 31,	
	2019	2018 ⁽¹⁾
Grant revenue	\$ 2,037	\$ 3,572
Royalties from product sales and license fees	1,221	392
Subscription and advertisement revenues ⁽²⁾	-	691
Sale of research products and services	257	333
Total revenues	<u>\$ 3,515</u>	<u>\$ 4,988</u>

(1) Amounts recognized prior to adoption of Topic 606 have not been adjusted under the Topic 606 modified retrospective transition method.

(2) These revenues were generated by LifeMap Sciences, a subsidiary of AgeX. The revenues shown for 2018 are for the period January 1, 2018 through August 29, 2018. As a result of the AgeX Deconsolidation on August 30, 2018, Lineage does not expect to recognize this type of revenue in subsequent accounting periods.

Prepaid expenses and other current assets at December 31, 2019 includes \$0.8 million of receivables related to royalties from product sales and license fees.

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, 2019, 2018, and 2017:

Sources of Revenues	Year Ended December 31,	
	2019	2018
NIH grant income ⁽¹⁾	17.5%	21.2%
IIA (formerly OCS) grant income (Cell Cure, Israel)	40.5%	50.4%
Royalties, licenses, subscriptions, advertising and other	34.7%	20.5%
Sale of research products	7.3%	4.2%
Other	-%	3.7%

17. 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, 2019	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenues, net	\$ 928	779	567	1,241
Operating expenses	13,621	11,493	8,875	7,990
Loss from operations	(12,761)	(10,821)	(8,422)	(6,872)
Net income (loss) attributable to Lineage	39,310	(30,032)	(16,505)	(4,482)
Basic net income (loss) per share	\$ 0.30	\$ (0.20)	\$ (0.11)	\$ (0.03)
Year Ended December 31, 2018				
Revenues, net	\$ 701	\$ 2,547	\$ 982	\$ 758
Operating expenses	12,779	11,585	11,304	10,813
Loss from operations	(12,187)	(9,144)	(10,357)	(10,107)
Net income (loss) attributable to Lineage	(63,548)	(4,215)	66,725	(44,952)
Basic net income (loss) per share	\$ (0.50)	\$ (0.03)	\$ 0.53	\$ (0.36)

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.

18. Subsequent Events

Sale of OncoCyte Shares

Lineage sold 2,383,090 shares of OncoCyte common stock for net proceeds of \$5.0 million on January 2, 2020. Lineage's ownership in OncoCyte was reduced to 9.98% at this time.

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, 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 period covered by this Report 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, 2019, based on criteria established in the 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management believes that, as of that date, our internal control over financial reporting was effective.

This Report includes an attestation report of our independent registered public accounting firm regarding internal control over financial reporting for the year ended December 31, 2019. The attestation is included with the accounting firm's report on our audited consolidated financial statements.

ITEM 9B. OTHER INFORMATION

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 2020 Annual Meeting of Shareholders (the “2020 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 caption “Corporate Governance” in our 2020 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 2020 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 2020 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 2020 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 2020 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING 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 2020 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements.

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

Consolidated Balance Sheets
 Consolidated Statements of Operations
 Consolidated Statements of Comprehensive Loss
 Consolidated Statements of Changes in Shareholders' Equity
 Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

(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.

Exhibit Number	Description	Incorporation by Reference			
		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				
10.1+	Employment Agreement dated October 10, 2007, between Registrant and Michael D. West ("West Employment Agreement")	10.23	10-KSB	April 14, 2008	001-12830
10.1(a)+	Amendment to West Employment Agreement dated November 24, 2015	10.1	8-K	December 1, 2015	001-12830
10.2+	Transition Agreement dated September 17, 2018, between Registrant and Michael D. West	10.3	8-K	September 18, 2018	001-12830
10.3	Commercial License and Option Agreement between Registrant and Wisconsin Alumni Research Foundation ("WARF Agreement")	10.1	8-K	January 9, 2008	001-12830
10.3(a)	First Amendment of WARF Agreement dated March 11, 2009	10.38	10-K	March 23, 2009	001-12830
10.4+	OrthoCyte Corporation 2010 Stock Option Plan; Form of OrthoCyte Corporation Stock Option Agreement	10.41	10-K	March 23, 2009	001-12830
10.5+	BioTime Asia, Limited 2010 Stock Option Plan; Form of BioTime Asia Limited Stock Option Agreement	10.42	10-K	March 15, 2011	001-12830
10.6+	Lineage Cell Therapeutics 2012 Equity Incentive Plan, as amended July 2015 ("2012 Plan")	4.1	S-8	July 15, 2015	333-205661
10.6(a)+	Amendment to 2012 Plan effective June 2017	4.2	S-8	July 7, 2017	333-219204
10.6(b)+	Amendment to 2012 Plan effective July 2019	99.3	S-8	August 8, 2019	333-233132

Incorporation by Reference

Exhibit Number	Description	Exhibit Number	Filing	Filing Date	File No.
10.6(c)+	Amendment to 2012 Plan effective August 2019	10.1	10-Q	November 12, 2019	001-12830
10.6(d)+	2012 Plan Form of Employee Incentive Stock Option Agreement	10.7	10-Q	November 12, 2013	001-12830
10.6(e)+	2012 Plan Form of Non-employee Director Stock Option Agreement	10.8	10-Q	November 12, 2013	001-12830
10.6(f)+	2012 Plan Stock Option Grant Agreement	10.2	10-Q	November 12, 2019	000-12830
10.6(g)*+	2012 Plan Form of Restricted Stock Unit				
10.7+	Cell Cure Neurosciences Ltd. Share Option Plan	10.38	10-K	March 16, 2017	001-12830
10.7(a)+	Form of Cell Cure Neurosciences Ltd. Share Option Plan Option Agreement	10.39	10-K	March 16, 2017	001-12830
10.8+	Inducement Stock Option Agreement between Registrant and Brian Culley	10.38	10-K	March 14, 2019	001-12830
10.9	Exclusive License Agreement dated February 15, 2006, between Registrant and the University of Utah Research Foundation, as amended	10.1	10-Q	November 9, 2012	001-12830
10.10+	Employment Agreement dated December 29, 2014, between Registrant and Aditya Mohanty (“Mohanty Employment Agreement”)	10.64	10-K	March 11, 2015	001-12830
10.10(a)+	Amendment of Mohanty Employment Agreement dated November 24, 2015	10.2	8-K	December 1, 2015	001-12830
10.11+	Transition Agreement dated September 17, 2018, between Registrant and Aditya P. Mohanty	10.2	8-K	September 18, 2018	001-12830
10.12+	Employment Agreement dated November 16, 2015, between Registrant and Russell Skibsted	10.1	8-K	November 16, 2015	001-12830
10.13	Lease dated December 10, 2015, between Registrant and BSREP Marina Village Owner LLC	10.1	8-K	December 15, 2015	001-12830
10.14	Controlled Equity OfferingSM Sales Agreement dated April 6, 2017 between Registrant, and Cantor Fitzgerald & Co.	1.2	S-3	April 6, 2017	333-217182
10.15†	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
10.15(a)	Amendment to Hadasit License dated January 8, 2018	10.38	10-K	March 15, 2018	001-12830
10.16†	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
10.17†	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
10.18†	Asset Contribution and Separation Agreement dated August 17, 2017, between Registrant and AgeX Therapeutics, Inc. (“AgeX”)	10.1	10-Q	November 9, 2017	001-12830
10.19†	License Agreement dated August 17, 2017, between Registrant and AgeX	10.2	10-Q	November 9, 2017	001-12830
10.20	Stock Purchase Agreement dated August 30, 2018, between Registrant, AgeX and Juvenescence Limited (“Juvenescence”)	10.1	8-K	August 21, 2018	001-12830

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
10.21	Convertible Promissory Note issued by Juvenescence dated August 30, 2018	10.2	8-K	August 21, 2018	001-12830
10.22+	Employment Agreement effective September 17, 2018, between Registrant and Brian Culley	10.1	8-K	September 18, 2018	001-12830
10.23+	Employment Agreement effective January 7, 2019, between Registrant and Brandi Roberts	10.38	10-K	March 14, 2019	001-12830
10.24+	Employment Agreement effective March 8, 2019, between Registrant and Edward D. Wirth, III	10.2	10-Q	May 9, 2019	001-12830
10.25*+	Employment Agreement effective May 20, 2019, between Registrant and Chase Leavitt				
10.26	Royalty Agreement dated October 1, 2013, between Asterias and Geron Corporation	10.6	Asterias S-1/A	August 13, 2013	333-187706
10.27	Exclusive Sublicense Agreement between Geron Corporation and Asterias	10.7	Asterias S-1/A	August 13, 2013	333-187706
10.28	Exclusive License Agreement dated February 20, 2003, and First Amendment thereto dated September 7, 2004, between The Regents of the University of California and Geron Corporation	10.4	Asterias 10-Q	November 12, 2013	000-55046
10.29†	Non-exclusive License Agreement dated October 7, 2013, between WARF and Asterias	10.5	Asterias 10-Q	November 12, 2013	000-55046
10.30†	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
21.1*	List of Subsidiaries				
23.1*	Consent of OUM & Co. LLP				
31.1*	Certification of Chief Executive Officer pursuant to Form of Rule 13a-14(a), as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of 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, dated March 14, 2019				
32.1#	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 14, 2019				
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				

* Filed herewith

Furnished herewith

+ Indicates management contract or compensatory plan

† Portions of this exhibit have been omitted pursuant to a request for confidential treatment

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 12th day of March 2020.

