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

FORM 10-Q

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from _____ to _____

Commission file number **001-12830**

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

California	**94-3127919**
(State or other jurisdiction of incorporation or organization)	(IRS 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	Name of exchange on which registered
Common shares no par value	**LCTX**	**NYSE American**

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 ☒
Emerging growth company ☐

Accelerated filer ☐
Smaller reporting 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 pursuant 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

The number of common shares outstanding as of November 5, 2021 was 168,558,000

PART I - FINANCIAL INFORMATION

This Quarterly Report on Form 10-Q (this "Report") contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Report are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would," or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, 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 to manufacture our product candidates for clinical development and, if approved, for commercialization, and the timing and costs of such manufacture;
- the performance of third parties in connection with the development and manufacture of our product candidates, including third parties conducting our clinical trials as well as third-party suppliers and manufacturers;
- the potential of our cell therapy platform, and our plans to apply our platform to research, develop and commercialize our product candidates;
- our ability to obtain funding for our operations, including funding necessary to initiate and complete clinical trials of our product candidates;
- the size and growth of the potential markets for our product candidates and our ability to serve those markets;
- the potential scope and value of our intellectual property rights;
- our ability, and the ability of our licensors, to obtain, maintain, defend and enforce intellectual property rights protecting our product candidates, and our ability to develop and commercialize our product candidates without infringing the proprietary rights of third parties;
- our ability to recruit and retain key personnel;
- the effects of the COVID-19 pandemic on our operations; and
- other risks and uncertainties, including those described under Part II, Item 1A, "Risk Factors" of this Report.

Any forward-looking statements in this Report reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under Part II, Item 1A, "Risk Factors" of this Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

RISK FACTOR SUMMARY

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

- We have incurred operating losses since inception, and we do not know if or when we will attain profitability.
- We will continue to spend a substantial amount of our capital on research and development, but we might not succeed in developing products and technologies that are useful in medicine.
- The amount and pace of research and development work that we can do or sponsor, and our ability to commence and complete clinical trials required to obtain regulatory approval to market our therapeutic and medical device products, depends upon the amount of funds we have.
- We will need to issue additional equity or debt securities in order to raise additional capital needed to pay our operating expenses.
- We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, including anti-kickback and false claims laws, transparency laws, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.
- If we do not receive regulatory approvals, we will not be permitted to sell our therapeutic and medical device products.
- Government-imposed bans or restrictions and religious, moral, and ethical concerns about the use of hES cells could prevent us from developing and successfully marketing stem cell products.
- We expect that the commercial opportunity for some of our products may depend on our ability to obtain reimbursement and continued coverage from various payors, including government entities and insurance companies.
- Clinical studies are costly, time consuming and are subject to risks that could delay or prevent commercialization of our current or future product candidates.
- Clinical and preclinical drug development involves a lengthy and expensive process with an uncertain outcome. The results of early preclinical trials and clinical trials of our product candidates are not necessarily predictive of future results. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval on a timely basis, if at all.
- Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- The ongoing COVID-19 pandemic has affected and may adversely affect our operations, including the conduct of our clinical trials.
- Our intellectual property may be insufficient to protect our products.
- If we are unable to obtain and enforce patents and to protect our trade secrets, others could use our technology to compete with us, which could limit opportunities for us to generate revenues by licensing our technology and selling products.
- We may become dependent on possible future collaborations to develop and commercialize many of our product candidates and to provide the regulatory compliance, sales, marketing and distribution capabilities required for the success of our business.
- Because we are engaged in the development of pharmaceutical and stem cell therapy products, the price of our common shares may rise and fall rapidly.
- Current economic and stock market conditions may adversely affect the price of our common shares.

Item 1. Financial Statements

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

	September 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 60,809	$ 32,585
Marketable equity securities	4,295	8,977
Trade accounts receivable, net	79	4
Prepaid expenses and other current assets	3,161	2,433
Total current assets	68,344	43,999
NONCURRENT ASSETS		
Property and equipment, net (Notes 6 and 15)	4,728	5,630
Deposits and other long-term assets	614	616
Goodwill	10,672	10,672
Intangible assets, net	46,854	47,032
TOTAL ASSETS	$ 131,212	$ 107,949
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 6,705	$ 6,813
Lease liabilities, current portion (Note 15)	801	746
Financing lease, current portion (Note 15)	17	16
Deferred revenues	975	193
Liability classified warrants, current portion	293	1
Total current liabilities	8,791	7,769
LONG-TERM LIABILITIES		
Deferred tax liability	894	2,076
Lease liability, net of current portion (Note 15)	1,887	2,514
Financing lease, net of current portion (Note 15)	12	26
Liability classified warrants, net of current portion	39	437
TOTAL LIABILITIES	11,623	12,822
Commitments and contingencies (Note 15)		
SHAREHOLDERS' EQUITY		
Preferred shares, no par value, 2,000 shares authorized; none issued and outstanding as of September 30, 2021 and December 31, 2020	-	-
Common shares, no par value, 250,000 shares authorized; 168,465 and 153,096 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	432,250	393,944
Accumulated other comprehensive loss	(3,433)	(3,667)
Accumulated deficit	(308,105)	(294,078)
Lineage Cell Therapeutics, Inc. shareholders' equity	120,712	96,199
Noncontrolling deficit	(1,123)	(1,072)
Total shareholders' equity	119,589	95,127
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 131,212	$ 107,949

See accompanying notes to the condensed consolidated interim financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
REVENUES:				
Royalties	$ 1,909	$ 342	$ 2,430	$ 607
Grant revenues	68	229	237	864
Collaboration revenues	293	-	506	-
Total revenues	2,270	571	3,173	1,471
Cost of sales	(985)	(102)	(1,222)	(271)
Gross profit	1,285	469	1,951	1,200
OPERATING EXPENSES:				
Research and development	2,811	3,566	9,136	9,710
General and administrative	5,317	3,628	13,788	12,055
Total operating expenses	8,128	7,194	22,924	21,765
Loss from operations	(6,843)	(6,725)	(20,973)	(20,565)
OTHER INCOME/(EXPENSES):				
Interest income (expense), net	1	252	(1)	1,037
Gain on sale of marketable securities	-	120	6,024	3,848
Unrealized loss on marketable equity securities	(2,450)	(2,003)	(621)	(7,487)
Gain on extinguishment of debt	-	-	523	-
Unrealized gain on warrant liability	53	55	105	84
Other income (expense), net	393	351	(318)	175
Total other income/(expense), net	(2,003)	(1,225)	5,712	(2,343)
LOSS BEFORE INCOME TAXES	(8,846)	(7,950)	(15,261)	(22,908)
Deferred income tax benefit	1,012	178	1,181	178
NET LOSS	(7,834)	(7,772)	(14,080)	(22,730)
Net loss attributable to noncontrolling interest	11	12	51	49
NET LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC.	$ (7,823)	$ (7,760)	$ (14,029)	$ (22,681)
NET LOSS PER COMMON SHARE:				
BASIC	$ (0.05)	$ (0.05)	$ (0.09)	$ (0.15)
DILUTED	$ (0.05)	$ (0.05)	$ (0.09)	$ (0.15)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING:				
BASIC	167,624	149,973	163,120	149,868
DILUTED	167,624	149,973	163,120	149,868

See accompanying notes to the condensed consolidated interim financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
NET LOSS	$ (7,834)	$ (7,772)	$ (14,080)	$ (22,730)
Other comprehensive loss, net of tax:				
Foreign currency translation adjustment, net of tax	(382)	(335)	234	(140)
COMPREHENSIVE LOSS	(8,216)	(8,107)	(13,846)	(22,870)
Less: Comprehensive loss attributable to noncontrolling interest	11	12	51	49
COMPREHENSIVE LOSS ATTRIBUTABLE TO LINEAGE CELL THERAPEUTICS, INC. COMMON SHAREHOLDERS	$ (8,205)	$ (8,095)	$ (13,795)	$ (22,821)

See accompanying notes to the condensed consolidated interim financial statements.

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

	Nine Months Ended September 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss attributable to Lineage Cell Therapeutics, Inc.	$ (14,029)	$ (22,681)
Net loss allocable to noncontrolling interest	(51)	(49)
Adjustments to reconcile net loss attributable to Lineage Cell Therapeutics, Inc. to net cash used in operating activities:		
Gain on sale of marketable securities	(6,024)	(3,848)
Unrealized loss on marketable equity securities	621	7,487
Gain on extinguishment of debt	(523)	-
Depreciation expense, including amortization of leasehold improvements	504	623
Amortization of right-of-use asset	19	47
Amortization of intangible assets	178	1,080
Stock-based compensation	2,601	1,733
Common stock issued for services	202	59
Change in unrealized gain on warrant liability	(105)	(84)
Write-off of security deposit	-	150
Deferred tax benefit	(1,181)	(178)
Foreign currency remeasurement and other gain	300	(116)
Gain on write-off and sales of assets	(5)	(154)
Amortization of deferred license fee	-	(200)
Changes in operating assets and liabilities:		
Accounts and grants receivable	(104)	51
Accrued interest receivable	-	(1,008)
Prepaid expenses and other current assets	(1,229)	1,634
Accounts payable and accrued liabilities	354	1,342
Deferred revenue and other liabilities	784	-
Net cash used in operating activities	(17,688)	(14,112)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from the sale of OncoCyte common shares	10,064	10,941
Proceeds from the sale of AgeX common shares	-	1,196
Proceeds from the sale of HBL common shares	21	3
Purchase of equipment	(208)	(40)
Proceeds from the sale of equipment	14	18
Other deposits	-	18
Net cash provided by investing activities	9,891	12,136
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from employee options exercised	6,269	24,624
Common shares received and retired for employee taxes paid	(41)	(19)
Repayment of financing lease liabilities	(13)	(24)
Proceeds from Paycheck Protection Program (“PPP”) Loan (Note 8)	-	523
Proceeds from sale of common shares	30,741	-
Payments for offering costs	(980)	(53)
Net cash provided by financing activities	35,976	25,051
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(34)	(36)
NET INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	28,145	23,039
CASH, CASH EQUIVALENTS AND RESTRICTED CASH:		
At beginning of the period	33,183	10,096
At end of the period	$ 61,328	$ 33,135

See accompanying notes to the condensed consolidated interim financial statements.

1. Organization and Business Overview

Lineage Cell Therapeutics, Inc. ("Lineage," "we," "us," or "our") is 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 that aid the body in detecting and combating cancer. Specifically, Lineage is testing therapies to treat dry age-related macular degeneration, spinal cord injuries, and non-small cell lung cancer. Our programs are based on our proprietary cell-based technology platform and associated development and manufacturing capabilities. From this platform, we develop and manufacture specialized, terminally or functionally differentiated human cells from established and well-characterized pluripotent cell lines. These differentiated cells are transplanted into a patient 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 a more robust and effective immune response to cancer.

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") (also known as, atrophic AMD). There are currently 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 one of the leading causes of blindness in people over the age of 60 in the developed world.

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

- *VAC2*, an allogeneic 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, one of the world's largest independent cancer research charities.

In addition to seeking to create value for shareholders by developing product candidates and other technologies through our clinical development programs, we also seek to create value from our technologies through partnering and strategic transactions. We founded two companies that later became publicly traded companies: OncoCyte Corporation ("OncoCyte") and AgeX Therapeutics, Inc. ("AgeX"). We continue to hold common stock in OncoCyte as of September 30, 2021.

Though our principal focus is on advancing our three cell therapy programs currently in clinical development, we may seek to create additional value by initiating new programs using existing protocols or new protocols and cell lines, or through corporate transactions, as we have in the past.

Asterias Merger

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

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

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

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

2. Basis of Presentation, Liquidity and Summary of Significant Accounting Policies

The unaudited condensed consolidated interim financial statements presented herein, and discussed below, have been prepared in accordance with generally accepted accounting principles in the United States ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. In accordance with those rules and regulations certain information and footnote disclosures normally included in comprehensive consolidated financial statements have been condensed or omitted. The condensed consolidated balance sheet as of December 31, 2020 was derived from the audited consolidated financial statements at that date. These condensed consolidated interim financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in Lineage's Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the Securities and Exchange Commission (the "Commission") on March 11, 2021.