LINEAGE CELL THERAPEUTICS, INC.

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Brian M. Culley</u> BRIAN M. CULLEY	Chief Executive Officer and Director (Principal Executive Officer)	March 12, 2020
<u>/s/ Brandi Roberts</u> BRANDI ROBERTS	Chief Financial Officer (Principal Financial and Accounting Officer)	March 12, 2020
<u>/s/ Deborah Andrews</u> DEBORAH ANDREWS	Director	March 12, 2020
<u>/s/ Don M. Bailey</u> DON M. BAILEY	Director	March 12, 2020
<u>/s/ Neal C. Bradsher</u> NEAL C. BRADSHER	Director	March 12, 2020
<u>/s/ Stephen C. Farrell</u> STEPHEN C. FARRELL	Director	March 12, 2020
<u>/s/ Alfred D. Kingsley</u> ALFRED D. KINGSLEY	Director	March 12, 2020
<u>/s/ Michael H. Mulroy</u> MICHAEL H. MULROY	Director	March 12, 2020
<u>/s/ Angus C. Russell</u> ANGUS C. RUSSELL	Director	March 12, 2020

DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 12, 2020, Lineage Cell Therapeutics, Inc. (the “**Company**”) has one class of securities registered under Section 12 of the Securities Exchange Act of 1934: common shares, no par value (the “common shares”).

The following is a description of the rights of the common shares and related provisions of: (i) the Company’s Restated Articles of Incorporation, as amended (as amended by the Certificate of Ownership, the “**Articles**”); (ii) the Company’s Amended and Restated Bylaws (the “**Bylaws**”); and (iii) applicable California law. This description is qualified in its entirety by, and should be read in conjunction with, the Articles, the Bylaws and applicable California law. The Articles and Bylaws are filed as exhibits to the Annual Report on Form 10-K of which this exhibit is a part. The Annual Report is filed with the U.S. Securities and Exchange Commission and is publicly available.

Authorized Capital Stock

Pursuant to the Articles, the Company is authorized to issue an aggregate of 252,000,000 shares of capital stock consisting of 250,000,000 common shares and 2,000,000 preferred shares. All of the outstanding common shares are fully paid and non-assessable.

Common Shares***Voting Rights***

Each holder of common shares is entitled to one vote for each common share held on every matter properly submitted to the shareholders for their vote; provided that such holders may have cumulative voting rights in the election of directors if the candidates’ names have been placed in nomination prior to commencement of the voting and a shareholder has given notice prior to commencement of the voting of the shareholder’s intention to cumulate votes.

Dividend Rights

Subject to any preferential rights or preferences of preferred shares outstanding, if any, holders of the common shares are entitled to any dividend declared by the Company’s Board of Directors (the “**Board**”) out of funds legally available for that purpose.

Liquidation Rights

Subject to any preferential rights or preferences of holders of preferred shares outstanding, if any, holders of the common shares are entitled to receive on a pro rata basis all of the Company’s remaining assets available for distribution to the holders of the common shares in the event of the liquidation, dissolution, or winding up of the Company’s operations.

No Preemptive or Similar Rights

Holders of the common shares do not have any preemptive rights to become subscribers or purchasers of additional shares of any class of the Company’s capital stock. There are no redemption or sinking fund provisions applicable to the common shares.

Rights of Preferred Shares May be Senior to Common Shares

The Company may issue preferred shares in one or more series, at any time, with such rights, preferences, privileges and restrictions as the Board may determine, all without further action of the Company’s shareholders. Any series of preferred shares authorized by the Board in the future may be senior to and have greater rights and preferences than the common shares and may have restrictions on the Company’s repurchase or redemption of shares.

Anti-takeover Provisions of the Articles, Bylaws and California Law

Provisions of the Articles and Bylaws may delay or discourage transactions involving an actual or potential change in control of the Company or change in its management, including transactions in which shareholders might otherwise receive a premium for their shares, or transactions that its shareholders might otherwise deem to be in their best interests. Among other things, the Articles and Bylaws:

- provide that, except for a vacancy caused by the removal of a director by the shareholders or by court order, a vacancy on the Board may be filled by approval of a majority of the remaining directors, though less than a quorum, or by a sole remaining director;
- provide that shareholders seeking to present proposals before a meeting of shareholders or to nominate candidates for election as directors at a meeting of shareholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of such notice;
- authorize the Board to issue preferred shares in series and to fix rights and preferences of the series (including, among other things, whether, and to what extent, the shares of any series will have voting rights and the extent of the preferences of the shares of any series with respect to dividends and other matters); and
- provide that, at a meeting of shareholders at which directors are to be elected, no shareholder shall be entitled to cumulate votes unless the candidates' names have been placed in nomination prior to commencement of the voting and a shareholder has given notice prior to commencement of the voting of the shareholder's intention to cumulate vote.

In addition, as a California corporation, the Company is subject to the provisions of Section 1203 of the California General Corporation Law, which requires it to provide a fairness opinion to its shareholders in connection with their consideration of any proposed "interested party" reorganization transaction.

Listing

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

Transfer Agent and Registrar

The transfer agent and registrar for the common shares is American Stock Transfer & Trust Company, LLC.

LINEAGE CELL THERAPEUTICS, INC.
RESTRICTED STOCK UNIT GRANT NOTICE
2012 EQUITY INCENTIVE PLAN

Lineage Cell Therapeutics, Inc., a California corporation (the “*Company*”), has granted to the participant listed below (“*Participant*”) the Restricted Stock Units (the “*RSUs*”) described in this Restricted Stock Unit Grant Notice (this “*Notice*”), subject to the terms of the Lineage Cell Therapeutics, Inc. 2012 Equity Incentive Plan (as amended from time to time, the “*Plan*”) and the Restricted Stock Unit Agreement attached as Exhibit A hereto (the “*Agreement*,” and, together with this Notice and the Plan, the “*RSU Documents*”), both of which are incorporated into this Notice by reference. Capitalized terms not defined in this Notice or the Agreement have the meanings given to them in the Plan.

- Participant:**
- Grant Date:**
- Number of RSUs:**
- Vesting Schedule:**
- Other Terms:**

By accepting the RSU, Participant agrees to be bound by the terms of the RSU Documents. Participant has reviewed the RSU Documents in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Notice, and fully understands all provisions of RSU Documents. Participant hereby agrees to accept as binding, conclusive, and final all decisions or interpretations of the Administrator (defined below) regarding any questions arising under the RSU Documents. “*Administrator*” means the Board or a Committee of the Board to the extent the Board’s powers or authority under the Plan have been delegated to such Committee pursuant to the Plan.

Lineage Cell Therapeutics, Inc.

Participant

By:

By:

Name:

Name:

Title:

Title:



EXHIBIT A

RESTRICTED STOCK UNIT AGREEMENT

Capitalized terms not defined in this Restricted Stock Unit Agreement (this “**Agreement**”) have the meanings specified in the Restricted Stock Unit Grant Notice (the “**Notice**”) or, if not defined in the Notice, in the Plan.

1. General

(a) Grant of RSU. The Company has granted the RSUs to Participant effective as of the grant date set forth in the Notice (the “**Grant Date**”). Each RSU represents the right to receive one common share, no par value, of the Company (a “**Share**”) as set forth in this Agreement. Participant will have no right to the distribution of any Shares until the RSUs vest. Prior to settlement, the RSUs represent an unsecured Company obligation payable only from the Company’s general assets.