The accompanying condensed consolidated interim financial statements, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of Lineage's financial condition and results of operations. The condensed consolidated results of operations are not necessarily indicative of the results to be expected for any other interim period or for any year.

Principles of consolidation

Lineage's condensed consolidated interim financial statements include the accounts of its subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation. The following table reflects Lineage's ownership, directly or through one or more subsidiaries, of the outstanding shares of its operating subsidiaries as of September 30, 2021.

Subsidiary	Field of Business	Lineage Ownership	Country
Asterias BioTherapeutics, Inc.	Cell therapy clinical development programs in spinal cord injury and oncology	100%	USA
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.

As of September 30, 2021, Lineage consolidated its direct and indirect wholly owned or majority-owned subsidiaries because Lineage has the ability to control their operating and financial decisions and policies through its ownership, and the noncontrolling interest is reflected as a separate element of shareholders' equity on Lineage's consolidated balance sheets.

Liquidity

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

On May 1, 2020, Lineage entered into a Controlled Equity Offering[SM] Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor Fitzgerald"), pursuant to which Lineage may, but is not obligated to, raise up to $25.0 million through the sale of common shares from time to time in at-the-market transactions under the Sales Agreement. On March 5, 2021, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of an additional $25.0 million of common shares under the Sales Agreement increasing the total offering to $50.0 million. As of June 30, 2021, Lineage had issued 13,859,776 common shares at a weighted average price per share of $2.39 for gross proceeds of $33.1 million. For the three months ended September 30, 2021, Lineage issued an additional 1,048,959 common shares at a weighted average price per share of $2.62 for gross proceeds of $2.7 million. As of September 30, 2021, Lineage had issued 14,908,735 common shares at a weighted average price per share of $2.41 for gross proceeds of $35.9 million under the Sales Agreement.

As of September 30, 2021, Lineage had an accumulated deficit of approximately $308.1 million, working capital of $59.6 million and shareholders' equity of $119.6 million. Lineage has evaluated its projected cash flows and believes that its $65.1 million of cash, cash equivalents and marketable equity securities are sufficient to fund Lineage's planned operations for at least the next twelve months from the issuance date of the condensed consolidated interim 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.

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

Marketable Equity Securities

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

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

Revenue Recognition

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

In applying the provisions of ASU 2014-09, Lineage has determined that government grants are out of the scope of ASU 2014-09 because the government entities do not meet the definition of a "customer," as defined by ASU 2014-09, as there is not considered to be a transfer of control of goods or services to the government entities funding the grant. In the absence of applicable guidance under U.S. GAAP, the Company's policy is to recognize grant revenue when the related costs are incurred and the right to payment is realized. Costs incurred are recorded in research and development and general and administrative expenses on the accompanying statements of operations (see Note 15).

Deferred grant revenues currently represent grant funds received from the Israel Innovation Authority ("IIA") for the development of Cell Cure's OpRegen and our bio retina program, for which the allowable expenses have not yet been incurred as of the latest balance sheet date reported. As of September 30, 2021, deferred grant revenue was $82,200, primarily comprised of remaining funds most recently received in July 2021, June 2021 and November 2020, for their respective programs.

Royalties from product sales and license fees: For agreements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, Lineage recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Lineage estimates and recognizes royalty revenues based on all available information, including estimates provided by the customer or licensee from which Lineage obtains such estimates directly for each reporting period. Actual revenues ultimately received may differ from those estimates recorded and are adjusted in the period when information to actuals is available to Lineage. For the three and nine months ended September 30, 2021, Lineage recorded additional royalty revenues of approximately $1.8 million from a certain customer, based on the customer's updated communication to Lineage regarding royalties due. Consequently, Lineage also recorded a corresponding 50% of these additional royalties in cost of sales, as an accrued royalty payable to a separate royalty party. As of September 30, 2021, the $1.8 million is included as a receivable within prepaid expenses and other current assets. The customer paid these royalties to Lineage in October 2021. The additional royalty revenue for certain amounts relating to prior periods was not material to Lineage's consolidated financial statements, taken as a whole, for any period presented.

Collaboration Agreements

On April 16, 2021, Lineage entered a worldwide license and development collaboration agreement with Immunomic Therapeutics, Inc. ("ITI"). Lineage is the sole and exclusive owner of the rights to the VAC platform and has licensed to ITI patents and materials for the development and commercialization of a novel cancer immunotherapy agent derived from this platform utilizing an antigen provided by ITI, for the treatment of glioblastoma multiforme. Under the terms of this agreement, Lineage is entitled to upfront licensing fees totaling $2.0 million paid over the first year, and up to $67.0 million in development and commercial milestones across multiple indications. Lineage will also be eligible to receive royalties up to 10% on net sales of future products.

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

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

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

Upfront Fees: If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize collaboration revenues from the transaction price allocated to the license when the license is transferred to the licensee, and the licensee is able to use and benefit from the license. When the license is determined to be non-distinct, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time, and, if over time, the appropriate method of measuring progress for purposes of recognizing collaboration revenue from the allocated transaction price. For example, when we receive upfront fees for the performance of research and development services, or when research and development services are not considered to be distinct from a license, we recognize collaboration revenue for those units of account over time using a measure of progress. We evaluate the measure of progress at each reporting period and, if necessary, adjust the measure of performance and related revenue as a change in estimate.

Milestone Payments: At the inception of each collaboration agreement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the collaboration partner's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of milestones that are within our or the collaboration partner's control, such as operational developmental milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and net income (loss) in the period of adjustment. Revisions to our estimate of the transaction price may also result in negative collaboration revenues and net income (loss) in the period of adjustment.

Royalties: For collaboration agreements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

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

As of September 30, 2021 we had $856,000 of deferred revenue on the consolidated balance sheet related to the ITI collaboration agreement, and for the three and nine months ended September 30, 2021, we recognized $293,000 and $506,000 of revenue, respectively, related to the ITI collaboration agreement.

Basic and diluted net loss per share attributable to common shareholders

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

For the three and nine months ended September 30, 2021 and 2020, respectively, Lineage reported a net loss attributable to common shareholders, and therefore, all potentially dilutive common shares were considered antidilutive for those periods.

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

	Nine Months Ended September 30, (unaudited)	
	2021	**2020**
Stock options	17,207	16,560
Lineage Warrants [(1)]	-	1,090
Restricted stock units	46	108

(1) Although the Lineage Warrants (as defined below) are classified as liabilities, the Lineage Warrants are considered for dilutive earnings per share calculations in accordance with ASC 260, Earnings Per Share, and determined to be antidilutive for the period presented.

Restricted Cash

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

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

	September 30, 2021	**December 31, 2020**
	(unaudited)	
Cash and cash equivalents	$ 60,809	$ 32,585
Restricted cash included in deposits and other long-term assets (see Note 15)	519	520
Restricted cash included in prepaid expenses and other current assets (see Note 15)	-	78
Total cash, cash equivalents, and restricted cash as shown in the condensed consolidated statements of cash flows	$ 61,328	$ 33,183

Recently Adopted Accounting Pronouncements

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

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

Recently Issued Accounting Pronouncements Not Yet Adopted

The recently issued accounting pronouncements applicable to Lineage that are not yet effective should be read in conjunction with the recently issued accounting pronouncements, as applicable and disclosed in Lineage's Annual Report on Form 10-K for the year ended December 31, 2020, as filed with the Commission on March 11, 2021.

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

3. Revenue

Our disaggregated revenues were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Royalties	$ 1,909	$ 342	$ 2,430	$ 607
Grant revenues				
Israel Innovation Authority ("IIA")	$ 68	$ 216	$ 237	$ 477
National Institutes of Health ("NIH")	-	13	-	387
Total grant revenues	68	229	237	864
Revenues under collaborative agreements				
Upfront license fees	36	-	72	-
Event-based development milestones	72	-	72	-
Reimbursements, cost-sharing payments	185	-	362	-
Total revenues under collaborative agreements	293	-	506	-
Total revenue	$ 2,270	$ 571	$ 3,173	$ 1,471

During the three months ended September 30, 2021 we recognized $2.3 million in total revenue. There was no revenue related to new license agreements granted during the period. Revenues recognized during the current period which had been included in deferred revenues at December 31, 2020 were not material.

During the nine months ended September 30, 2021 we recognized $3.2 million in total revenue. We recognized $0.5 million in revenues from new license agreements granted in the period, which were recorded as revenues under collaboration agreements. We recognized revenue of $0.1 million during the period which had been included in deferred revenues at December 31, 2020.

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

	September 30, 2021	December 31, 2020
	(unaudited)	
Accounts receivable and other receivable, net [1]	$ 2,122	$ 242
Deferred revenues [1]	893	-

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

As of September 30, 2021, the amounts in the transaction price of our contracts with customers, including collaboration partners, and allocated good and services not yet provided were $3.0 million, of which $2.1 million relates to unfulfilled commitments and $0.9 million has been collected and is reported as deferred revenues. The unfulfilled commitments are estimated to be delivered by the end of the second quarter of 2022. Of the total deferred revenues of $0.9 million, substantially all is expected to be recognized within the next 12 months.

4. Marketable Equity Securities

As of September 30, 2021, Lineage owned approximately 1.1 million shares of OncoCyte common stock. These shares had a fair value of approximately $4.0 million, based on the closing price of OncoCyte of $3.56 per share on September 30, 2021. As of December 31, 2020, Lineage owned approximately 3.6 million shares of OncoCyte common stock. These shares had a fair value of approximately $8.7 million, based on the closing price of OncoCyte of $2.39 per share on December 31, 2020.

For the three months ended September 30, 2021, Lineage recorded a net unrealized loss on marketable equity securities of $2.5 million related to changes in fair market value of OncoCyte's common stock price during the quarter. For the three months ended September 30, 2020, Lineage recorded an unrealized loss of $1.9 million related to changes in the fair market value of OncoCyte's common stock price during the quarter.

For the nine months ended September 30, 2021, Lineage recorded a realized gain of $6.0 million due to sales of OncoCyte shares in the period. Lineage also recorded a net unrealized loss on marketable equity securities of $0.6 million related to changes in fair market value of OncoCyte's common stock price during the period. For the nine months ended September 30, 2020, Lineage recorded a realized gain of $3.1 million due to sales of OncoCyte shares in the period. Lineage also recorded a net unrealized loss on marketable equity securities of $6.1 million related to changes in fair market value of OncoCyte's common stock price in the period.

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

We account for the shares we hold in HBL as marketable equity securities as of September 30, 2021. These securities were carried at fair market value on our consolidated balance sheets, and the accounting transactions for the three and nine months ended were not material.

For the three and nine months ended September 30, 2021, we did not hold any marketable securities related to AgeX. For the three and nine months ended September 30, 2020, Lineage recorded realized gains of $0.1 million and $0.7 million, respectively, due to sales of AgeX shares in the period. For the three and nine months ended September 30, 2020, we recorded unrealized losses of $0.1 million and $1.4 million, respectively, due to changes in fair market value of AgeX's common stock price during the period.

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

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

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

6. Property and Equipment, Net

At September 30, 2021 and December 31, 2020, property and equipment, net was comprised of the following (in thousands):

	September 30, 2021	December 31, 2020
	(unaudited)	
Equipment, furniture and fixtures	$ 3,626	$ 3,628
Leasehold improvements	2,462	2,472
Right-of-use assets	3,833	3,845
Accumulated depreciation and amortization	(5,193)	(4,315)
Property and equipment, net	$ 4,728	$ 5,630

Property and equipment at September 30, 2021 and December 31, 2020 includes $79,000 in financing leases. In September 2020, Lineage terminated its leases in Alameda and entered into a new lease for a reduced amount of square footage. This resulted in a reduction to right-of-use assets of approximately $1.4 million. See additional information in Note 15.

Depreciation and amortization expense amounted to $165,000 and $200,000 for the three months ended September 30, 2021 and 2020, and $504,000 and $623,000 for the nine months ended September 30, 2021 and 2020, respectively. During the nine months ended September 30, 2021, Lineage sold non-capitalized assets for a net gain of $30,000, which was included in research and development expenses on the condensed consolidated statements of operations. During the nine months ended September 30, 2021, Lineage sold equipment with a net book value of $9,000 and recognized a gain of $5,000.