(b) Incorporation of Terms of Plan. The RSUs are subject to the terms of this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the Plan will control.

2. Vesting, Forfeiture, and Settlement

(a) Vesting; Forfeiture. The RSUs will vest according to the vesting schedule in the Notice; provided that any fraction of an RSU will accumulate and vest only when a whole RSU has accumulated. Notwithstanding anything in the RSU Documents, except as set forth in the Notice, a separate Agreement between Participant and the Company or as determined by the Administrator, any unvested RSUs will immediately and automatically be cancelled and forfeited on the date of termination of Participant’s Continuous Service (“**Termination of Service**”) for any reason.

(b) Settlement. RSUs will be paid in Shares as soon as administratively practicable after the vesting of the applicable RSU, but in no event more than 60 days following the RSUs’ vesting date unless otherwise provided in the Notice. Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)); provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

3. Taxation and Tax Withholding

(a) Representation. Participant represents that Participant has reviewed with Participant’s own tax advisors the tax consequences of this Award and the transactions contemplated by the Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

(b) Tax Withholding.

(i) The Company shall withhold, or cause to be withheld, Shares otherwise vesting or issuable under this Award (including the RSUs) in satisfaction of any applicable withholding tax obligations. The number of Shares withheld shall be limited to the number of Shares which have a fair market value on the date of withholding no greater than the aggregate amount of liabilities based on the maximum individual statutory withholding rates in Participant's applicable jurisdictions for federal, state, local, and foreign income tax and payroll tax purposes that are applicable to such taxable income.

(ii) Participant acknowledges that Participant is liable and responsible for all taxes owed in connection with the RSUs, regardless of any action the Company or any Subsidiary takes with respect to any tax withholding obligations that arise in connection with the RSUs. Neither the Company nor any Subsidiary makes any representation or undertaking regarding the treatment of any tax withholding in connection with the awarding, vesting, or payment of the RSUs or the subsequent sale of Shares. The Company and its Subsidiaries are under no obligation to structure the RSUs to reduce or eliminate Participant's tax liability

4. Other Provisions

(a) Adjustments. Participant acknowledges that the RSUs and the Shares subject to the RSUs are subject to adjustment, modification, and termination in certain events as provided in this Agreement and the Plan.

(b) Notices. Any notice to be given under this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address. Any notice to be given under this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address or email address. Either party may designate a different address or email address for notices to be given to that party by providing notice to the other party of such change pursuant to this Section 4(b). Any notice will be deemed duly given when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, or when delivered by a nationally recognized express shipping company.

(c) Titles. Titles are provided herein for convenience only and do not serve as a basis for interpretation or construction of this Agreement.

(d) Conformity to Securities Laws. Participant acknowledges that each RSU Document is intended to conform to all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.

(e) Successors and Assigns. The Company may assign any of its rights under this Agreement to one or more assignees, and this Agreement will inure to the benefit of the Company's successors and assigns. Subject to any transfer restrictions in this Agreement or the Plan, this Agreement will be binding on and inure to the benefit of the heirs, legatees, legal representatives, successors, and assigns of the parties hereto.

(f) Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, each RSU Document will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.

(g) Entire Agreement. The RSU Documents constitute the entire agreement of the parties and supersede all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.

(h) Agreement Severable. If any provision of the Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Notice or this Agreement.

(i) Limitation on Participant's Rights. Participation in the Plan provides no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs, and rights no greater than the right to receive Shares as a general unsecured creditor with respect to the RSU, as and when settled pursuant to the terms hereof.

(j) Not a Contract of Employment. Nothing in the RSU Documents: (i) provides Participant any right to continued employment or service with the Company or any Subsidiary; or (ii) interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the employment or services of Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.

(k) Counterparts. The Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

(l) Governing Law. This Agreement is governed by and construed under the laws of the state of California, without regard to conflict of law provisions.

EMPLOYMENT AGREEMENT

EMPLOYMENT AGREEMENT (“Agreement”) is made May 20, 2019 (“Effective Date”), by and between BioTime, Inc. (“Company”), a California corporation, and Chase C. Leavitt (“Executive”).

NOW, THEREFORE, in consideration of the terms and conditions hereinafter set forth, the parties hereto agree as follows:

1. Engagement; Position and Duties.

(a) Position and Duties. Company agrees to employ Executive in the position of General Counsel and Corporate Secretary to perform the duties as outlined on Exhibit A and as the Chief Executive Officer (CEO) or the Board of Directors of the Company (the “Board of Directors”) may from time to time direct or require. Executive shall report to the Chief Executive Officer. Executive shall devote best efforts, skills and abilities, on a full-time basis, exclusively to the Company’s business. Executive covenants and agrees to faithfully adhere to and fulfill such policies as are established from time to time by the Board of Directors or Company (“Policies”).

(b) No Conflicting Obligations. Executive represents and warrants to Company that Executive is under no obligations or commitments, whether contractual or otherwise, that are inconsistent with Executive’s obligations under this Agreement or that would prohibit Executive, contractually or otherwise, from performing Executive’s duties under this Agreement and the Policies.

(c) No Unauthorized Use of Third Party Intellectual Property. Executive represents and warrants to Company that Executive will not use or disclose, in connection with Executive’s employment by Company, any patents, trade secrets, confidential information, or other proprietary information or intellectual property as to which any other person has any right, title or interest, except to the extent that Company holds a valid license or other written permission for such use from the owner(s) thereof. Executive represents and warrants to Company that Executive has returned all property and confidential information belonging to any prior employer.

2. Compensation

(a) Salary. During the term of this Agreement, Company shall pay to the Executive a salary of \$340,000.00 annually. Executive’s salary shall be paid in equal semi-monthly installments, consistent with Company’s regular salary payment practices. Executive’s salary may be increased from time-to-time by Company, in Company’s sole and absolute discretion, without affecting this Agreement. Company shall pay Executive a sign-on bonus in the amount of \$35,000 (minus applicable state and federal income tax deductions): paid in two installments. First payment of \$17,500 on May 31, 2019; second payment of \$17,500 on August 31, 2019.

(b) Bonus. Executive may be eligible for an annual bonus of up to 40% of Executive's annual salary, as may be approved by the Board of Directors (or the Compensation Committee of the Board of Directors (the "Compensation Committee")) in its discretion, based on Executive's achievement of predetermined Company and/or individual objectives set by the Board of Directors or the Compensation Committee, from time to time. Executive also agrees that neither the Board of Directors nor Company is obligated to adopt any bonus plan, to maintain in effect any bonus plan that may now be in effect or that may be adopted during the term of Executive's employment, or to pay Executive a bonus unless a bonus is earned under the terms and conditions of any bonus plan adopted by Company.

(c) Expense Reimbursements. Company shall reimburse Executive for reasonable travel and other business expenses (but not expenses of commuting to a primary workplace) incurred by Executive in the performance of Executive's duties under this Agreement, subject to, and in accordance with, the Policies and Company procedures in effect from time to time, and provided that Executive submits supporting vouchers.

(d) Benefit Plans. Executive may be eligible (to the extent Executive qualifies) to participate in certain retirement, pension, life, health, accident and disability insurance, equity incentive plan or other similar employee benefit plans (collectively, "Benefit Plans"), which may be adopted by Company from time to time for its executive officers or other employees, in each case, subject to the terms thereof, including any eligibility requirements thereof. Company has the right, at any time and without any amendment of this Agreement, and without prior notice to or consent from Executive, to adopt, amend, change, or terminate any and all Benefit Plans that may now be in effect or that may be adopted in the future, in each case without any further obligation (financial or otherwise) to Executive; provided that any such amendment, change or termination effected without the consent of Executive does not apply to Executive in a manner that is substantially different than it applies to other Company executives or employees of a comparable executive level, except for amendments, changes or terminations required by applicable federal, state or local law or regulation, or implemented in response to any change of federal, state or local law or regulation. Any benefits to which Executive may be entitled under any Benefit Plan shall be governed by the terms and conditions of the applicable Benefit Plan, and any related plan documents, as in effect from time to time. If Executive receives any grant of stock options or stock or stock related equity awards ("Awards") under any stock option plan, stock purchase plan, or other equity incentive plan of Company (an "Equity Plan"), the terms and conditions of the Award, and Executive's rights with respect to the Award, shall be governed by (i) the terms of the Equity Plan, as the same may be amended from time to time, and (ii) the terms and conditions of any stock option agreement, stock purchase agreement, or other agreement that Executive may sign or be required to sign with respect to any Award.

(e) Vacation; Sick Leave. Executive shall be entitled to 20 paid time off (“PTO”) days (accrued on a biweekly pay period basis and capped at 1.5 times the yearly accrual), 24 hours of annual sick leave, without reduction in compensation, during each calendar year, or as may be provided by the Policies. Executive’s vacation shall be taken at such time as is consistent with the Company needs and the Policies. All PTO days and sick leave hours shall accrue annually based upon days of service. Executive’s right to leave from work due to illness is subject to the Policies and the provisions of this Agreement governing termination due to disability, sickness or illness. The Policies governing the disposition of unused PTO days and sick leave hours remaining at the end of Company’s fiscal year shall govern whether unused vacation days or sick leave hours will be paid, lost, or carried over into subsequent fiscal years.

(f) Stock Option Grants. On the date of this agreement, Executive shall be granted a stock option to purchase up to 300,000 shares of Company common stock (the “Initial Option”). In addition, Executive will be granted another stock option to purchase up to 125,000 shares of Company common stock on July 31, 2019 (the “Second Option”). Each of the Initial Option and the Second Option: (1) will have an exercise price equal to the closing price of Company common stock on the grant date, (2) will vest as to $\frac{1}{4}$ of the shares subject to the application option on the first anniversary of the date Executive commences employment with the Company and the remainder of the shares will vest in a series of 36 successive substantially equal monthly installments thereafter, and (3) will be subject to the terms set forth in Company’s equity incentive plan pursuant to which the option grant is being made and to the terms of the stock option agreement Executive will be required to sign with respect to each grant.

3. Competitive Activities. During the term of Executive’s employment, and for 24 months thereafter, Executive shall not, for Executive or any third party, directly or indirectly employ, solicit for employment or recommend for employment any person employed by Company. During the term of Executive’s employment, Executive shall not, directly or indirectly as an employee, contractor, officer, director, member, partner, agent, or equity owner, engage in any activity or business that competes or could reasonably be expected to compete with the business of Company. Executive acknowledges that there is a substantial likelihood that the activities described in this Section would (a) involve the unauthorized use or disclosure of Company’s confidential information and that use or disclosure would be extremely difficult to detect, and (b) result in substantial competitive harm to the business of Company. Executive has accepted the limitations of this Section as a reasonably practicable and unrestrictive means of preventing such use or disclosure of Company confidential information and preventing such competitive harm.

4. Inventions/Intellectual Property/Confidential Information. Executive acknowledges the execution and delivery to Company of an Employee Confidential Information and Inventions Assignment Agreement” (the “Confidentiality and IP Agreement”), attached hereto as **Exhibit B**.

5. Termination of Employment. Executive understands and agrees that Executive’s employment has no specific term. This Agreement, and the employment relationship, are “at will” and may be terminated by Executive or by Company with or without cause at any time by notice given orally or in writing. Except as otherwise agreed in writing or as otherwise provided in this Agreement, upon termination of Executive’s employment, Company shall have no further obligation to Executive, by way of compensation or otherwise, as expressly provided in this Agreement.

(a) Payments Due Upon Termination of Employment. Upon termination of Executive's employment with Company at any time and for any reason, in the event of the termination of Executive's employment by Company for Cause, or termination of Executive's employment as a result of death, Disability (as defined below), or resignation, Executive will be entitled to receive only the severance benefits set forth below, and Executive will not be entitled to any other compensation, award, or damages with respect to Executive's employment or termination of employment.

(i) Termination for Cause, Death, Disability, or Resignation. In the event of the termination of Executive's employment by Company for Cause (as defined below), or termination of Executive's employment as a result of death, Disability, or resignation, Executive will be entitled to receive payment for all accrued but unpaid salary actually earned prior to or as of the date of termination of Executive's employment, and PTO accrued as of the date of termination of Executive's employment. Executive will not be entitled to any severance benefits or additional vesting of any stock options or other equity or cash awards.

(ii) Termination Without Cause. In the event of termination of Executive's employment by Company without Cause, Executive will be entitled to (A) the benefits set forth in paragraph (a)(i) of this Section; (B) (1) 3 months' base salary if terminated on or before the first anniversary of the date on which Executive's employment with Company commences, or (2) 9 months' base salary if terminated after such first anniversary, either of which may be paid in a lump sum or, at the election of Company, in installments consistent with Company's payroll procedures, subject to such deductions and withholdings as are required by law; (C) payment in full of the prorated target bonus due for the year in which Executive was terminated without Cause, subject to such deductions and withholdings as are required by law; and (D) payment, for a period of 6 months, of any health insurance benefits that Executive was receiving at the time of termination of Executive's employment under a Company employee health insurance plan subject to COBRA.

(iii) Change of Control. If Company (or any successor in interest to Company that has assumed Company's obligation under this Agreement) terminates Executive's employment without Cause or Executive resigns for Good Reason within the one-year period following the effective date of a Change in Control, Executive will be entitled to (A) the benefits set forth in paragraph (a)(i) and (a)(ii) of this Section, and (B) accelerated vesting of 50% of any then unvested options, restricted stock or restricted stock units as may have been granted to Executive by Company if termination of employment occurs on or before the first anniversary of the date on which Executive's employment with Company commences, or accelerated vesting of 100% of any then unvested options, restricted stock or restricted stock units as may have been granted to Executive by Company if termination of employment occurs after such first anniversary.

(b) Release. The Company's obligation to make such payments under paragraphs (a)(ii) and (a)(iii) of this Section and provide any other such benefits contemplated herein shall be contingent upon:

(i) Executive's execution of a release in a form reasonably acceptable to the Company (the "Release"), which Release must be signed and any applicable revocation period with respect thereto must have expired by the 30th day following Executive's termination of employment. The Release will not waive any of Executive's rights, or obligations of the Company or its successor in interest, regarding: (1) any right to indemnification and/or contribution, advancement or payment of related expenses Executive may have pursuant to the Company's Bylaws, Articles of Incorporation, under any written indemnification or other agreement between the parties, and/or under applicable law; (2) any rights that Executive may have to insurance coverage under any directors and officers liability insurance, other insurance policies of the Company, COBRA or any similar state law; (3) any claims for worker's compensation, state disability or unemployment insurance benefits, or any other claims that cannot be released as a matter of applicable law; (4) rights to any vested benefits under any stock, compensation or other employee benefit plan of the Company; (5) any rights Executive may have as an existing shareholder of the Company; and (6) any claims arising after the effective date of the Release. Nothing in the Release or any other agreement between Executive and the Company will prohibit or prevent Executive from providing truthful testimony or otherwise responding accurately and fully to any question, inquiry or request for information or documents when required by legal process, subpoena, notice, court order or law (including, without limitation, in any criminal, civil, or regulatory proceeding or investigation), or as necessary in any action for enforcement or claimed breach of this Agreement or any other legal dispute with the Company. If the Release has been signed and any applicable revocation period has expired prior to the 30th day following Executive's termination of employment, then the severance payments above may be made on such earlier date; provided, however, that if the 30th day following Executive's termination of employment occurs in the calendar year following the year of Executive's termination date, then the payments shall not be made earlier than January 1 of such subsequent calendar year; and

(ii) Executive's tendering a written resignation as a director, if serving as a director of BioTime, as provided in Section 7.

(c) Section 280G of the Code.

(i) Notwithstanding anything in this Agreement to the contrary, if any payment, distribution, or other benefit provided by the Company to or for the benefit of Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise (collectively, the "Payments"), (x) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (y) but for this Section 5(c) would be subject to the excise tax imposed by Section 4999 of the Code or any similar or successor provision thereto (the "Excise Tax"), then the Payments shall be either: (A) delivered in full pursuant to the terms of this Agreement, or (B) delivered to such lesser extent as would result in no portion of the payment being subject to the Excise Tax, as determined in accordance with Section 5(b).

(ii) The determination of whether Section 5(c)(i)(A) or Section 5(c)(i)(B) shall be given effect shall be made by the Company on the basis of which of such clauses results in the receipt by Executive of the greater Net After-Tax Receipt (as defined herein) of the aggregate Payments. The term "Net After-Tax Receipt" shall mean the present value (as determined in accordance with Section 280G of the Code) of the payments net of all applicable federal, state and local income, employment, and other applicable taxes and the Excise Tax.