During the three and nine months ended September 30, 2020, Lineage sold equipment with a net book value of $39,000 and $52,000, respectively, and recognized losses of $32,000 and $34,000, respectively. During the nine months ended September 30, 2020, Lineage sold non-capitalized assets for a net gain of $67,000, which was included in research and development expenses on the condensed consolidated statements of operations.

7. Goodwill and Intangible Assets, Net

At September 30, 2021 and December 31, 2020, goodwill and intangible assets, net consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
	(unaudited)	
Goodwill[1]	$ 10,672	$ 10,672
Intangible assets:		
Acquired IPR&D - OPC1 (from the Asterias Merger)[2]	$ 31,700	$ 31,700
Acquired IPR&D - VAC2 (from the Asterias Merger)[2]	14,840	14,840
Intangible assets subject to amortization:		
Acquired patents	18,953	18,953
Acquired royalty contracts[3]	650	650
Total intangible assets	66,143	66,143
Accumulated amortization[4]	(19,289)	(19,111)
Intangible assets, net	$ 46,854	$ 47,032

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

(2) Asterias had two in-process research and development ("IPR&D") intangible assets that were valued at $46.5 million as part of the purchase price allocation that was performed in connection with the Asterias Merger. The fair value of these assets consisted of $31.7 million pertaining to the OPC1 program and $14.8 million pertaining to the VAC2 program.

(3) Asterias had royalty cash flows under certain specific patent families that Asterias previously acquired from Geron Corporation ("Geron"). The Geron patents are expected to continue to generate revenue and are not used in the OPC1 or the VAC2 program, these patents are considered to be separate long-lived intangible assets under ASC 805.

(4) As of September 30, 2021 the acquired patents were fully amortized and the acquired royalty contracts had a remaining unamortized balance of $314,000.

Amortization expenses was $33,000 and $250,000 for the three months ended September 30, 2021 and 2020, and $178,000 and $1,080,000 for the nine months ended September 30, 2021, and 2020, respectively.

Future aggregate approximate amortization expense for the Company's intangible assets are as follows (in thousands):

Year Ending December 31,	
2021	$ 32
2022	130
2023	130
2024	22
2025	-
Thereafter	-
Total	$ 314

8. Accounts Payable and Accrued Liabilities

At September 30, 2021 and December 31, 2020, accounts payable and accrued liabilities consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
	(unaudited)	
Accounts payable	$ 3,457	$ 2,611
Accrued compensation	1,639	1,959
Accrued liabilities	1,540	1,711
PPP loan payable	-	523
Other current liabilities	69	9
Total	$ 6,705	$ 6,813

PPP Loan Payable

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

9. Fair Value Measurements

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

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

We measure cash and cash equivalents, marketable equity securities and our liability classified warrants at fair value on a recurring basis. The fair values of such assets were as follows for September 30, 2021 and December 31, 2020 (in thousands):

	Balance at September 30, 2021	Fair Value Measurements Using: Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Cash and cash equivalents	$ 60,809	$ 60,809	$ -	$ -
Marketable equity securities	4,295	4,295	-	-
Liabilities:				
Cell Cure Warrants	332	-	-	332

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

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

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

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

(Dollars in thousands)	Cell Cure Warrants	Lineage Warrants	Total
Balance as of December 31, 2020	$ 437	$ 1	$ 438
Change in fair value and other adjustments	(105)	-	(105)
Expiration of warrants	-	(1)	(1)
Balance as of September 30, 2021	$ 332	$ -	$ 332

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

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

10. Related Party Transactions

Lineage incurred costs of $5,050 per month for the use of approximately 900 square feet of office space in New York City, which was made available to Lineage on a month-by-month basis by one of its directors at an amount that approximates his cost (see Note 15). In March 2021, Lineage terminated without penalty its leasing term related to the New York City office lease.

In connection with the putative shareholder class action lawsuits filed in February 2019 and October 2019 challenging the Asterias Merger (see Note 15), Lineage has agreed to pay for the legal defense of Neal Bradsher, director, Broadwood Partners, L.P., a shareholder of Lineage, and Broadwood Capital, Inc., which manages Broadwood Partners, L.P., all of which were named in the lawsuits. Through September 30, 2021, Lineage has incurred a total of $657,000 in legal expenses on behalf of the director, shareholder and the manager of the shareholder.

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

11. Shareholders' Equity

Preferred Shares

Lineage is authorized to issue 2,000,000 preferred shares. The preferred shares may be issued in one or more series as our board of directors may determine by resolution. Our 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. Our board of directors may, by resolution, increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series of preferred shares subsequent to the issue of shares of that series. There are no preferred shares issued and outstanding.

Common Shares

At September 30, 2021, Lineage was authorized to issue 250,000,000 common shares, no par value. As of September 30, 2021, and December 31, 2020, Lineage had 168,465,000 and 153,095,883 issued and outstanding common shares, respectively.

At-The-Market Offering

On May 1, 2020, Lineage entered into the Sales Agreement, pursuant to which Lineage may offer and sell, from time to time, through Cantor Fitzgerald, common shares of Lineage having an aggregate offering price of up to $25.0 million. 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 (File No. 333-237975), which was filed with the Commission on May 1, 2020 and was declared effective on May 8, 2020. The Sales Agreement replaced the previous sales agreement with Cantor that had been entered into in April 2017. On March 5, 2021, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of an additional $25.0 million of common shares under the Sales Agreement increasing the total offering to $50.0 million. As of June 30, 2021, Lineage had issued 13,859,776 common shares at a weighted average price per share of $2.39 for gross proceeds of $33.1 million. For the three months ended September 30, 2021, Lineage issued an additional 1,048,959 common shares at a weighted average price per share of $2.62 for gross proceeds of $2.7 million. As of September 30, 2021, Lineage had issued 14,908,735 common shares at a weighted average price per share of $2.41 for gross proceeds of $35.9 million under the Sales Agreement.

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

Reconciliation of Changes in Shareholders' Equity

The following tables document the changes in shareholders' equity for the three and nine months ended September 30, 2021 and 2020 (unaudited and in thousands):

	Preferred Shares		Common Shares			Noncontrolling	Accumulated Other	Total
	Number of Shares	Amount	Number of Shares	Amount	Accumulated Deficit	Interest/ (Deficit)	Comprehensive Income/(Loss)	Shareholders' Equity
BALANCE AT DECEMBER 31, 2020	**-**	**$ -**	**153,096**	**$ 393,944**	**$ (294,078)**	**$ (1,072)**	**$ (3,667)**	**$ 95,127**
Shares issued through ATM	-	-	7,941	19,008	-	-	-	19,008
Shares issued for services	-	-	78	202	-	-	-	202
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	10	(12)	-	-	-	(12)
Shares issued upon exercise of stock options	-	-	942	1,751				1,751
Financing related fees	-	-	-	(173)	-	-	-	(173)
Stock-based compensation	-	-	-	539	-	-	-	539
Foreign currency translation gain	-	-	-	-	-	-	1,576	1,576
NET LOSS	-	-	-	-	(1,416)	(32)	-	(1,448)
BALANCE AT MARCH 31, 2021	**-**	**$ -**	**162,067**	**$ 415,259**	**$ (295,494)**	**$ (1,104)**	**$ (2,091)**	**$ 116,570**
Shares issued through ATM	-	-	2,824	7,874	-	-	-	7,874
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	10	(15)	-	-	-	(15)
Shares issued upon exercise of stock options	-	-	2,116	4,033	-	-	-	4,033
Financing related fees	-	-	-	(26)	-	-	-	(26)
Stock-based compensation	-	-	-	919	-	-	-	919
Shares issues for retirement of stock warrants	-	-	20	2				2
Foreign currency translation loss	-	-	-	-	-	-	(960)	(960)
NET LOSS	-	-	-	-	(4,788)	(8)	-	(4,796)
BALANCE AT JUNE 30, 2021	**-**	**$ -**	**167,037**	**$ 428,046**	**$ (300,282)**	**$ (1,112)**	**$ (3,051)**	**$ 123,601**
Shares issued through ATM	-	-	1,049	2,667	-	-	-	2,667
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	10	(13)	-	-	-	(13)
Shares issued upon exercise of stock options	-	-	369	485	-	-	-	485
Financing related fees	-	-	-	(79)	-	-	-	(79)
Stock-based compensation	-	-	-	1,144	-	-	-	1,144
Foreign currency translation loss	-	-	-	-	-	-	(382)	(382)
NET LOSS	-	-	-	-	(7,823)	(11)	-	(7,834)
BALANCE AT SEPTEMBER 30, 2021	**-**	**$ -**	**168,465**	**$ 432,250**	**$ (308,105)**	**$ (1,123)**	**$ (3,433)**	**$ 119,589**

	Preferred Shares		Common Shares			Noncontrolling	Accumulated Other	Total
	Number of Shares	Amount	Number of Shares	Amount	Accumulated Deficit	Interest/ (Deficit)	Comprehensive Income/(Loss)	Shareholders' Equity
BALANCE AT DECEMBER 31, 2019	**-**	**$ -**	**149,804**	**$ 387,062**	**$ (273,422)**	**$ (1,712)**	**$ (681)**	**$ 111,247**
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	14	(2)	-	-	-	(2)
Stock-based compensation	-	-	-	626	-	-	-	626
Foreign currency translation gain	-	-	-	-	-	-	1,315	1,315
NET LOSS	-	-	-	-	(8,399)	(29)	-	(8,428)
BALANCE AT MARCH 31, 2020	**-**	**$ -**	**149,818**	**$ 387,686**	**$ (281,821)**	**$ (1,741)**	**$ 634**	**$ 104,758**
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	13	(11)	-	-	-	(11)
Stock-based compensation	-	-	-	606	-	-	-	606
Financing related fees	-	-	-	(10)	-	-	-	(10)
Foreign currency translation loss	-	-	-	-	-	-	(1,120)	(1,120)
NET LOSS	-	-	-	-	(6,522)	(8)	-	(6,530)
BALANCE AT JUNE 30, 2020	**-**	**$ -**	**149,831**	**$ 388,271**	**$ (288,343)**	**$ (1,749)**	**$ (486)**	**$ 97,693**
Shares issued upon vesting of restricted stock units, net of shares retired to pay employees' taxes	-	-	10	(6)	-	-	-	(6)
Shares issued for services	-	-	150	119	-	-	-	119
Dissolution of BioTime Asia	-	-	-	(679)	-	679	-	-
Stock-based compensation	-	-	-	501	-	-	-	501
Financing related fees	-	-	-	(16)	-	-	-	(16)
Foreign currency translation loss	-	-	-	-	-	-	(335)	(335)
NET LOSS	-	-	-	-	(7,760)	(12)	-	(7,772)
BALANCE AT SEPTEMBER 30, 2020	**-**	**$ -**	**149,991**	**$ 388,190**	**$ (296,103)**	**$ (1,082)**	**$ (821)**	**$ 90,184**

Warrants

Lineage (previously Asterias) Warrants - Liability Classified

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

Cell Cure Warrants - Liability Classified

Cell Cure has two sets of issued warrants (the "Cell Cure Warrants"). Warrants to purchase 24,566 Cell Cure ordinary shares at an exercise price of $40.5359 per share were issued to HBL in July 2017. These warrants expire in July 2022. Warrants to purchase 13,738 Cell Cure ordinary shares at exercise prices ranging from $32.02 to $40.00 per share have been issued to consultants. Of these warrants, 11,738 were cashless exercised in October 2020. The remaining 2,000 warrants have an exercise price of $40.00 per share and expire in January 2024.

12. Stock-Based Awards

Equity Incentive Plan Awards

On September 13, 2021, the shareholders of Lineage approved the 2021 Equity Incentive Plan (the "2021 Plan"), and the plan became effective. The 2021 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units awards ("RSUs"), and other stock awards. All of our employees (including our affiliates'), non-employee directors and consultants are eligible to participate in the 2021 Plan.