(iii) If Section 5(c)(i)(B) is given effect, the reduction shall be accomplished in accordance with Section 409A of the Code and the following: first by reducing, on a pro rata basis, cash Payments that are exempt from Section 409A of the Code; second by reducing, on a pro rata basis, other cash Payments; and third by forfeiting any equity-based awards that vest and become payable, starting with the most recent equity-based awards that vest, to the extent necessary to accomplish such reduction.

(iv) Unless the Company and Executive otherwise agree in writing, any determination required under this Section 5(c) shall be made by the Company's independent accountants or compensation consultants (the "Third Party"), and all such determinations shall be conclusive, final and binding on the parties hereto. The Company and Executive shall furnish to the Third Party such information and documents as the Third Party may reasonably request in order to make a determination under this Section 5(c). The Company shall bear all fees and costs of the Third Party with respect to all determinations under or contemplated by this Section 5(c).

(d) Definitions. For purposes of this Section, the following definitions shall apply:

(i) "Affiliated Group" means (A) a Person and one or more other Persons in control of, controlled by, or under common control with such Person; and (B) two or more Persons who, by written agreement among them, act in concert to acquire Voting Securities entitling them to elect a majority of the directors of Company.

(ii) "Cause" shall mean a termination of Executive's employment based upon a finding by a majority of the Board of Directors of the Company or its successor, acting in good faith and based on its reasonable belief at the time, that Executive (a) has refused to perform the explicitly stated or reasonably assigned, lawful, and material duties required by Executive's position (other than by reason of a disability or analogous condition); (b) has committed or engaged in a material act of theft, embezzlement, dishonesty or fraud, a breach of confidentiality, an unauthorized disclosure or use of inside information, customer lists, trade secrets or other confidential information; (c) has breached a material fiduciary duty, or willfully and materially violated any other duty, law, rule, or regulation relating to the performance of Executive's duties to the Company or material policy of the Company or its successor; (d) has been convicted of, or pled guilty or nolo contendere to, misdemeanor involving moral turpitude or a felony; (e) has willfully and materially breached any of the provisions of any agreement with the Company or its successor which causes material injury to the Company; (f) has willfully engaged in unfair competition with, or otherwise acted intentionally in a manner materially injurious to the reputation, business or assets of, the Company or its successor; or (g) has improperly induced a vendor or customer to break or terminate any material contract with the Company or its successor or induced a principal for whom the Company or its successor acts as agent to terminate such agency relationship. "Cause" shall only exist if the Company first provides Executive with written notice of any claimed ground for Cause and an opportunity to cure such ground, if curable, for thirty (30) days. For purposes of this Agreement, no act or failure to act on Executive's part will be considered "willful" unless it is done, or omitted to be done, by Executive intentionally, not in good faith or without reasonable belief that the action or omission was in the best interest of the Company.

(iii) "Change of Control" means (A) the acquisition of Voting Securities of Company by a Person or an Affiliated Group entitling the holder thereof to elect a majority of the directors of Company; provided, that an increase in the amount of Voting Securities held by a Person or Affiliated Group who on the date of this Agreement beneficially owned (as defined in Section 13(d) of the Securities Exchange Act of 1934, as amended, and the regulations thereunder) more than 10% of the Voting Securities shall not constitute a Change of Control; and provided, further, that an acquisition of Voting Securities by one or more Persons acting as an underwriter in connection with a sale or distribution of such Voting Securities shall not constitute a Change of Control under this clause (A); (B) the sale of all or substantially all of the assets of Company; or (C) a merger or consolidation of Company with or into another corporation or entity in which the stockholders of Company immediately before such merger or consolidation do not own, in the aggregate, Voting Securities of the surviving corporation or entity (or the ultimate parent of the surviving corporation or entity) entitling them, in the aggregate (and without regard to whether they constitute an Affiliated Group) to elect a majority of the directors or persons holding similar powers of the surviving corporation or entity (or the ultimate parent of the surviving corporation or entity).

(iv) "Disability" shall mean Executive's inability to perform the essential functions of Executive's job responsibilities for a period of 180 days in the aggregate in any 12 month period.

(v) "Good Reason" shall mean the occurrence of any of the following events or circumstances without Executive's written consent: (i) a material diminution in Executive's base compensation; (ii) a material diminution in Executive's authority, duties or responsibility; (iii) a material change in the principal geographic location at which Executive performs services; (iv) any requirement that Executive engage in any illegal conduct; or (v) a material breach by the Company of this Agreement or any other material written agreement between Executive and the Company.

(vi) "Person" means any natural person or any corporation, partnership, limited liability company, trust, unincorporated business association, or other entity.

(vii) "Voting Securities" means shares of capital stock or other equity securities entitling the holder thereof to regularly vote for the election of directors (or for person performing a similar function if the issuer is not a corporation), but does not include the power to vote upon the happening of some condition or event which has not yet occurred.

6. Turnover of Property and Documents on Termination. Executive agrees that on or before termination of Executive's employment, Executive will return to Company, all equipment and other property belonging to Company, and all originals and copies of confidential information (in any and all media and formats, and including any document or other item containing confidential information) in Executive's possession or control, and all of the following (in any and all media and formats, and whether or not constituting or containing confidential information) in Executive's possession or control: (a) lists and sources of customers; (b) proposals or drafts of proposals for any research grant, research or development project or program, marketing plan, licensing arrangement, or other arrangement with any third party; (c) reports, notations of the Executive, laboratory notes, specifications, and drawings pertaining to the research, development, products, patents, and technology of Company; (d) any and all intellectual property developed by Executive during the course of employment; and (e) the manual and memoranda related to the Policies. To the extent there is a conflict between this Section 6 and the Confidentiality and IP Agreement executed by the Executive, the Confidentiality and IP Agreement provisions control.

7. Resignation as a Director on Termination of Employment. If Executive's employment by Company is terminated for any reason or for no reason, whether by way of resignation, Disability, or termination by Company with or without Cause, and if Executive is then a member of the Board of Directors, Executive shall within two business days after such termination of employment resign from the Board of Directors of Company, by delivering to Company a letter or other written communication addressed to the Board of Directors of Company stating that Executive is resigning from the Board of Directors effective immediately. A business day shall be any day other than a Saturday, Sunday, or federal holiday on which federal offices are closed.

8. Arbitration. Except for injunctive proceedings against unauthorized disclosure of confidential information, any and all claims or controversies between and Executive, including but not limited to (a) those involving the construction or application of any of the terms, provisions, or conditions of this Agreement or the Policies; (b) all contract or tort claims of any kind; and (c) any claim based on any federal, state, or local law, statute, regulation, or ordinance, including claims for unlawful discrimination or harassment, shall be settled by arbitration in accordance with the then current Employment Dispute Resolution Rules of the American Arbitration Association. Judgment on the award rendered by the arbitrator(s) may be entered by any court having jurisdiction over Company and Executive. The location of the arbitration shall be San Diego, California. Unless Company or Executive mutually agree otherwise, the arbitrator shall be a retired judge selected from a panel provided by the American Arbitration Association, or the Judicial Arbitration and Mediation Service (JAMS). Company, shall pay the arbitrator's fees and costs. Executive shall pay for Executive's own costs and attorneys' fees, if any. If the Company is a party to an arbitration proceeding it shall pay for its own costs and attorneys' fees, if any. However, if any party prevails on a statutory claim which affords the prevailing party attorneys' fees, the arbitrator may award reasonable attorneys' fees and costs to the prevailing party.

EXECUTIVE UNDERSTANDS AND AGREES THAT THIS AGREEMENT TO ARBITRATE CONSTITUTES A WAIVER OF EXECUTIVE'S RIGHT TO A TRIAL BY JURY OF ANY MATTERS COVERED BY THIS AGREEMENT TO ARBITRATE.

9. Severability. In the event that any of the provisions of this Agreement or the Policies shall be held to be invalid or unenforceable in whole or in part, those provisions to the extent enforceable and all other provisions shall nevertheless continue to be valid and enforceable as though the invalid or unenforceable parts had not been included in this Agreement or the Policies. In the event that any provision relating to a time period of restriction shall be declared by a court of competent jurisdiction to exceed the maximum time period such court deems reasonable and enforceable, then the time period of restriction deemed reasonable and enforceable by the court shall become and shall thereafter be the maximum time period.

10. Agreement Read and Understood. Executive acknowledges that Executive has carefully read the terms of this Agreement, that Executive has had an opportunity to consult with an attorney or other representative of Executive's own choosing regarding this Agreement, that Executive understands the terms of this Agreement and that Executive is entering this Agreement of Executive's own free will.

11. Complete Agreement, Modification. This Agreement is the complete agreement between Executive and Company on the subjects contained in this Agreement. This Agreement supersedes and replaces all previous correspondence, promises, representations, and agreements, if any, either written or oral with respect to Executive's employment by Company and any matter covered by this Agreement, including, to the extent the matter is addressed in this Agreement, the offer letter dated April 30, 2019 accepted by Executive. No provision of this Agreement may be modified, amended, or waived except by a written document signed both by Company and Executive.

12. Governing Law. This Agreement shall be construed and enforced according to the laws of the State of California.

13. Assignability. This Agreement, and the rights and obligations of Executive and Company under this Agreement, may not be assigned by Executive. Company may assign any of its rights and obligations under this Agreement to any successor or surviving corporation, limited liability company, or other entity resulting from a merger, consolidation, sale of assets, sale of stock, sale of membership interests, or other reorganization, upon condition that the assignee shall assume, either expressly or by operation of law, all of Company's obligations under this Agreement.

14. Survival. This Section 14 and the covenants and agreements contained in Sections 3, 4 and 6 of this Agreement shall survive termination of this Agreement and Executive's employment.

15. Notices. Any notices or other communication required or permitted to be given under this Agreement shall be in writing and shall be mailed by certified mail, return receipt requested, or sent by next business day air courier service, or personally delivered to the party to whom it is to be given at the address of such party set forth on the signature page of this Agreement (or to such other address as the party shall have furnished in writing in accordance with the provisions of this Section 15).

[SIGNATURES TO THE EMPLOYMENT AGREEMENT ARE FOUND ON THE FOLLOWING PAGE]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the day and year first above written.

EXECUTIVE:

/s/ Chase Leavitt

Chase Leavitt

Address: #####

COMPANY:

BIOTIME, INC.

By: */s/ Brian Michael Culley*

Brian Michael Culley

Chief Executive Officer

BioTime, Inc.

1010 Atlantic Avenue, Suite 102

Alameda, California 94501

[SIGNATURE PAGE TO THE EMPLOYMENT AGREEMENT]

Exhibit A

General Counsel and Corporate Secretary

Position Description:

The General Counsel and Corporate Secretary will provide proactive legal and business advice on a broad range of topics, including SEC compliance, corporate governance, contract interpretation, employment law, general commercial law and intellectual property. The General Counsel and Corporate Secretary is an officer of the Company and will be a significant contributor to the leadership team as well as the Board of Directors.

Job Responsibilities:

- Ensure compliance with SEC requirements by managing, reviewing, and editing periodic reports. In partnership with CFO and Sr. Finance team will prepare annual proxy statement, quarterly and annual financial filings, review earnings release and conference call scripts, prepare and file registration statements, etc.
 - Partner with senior executive officers in review of corporate structure and product portfolio. Will also advise board of directors on corporate governance and compliance matters and assist in management of board meetings and actions.
 - Develop and revise standard form agreements and implementing processes and procedures for review and approval of day-to-day business agreements.
 - Draft and negotiate a wide range of contracts, including confidentiality agreements, consulting agreements, material transfer agreements, funded research agreements, license agreements, development and supply agreements and various vendor services agreements.
 - Primary point of contact on legal contract issues for BioTime and its subsidiaries. Responsible for drafting and negotiating contracts and other legal documents in support of a broad range of groups such as R&D, Regulatory, Business Development, Intellectual Property and Human Resources.
 - Will provide legal contractual support for the company's existing collaborations and partnerships, including with third party licensees.
 - Will work closely with IP / Patent Agent on patent and trademark infringements, copyright disputes, etc.
 - Partner with CEO and Business Development to conduct and coordinate due diligence efforts in licensing and M&A transactions.
 - Engage in pre-litigation activities, and supervise and manage outside counsel in litigation activities.
 - In conjunction with the other departments, review and advise company policies and procedures.
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Exhibit B

EMPLOYEE CONFIDENTIAL INFORMATION AND INVENTIONS ASSIGNMENT AGREEMENT

In consideration of my employment or continued employment by **BioTIME, Inc.**, its subsidiaries, parents, affiliates, successors and assigns (together "**Company**"), and the compensation paid to me now and during my employment with Company, I, Chase C. Leavitt, hereby enter into this Employee Confidential Information and Invention Assignment Agreement (the "**Agreement**") and agree as follows:

1. CONFIDENTIAL INFORMATION PROTECTIONS.

1.1 Recognition of Company's Rights; Nondisclosure. I understand and acknowledge that my employment by Company creates a relationship of confidence and trust with respect to Company's Confidential Information (as defined below) and that Company has a protectable interest therein. At all times during and after my employment, I will hold in confidence and will not disclose, use, lecture upon, or publish any of Company's Confidential Information, except as such disclosure, use or publication may be required in connection with my work for Company, or unless an officer of Company expressly authorizes such disclosure. I will obtain Company's written approval before publishing or submitting for publication any material (written, oral, or otherwise) that discloses and/or incorporates any Confidential Information. I hereby assign to Company any rights I may have or acquire in such Confidential Information and recognize that all Confidential Information shall be the sole and exclusive property of Company and its assigns. I will take all reasonable precautions to prevent the inadvertent accidental disclosure of Confidential Information. Notwithstanding the foregoing, pursuant to 18 U.S.C. Section 1833(b), I shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that: (1) is made in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (2) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

1.2 Confidential Information. The term "**Confidential Information**" shall mean any and all confidential knowledge, data or information of Company. By way of illustration but not limitation, "**Confidential Information**" includes (a) trade secrets, inventions, mask works, ideas, processes, formulas, software in source or object code, data, programs, other works of authorship, know-how, improvements, discoveries, developments, designs and techniques and any other proprietary technology and all Intellectual Property Rights (as defined below) therein (collectively, "**Inventions**"); (b) information regarding research, development, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, margins, discounts, credit terms, pricing and billing policies, quoting procedures, methods of obtaining business, forecasts, future plans and potential strategies, financial projections and business strategies, operational plans, financing and capital-raising plans, activities and agreements, internal services and operational manuals, methods of conducting Company business, suppliers and supplier information, and purchasing; (c) information regarding customers and potential customers of Company, including customer lists, names, representatives, their needs or desires with respect to the types of products or services offered by Company, proposals, bids, contracts and their contents and parties, the type and quantity of products and services provided or sought to be provided to customers and potential customers of Company and other non-public information relating to customers and potential customers; (d) information regarding any of Company's business partners and their services, including names, representatives, proposals, bids, contracts and their contents and parties, the type and quantity of products and services received by Company, and other non-public information relating to business partners; (e) information regarding personnel, employee lists, compensation, and employee skills; and (f) any other non-public information which a competitor of Company could use to the competitive disadvantage of Company. Notwithstanding the foregoing, it is understood that, at all such times, I am free to use information which was known to me prior to my employment with Company or which is generally known in the trade or industry through no breach of this Agreement or other act or omission by me, and I am free to discuss the terms and conditions of my employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act.

1.3 Third Party Information. I understand, in addition, that Company has received and in the future will receive from third parties their confidential and/or proprietary knowledge, data or information (“**Third Party Information**”) subject to a duty on Company’s part to maintain the confidentiality of such information and to use it only for certain limited purposes. During the term of my employment and thereafter, I will hold Third Party Information in confidence and will not disclose to anyone (other than Company personnel who need to know such information in connection with their work for Company) or use, except in connection with my work for Company, Third Party Information or unless expressly authorized by an officer of Company in writing.

1.4 Term of Nondisclosure Restrictions. I understand that Confidential Information and Third Party Information is never to be used or disclosed by me, as provided in this Section 1. If a temporal limitation on my obligation not to use or disclose such information is required under applicable law, and the Agreement or its restriction(s) cannot otherwise be enforced, I agree and Company agrees that the two-year period after the date my employment ends will be the temporal limitation relevant to the contested restriction; **provided, however**, that this sentence will not apply to trade secrets protected without temporal limitation under applicable law.

1.5 No Improper Use of Information of Prior Employers and Others. During my employment by Company, I will not improperly use or disclose confidential information or trade secrets, if any, of any former employer or any other person to whom I have an obligation of confidentiality, and I will not bring onto the premises of Company any unpublished documents or any property belonging to any former employer or any other person to whom I have an obligation of confidentiality unless consented to in writing by that former employer or person.