Subject to adjustment for certain changes in our capitalization, the aggregate number of our common shares that may be issued under the 2021 Plan will not exceed the sum of (i) 15,000,000 shares and (ii) the Prior Plan Returning Shares ("Prior Plan Returning Shares"). The Prior Plan Returning Shares are defined as an award granted under the Lineage Cell Therapeutics Inc. 2012 Equity Incentive Plan (the "2012 Plan"), which were outstanding when the 2021 Plan became effective, and are not issued because such Prior Plan Award or any option thereof expires or otherwise terminates without all of the shares covered by such Prior Plan Award having been issued. Given the approval of the 2021 Plan, no additional awards will be granted from the 2012 Plan or the Asterias 2013 Equity Incentive Award (the "Asterias Equity Plan"). As of September 30, 2021, there were no outstanding equity awards issued under the 2021 Plan.

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

	Number of Options Outstanding	Number of RSUs Outstanding	Weighted Average Exercise Price
December 31, 2020	15,865	93	$ 1.57
Restricted stock units vested	-	(47)	-
Options granted	6,245	-	2.50
Options exercised	(3,427)	-	1.83
Options expired/forfeited/cancelled	(1,826)	-	2.18
September 30, 2021	16,857	46	$ 1.80
Options exercisable at September 30, 2021	6,806		$ 1.66

At the effective time of the Asterias Merger, Lineage assumed sponsorship of the Asterias 2013 Equity Incentive Plan, with references to Asterias and Asterias common stock therein to be deemed references to Lineage and Lineage common shares.

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

	Number of Options Outstanding	Weighted Average Exercise Price
December 31, 2020	350	$ 1.57
Options granted	-	-
Options exercised	-	-
Options forfeited		-
September 30, 2021	350	$ 1.57
Options exercisable at September 30, 2021	219	$ 1.57

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:

	Nine Months Ended September 30, (unaudited)	
	2021	2020
Expected life (in years)	6.19	6.21
Risk-free interest rates	1.05%	0.8%
Volatility	73.2%	67.7%
Dividend yield	-%	-%

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

	Three Months Ended September 30, (unaudited)		Nine Months Ended September 30, (unaudited)	
	2021	2020	2021	2020
Research and development	$ 235	$ 126	$ 613	$ 343
General and administrative	909	375	1,988	1,390
Total stock-based compensation expense	$ 1,144	$ 501	$ 2,601	$ 1,733

13. Income Taxes

The provision for income taxes for interim periods is generally determined using an estimated annual effective tax rate as prescribed by ASC 740-270, *Income Taxes, Interim Reporting*. The effective tax rate may be subject to fluctuations during the year as new information is obtained, which may affect the assumptions used to estimate the annual effective tax rate, including factors such as valuation allowances and changes in valuation allowances against deferred tax assets, the recognition or de-recognition of tax benefits related to uncertain tax positions, if any, and changes in or the interpretation of tax laws in jurisdictions where Lineage conducts business. ASC 740-270 also states that if an entity is unable to reliably estimate some or a part of its ordinary income or loss, the income tax provision or benefit applicable to the item that cannot be estimated shall be reported in the interim period in which the item is reported.

For items that Lineage cannot reliably estimate on an annual basis (principally unrealized gains or losses generated by changes in the market prices of OncoCyte shares), Lineage uses the actual year to date effective tax rate rather than an estimated annual effective tax rate to determine the tax effect of each item, including the use of all available net operating losses and other credits or deferred tax assets.

The market value of the shares of OncoCyte common stock Lineage holds creates a deferred tax liability to Lineage based on the closing prices of the shares, less Lineage's tax basis in the shares. The deferred tax liability generated by the OncoCyte shares that Lineage holds as of September 30, 2021, 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 the deferred tax liability. This deferred tax liability is determined based on the closing prices of the OncoCyte shares as of September 30, 2021. Due to the inherent unpredictability of future prices of those shares, Lineage cannot reliably estimate or project those deferred tax liabilities on an annual basis. Therefore, the deferred tax liability pertaining to OncoCyte shares, determined based on the actual closing prices on the last stock market trading day of the applicable accounting period, and the related impacts to the valuation allowance and deferred tax asset changes, are recorded in the accounting period in which they occur.

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

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. Lineage established a full valuation allowance as of December 31, 2018 due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets, including foreign net operating losses generated by its subsidiaries. During the year ended December 31, 2020, 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 $1.2 million; 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.

For the three and nine months ended September 30, 2021, Lineage recorded a $1.0 million and $1.2 million deferred tax benefit, respectively, that was primarily related to federal net operating losses generated for the three and nine months ended September 30, 2021, which was available and indefinite in nature.

For the three and nine months ended September 30, 2020, Lineage recorded a $0.2 million deferred tax benefit for income taxes.

14. Supplemental Cash Flow Information

Supplemental disclosure of cash flow information for the nine months ended September 30, 2021 and 2020 is as follows (in thousands):

	Nine Months Ended September 30, (unaudited)	
	2021	**2020**
Cash paid during period for interest	$ 12	$ 19

15. Commitments and Contingencies

Carlsbad Lease

In May 2019, Lineage entered into a lease for approximately 8,841 square feet of rentable space in an office park in Carlsbad, California (the "Carlsbad Lease"). The term of the Carlsbad Lease commenced on August 1, 2019 and expires on October 31, 2022.

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

In addition to base rent, Lineage pays a pro rata portion of increases in certain expenses, including real property taxes, utilities (to the extent not separately metered to the leased space) and the landlord's operating expenses, over the amounts of those expenses incurred by the landlord. As security for the performance of its obligations under the Carlsbad Lease, Lineage provided the landlord with a security deposit of $17,850.

Alameda Leases and Alameda Sublease

In December 2015, Lineage entered into leases of office and laboratory space located in two buildings in Alameda, California (the "Alameda Leases") comprised of 22,303 square feet (the "1010 Atlantic Premises") and 8,492 square feet (the "1020 Atlantic Premises"). Base rent under the Alameda Leases beginning on February 1, 2020 was $72,676 per month with annual increases of approximately 3%. In addition to base rent, Lineage paid a pro rata portion of increases in certain expenses, including real property taxes, utilities (to the extent not separately metered to the leased space) and the landlord's operating expenses, over the amounts of those expenses incurred by the landlord. As security for its obligations, Lineage provided the landlord with a security deposit of approximately $424,000, which was reduced to $78,000 on January 24, 2019 in accordance with the terms of the lease. The security deposit was returned to Lineage in March 2021.

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

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

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

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

New York Leased Office Space

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

Cell Cure Leases

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

On January 28, 2018, Cell Cure entered into another lease agreement for an additional 934 square meters (approximately 10,054 square feet) of office space in the same facility in Jerusalem, Israel under a lease that expires on December 31, 2025, with two options to extend the lease for five 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 US $1.1 million using the December 31, 2018 exchange rate) from the landlord. The leasehold improvements were completed in December 2018 and the entire allowance was used. Beginning on January 1, 2019, combined base rent and construction allowance payments for the January 2018 Lease are NIS 93,827 per month (approximately $26,000 per month).

In December 2018, Cell Cure made a $420,000 deposit required under the January 2018 Lease, which is included in deposits and other long-term assets on the consolidated balance sheet as of September 30, 2021, to be held as restricted cash during the term of the January 2018 Lease.

The below table provides supplemental cash flow information related to leases as follows (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 687	$ 1,157
Operating cash flows from financing leases	12	19
Financing cash flows from financing leases	13	24
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	32	29

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

	September 30, 2021	December 31, 2020
Operating leases		
Right-of-use assets, net	$ 2,327	$ 2,916
Lease liabilities, current	$ 801	$ 746
Lease liabilities, noncurrent	1,887	2,514
Total operating lease liabilities	$ 2,688	$ 3,260
Financing leases		
Property and equipment, gross	$ 79	$ 79
Accumulated depreciation	(76)	(65)
Property and equipment, net	$ 3	$ 14
Current liabilities	$ 17	$ 16
Long-term liabilities	12	26
Total finance lease liabilities	$ 29	$ 42
Weighted average remaining lease term		
Operating leases	3.7 years	4.2 years
Finance leases	1.7 years	2.4 years
Weighted average discount rate		
Operating leases	8.0%	8.0%
Finance leases	10.0%	10.0%

Future minimum lease commitments are as follows as of September 30, 2021 (in thousands):

	Operating Leases	Finance Leases
Year Ending December 31,		
2021	$ 248	$ 5
2022	913	19
2023	489	8
2024	460	-
2025	442	-
Thereafter	586	-
Total lease payments	$ 3,138	$ 32
Less imputed interest	(450)	(3)
Total	$ 2,688	$ 29

Research and Option Agreement

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

Litigation

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 will disclose 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 disclosed 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. Lineage believed that the claims and allegations in the action lacked 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. The court granted the stipulation and dismissed the action on August 14, 2019.

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. On December 20, 2019, the defendants moved to dismiss the complaint. On February 10, 2020, the plaintiff filed an opposition. Defendants filed their replies on March 13, 2020. On June 23, 2020, a hearing on the motions to dismiss occurred. On September 21, 2020, the Chancery Court denied the motion to dismiss as to Lineage and certain members of the Asterias board of directors, and it granted the motion to dismiss as to all other defendants. On October 30, 2020, the remaining defendants filed an answer to the complaint. The parties are currently engaged in discovery. A five-day trial before the Chancery Court is currently scheduled for October 17-21, 2022.

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

Employment contracts

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

Indemnification

In the normal course of business, Lineage may provide indemnifications of varying scope under Lineage's agreements with other companies or consultants, typically Lineage's clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, Lineage will generally agree to indemnify, hold harmless, and reimburse the indemnified parties for losses and expenses suffered or incurred by the indemnified parties arising from claims of third parties in connection with the use or testing of Lineage's products and services. Indemnification provisions could also cover third party infringement claims with respect to patent rights, copyrights, or other intellectual property pertaining to Lineage products and services. The term of these indemnification agreements will generally continue in effect after the termination or expiration of the particular research, development, services, or license agreement to which they relate. The potential future payments Lineage could be required to make under these indemnification agreements will generally not be subject to any specified maximum amount. Historically, Lineage has not been subject to any claims or demands for indemnification. Lineage also maintains various liability insurance policies that provide Lineage with insurance against claims or demands for indemnification in specified circumstances. 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 September 30, 2021 and December 31, 2020.

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

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

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

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

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 September 30, 2021, 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. Annual minimum maintenance fees are expected to be approximately $30,000 to $60,000 per year.

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

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 interest rate benchmark. 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, the 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 additional payment obligations in the event of any transfer outside of Israel of intellectual property related to, or the manufacture, or both, of products developed under the grant, as defined by the IIA.

Collaboration Agreements

Under our collaborative agreement with ITI we agreed to perform certain research, development, manufacturing, and oversight activities related to a VAC-CMV product up to a budgeted amount of approximately $2.5 million. ITI will reimburse the Company for material costs and full-time employee costs with no markup related to the manufacturing of the VAC-CMV product.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The matters addressed in this Item 2 that are not historical information constitute "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") including statements about any of the following: any projections of earnings, revenue, gross profit, cash, effective tax rate, use of net operating losses, or any other financial items; the plans, strategies and objectives of management for future operations or prospects for achieving such plans; and any statements of assumptions underlying any of the foregoing. Any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "seeks," "estimates," and similar expressions are intended to identify forward-looking statements. While Lineage may elect to update forward-looking statements in the future, it specifically disclaims any obligation to do so, even if Lineage's estimates change, and readers should not rely on those forward-looking statements as representing Lineage's views as of any date subsequent to the date of the filing of this Report. Although we believe that the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risks and Lineage can give no assurances that its expectations will prove to be correct. Actual results could differ materially from those described in this Report because of numerous factors, many of which are beyond the control of Lineage. A number of important factors could cause the results of the Company to differ materially from those indicated by such forward-looking statements, including those detailed in Part II, Item IA, "Risk Factors" of this Report.

The following discussion should be read in conjunction with Lineage condensed consolidated interim financial statements and the related notes provided under "Item 1 - Financial Statements" above.

Company and 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. Specifically, Lineage is testing therapies to treat dry age-related macular degeneration, spinal cord injuries, and non-small cell lung cancer. Our programs are based on our proprietary cell-based technology platform and associated development and manufacturing capabilities. From this platform, we develop and manufacture specialized, terminally, or functionally differentiated human cells from established and well-characterized pluripotent cell lines. These differentiated cells are transplanted into a patient 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 a more robust and effective immune response to cancer.