2. ASSIGNMENTS OF INVENTIONS.

2.1 Definitions. As used in this Agreement, the term “**Intellectual Property Rights**” means all trade secrets, Copyrights, trademarks, mask work rights, patents and other intellectual property rights recognized by the laws of any jurisdiction or country; the term “**Copyright**” means the exclusive legal right to reproduce, perform, display, distribute and make derivative works of a work of authorship (as a literary, musical, or artistic work) recognized by the laws of any jurisdiction or country; and the term “**Moral Rights**” means all paternity, integrity, disclosure, withdrawal, special and any other similar rights recognized by the laws of any jurisdiction or country.

2.2 Excluded Inventions and Other Inventions. Attached hereto as **Exhibit A** is a list describing all existing Inventions, if any, (a) that are owned by me or in which I have an interest and were made or acquired by me prior to my date of first employment by Company, (b) that may relate to Company’s business or actual or demonstrably anticipated research or development, and (c) that are not to be assigned to Company (“**Excluded Inventions**”). If no such list is attached, I represent and agree that it is because I have no Excluded Inventions. For purposes of this Agreement, “**Other Inventions**” means Inventions in which I have or may have an interest, as of the commencement of my employment or thereafter, other than Company Inventions (as defined below) and Excluded Inventions. I acknowledge and agree that if I use any Excluded Inventions or any Other Inventions in the scope of my employment, or if I include any Excluded Inventions or Other Inventions in any product or service of Company, or if my rights in any Excluded Inventions or Other Inventions may block or interfere with, or may otherwise be required for, the exercise by Company of any rights assigned to Company under this Agreement, I will immediately so notify Company in writing. Unless Company and I agree otherwise in writing as to particular Excluded Inventions or Other Inventions, I hereby grant to Company, in such circumstances (whether or not I give Company notice as required above), a non-exclusive, perpetual, transferable, fully-paid and royalty-free, irrevocable and worldwide license, with rights to sublicense through multiple levels of sublicensees, to reproduce, make derivative works of, distribute, publicly perform, and publicly display in any form or medium, whether now known or later developed, make, have made, use, sell, import, offer for sale, and exercise any and all present or future rights in, such Excluded Inventions and Other Inventions. To the extent that any third parties have rights in any such Other Inventions, I hereby represent and warrant that such third party or parties have validly and irrevocably granted to me the right to grant the license stated above.

2.3 Assignment of Company Inventions. Inventions assigned to Company or to a third party as directed by Company pursuant to Section 2.6 are referred to in this Agreement as “**Company Inventions.**” Subject to Section 2.4 and except for Excluded Inventions set forth in **Exhibit A** and Other Inventions, I hereby assign to Company all my right, title, and interest in and to any and all Inventions (and all Intellectual Property Rights with respect thereto) made, conceived, reduced to practice, or learned by me, either alone or with others, during the period of my employment by Company. To the extent required by applicable Copyright laws, I agree to assign in the future (when any copyrightable Inventions are first fixed in a tangible medium of expression) my Copyright rights in and to such Inventions. Any assignment of Company Inventions (and all Intellectual Property Rights with respect thereto) hereunder includes an assignment of all Moral Rights. To the extent such Moral Rights cannot be assigned to Company and to the extent the following is allowed by the laws in any country where Moral Rights exist, I hereby unconditionally and irrevocably waive the enforcement of such Moral Rights, and all claims and causes of action of any kind against Company or related to Company’s customers, with respect to such rights. I further acknowledge and agree that neither my successors-in-interest nor legal heirs retain any Moral Rights in any Company Inventions (and any Intellectual Property Rights with respect thereto).

2.4 Unassigned or Nonassignable Inventions. I recognize that this Agreement will not be deemed to require assignment of any Invention that is covered under California Labor Code section 2870(a) (the “**Specific Inventions Law**”) except for those Inventions that are covered by a contract between Company and the United States or any of its agencies that require full title to such patent or Invention to be in the United States.

2.5 Obligation to Keep Company Informed. During the period of my employment, I will promptly and fully disclose to Company in writing all Inventions authored, conceived, or reduced to practice by me, either alone or jointly with others. At the time of each such disclosure, I will advise Company in writing of any Inventions that I believe fully qualify for protection under the provisions of the Specific Inventions Law; and I will at that time provide to Company in writing all evidence necessary to substantiate that belief. Company will keep in confidence and will not use for any purpose or disclose to third parties without my consent any confidential information disclosed in writing to Company pursuant to this Agreement relating to Inventions that qualify fully for protection under the Specific Inventions Law. I will preserve the confidentiality of any Invention that does not fully qualify for protection under the Specific Inventions Law.

2.6 Government or Third Party. I agree that, as directed by Company, I will assign to a third party, including without limitation the United States, all my right, title, and interest in and to any particular Company Invention.

2.7 Ownership of Work Product. I agree that Company will exclusively own all work product that is made by me (solely or jointly with others) within the scope of my employment, and I hereby irrevocably and unconditionally assign to Company all right, title and interest worldwide in and to such work product. I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment and which are protectable by Copyright are “works made for hire,” pursuant to United States Copyright Act (17 U.S.C., Section 101). I understand and agree that I have no right to publish on, submit for publishing, or use for any publication any work product protected by this Section, except as necessary to perform services for Company.

2.8 Enforcement of Intellectual Property Rights and Assistance. I will assist Company in every proper way to obtain, and from time to time enforce, United States and foreign Intellectual Property Rights and Moral Rights relating to Company Inventions in any and all countries. To that end I will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Intellectual Property Rights and the assignment thereof. In addition, I will execute, verify and deliver assignments of such Intellectual Property Rights to Company or its designee, including the United States or any third party designated by Company. My obligation to assist Company with respect to Intellectual Property Rights relating to such Company Inventions in any and all countries will continue beyond the termination of my employment, but Company will compensate me at a reasonable rate after my termination for the time actually spent by me at Company's request on such assistance. In the event Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in the preceding paragraph, I hereby irrevocably designate and appoint Company and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for and on my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quitclaim to Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Intellectual Property Rights assigned under this Agreement to Company.

2.9 Incorporation of Software Code. I agree that I will not incorporate into any Company software or otherwise deliver to Company any software code licensed under the GNU General Public License or Lesser General Public License or any other license that, by its terms, requires or conditions the use or distribution of such code on the disclosure, licensing, or distribution of any source code owned or licensed by Company **except** in strict compliance with Company's policies regarding the use of such software.

3. RECORDS. I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that is required by Company) of all Confidential Information developed by me and all Company Inventions made by me during the period of my employment at Company, which records will be available to and remain the sole property of Company at all times.

4. DUTY OF LOYALTY DURING EMPLOYMENT. I agree that during the period of my employment by Company, I will not, without Company's express written consent, directly or indirectly engage in any employment or business activity which is directly or indirectly competitive with, or would otherwise conflict with, my employment by Company.

5. NO SOLICITATION OF EMPLOYEES, CONSULTANTS OR CONTRACTORS. I agree that during the period of my employment and for the one year period after the date my employment ends for any reason, including but not limited to voluntary termination by me or involuntary termination by Company, I will not, as an officer, director, employee, consultant, owner, partner, or in any other capacity, either directly or through others, except on behalf of Company, solicit, induce, encourage, or participate in soliciting, inducing or encouraging any person known to me to be an employee, consultant, or independent contractor of Company to terminate his or her relationship with Company, even if I did not initiate the discussion or seek out the contact.

6. REASONABLENESS OF RESTRICTIONS.

6.1 I agree that I have read this entire Agreement and understand it. I agree that this Agreement does not prevent me from earning a living or pursuing my career. I agree that the restrictions contained in this Agreement are reasonable, proper, and necessitated by Company's legitimate business interests. I represent and agree that I am entering into this Agreement freely and with knowledge of its contents with the intent to be bound by the Agreement and the restrictions contained in it.

6.2 In the event that a court finds this Agreement, or any of its restrictions, to be ambiguous, unenforceable, or invalid, I and Company agree that the court will read the Agreement as a whole and interpret the restriction(s) at issue to be enforceable and valid to the maximum extent allowed by law.

6.3 If the court declines to enforce this Agreement in the manner provided in subsection 6.2, Company and I agree that this Agreement will be automatically modified to provide Company with the maximum protection of its business interests allowed by law and I agree to be bound by this Agreement as modified.

7. NO CONFLICTING AGREEMENT OR OBLIGATION. I represent that my performance of all the terms of this Agreement and as an employee of Company does not and will not breach any agreement to keep in confidence information acquired by me in confidence or in trust prior to my employment by Company. I have not entered into, and I agree I will not enter into, any agreement either written or oral in conflict with this Agreement.