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") (also known as atrophic AMD). There are currently 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 one of the leading causes 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 subacute spinal cord injuries ("SCI"). This clinical trial has been partially funded by the California Institute for Regenerative Medicine ("CIRM").

- *VAC2*, an allogeneic 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, one of the world's largest independent cancer research charities.

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

Though our principal focus is on advancing our three cell therapy programs currently in clinical development, we may seek to create additional value by initiating new programs using existing protocols or new protocols and cell lines, or through corporate transactions, as we have in the past.

Critical Accounting Policies

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses and analyzes data in our unaudited Condensed Consolidated Interim Financial Statements, which we have prepared in accordance with generally accepted accounting principles in the United States. Preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. Management bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our board of directors. Actual conditions may differ from our assumptions and actual results may differ from our estimates.

An accounting policy is deemed critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made, if different estimates reasonably could have been used, or if changes in the estimate that are reasonably likely to occur could materially impact the financial statements. Management believes that there have been no significant changes to the items that we disclosed as our critical accounting policies and estimates in Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2020 as filed with the Securities and Exchange Commission (the "Commission") on March 11, 2021, except as follows:

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.

IPR&D assets are indefinite-lived intangible assets until the completion or abandonment of the associated research and development 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 condensed consolidated balance sheet.

ROU assets represent our right to use an underlying asset during the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating 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 ROU assets in property and equipment, and ROU lease liabilities, current and long-term, in the condensed consolidated balance sheets. Financing leases are included in property and equipment, and in financing lease liabilities, current and long-term, in the condensed consolidated balance sheets.

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

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

In applying the provisions of ASU 2014-09, Lineage has determined that government grants are out of the scope of ASU 2014-09 because the government entities do not meet the definition of a "customer," as defined by ASU 2014-09, as there is not considered to be a transfer of control of goods or services to the government entities funding the grant. In the absence of applicable guidance under U.S. GAAP, the Company's policy is to recognize grant revenue when the related costs are incurred and the right to payment is realized. Costs incurred are recorded in research and development and general and administrative expenses on the accompanying statements of operations (see Note 15).

Royalties from product sales and license fees: For agreements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, Lineage recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

Lineage estimates and recognizes royalty revenues based on all available information, including estimates provided by the customer or licensee from which Lineage obtains such estimates directly for each reporting period. Actual revenues ultimately received may differ from those estimates recorded and are adjusted in the period when information to actuals is available to Lineage.

Collaborative Agreements

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

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

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

Upfront Fees: If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize collaboration revenues from the transaction price allocated to the license when the license is transferred to the licensee, and the licensee is able to use and benefit from the license. When the license is determined to be non-distinct, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time, and, if over time, the appropriate method of measuring progress for purposes of recognizing collaboration revenue from the allocated transaction price. For example, when we receive upfront fees for the performance of research and development services, or when research and development services are not considered to be distinct from a license, we recognize collaboration revenue for those units of account over time using a measure of progress. We evaluate the measure of progress at each reporting period and, if necessary, adjust the measure of performance and related revenue as a change in estimate.

Milestone Payments: At the inception of each collaboration agreement that includes milestone payments (variable consideration), we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our or the collaboration partner's control, such as non-operational developmental and regulatory approvals, are generally not considered probable of being achieved until those approvals are received. At the end of each reporting period, we re-evaluate the probability of achievement of milestones that are within our or the collaboration partner's control, such as operational developmental milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues and net income (loss) in the period of adjustment. Revisions to our estimate of the transaction price may also result in negative collaboration revenues and net income (loss) in the period of adjustment.

Royalties: For collaboration agreements that include sales-based royalties, including commercial milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

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

Results of Operations

Comparison of Three and Nine Months Ended September 30, 2021 and 2020

Revenues and Cost of Sales

The amounts in the tables below show our consolidated revenues, by source, and cost of sales for the periods presented (in thousands).

	Three Months Ended September 30, (unaudited)		$ Increase/ (Decrease)	% Increase/ (Decrease)
	2021	2020		
Royalties	$ 1,909	$ 342	$ 1,567	458%
Grant revenues	68	229	(161)	(70)%
Collaboration revenues	293	-	293	100%
Total revenues	2,270	571	1,699	298%
Cost of sales	(985)	(102)	(883)	866%
Gross profit	$ 1,285	$ 469	$ 816	174%

	Nine Months Ended September 30, (unaudited)		$ Increase/ (Decrease)	% Increase/ (Decrease)
	2021	2020		
Royalties	$ 2,430	$ 607	$ 1,823	300%
Grant revenues	237	864	(627)	(73)%
Collaboration revenues	506	-	506	100%
Total revenues	3,173	1,471	1,702	116%
Cost of sales	(1,222)	(271)	(951)	351%
Gross profit	$ 1,951	$ 1,200	$ 751	63%

Our total revenues increased by $1.7 million for the three months ended September 30, 2021 as compared to the same period in the prior year, due to a $1.6 million increase in royalties, a $0.3 million increase in collaboration revenues related to the Immunomic Therapeutics, Inc. ("ITI") collaborative agreement, offset by a $0.2 million decrease in grant revenues due to less grant-related activities during the period.

Our total revenues increased by $1.7 million for the nine months ended September 30, 2021 as compared to the same period in the prior year, due to a $1.8 million increase in royalties and a $0.5 million increase in collaboration revenues related to the ITI collaborative agreement, offset by a $0.6 million decrease in grant revenues due to less grant-related activities during the period.

Our royalties are derived from product sales and license fees. For the three months and nine months ended September 30, 2021 royalties were significantly higher compared to the same periods in the prior year, primarily due to additional royalty revenues of $1.8 million from a certain royalty customer, based on the customer's updated communication to us regarding royalties due. Consequently, Lineage also recorded a corresponding 50% of these additional royalties in cost of sales, as an accrued royalty payable to a separate royalty party. As of September 30, 2021, the $1.8 million is included as a receivable within prepaid expenses and other current assets. The customer paid these royalties to us in October 2021.

Our grant revenues are generated primarily by our subsidiary Cell Cure Neurosciences Ltd. ("Cell Cure") from the Israel Innovation Authority ("IIA") for the development of OpRegen and our bio retina program, and from a Small Business Innovation Research grant from the National Institutes of Health for our vision restoration program (the "NIH grant").

Grant revenues generated by Cell Cure from the IIA for the development of OpRegen and our bio retina program amounted to $68,000 and $237,000 for the three and nine months ended September 30, 2021 and $216,000 and $477,000 for the three and nine months ended September 30, 2020, respectively.

Grant revenues generated by the NIH grant were $13,000 and $387,000 for the three and nine months ended September 30, 2020. NIH grant related activities were completed in the third quarter of 2020.

Operating expenses

The amounts in the tables below are our consolidated operating expenses for the periods presented (in thousands).

	Three Months Ended September 30, (unaudited)		$ Increase/	% Increase/
	2021	2020	(Decrease)	(Decrease)
Research and development expenses	$ 2,811	$ 3,566	$ (755)	(21)%
General and administrative expenses	5,317	3,628	1,689	47%

	Nine Months Ended September 30, (unaudited)		$ Increase/	% Increase/
	2021	2020	(Decrease)	(Decrease)
Research and development expenses	$ 9,136	$ 9,710	$ (574)	(6)%
General and administrative expenses	13,788	12,055	1,733	14%

Research and development expenses

Research and development expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct and research-related overhead expenses including compensation and related benefits, stock-based compensation, consulting fees, research and laboratory fees, rent of research facilities, amortization of intangible assets, and license fees paid to third parties to acquire patents or licenses to use patents and other technology. 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.

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

	Three Months Ended September 30, (unaudited)			
	Amount		Percent of Total	
Program	2021	2020	2021	2020
OpRegen®	$ 777	$ 1,066	28%	30%
OPC1	1,514	576	54%	16%
VAC platform	490	1,871	17%	52%
All other programs	30	53	1%	2%
Total research and development expenses	$ 2,811	$ 3,566	100%	100%

	Nine Months Ended September 30, (unaudited)			
	Amount		Percent of Total	
Program	2021	2020	2021	2020
OpRegen®	$ 2,909	$ 4,323	32%	45%
OPC1	4,637	2,947	51%	30%
VAC platform	1,499	2,167	16%	22%
All other programs	91	273	1%	3%
Total research and development expenses	$ 9,136	$ 9,710	100%	100%

The net decrease of $0.8 million in total research and development expenses for the three months ended September 30, 2021 as compared to the same period in the prior year is mainly attributable to the following:

- a net decrease of $0.3 million in OpRegen, attributable primarily to a decrease in manufacturing activities in 2021 as compared to 2020,
- an increase of $0.9 million in OPC1-related expenses, primarily driven by a return of unspent project funds of approximately $0.8 million in the prior year period from a former Asterias service provider, and
- a net decrease of $1.4 million in VAC program expenses, primarily driven by the prior year signature fee accrual of $1.6 million to Cancer Research UK related to our license agreement, partially offset by increased manufacturing activities and support of the ITI collaborative agreement.

The net decrease of $0.6 million in total research and development expenses for the nine months ended September 30, 2021 as compared to the same period in the prior year is mainly attributable to the following:

- a net decrease of $1.4 million in OpRegen, attributable primarily to a decrease in manufacturing activities in 2021 as compared to 2020,
- an increase of $1.7 million in OPC1-related expenses, primarily related to an increase in manufacturing and development activities for this program, and a return of unspent project funds of approximately $0.8 million in the prior year period from a former Asterias service provider,
- a net decrease of $0.7 million in VAC program expenses, primarily driven by the prior year signature fee accrual of $1.6 million to Cancer Research UK related to our license agreement, partially offset with. increased manufacturing activities and support of the ITI collaborative agreement, and
- a net decrease of $0.2 million in Renevia and related expenses due to a reduction in research activities.

General and administrative expenses

General and administrative expenses include employee and director compensation, 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, legal and accounting costs, and other miscellaneous expenses which are allocated to general and administrative expense.

The total net increase of $1.7 million in general and administrative expenses for the three months ended September 30, 2021 compared to the same period in 2020, was primarily attributable to a $0.8 million increase in litigation and other expenses related to Lineage’s merger with Asterias and a $0.5 million increase in share-based compensation expense.

The total net increase of $1.7 million in general and administrative expenses for the nine months ended September 30, 2021 compared to the same period in 2020, was primarily attributable to a $0.7 million increase in litigation and other expenses related to Lineage’s merger with Asterias, a $0.6 million increase in share-based compensation expense and a $0.4 million increase in investor relations expenses.

Other income and (expenses), net

The following table shows the amount of other income and (expense), net, for the periods presented (in thousands):

	Three Months Ended September 30, (unaudited)	
	2021	**2020**
Other income (expenses), net		
Interest income, net	$ 1	$ 252
Gain on sale of marketable equity securities	-	120
Unrealized loss on marketable equity securities	(2,450)	(2,003)
Unrealized gain on warrant liability	53	55
Other income, net	393	351
Total other expenses, net	$ (2,003)	$ (1,225)

	Nine Months Ended September 30, (unaudited)	
	2021	**2020**
Other income (expenses), net		
Interest income (expenses), net	$ (1)	$ 1,037
Gain on sale of marketable equity securities	6,024	3,848
Gain on extinguishment of debt	523	-
Unrealized loss on marketable equity securities	(621)	(7,487)
Unrealized gain on warrant liability	105	84
Other income (expenses), net	(318)	175
Total other income (expenses), net	$ 5,712	$ (2,343)

Interest income, net – During the three and nine months ended September 30, 2020 we earned $0.3 million and $1.0 million of interest income, respectively. In August 2020, Lineage received $24.6 million from Juvenescence, representing the outstanding principal and accrued interest on the promissory note.

Marketable equity securities - As of September 30, 2021, Lineage owned 1.1 million shares of OncoCyte common stock. These shares had a fair value of $4.0 million, based on the closing price of OncoCyte common stock of $3.56 per share on September 30, 2021. As of December 31, 2020, Lineage owned 3.6 million shares of OncoCyte common stock. These shares had a fair value of $8.7 million, based on the closing price of OncoCyte common stock of $2.39 per share on December 31, 2020.

For the three months ended September 30, 2021, Lineage recorded a net unrealized loss on marketable equity securities of $2.5 million related to changes in fair market value of OncoCyte's common stock price during the quarter. For the three months ended September 30, 2020, Lineage recorded an unrealized loss of $1.9 million due to sales of OncoCyte shares in the period.

For the nine months ended September 30, 2021, Lineage recorded a realized gain of $6.0 million due to sales of OncoCyte shares in the period. Lineage recorded a net unrealized loss on marketable equity securities of $0.6 million related to changes in fair market value of OncoCyte's common stock price during the quarter. For the nine months ended September 30, 2020, Lineage recorded a realized gain of $3.1 million due to sales of OncoCyte shares in the period. Lineage also recorded an unrealized loss on marketable equity securities of $6.1 million related to changes in fair market value of OncoCyte's common stock price during the quarter.

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

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

We account for the shares we hold in HBL as marketable equity securities as of September 30, 2021. These securities were carried at fair market value on our consolidated balance sheets, and the accounting transactions for the three and nine months ended September 30, 2021 were not material. For the three and nine months ended September 30, 2021, we did not hold any marketable securities related to AgeX.

For the three and nine months ended September 30, 2020, Lineage recorded realized gains of $0.1 million and $0.7 million, respectively, due to sales of AgeX shares in the period. For the three and nine months ended September 30, 2020, we recorded unrealized losses of $0.1 million and $1.4 million, respectively, due to changes in fair market value of AgeX's common stock price during the period.

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

Other expenses, net - Other expenses, net, in 2021 and 2020 consist primarily of net foreign currency transaction gains and losses recognized by our subsidiaries Cell Cure and ES Cell International Pte. Ltd. ("ESI"), changes in the fair value of warrants issued by Cell Cure, dividend income and interest income, net. 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 market value of the shares of OncoCyte common stock we hold creates a deferred tax liability based on the closing prices of the shares, less our tax basis in the shares. The deferred tax liability generated by the OncoCyte shares that we hold as of September 30, 2021, is a source of future taxable income to us, as prescribed by ASC 740-10-30-17, that will more likely than not result in the realization of our deferred tax assets to the extent of the deferred tax liability. This deferred tax liability is determined based on the closing prices of the OncoCyte shares as of September 30, 2021. Due to the inherent unpredictability of future prices of those shares, we cannot reliably estimate or project those deferred tax liabilities on an annual basis. Therefore, the deferred tax liability pertaining to OncoCyte shares, determined based on the actual closing prices on the last stock market trading day of the applicable accounting period, and the related impacts to the valuation allowance and deferred tax asset changes, are recorded in the accounting period in which they occur.

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

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

A valuation allowance is provided when it is more likely than not that some portion of the deferred tax assets will not be realized. Lineage established a full valuation allowance as of December 31, 2018 due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets, including foreign net operating losses generated by its subsidiaries. During the year ended December 31, 2020, 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 $1.2 million; 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.

For the three and nine months ended September 30, 2021, Lineage recorded a $1.0 million and $1.2 million deferred tax benefit, respectively, that was primarily related to federal net operating losses generated for the three and nine months ended September 30, 2021, which was available and indefinite in nature.

For the three and nine months ended September 30, 2020, Lineage recorded a $0.2 million deferred tax benefit for income taxes.

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

Liquidity and Capital Resources

At September 30, 2021, we had $65.1 million of cash, cash equivalents and marketable equity securities on hand, which includes our investments in OncoCyte and HBL. We may use our marketable equity securities for liquidity, as necessary, and as market conditions allow. The market value may not represent the amount that could be realized in a sale of investment shares due to various market and regulatory factors, including trading volume or market depth factors and volume and manner of sale restrictions under Federal securities laws, prevailing market conditions and prices at the time of any sale, and subsequent sales of securities by the entities. In addition, the value of our marketable equity securities may be significantly and adversely impacted by deteriorating global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

Since inception, we have incurred significant operating losses and have funded our operations primarily through the issuance of equity securities, the sale of common stock of our former subsidiaries, OncoCyte and AgeX, payments from research grants, royalties from product sales and sales of research products and services. At September 30, 2021, we had an accumulated deficit of $308.1 million, working capital of $59.6 million and shareholders' equity of $119.6 million. We evaluated the projected cash flows for Lineage and our subsidiaries, and we believe that our $65.1 million in cash, cash equivalents and marketable equity securities 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 condensed consolidated interim 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.

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

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

Cash flows used in operating activities

Net cash used in operating activities of $17.7 million for the nine months ended September 30, 2021 primarily reflects the loss from operations of $21.0 million. These items were offset primarily by non-cash expenses of $2.6 million for stock-based compensation and $0.7 million of depreciation and amortization. The unrealized loss on marketable equity securities and deferred tax benefit had no effect on cash flows.

Net cash used in operating activities of $14.1 million for the nine months ended September 30, 2020 primarily reflects the loss from operations of $20.6 million less the changes in assets and liabilities of $2.0 million. These items were offset primarily by non-cash expenses of $1.8 million of depreciation and amortization and $1.7 million for stock-based compensation. The unrealized loss on marketable equity securities and deferred tax benefit had no effect on cash flows.

Cash flows provided by investing activities

Cash provided by investing activities of $9.9 million for the nine months ended September 30, 2021 was associated primarily with receipts of $10.1 million from sales of a portion of our OncoCyte holdings, offset by purchases of equipment for $0.2 million.

Cash provided by investing activities of $12.1 million for the nine months ended September 30, 2020 was associated primarily with receipts of $10.9 million from sales of a portion of our OncoCyte holdings and $1.2 million from sales of a portion of our AgeX holdings.

Cash flows provided by financing activities

Cash provided by financing activities of $36.0 million for the nine months ended September 30, 2021 was associated primarily with proceeds net of financing costs of $29.8 million from the sale of common shares and proceeds of $6.3 million from the exercise of employee stock options.

Cash provided by financing activities of $25.1 million for the nine months ended September 30, 2020 was associated primarily with proceeds of $24.6 million from payment of the Juvenescence promissory note and proceeds of $0.5 million from a Paycheck Protection Program ("PPP").

Off-Balance Sheet Arrangements

As of September 30, 2021 and December 31, 2020, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Commission Regulation S-K.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Exchange Act. Our management, including our principal executive officer and our principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Report. 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 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.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

The information required by this Item is incorporated herein by reference to Notes to Condensed Consolidated Interim Financial Statements—Note 15. “Commitments and Contingencies” under the heading “Litigation,” in Part I, Item 1, of this Report.

From time-to-time we may be involved in a variety of claims or litigation proceedings. Such proceedings may initially be viewed as immaterial but could later prove to be material. Litigation proceedings are inherently unpredictable and excessive verdicts do occur. Given the inherent uncertainties in litigation, even when we can reasonably estimate the amount of possible loss or range of loss and reasonably estimable loss contingencies, the actual outcome may change in the future due to new developments or changes in approach. In addition, such claims or litigation proceedings could involve significant expense and diversion of management’s attention and resources from other matters.

Item 1A. Risk Factors

An investment in our common shares involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this Report, before deciding whether to purchase, hold or sell our common shares. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. We have marked with an asterisk (*) those risk factors that reflect changes from the similarly titled risk factors included in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the Commission on March 11, 2021.

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 year ended December 31, 2020 were $26.4 million and our total operating losses for the nine months ended September 30, 2021 were $21.0 million, and we had an accumulated deficit of $308.1 million as of September 30, 2021. Since inception, we have incurred significant operating losses and have funded our operations primarily through sales of our equity securities and the equity securities of former subsidiaries, receipt of research grants, royalties on product sales, license revenues, sales of research products, and revenues from subscription fees and advertising revenue from database products of a former subsidiary. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. All of our product candidates will require substantial additional development time and resources before we would be able to apply for or receive regulatory approvals. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as we continue our development of, seek regulatory approval for and potentially commercialize any of our product candidates and seek to identify, assess, acquire, in-license or develop additional product candidates.

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

We will continue to spend a substantial amount of our capital on research and development, but we might not succeed in developing products and technologies that are useful in medicine.*

We are attempting to develop new medical products and technology. These new products and technologies might not prove to be safe and efficacious in the human medical applications for which they are being developed. Our research and development activities are costly, time consuming, and their results are uncertain. We incurred research and development expenses amounting to approximately $9.1 million during the nine months ended September 30, 2021, and $12.3 million during the fiscal year ended December 31, 2020. 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 September 30, 2021, we had $65.1 million of cash, cash equivalents and marketable equity securities. There can be no assurance that we will be able to raise additional funds on favorable terms or at all, or that any funds raised will be sufficient to permit us to develop and market our products and technology, if and when approved. Our ability to raise additional funds may be adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. Unless we are able to generate sufficient revenue or raise additional funds when needed, it is likely that we will be unable to continue our planned activities, even if we make progress in our research and development projects. We may have to postpone or limit the pace of our research and development work and planned clinical trials of our product candidates unless our cash resources increase through a growth in revenues, royalties, license fees, equity financings or borrowings.

We 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 September 30, 2021 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 our company and certain members of our company's and Asterias Biotherapeutics, Inc.'s ("Asterias") boards of directors relating to our acquisition of Asterias (the "Asterias Merger"). An adverse ruling in any such lawsuit may result in additional payments and costs.

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

The 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, the legislation enacted in 2017, informally titled 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. For example, the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") modified certain provisions of the 2017 Tax Act. In addition, it is uncertain if and to what extent various states will conform to the 2017 Tax Act, the CARES 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 and other tax attributes to offset future taxable income or taxes may be subject to limitations.

As of December 31, 2020, we had net operating loss ("NOL") carryforwards for U.S. federal and state tax purposes of approximately $169.9 million and $118.6 million, respectively. In addition, the Company has U.S. federal and California research and development (R&D) credit carryforwards of $3.2 million and $5.7 million, respectively. Included in these amounts are NOLs and R&D credits acquired through the merger with Asterias (see below). A portion of the federal and state NOL carryforwards will begin to expire, if not utilized, in varying amounts between 2027 and 2037. NOLs that expire unused will be unavailable to offset future income tax liabilities. Under federal income tax law, federal NOLs incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOLs in tax years beginning after December 31, 2020, is limited to 80% of taxable income. The federal R&D credits expire in varying amounts between 2021 and 2040, the California credits have no expiration date. It is uncertain if and to what extent various states that we may operate in will conform to the federal tax law. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "IRC"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, in 2020 California enacted A.B. 85 which imposed limits on the usability of California state net operating losses and certain tax credits in tax years beginning after 2019 and before 2023.

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

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

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

If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arm's length transactions, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our tax liability, which could adversely affect our financial condition, results of operations and cash flows.

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

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

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

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

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

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

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

As of September 30, 2021, we had an equity investment in OncoCyte, a U.S. publicly traded company. As of September 30, 2021, the value of our investment in OncoCyte was approximately $4.0 million based on its closing stock price as of that date. If OncoCyte were to have delays in clinical trials or commercialization activities or otherwise realize the specific business, regulatory and other risks applicable to them, the value of its common stock and the valuation of our investment could be negatively affected. If OncoCyte were to fail and ultimately cease operations, we may lose the entire value of our investment. In addition, the value of our marketable equity securities may be significantly and adversely impacted by deteriorating global economic conditions and the disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

Risks Related to Government Regulation

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

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

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

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

- 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, and their subcontractors that use, disclose, access, or otherwise process individually identifiable protected health information, relating to the privacy, security, and transmission of individually identifiable health information;

- The Physician Payments Sunshine Act which requires manufacturers of drugs, devices, biologics, and medical supplies to report annually to the Centers for Medicare & Medicaid Services ("CMS"), information related to payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations, and, beginning in 2022 will require applicable manufacturers to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists and anesthesiologist assistants, and certified nurse-midwives; 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, the federal government, pursuant to a presidential executive order, lifted certain restrictions on federal funding of research involving the use of hES cells, and in accordance with the executive order, the 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 and maintain reimbursement and continued coverage from various payors, including government entities and insurance companies.*

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

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

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

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

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

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

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

Separately, in response to the global COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and temporarily postponed routine surveillance inspections of domestic manufacturing facilities. In July 2020 domestic inspections restarted only on a risk-based basis. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

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

There have been executive, judicial and Congressional challenges to certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, and eliminating the implementation of certain ACA-mandated fees. For example, on June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Moreover, prior to the United States Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, other litigation, and the healthcare reform measures of the Biden administration will impact the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, 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. Additionally, Congress is considering additional health reform measures as part of the budget reconciliation process.