8. RETURN OF COMPANY PROPERTY. When I leave the employ of Company, I will deliver to Company any and all drawings, notes, memoranda, specifications, devices, formulas and documents, together with all copies thereof, and any other material containing or disclosing any Company Inventions, Third Party Information or Confidential Information of Company. I agree that I will not copy, delete, or alter any information contained upon my Company computer or Company equipment before I return it to Company. In addition, if I have used any personal computer, server, or e-mail system to receive, store, review, prepare or transmit any Company information, including but not limited to, Confidential Information, I agree to provide Company with a computer-useable copy of all such Confidential Information and then permanently delete and expunge such Confidential Information from those systems; and I agree to provide Company access to my system as reasonably requested to verify that the necessary copying and/or deletion is completed. I further agree that any property situated on Company's premises and owned by Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company's personnel at any time with or without notice. Prior to leaving, I will cooperate with Company in attending an exit interview and completing and signing Company's termination statement if required to do so by Company.

9. LEGAL AND EQUITABLE REMEDIES.

9.1 I agree that it may be impossible to assess the damages caused by my violation of this Agreement or any of its terms. I agree that any threatened or actual violation of this Agreement or any of its terms will constitute immediate and irreparable injury to Company, and Company will have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that Company may have for a breach or threatened breach of this Agreement.

9.2 In the event Company enforces this Agreement through a court order, I agree that the restrictions of Section 5 will remain in effect for a period of 12 months from the effective date of the Order enforcing the Agreement.

10. NOTICES. Any notices required or permitted under this Agreement will be given to Company at its headquarters location at the time notice is given, labeled "Attention Chief Executive Officer," and to me at my address as listed on Company payroll, or at such other address as Company or I may designate by written notice to the other. Notice will be effective upon receipt or refusal of delivery. If delivered by certified or registered mail, notice will be considered to have been given five business days after it was mailed, as evidenced by the postmark. If delivered by courier or express mail service, notice will be considered to have been given on the delivery date reflected by the courier or express mail service receipt.

11. PUBLICATION OF THIS AGREEMENT TO SUBSEQUENT EMPLOYER OR BUSINESS ASSOCIATES OF EMPLOYEE.

11.1 If I am offered employment or the opportunity to enter into any business venture as owner, partner, consultant or other capacity while the restrictions described in Section 5 of this Agreement are in effect I agree to inform my potential employer, partner, co-owner and/or others involved in managing the business with which I have an opportunity to be associated of my obligations under this Agreement and also agree to provide such person or persons with a copy of this Agreement.

11.2 I agree to inform Company of all employment and business ventures which I enter into while the restrictions described in Section 5 of this Agreement are in effect and I also authorize Company to provide copies of this Agreement to my employer, partner, co-owner and/or others involved in managing the business with which I am employed or associated and to make such persons aware of my obligations under this Agreement.

12. GENERAL PROVISIONS.

12.1 Governing Law; Consent to Personal Jurisdiction. This Agreement will be governed by and construed according to the laws of the State of California as such laws are applied to agreements entered into and to be performed entirely within California between residents of California. I hereby expressly consent to the personal jurisdiction and venue of the state and federal courts located in California for any lawsuit filed there against me by Company arising from or related to this Agreement.

12.2 Severability. In case any one or more of the provisions, subsections, or sentences contained in this Agreement will, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect the other provisions of this Agreement, and this Agreement will be construed as if such invalid, illegal or unenforceable provision had never been contained in this Agreement. If moreover, any one or more of the provisions contained in this Agreement will for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it will be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it will then appear.

12.3 Successors and Assigns. This Agreement is for my benefit and the benefit of Company, its successors, assigns, parent corporations, affiliates, and purchasers, and will be binding upon my heirs, executors, administrators and other legal representatives.

12.4 Survival. This Agreement shall survive the termination of my employment, regardless of the reason, and the assignment of this Agreement by Company to any successor in interest or other assignee.

12.5 Employment At-Will. I agree and understand that nothing in this Agreement will change my at-will employment status or confer any right with respect to continuation of employment by Company, nor will it interfere in any way with my right or Company's right to terminate my employment at any time, with or without cause or advance notice.

12.6 Waiver. No waiver by Company of any breach of this Agreement will be a waiver of any preceding or succeeding breach. No waiver by Company of any right under this Agreement will be construed as a waiver of any other right. Company will not be required to give notice to enforce strict adherence to all terms of this Agreement.

12.7 Export. I agree not to export, reexport, or transfer, directly or indirectly, any U.S. technical data acquired from Company or any products utilizing such data, in violation of the United States export laws or regulations.

12.8 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall be taken together and deemed to be one instrument. This Agreement may also be executed and delivered by facsimile signature, PDF or any electronic signature complying with the U.S. federal ESIGN Act of 2000 (e.g., www.docusign.com).

12.9 Advice of Counsel. I ACKNOWLEDGE THAT, IN EXECUTING THIS AGREEMENT, I HAVE HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND I HAVE READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT WILL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION OF THIS AGREEMENT.

This Agreement shall be effective as of May 20, 2019.

EMPLOYEE:

I HAVE READ, UNDERSTAND, AND ACCEPT THIS AGREEMENT AND HAVE BEEN GIVEN THE OPPORTUNITY TO REVIEW IT WITH INDEPENDENT LEGAL COUNSEL.

(Signature)

Chase C. Leavitt

Name

Date

Address:

COMPANY:

ACCEPTED AND AGREED

BioTIME, INC.

By:

Name: Brian Michael Culley

Title: Chief Executive Officer

Address: 1010 Atlantic Avenue, Suite 102
Alameda, CA 94501

Employee Confidential Information and Inventions Assignment Agreement
Chase C. Leavitt Page 8

EXHIBIT A
TO THE
EMPLOYEE CONFIDENTIAL INFORMATION AND INVENTIONS ASSIGNMENT AGREEMENT

EXCLUDED INVENTIONS

TO: BioTime, Inc.
FROM: Chase C. Leavitt
DATE: _____

1. Excluded Inventions Disclosure. Except as listed in Section 2 below, the following is a complete list of all Excluded Inventions:

No Excluded Inventions.

See below:

Additional sheets attached.

2. Due to a prior confidentiality agreement, I cannot complete the disclosure under Section 1 above with respect to the Excluded Inventions generally listed below, the intellectual property rights and duty of confidentiality with respect to which I owe to the following party(ies):

	Excluded Invention	Party(ies)	Relationship
1.	_____	_____	_____
2.	_____	_____	_____
3.	_____	_____	_____

Additional sheets attached.

3. Limited Exclusion Notification.

This is to notify you in accordance with Section 2872 of the California Labor Code that the foregoing Agreement between you and Company does not require you to assign or offer to assign to Company any Invention that you develop entirely on your own time without using Company's equipment, supplies, facilities or trade secret information, except for those Inventions that either:

a. Relate at the time of conception or reduction to practice to Company's business, or actual or demonstrably anticipated research or development; or

b. Result from any work performed by you for Company.

To the extent a provision in the foregoing Agreement purports to require you to assign an Invention otherwise excluded from the preceding paragraph, the provision is against the public policy of this state and is unenforceable.

This limited exclusion does not apply to any patent or Invention covered by a contract between Company and the United States or any of its agencies requiring full title to such patent or Invention to be in the United States.

Lineage Cell Therapeutics, Inc.

The following is a list of subsidiaries of Lineage Cell Therapeutics, Inc. as of December 31, 2019, 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

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, and 333-218807), 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 reports dated March 12, 2020, with respect to the consolidated financial statements of Lineage Cell Therapeutics, Inc. and Subsidiaries (which report expresses an unqualified opinion and includes an explanatory paragraph related to a change in its method of accounting for revenue) and the effectiveness of Lineage Cell Therapeutics, Inc. and Subsidiaries' internal control over financial reporting, which appear in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ OUM & Co. LLP

San Francisco, California
March 12, 2020

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 12, 2020

/s/ Brian M. Culley

Brian M. Culley
Chief Executive Officer

CERTIFICATIONS

I, Brandi Roberts, 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 12, 2020

/s/ Brandi Roberts

Brandi Roberts
Chief Financial Officer

**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, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Brian M. Culley, Chief Executive Officer and Brandi Roberts, Chief Financial Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 12, 2020

/s/ Brian M. Culley

Brian M. Culley
Chief Executive Officer

/s/ Brandi Roberts

Brandi Roberts
Chief Financial Officer