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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that attempted to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the U.S. Department of Health & Human Services finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries. The Most Favored Nation regulations mandate participation by identified Medicare Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. As a result of litigation challenging the Most Favored Nation model, on August 10, 2021, CMS published a proposed rule that seeks to rescind the Most Favored Nation model interim final rule. Further, in July 2021, the Biden administration released an executive order that included multiple provisions aimed at prescription drugs. In response to President Biden's executive order, on September 9, 2021, the U.S. Department of Health and Human Services, or HHS, released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform. The plan sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. Additionally, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

If we fail to comply with the extensive legal and regulatory requirements affecting the 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, future advertising and promotion, product distribution, adverse event reporting and product risk management. Our current and future interactions in the U.S. or abroad with physicians and other health care providers that may prescribe or purchase our products once commercialized are also subject to government regulation designed to prevent fraud and abuse in the sale and use of the products and place greater restrictions on the marketing practices of 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 outweigh the risks. If we are required to conduct such a post-approval study, periodic status reports must be submitted to the FDA or foreign regulatory agency. Failure to conduct such post-approval studies in a timely manner may result in substantial civil or criminal penalties. Data resulting from these clinical trials may result in expansions or restrictions to the labeled indications for which a product has already been approved. Any of these requirements or actions may negatively impact our business or operations.

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

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

Risks Related to Our Clinical Development and Commercial Operations

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

We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical studies can occur at any stage of development. Events that may prevent successful or timely completion of clinical development include but are not limited to:

- inability to generate satisfactory preclinical, toxicology, or other *in vivo* or *in vitro* data or diagnostics to support the initiation or continuation of clinical studies necessary for product approval;
- delays in securing clinical investigators and agreeing on acceptable terms with contract research organizations ("CROs") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among CROs and clinical trial sites;
- delays in obtaining required 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, these are not necessarily predictive of future results, including clinical trial results. The historical failure rate for product candidates in our industry is high.

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

- we may not demonstrate the potency and efficacy benefits observed in previous studies;
- our efforts to improve, standardize and automate the manufacture of our product candidates, including *OpRegen*®, OPC1 and VAC2, and any resulting deviations in the manufacture of our product candidates, may adversely affect the safety, purity, potency or efficacy of such product candidates;
- differences in trial design, including differences in size, eligibility criteria, and patient populations;
- advancements in the standard of care may affect our ability to demonstrate efficacy or achieve trial endpoints in our current or future clinical trials;
- safety issues or adverse events in patients that enroll in our current or future clinical trials; and
- results in preclinical and clinical tests may not be repeated in subsequent tests or be predictive of future results.

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

Specifically, additional data presented showed that as patients continued to progress into post-operative follow-up, eyes receiving OpRegen trended toward improvement in visual acuity, a secondary objective under the study, while their untreated eyes typically lost visual acuity, as expected with this progressive disease. As additional patients have reached longer periods post-treatment, differences in visual acuity between treated and untreated eyes across Cohort 4 patients became statistically significant beginning at month 9 ($P = 0.0085$), as well as months 12 ($P = 0.0220$) and 15 ($P = 0.0273$) as determined via 2-sided Wilcoxon Signed Rank (using NCSS, LLC statistical software). These results, when combined with the OCT findings, suggest that both a structural and functional benefit is possible with OpRegen therapy. The totality of these findings supports the view that atrophic AMD is not an irreversible degenerative condition. OpRegen has been well tolerated with no unexpected adverse events, and evidence of durable engraftment of OpRegen RPE cells have extended to more than 5 years post-transplant in earliest treated patients. However, we do not know how OpRegen will perform in future clinical trials.

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

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

Even if our current and planned clinical trials are successful, we will need to conduct additional clinical trials, which may include registrational trials, trials in additional patient populations or under different treatment conditions, and trials using different manufacturing protocols, processes, materials or facilities or under different manufacturing conditions, before we are able to seek approvals for our product candidates from the FDA and regulatory authorities outside the United States to market and sell these product candidates. Our failure to meet the requirements to support marketing approval for our product candidates in our ongoing and future clinical trials would substantially harm our business and prospects. For the foregoing reasons, our ongoing and planned clinical trials may not be successful, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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

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

We have three cell therapy programs in clinical development. OpRegen is currently in a Phase 1/2a multicenter clinical trial for the treatment of dry AMD, OPC-1 is currently in a Phase 1/2a clinical trial for subacute spinal cord injuries, and VAC2 is in a Phase 1 clinical trial in non-small cell lung cancer. As a result of these and other future clinical trials for these product candidates or any of our future product candidates 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, particularly as additive to existing treatments;
- the willingness of the patients and physicians to accept and use these therapies;
- the marketing, sales and distribution support for the products;
- the publicity concerning our products or competing products and treatments; and
- the pricing and availability of coverage and adequate reimbursement by third-party payors and government authorities.

Even if a product displays a favorable efficacy and safety profile upon approval, market acceptance of the product will be uncertain. Efforts to educate the medical community and third-party payors on the benefits of the products may require significant investment and resources and may never succeed. If our products fail to achieve an adequate level of acceptance by physicians, patients, third-party payors, other 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 hES cell products designed to treat age-related macular degeneration. If their products are proven to be safe and effective, they may reach the market ahead of OpRegen.

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

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

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

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

- We or any third-party manufacturers might not timely formulate and manufacture our products or produce the quantity and quality required to meet our clinical and commercial needs, if any.
- We or any third-party manufacturers may not execute our manufacturing procedures appropriately.
- Any third-party manufacturers we engage may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our products on a commercial scale.
- We or any third-party manufacturers will be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with 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 marketplace would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, could require us to either commence new clinical trials at additional expense or terminate clinical trials completely. Each risk could delay our clinical trials, any approval of our product candidates by the FDA, or the commercialization of our product candidates, and could result in higher costs or deprive us of potential product revenue.

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

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

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. We continue to seek a commercialization partner in the European Union but we can give no assurance that we will secure a partner or commercialize Renevia in any territory.

The ongoing COVID-19 pandemic has affected and 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.

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

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

- delays or difficulties in 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;
- manufacturing difficulties for us and our suppliers of raw materials caused by business closures;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the COVID-19 outbreak which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;

- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; and

- refusal of the FDA to accept data from clinical trials in affected geographies.

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

Our clinical trials have been, and may in the future be, affected by the COVID-19 pandemic. For example, the COVID-19 pandemic previously impacted patient enrollment in our OpRegen Phase 1/2a multicenter clinical trial and is currently affecting the VAC2 Phase 1 multicenter clinical trial. In particular, some sites paused enrollment to focus on, and direct resources to, the COVID-19 pandemic or adhere to national or local guidelines, while at other sites, patients may decide not to enroll or continue participating in follow-up visits as part of the ongoing clinical trial, as a result of the pandemic. We are unable to predict with confidence the duration of such patient enrollment delays or missed study visits, as the COVID-19 pandemic continues or gets worse. If patient enrollment or study follow-up is delayed for an extended period of time, our clinical trials could be delayed or otherwise adversely affected. Our inability to enroll or follow a sufficient number of patients for any of our current or future clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether.

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

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

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

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

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

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

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

Since a significant proportion of the regulatory framework in the U.K. applicable to our business and our product candidates is derived from EU directives and regulations, Brexit has had, and may continue to have, a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. For example, Great Britain is no longer covered by the centralized procedures for obtaining EU-wide marketing authorization from the European Medicines Agency and a separate process for authorization of drug products, including our product candidates, will be required in Great Britain. It is currently unclear whether the Medicines & Healthcare products Regulatory Agency in the U.K. is sufficiently prepared to handle the increased volume of marketing authorization applications that it is likely to receive. 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.

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

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

We face the risk of incurring liabilities to clinical trial patients if they are injured as a result of their participation in our clinical trials. In the event we commercialize Renevia in the EU or in other countries that recognize the CE Mark, we will also face product liability risks associated with the use of Renevia by consumers. If any claims are made and if liability can be established, the amount of any liability we or our affiliates may incur, could exceed any insurance coverage in effect, and the amount of the liability could be material to our financial condition.

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

- impairment of our business reputation;
- initiation of investigations by regulators;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management’s attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions; and
- decreased demand for our product candidates, if approved for commercial sale.

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

Cell Cure has received Israeli government grants for certain of its research and development activities. The terms of these grants may require Cell Cure to seek approvals and to satisfy specified conditions to manufacture products, or transfer or license grant-supported technologies, outside of Israel. In the context of such approvals, Cell Cure will be required to make substantial monetary payments 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 non-Israeli entity of know-how developed as part of the programs under which the grants were given.

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

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

Part of Cell Cure's research and development efforts have been financed, partially, through grants that it has received from the IIA and when we acquired our holdings in Cell Cure, we undertook in writing, vis-à-vis the IIA, to abide by, and to ensure the abidance of Cell Cure to, the Innovation Law. We therefore must comply with the requirements of the Innovation Law and related regulations. As of December 31, 2020, we received approximately $15.4 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, or limit the economic benefit that we might derive under such agreements. We cannot be certain that any approval of IIA will be obtained on terms that are acceptable to us, or at all. We may not receive the required approvals should we wish to transfer or license IIA-funded know-how, manufacturing and/or development outside of Israel in the future. Furthermore, in the event that we undertake a transaction involving the transfer to a non-Israeli entity of know-how developed with IIA-funding pursuant to a merger or similar transaction, the consideration available to our shareholders may be significantly reduced by the amounts we are required to pay to the IIA. Any approval, if given, will generally be subject to additional financial obligations. Failure to comply with the requirements under the Innovation Law may subject Cell Cure to mandatory repayment of grants received by it (together with interest and penalties), as well as expose its directors and management to criminal proceedings. In addition, the IIA may from time to time conduct royalty audits. Further grants may not be approved or reduced in the future, which would increase our costs. IIA approval is not required for the marketing or distribution of products resulting from the IIA-funded research or development in the ordinary course of business.

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

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

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

Any of these factors could significantly harm our international operations and, consequently, our results of operations. In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our clinical trial activities.

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

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

Risks Related to our Intellectual Property

Our intellectual property may be insufficient to protect our products.

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

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

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

In addition, others may independently develop similar or alternative technologies, duplicate any of our technologies and, if patents are licensed or issued to us, design around the patented technologies licensed to or developed by us. As an example, Astellas' patent portfolio with respect to the manufacture of its RPE products could adversely impact our rights to manufacture OpRegen. Moreover, we could incur substantial costs in litigation if we have to defend ourselves in patent lawsuits brought by third parties or if we initiate such lawsuits.

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

Our success will depend in part on our ability to obtain and enforce patents and maintain trade secrets in the United States and in other countries. If we are unsuccessful at obtaining and enforcing patents, our competitors could use our technology and create products that compete with our products, without paying license fees or royalties to us. The preparation, filing, and prosecution of patent applications can be costly and time consuming. Our limited financial resources may not permit us to pursue patent protection of all of our technology and products in all key markets. Even if we are able to obtain issued patents covering our technology or products, we may have to incur substantial legal fees and other expenses to enforce our patent rights to protect our technology and products from infringing uses. We may not have the financial resources to finance the litigation required to preserve our patent and trade secret rights. Litigation, interferences, oppositions, inter partes reviews or other proceedings are, have been and may in the future be necessary in some instances to determine the validity and scope of certain of our proprietary rights, and in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. This means that patents owned or licensed by us may be lost if the outcome of a proceeding is unfavorable to us.

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

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

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

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

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

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

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

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

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

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

Risks Related to our Dependence on Third Parties

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

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

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

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

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

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

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

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

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

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

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

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

Risks Pertaining to Our Common Shares

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

The market price of our common shares, like that of the shares of many biotechnology companies, has been highly volatile. The price of our common shares may rise rapidly in response to certain events, such as the commencement of clinical trials of an experimental new therapy, even though the outcome of those trials and the likelihood of ultimate FDA approval of a therapeutic product remain uncertain. Similarly, prices of our common shares may fall rapidly in response to certain events such as unfavorable results of clinical trials or a delay or failure to obtain FDA approval. For example, from January 1, 2021 through November 5, 2021 the closing price of our common shares has ranged between $1.77 and $3.10 per shares. In addition, the failure of our earnings to meet analysts' expectations could result in a significant rapid decline in the market price of our common shares.

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

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

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

Our directors, executive officers and their affiliates, in the aggregate, owned approximately 24.6% of our outstanding common shares as of September 30, 2021. As a result, these shareholders, if acting together, will be able to heavily influence or control matters requiring approval by our shareholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree, and which may be averse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change of control of our company, could deter certain public investors from purchasing our common shares and might ultimately affect the market price of our common shares.

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

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

We are currently authorized to issue an aggregate of 252,000,000 shares of capital stock consisting of 250,000,000 common shares and 2,000,000 "blank check" preferred shares, which means we may issue, without 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 September 30, 2021, Lineage had 168,465,000 common shares outstanding, 17,207,345 common shares reserved for issuance upon the exercise of outstanding options under our employee stock option plans, 46,350 common shares reserved for issuance upon the vesting and settlement of restricted stock units under our equity incentive plan.

On May 1, 2020, Lineage entered into a Controlled Equity Offering^{SM} Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor Fitzgerald"), pursuant to which Lineage may, but is not obligated to, raise up to $25.0 million through the sale of common shares from time to time in at-the-market transactions under the Sales Agreement. On March 5, 2021, Lineage filed a prospectus supplement with the SEC in connection with the offer and sale of an additional $25.0 million of common shares under the Sales Agreement increasing the total offering to $50.0 million. As of June 30, 2021, Lineage had issued 13,859,776 common shares at a weighted average price per share of $2.39 for gross proceeds of $33.1 million. For the three months ended September 30, 2021, Lineage issued an additional 1,048,959 common shares at a weighted average price per share of $2.62 for gross proceeds of $2.7 million. As of September 30, 2021, Lineage had issued 14,908,735 common shares at a weighted average price per share of $2.41 for gross proceeds of $35.9 million under the Sales Agreement.

The operation of some of our subsidiaries has been financed in part through the sale of shares of capital stock and warrants to purchase securities of those subsidiaries to private investors. Future sales of such securities by our subsidiaries could reduce our ownership interest in the applicable subsidiary, and correspondingly dilute our shareholder's ownership interests in our consolidated enterprise. Certain of our subsidiaries also have their own stock option plans and the exercise of stock options or the sale of restricted stock under those plans would also reduce our ownership interest in the applicable subsidiary, with a resulting dilutive effect on the ownership interest of our shareholders in our consolidated enterprise.

General Risk Factors

Significant disruptions of information technology systems or data security breaches, including the theft of our intellectual property, 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.

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

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

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

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

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

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

Shareholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of our business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue our strategic initiatives, or limit our ability to attract and retain qualified personnel and business partners, any of which could adversely affect our business and operating results. If individuals are ultimately elected to our board of directors with a specific agenda, it may adversely affect our ability to effectively implement our business strategy and create additional value for our stockholders. We may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

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

The trading market for our common shares depends, in part, on the research and reports that securities analysts publish about our business and our common shares. We do not have any control over these analysts. There is no guarantee that securities analysts will cover our common shares. If securities analysts do not cover our common shares, the lack of research coverage may adversely affect the market price of those shares. If securities analysts do cover our common shares, they could issue reports or recommendations that are unfavorable to the price of our common shares, and they could downgrade a previously favorable report or recommendation, and in either case our share prices could decline as a result of the report. If one or more of these analysts does not initiate coverage, ceases to cover our common shares or fails to publish regular reports on our business, we could lose visibility in the financial markets, which could cause our share prices or trading volume to decline.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Default Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit Number	Description	Incorporation by Reference			
		Exhibit Number	Filing	Filing Date	File No.
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
10.1*+	First Amendment to Separation and Consulting Agreement dated July 20, 2021, between Registrant and Brandi L. Roberts				
10.2*+	Employment Agreement dated August 5, 2021, between Registrant and George A. Samuel III				
10.3+	Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan,	10.1	8-K	September 15, 2021	001-12830
10.4+	Standard Form of Stock Option Grant Notice and Agreement for Employees and Consultants under the Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan	99.2	S-8	September 28, 2021	333-259853
10.5+	Form of Stock Option Grant Notice and Agreement for Non-Employee Directors under the Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan	99.3	S-8	September 28, 2021	333-259853
10.6+	Standard Form of Restricted Stock Unit Award Grant Notice and Agreement under the Lineage Cell Therapeutics, Inc. 2021 Equity Incentive Plan	99.4	S-8	September 28, 2021	333-259853
31.1*#	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002				
31.2*#	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302(a) of the Sarbanes-Oxley Act of 2002				
32.1*#	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101*	Interactive Data File				
101.INS*	XBRL Instance Document				
101.SCH*	XBRL Taxonomy Extension Schema				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase				
101.DEF*	XBRL Taxonomy Extension Definition Document				
101.LAB*	XBRL Taxonomy Extension Label Linkbase				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase				
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)				

* Filed herewith
# Furnished herewith
+ Indicates management contract or compensatory plan

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

LINEAGE CELL THERAPEUTICS, INC.

Date: November 10, 2021

/s/ Brian M. Culley

Brian M. Culley
Chief Executive Officer

Date: November 10, 2021

/s/ Kevin Leon Cook

Kevin Leon Cook
Chief Financial Officer

Exhibit 10.1

FIRST AMENDMENT TO CONSULTING AGREEMENT

This First Amendment to the Consulting Agreement (the "**Amendment**") is entered into as of July 20, 2021 among Brandi L. Roberts, ("**Consultant**") and **Lineage Cell Therapeutics, Inc.**, ("**Lineage**") (collectively, the "**Parties**").

WHEREAS, the Parties have previously entered into that certain Separation and Consulting Agreement, dated January 20, 2021 (the "**Agreement**");

WHEREAS, the Parties desire to amend sections of the Agreement.

NOW, THEREFORE, in consideration of the premises and mutual promises and covenants herein and for good and valuable consideration, the Parties agree as follows:

1. Section 3(a) of the Agreement is deleted in its entirety and replaced with the following:

   (a) Consulting Period. The Consulting Relationship will be deemed to have commenced on the Separation Date and will continue until August 20, 2021, unless terminated earlier pursuant to Section 3(g) below (the "***Consulting Period***"). The Consulting Period can be extended only by a writing signed by you and the Chief Executive Officer of Lineage.

2. Capitalized terms used herein have the same meaning as given them in the Agreement.

3. Other than as amended herein, the Agreement remains in full force and effect.

[Signatures Found on Following Page]

IN WITNESS WHEREOF, the parties have executed this Amendment by their duly authorized officers as of the date first above written.

LINEAGE CELL THERAPEUTICS, INC.	**CONSULTANT**
By: */s/ Brian M Culley*	By: */s/ Brandi L. Roberts*
Name: Brian Culley	Name: Brandi L. Roberts
Title: CEO	Title: Individual
Date: 7/14/2021	Date: 7/15/2021

Exhibit 10.2

EMPLOYMENT AGREEMENT

EMPLOYMENT AGREEMENT (this "Agreement") is made August 5, 2021, by and between Lineage Cell Therapeutics, Inc. ("Company"), a California corporation, and George Samuel ("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 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 CEO. Executive shall devote his best efforts, skills and abilities, on a full-time basis, exclusively to 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 (collectively, the "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/or 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.

(d) Start Date. Executive shall commence employment with Company on September 1, 2021 (the date on which Executive actually commences employment with Company, the "Start Date").

2. Compensation

(a) Salary. During the term of this Agreement, Company shall pay to the Executive an annual salary of $376,000.00 (minus applicable taxes, deductions and withholdings). Executive's salary shall be paid in equal semi-monthly installments, consistent with Company's regular salary payment practices. Executive's salary may be adjusted from time-to-time by Company, in Company's sole and absolute discretion, without affecting the rights or obligations of Executive or Company under this Agreement.

(b) Bonus. Executive may be eligible for an annual bonus targeted at 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. The annual bonus for 2021 will be pro-rated by multiplying (i) the amount of the bonus earned by Executive for 2021, if any, by (ii) a fraction, the numerator of which is the number of days between the Start Date and December 31, 2021, and the denominator of which is 365.

(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 semi-monthly 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 Grant. Executive shall be granted a stock option to purchase up to 695,000 shares of Company common stock (the "Option"). The 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 ¼ of the shares subject to the Option on the first anniversary of the Start Date 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 made and to the terms of the stock option agreement Executive will be required to sign with respect to the Option.

(g) Withholdings. All compensation payable to Executive, including amounts payable under Section 5, if any, is subject to applicable taxes, deductions and withholdings.

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 signed on behalf of the Company with the express authorization of the Board of Directors or the Compensation Committee 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.

(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 or as a result of the death or Disability of Executive or if Executive resigns , 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, or Resignation for Good Reason.** In the event of termination of Executive's employment by Company without Cause or if Executive resigns for Good Reason, Executive will be entitled to: (A) the benefits set forth in paragraph (a)(i) of this Section; (B) 9 months' base salary, paid in a lump sum or, at the election of Company, in installments consistent with Company's payroll procedures; (C) payment of a prorated target bonus due, if any, for the year in which Executive was terminated without Cause, or resigns with Good Reason; and (D) payment, for a period of 6 months, of any health insurance benefits 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 if Executive resigns for Good Reason, in each case, 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 100% of any then unvested options, restricted stock or restricted stock units as may have been granted to Executive by Company.

(b) Release. The Company's obligation to make the payments and to provide the benefits under paragraphs (a)(ii) and (a)(iii) of this Section and to provide any other benefits contemplated herein is 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 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 or Articles of Incorporation or under any written indemnification or other agreement between Company and Executive, and/or under applicable law; (2) any rights 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 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 Company, 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 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(c)(ii).

(ii) The determination of whether Section 5(c)(i)(A) or Section 5(c)(i)(B) shall be given effect shall be made by 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 Company and Executive otherwise agree in writing, any determination required under this Section 5(c) shall be made by Company's independent accountants or compensation consultants (the "Third Party"), and all such determinations shall be conclusive, final and binding on the parties hereto. 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). 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 conceit to acquire Voting Securities entitling them to elect a majority of the directors of Company.

(ii) "Cause" means 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 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 shareholders 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" means 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" means 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 Company of this Agreement or any other material written agreement between Executive and the Company. "Good Reason" shall only exist if Executive first provides Company with written notice of any claimed ground for Good Reason within thirty (30) days of the first occurrence of such ground and an opportunity to cure such ground, if curable, for thirty (30) days.

(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 by delivering to Company a letter or other written communication addressed to the Board of Directors 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 Company 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 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. No provision of this Agreement may be modified, amended, or waived except by a written document signed both by Executive and Company, and with respect to the Company, with the express authorization of the Board of Directors or the Compensation Committee.

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/ George A. Samuel III
George Samuel
Address: 2173 Salk Avenue, Suite 200
Carlsbad, CA 92008

COMPANY:

LINEAGE CELL THERAPEUTICS, INC.

By: */s/ Brian M. Culley*
Brian Michael Culley
Chief Executive Officer
Lineage Cell Therapeutics, Inc
2173 Salk Avenue, Suite 200
Carlsbad, CA 92008

[Signature Page to the Employment Agreement]

Exhibit 31.1

CERTIFICATIONS

I, Brian M. Culley, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2021

/s/ Brian M. Culley
Brian M. Culley
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Kevin Leon Cook, certify that:

1. I have reviewed this quarterly report on Form 10-Q 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. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2021

/s/ Kevin Leon Cook

Kevin Leon Cook
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Lineage Cell Therapeutics, Inc. (the "Company") for the quarter ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Brian M. Culley, Chief Executive Officer and I, Kevin Leon Cook, 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: November 10, 2021

/s/ Brian M. Culley
Brian M. Culley
Chief Executive Officer
(Principal Executive Officer)

/s/ Kevin Leon Cook
Kevin Leon Cook
Chief Financial Officer
(Principal Financial Officer)